Prevalence of hearing impairment and auditory pathology in the Limpopo Province, South Africa

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Declaration

I, Donna Pullen, hereby declare that this dissertation is my own work. Assistance that I have received is detailed in the acknowledgements of this report. No part of this dissertation has been previously submitted for a degree at any other University, except where references have been made in this report. I am responsible for the content of this study and the conclusions reached.

Signature: _____

Date: _____

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Abstract

Background: The lack of prevalence data for hearing impairment (HI) in South Africa may negatively impact on the type of audiological services currently available to individuals residing in the rural areas of South Africa. Without relevant prevalence data, the government is unable to plan and budget for appropriate, comprehensive ear and hearing health services.

Objective: The aim of this study was therefore to obtain epidemiological data on the prevalence and distribution of auditory pathology and HI in the Elias Motsoaledi Local Municipality of the Limpopo Province.

Method: A quantitative, non-experimental, cross-sectional survey design was used for this study. Using a random multi-stage cluster sampling strategy, 357 households were selected in seven wards using the probability proportional to size method. The Ear and Hearing Disorders Survey developed by the World Health Organisation was used to gather information.

Participants: All individuals living in the households selected who gave consent and/or assent to participate in the study were included in the study. In total the hearing of 850 individuals from 357 households were tested. The mean age of participants was 27.9 years (range: 1 month to 94.5 years; SD - 22.08).

Results: The overall prevalence of disabling HI (> 40 dB) in this rural population is 8.9% (95% CI: 0.08 - 0.12). The age group 65 years and older presented with the highest prevalence of disabling HI at 74.65% (95% CI: 0.62 - 0.83). The prevalence of auditory pathology is 27.53% (95% CI: 0.26 - 0.32) with undetermined causes, impacted cerumen and otitis media occurring most often.

Conclusion: The study provided evidence-based data on the prevalence on HI and auditory pathology in the rural context in South Africa. This information will assist all stakeholders in the ear and hearing health care sector to plan for, prioritize, allocate adequate resources and initiate programmes to ameliorate the impact of HI and auditory pathology in the EMLM of the Limpopo Province.

Keywords: prevalence; hearing impairment, auditory pathology; Ear and Hearing Disorders Survey, rural, South Africa

Table of Contents

Declarationii
Acknowledgements iii
Abstractiv
List of Tablesx
List of Figuresxi
List of Appendicesxii
Chapter 1: Orientation1
Background and rationale1
Abbreviations
Chapter outlines4
Summary5
Chapter 2: Literature Review
Hearing Impairment and Auditory Pathology6
Risk factors for hearing impairment11
Screening assessment for hearing impairment12
Impact of Hearing Impairment14
Epidemiology of Hearing Impairment17
Prevalence of Hearing Impairment
Prevention of Hearing Impairment
Lack of Prevalence Data in South Africa

PREVALENCE OF HEARING IMPAIRMENT AND AUDITORY PATHOLOGY IN LIMPOPO

Summary	25
Chapter 3: Methodology	27
Research Aims	27
Research Design	27
Research Phases	28
Context	28
Pilot Study	
Objectives	
Participant description.	
Procedures	31
Results and recommendations	31
Main Study	32
Study sample	
Participants	36
Measuring Instruments and Equipment.	
Ethical Considerations	49
Reliability and Validity	
Data analysis	55
Summary	56
Chapter 4: Results and Discussion	57
Distribution of Participants per Cluster	57

Demographic Information of the Sample Population	57
Prevalence and Distribution of Hearing Impairment	63
Prevalence and distribution of auditory pathology	66
Summary	71
Chapter 5: Conclusion and Implications	72
Summary of findings	72
Evaluation of the study	73
Study strengths	73
Study limitations	74
Implications of the study	74
Recommendations for future research	76
Conclusion	77
Summary	78
References	79
Appendices	96
Appendix A: WHO Ear and Hearing Survey	96
Appendix B: Self-developed Case History Form	98
Appendix C: Research Assistants Manual	100
Appendix D: Participant Information Sheet	110
Appendix E: Ethical Clearance	114
Appendix F: Permission letter from Limpopo Department of Health and Social	
Development	115

Appendix G: Ndlovu Care Group Chief Operations Officer Permission letter116

List of Tables

Table 1:	Classification of hearing impairment in adults	7
Table 2:	Classification of hearing impairment in children	8
Table 3:	A comparison of prevalence rates of moderate and severe hearing impairment between high-income and middle- and low-income areas	21
Table 4:	Total number of households per ward	.33
Table 5:	Number of households visited per ward	.34
Table 6:	Description and rationale for the WHO Ear and Hearing Disorders Survey components.	37
Table 7:	Description and rationale for the self-developed case history forms	39
Table 8:	Audiological measures, equipment and norms	.41
Table 9:	Statistical analysis completed	54
Table 10:	Distribution of participants per cluster	.55
Table 11:	Distribution of participants by age and gender	.56
Table 12:	Educational status of participants	.57
Table 13:	Significant medical history obtained from the participants	59
Table 14:	Proportion (%) of individuals with hearing impairment by WHO age categories.	.61
Table 15:	Proportion (%) of individuals (by age group) with hearing impairment	.62
Table 16:	Proportion of children (by gender) with a pass and refer test result	.64
Table 17:	Ear disease found according to the WHO age group categories	65
Table 18:	Types of ear disease found according to the WHO age group categories	.66
Table 19:	Distribution of participants in need of ear and hearing services	68
Table 20:	Distribution of action needed in the population with ear and hearing disorders	.68

List of Figures

Figure 1:	Disabling hearing impairment across the world19
Figure 2:	Prevalence of disabling hearing impairment in adults and children by regions20
Figure 3:	Test protocol: > 4 years and older
Figure 4:	Test protocol: 0 - 3.11 years47
Figure 5:	Employment status of participants older than 15 years of age
Figure 6:	Hypertension and hearing impairment

List of Appendices

- Appendix A: WHO Ear and Hearing Disorders Survey form
- Appendix B: Self-developed Case History Form
- Appendix C: Research Assistants Manual
- Appendix D: Participation information sheet
- Appendix E: Ethical Clearance form from the Human Research Ethics Committee (Medical) of the University of the Witwatersrand
- Appendix F: Permission letter from Limpopo Department of Health and Social Development
- Appendix G: Ndlovu Care Group Chief Operations Officer's permission

Chapter 1: Orientation

"Deafness is a much worse misfortune, for it means the loss of the most vital stimulus – the sound of the voice that brings language, sets thoughts astir and keeps us in the intellectual company of man" (Helen Keller, 1910 as cited in Dalebout, 2009).

Introduction

This chapter provides an orientation to the research. It includes the background to and rationale of the study, the purpose of the research, the abbreviations used within the context of the study as well as an outline of each of the chapters in the research.

Background and rationale

Hearing impairment (HI), a non-communicable disease, is regarded as the most common sensory deficit in the human population (Olusanya, Neumann & Saunders, 2014). HI is referred to as an 'invisible condition' and in some instances a 'silent epidemic' (Suter, 1998). Undetected HI in children, depending on the severity thereof, may lead to permanent speech, language and cognitive delays, with far-reaching social and economic consequences (Joint Commission of Infant Hearing [JCIH], 2007). Adult onset of HI is ranked as one of the highest (and worst) impactful conditions. The difficulty with adult-onset of HI is that is it often detected several years after onset and often this is after the loss having led to multiple negative consequences such as effects on employment, depressive symptoms and increased risk of mortality (McMahan, Gopinath, Schneider, Reath, Hickson, Leeder, Mitchell & Cowan, 2013). In addition, the use of hearing aids have found to be associated with reduced depression, longer life expectancy and retention in the work place (McMahan et al., 2013).

The prevalence of HI has since 1985 increased at an alarming rate. In 1985, the global prevalence of permanent disabling hearing impairment (DHI) (> 40 dB) was estimated at 42 million individuals. By 1995, this increased to 120 million individuals and by 2012, 360 million people with permanent DHI contributed to the global burden of disease on individuals, families, communities and countries (Olusanya et al., 2014)). Two thirds of these individuals live in developing countries such as South Africa (World Health Organization [WHO], 2013). The prevalence rate of DHI in developing countries reportedly range from 2 to 9% of the populations studied (Pascolini & Smith, 2009). In South Africa however, the reported prevalence rate of HI is as high as 20% (Statistics South Africa [Stats SA], 2012).

Even though South African governmental policy guidelines favour the philosophy of prevention of hearing loss as well as early identification and intervention, HI has received limited institutional support. The public health care sector is specifically challenged due to a significant shortage of human resources to offer these services. In 2010, only 396 of the 1545 speech therapists and audiologists registered with the Health Professions Council of South Africa (HPCSA) were employed in the public health care sector (Human Resources for Health South Africa Strategy [HRH], 2011). The lack of adequate audiological services at particularly the primary health care (PHC) level has a direct effect on the age of diagnosis and the provisioning of appropriate intervention for individuals diagnosed with HI and their families.

Given the lack of information on the current HI and auditory pathology prevalence rates, especially in rural communities across South Africa, the government is unable to plan and implement appropriate ear and hearing health care services for the majority of its citizens. Better and more comprehensive information is required to carry out economic analysis studies in developing countries, especially to determine the costs of burden of HI and

the cost-effectiveness of different interventions against it. This will encourage, assist and justify the allocation of increased resources by more developing countries (Smith, 2008).

In an attempt to illuminate the extent of HI and auditory pathology in rural areas of South Africa, the research study aimed to address the following research question: What is the prevalence of ear and hearing disorders in the Elias Motsoaledi Local Municipality (EMLM) area of Limpopo Province, South Africa. By highlighting the extent of HI and auditory pathology, it would allow the expansion of services based on evidence-based data.

Abbreviations

AABR	:	Automated auditory brainstem response
CHL	:	Conductive hearing loss
dB	:	Decibels
dB A	:	A-weighted decibels
dB HL	:	Decibel hearing level
DHI	:	Disabling hearing impairment
EMLM	:	Elias Motsoaledi Local Municipality
НА	:	Hearing aid
HI	:	Hearing impairment
Hz	:	Hertz
kHz	:	Kilohertz

ME	:	Middle ear
MHL	:	Mixed hearing loss
OAEs	:	Otoacoustic emissions
SNHL	:	Sensorineural hearing loss
WHO	:	World Health Organisation

Chapter outlines

The research is presented in five chapters.

Chapter 1 provides an orientation to the study and includes the background to and rationale for the study, the abbreviations used as well as an outline of the chapters in the study.

Chapter 2 is the literature review and provides the theoretical framework and rationale for the study. This chapter includes information on the prevalence rates for HI both internationally and nationally. This is followed by the definition of HI, a description of auditory pathology as well as the risk factors for HI. The impact of HI on the life of individuals is also discussed. The lack of prevalence data on HI in South Africa is highlighted.

In Chapter 3 the methodology is outlined and incorporates research aims, design and phases. The cluster and participant selection and description as well as the research measures used are presented. Data collection procedures, ethical considerations, together with reliability, validity and data analysis methods employed, are discussed and presented. Chapter 4 provides an overview of the results in accordance with the sub-aims of the study. The findings are critically discussed in relation to current literature. Data is organised, analysed and interpreted so that conclusions can be drawn regarding the current prevalence rate of HI and DHI in the EMLM area of Limpopo, South Africa. The discussion of the findings is integrated throughout this chapter.

In Chapter 5, the conclusions and critical evaluation of the study are presented, followed by the implications and recommendations for future research.

The appendices supply important information for the understanding of the data collection and analysis procedure as well as replication of the study.

Summary

This chapter provided the rationale for the study by describing background information such as the current prevalence rates worldwide as well as nationally, and shows the importance and need for additional prevalence studies to be conducted, especially in rural communities. This chapter also included an explanation of abbreviations and an outline of chapters that further described the aims and execution of the research study.

Chapter 2: Literature Review

Introduction

This chapter will critically discuss literature relevant to the current study. Information regarding HI and auditory pathology as well as the impact thereof will be presented. Information regarding the epidemiology, prevalence and prevention of HI will be discussed and concludes with a discussion of planning for hearing services.

Hearing Impairment and Auditory Pathology

HI is defined as the reduction in the ability to perceive sound and may range from slight inability to complete deafness (Stedman, 2005). A HI occurs when there is a diminished sensitivity to the sounds that individuals normally hear. The terms HI and hearing loss (HL) are used interchangeably to describe a reduction in hearing sensitivity. The severity or degree of a HI is categorised according to the increase in decibels above the usual level necessary before the listener can detect it. Audiologists describe each individual's HI in terms of type, degree, configuration, laterality and classification of HI. The degree of HI refers to the severity of the HI and is represented as a range of the HI experienced by an individual.

Classification of hearing impairment.

There are a number internationally accepted classification systems for HI (American Speech-Language-Hearing Association [ASHA], 2011; WHO, 2011; Northern & Downs, 2003). The classification of a HI gives an indication of the extent of an individual's HI (ASHA, 2011). As the effects of HI differ according to age, different systems are used to classify HI in adults and children. For the purpose of the current study, two classification

systems were used; the WHO (2011) classification was used for adults and for children the Northern and Downs (2003) classification.

The classification of HI for adults according to the WHO (2011) is presented in Table 1. It provides a description of the grade (degree) of impairment, the corresponding dB levels, and a description of the performance by individuals with a specific degree of HI as well as the recommendations for management.

Table 1

Grade of impairment	Corresponding audiometric ISO* value (better ear)	Performance	Recommendations
0 – None	25 dB or better	No or very slight hearing problems. Able to hear whispers.	N/A
1 – Slight	26-40 dB	Able to hear and repeat words spoken in normal voice at 1 meter.	Counselling and hearing aids (HAs) may be needed.
2 – Moderate	41-60 dB	Able to hear and repeat words spoken in raised voice at 1 meter.	HAs usually recommended.
3 – Severe	61-80 dB	Able to hear some words when shouted into better ear.	HAs needed. If no HAs available, lip-reading and signing should be taught.
4 – Profound (including Deafness)	> 81 dB	Unable to hear and understand even a shouted voice.	HAs may help understanding words. Additionally aural rehabilitation is needed. Lip- reading and sometimes signing essential.

Classification of hearing impairment in adults (WHO, 2011)

* ISO = reference values for calibration of equipment

The classification of HI in children is slightly different in that an additional category,

mild HI, is included. The classification system proposed by Northern and Downs (2003) is

presented in Table 2.

Table 2

Classification of hearing impairment in children (Northern & Downs, 2003)

Audiometric value	Hearing impairment
0 - 15 dB HL	Hearing within normal limits
16 – 25 dB HL	Slight hearing loss
26 – 30 dB HL	Mild hearing loss
31 – 50 dB HL	Moderate hearing loss
51 – 70 dB HL	Severe hearing loss
71 – 90+ dB HL	Profound hearing loss

The classifications were initially designed for the main purpose of identifying HI that may be remediable, i.e. by fitting HAs. The classification is derived from averaging frequencies, or the pure tone average (PTA), particularly important for speech (Gelfand, 2011). These classification systems do however have some limitations. One of the limitations is that these systems fail to account for losses that may be irregular or confined to the opposite ends of the frequency spectrum. Instead, this classification is useful for categorizing the degree of loss at the different frequencies so as to look at the configuration of the loss and not just on the PTA.

In an attempt to standardize what a DHI is, the WHO defined DHI as a permanent unaided hearing loss of > 40 dB, averaged over frequencies 0.5, 1, 2 and 4 kilohertz (kHz) in the better ear in adults and 30 dB in children (WHO, 2001). This definition is noted to exclude individuals with mild or unilateral hearing loss and it does not take into account the

functional impact a hearing loss has on individual's environmental contexts (Olusanya et al., 2014; WHO, 2001).

Type and causes of hearing impairment.

The type of HI assists in determining the possible pathology and underlying cause of an individual's HI (Hersh & Johnson, 2003). HI can be separated into three categories namely, conductive hearing loss (CHL), sensorineural hearing loss (SNHL) and mixed hearing loss (MHL). Depending on the underlying cause, HI may be temporary or permanent and bilateral (both ears affected) or unilateral (only one ear affected) (Balch, 2006).

Conductive HL. A CHL is present when the pinna, outer ear canal and middle ear system impedes the effective transmission of sound through the outer ear to the tympanic membrane and then the ossicles, situated within the middle ear (ASHA, 2014a).

Some causes of CHL in the outer ear include congenital deficits such as deformities of the pinna (such as atresia), impacted cerumen, otitis externa or foreign bodies obstructing the ear canal. Causes of CHL as a result of middle ear involvement include fluid in the middle ear from colds, flu and allergies that then presents as some form of otitis media (including serous otitis media). In addition, a perforated tympanic membrane (due to otitis media or trauma), dislocation of the ossicles within the middle ear cavity and poor Eustachian tube function can result in CHL (ASHA, 2014a; Balch, 2006; Hersh & Johnson, 2003). In most cases, a CHL is temporary in nature and can be treated either medically or surgically. Some individuals presenting with a CHL may benefit from the use of HAs or assistive listening devices.

Sensorineural HL. A SNHL is caused by failure in the cochlear transduction of sound from mechanical energy in the middle ear to neural impulses in the auditory nerve. The cochlea is a highly specialized sensory receptor organ that converts hydraulic fluid

movement, caused by mechanical energy from stapes movement, into electrical potentials in the nerve endings of the organ of Corti. The intricate sensory system is composed of receptor cells that convert this fluid movement into electrical potentials containing both sensory and neural elements. When a structure of this sensorineural mechanism is in some way damaged, its ability to transduce mechanical energy into electrical energy is reduced. This results in a number of changes in cochlear processing, including; a reduction in the sensitivity of the cochlear receptor cells, a reduction in the frequency-resolving ability of the cochlear and, a reduction in the dynamic range of the hearing mechanism (Pocock, Richards & Richards, 2013).

SNHL can be caused by a variety of pathologies including viral infections, the use of ototoxic medication, tumours, damage to the hair cells in the cochlea, hereditary hearing loss, presbycusis, malformation of the inner ear and extended exposure to loud noises (ASHA, 2014b). This may result in a reduction of an individuals' ability to hear soft sounds, even when speech is loud enough to hear, it comes across unclear or muffled to the individual, i.e. it affects the clarity and acuity (perception) (Balch, 2006; Hersh & Johnson, 2003). The most common type of SNHL, especially in sub-Saharan Africa is due to ototoxicity (Whitehorn, Sibanda, Lacerda, Spracklen, Ramma, Dalvie & Ramesar, 2014). The significant increase in multi-drug resistant tuberculosis (MDR-TB) that is resistant to both isoniazid and rifampicin, has been closely linked to the human immunodeficiency virus (HIV) epidemic (Harris et al., 2012).

Numerous medications are known to cause a HI (Neely, 2008). The high incidence of MDR-TB in South Africa and the simultaneous lack of effective alternative drugs mean that increasing numbers of individuals are at risk of developing aminoglycoside or polypeptide related ototoxicity (Harris et al., 2012). Often, ototoxicity goes undetected as there appears to be a lack of audiological monitoring (Whitehorn et al., 2014). A SNHL is the most common

type of HI and is typically irreversible and thus permanent (ASHA, 2014b). In the majority of cases SNHL cannot be treated medically or surgically.

Mixed HL. When a conductive component is present in the presence of a SNHL, it is referred to as a MHL (ASHA, 2014c). Possible disorders causing a MHL is otosclerosis-involving the ossicles and cochlea, middle ear tumours, some inner ear malformations and head trauma (ASHA, 2014c).

Risk factors for hearing impairment.

There are a number of factors that contribute to the development of HI in children and adults. Research has confirmed that risk factors for HI accounts for approximately 50% of infants with congenital HI (Chu et al., 2003). The JCIH (2000) indicate that for infants from birth to 28 days of age risk factors include: (i) an illness or condition requiring admission of 48 hours of longer to a neonatal intensive care unit (NICU); (ii) low birth weight and prematurity (iii) stigmata or other findings associated with a syndrome known to include a SNHL or CHL; (iv) in-utero infections such as cytomegalovirus (CMV), herpes, toxoplasmosis, human immunodeficiency virus (HIV), malaria, measles; (v) craniofacial anomalies, including morphological abnormalities of the pinna and ear canal; (vi) birth complications such as asphyxia and intracranial haemorrhage; and (vii) family history of permanent childhood SNHL.

For infants from 29 days through to 3 years of age additional risk factors include HI acquired later in life as a result of trauma, infection, use of ototoxic medication or unknown causes. Neonatal indicators such as hyperbillirubinemia, persistent pulmonary hypertension and syndromes associated with progressive HI and recurrent or persistent otitis media for at least 3 months; and HIV infection and malaria are also viewed as risk factors in this age group (Fortnum, 2003; JCIH, 2000.

Adults are also exposed to risk factors that may contribute to HI. One of the most prevalent risk factors is age-related HI or better known as presbycusis. Hereditary causes of presbycusis make individuals more susceptible to auditory pathology and HI. It is estimated that 50-60% of all HI have a component relating back to genetics (Kelly & Teplin, 2003).

In addition, illnesses (such as meningitis), noise exposure (occupational or other) and use of ototoxic medications for illnesses such as cancer, TB, human immunodeficiency virus and acquired immune deficiency syndrome (HIV/AIDS) and malaria may cause HI (Mathers et al., 2000; WHO, 2010). Ear infections which are poorly treated and become recurrent may cause irreversible damage to the middle ear and the cochlea and could lead to HI later in life. Lastly, trauma or injury to the brain or head region may put the individual at risk for HI (Mathers et al., 2000; WHO, 2010). It is important that individuals should undergo regular hearing assessments especially if they are at risk for HI.

Screening assessment for hearing impairment.

The hearing ability of individuals is assessed by audiologists by means of diagnostic or screening audiological assessments. A full diagnostic assessment gives information on the type, degree, configuration and nature (permanent vs. temporary) of HI. Should a HI be identified, a full diagnostic assessment often provides information as to whether an individual will benefit from hearing amplification (WHO, 2010). In contrast, a screening test only allows for the detection of a HI at the frequencies tested.

The objective of a hearing screening program is to identify individuals that may present with a possible HI as early as possible in order to facilitate further diagnosis and treatment. A variety of screening protocols can be used and should be adapted for specific age groups. One of the most widely used surveying hearing disorders protocols was proposed by the WHO in 1999. The first step in the protocol is to obtain case history information as to identify potential contributing factors to the presence of HI (Stach, 2010). Information such as age, occupation as well as medical history and complaints are thus pivotal. For children, additional aspects such as prenatal, perinatal and birth history, as well as developmental milestones is included (Welling & Ukstins, 2013a).

This is followed by the visual inspection of the ear, usually performed through otoscopic examination. The status of the pinna, outer ear canal and the tympanic membrane is assessed. The otoscopic examination is the first indicator of whether or not the outer ear and middle ear is healthy (Martin & Clark, 2009) and is essential in identifying any observable abnormalities which may impact on the test results. Observable abnormalities can include malformations, traumas, infections, obstructions and/or ear canal collapse.

Tympanometry is performed to measure the compliance or mobility and function of the tympanic membrane as well as to determine the status of the middle ear (Martin & Clark, 2009). Adjustments are made for infants younger than 6 months of age by changing the probe tone from a low frequency (226 Hz) to a high frequency probe tone (1000 Hz).

Pure tone audiometry (air conduction only) is then performed to determine the presence of a potential HI at only four of the frequencies (500 Hz, 1000 Hz, 2000 Hz and 4000 Hz) (ASHA, 2005).

For children younger than four years of age, pure tone audiometry is not typically performed but is replaced by two physiological screening technologies; distortion production otoacoustic emission (DPOAEs) and the Automated Auditory Brainstem Response (AABR). DPOAEs are designed to measure the outer hair cell functioning in the cochlea, whilst the AABR measures the neural synchrony in the VIII cranial nerve and lower brainstem (Iwasaki

et al., 2004; Prieve & Stevens, 2000). A more comprehensive description of these screening measures is presented in the methodology.

Impact of Hearing Impairment

The International Classification of Functioning, Health and Disability (ICF) was introduced by the WHO to serve as an international framework to define the experience of health and disability, based on a biopsychosocial model. The ICF thus views disability and functioning as the outcomes of interactions between health conditions, environmental- and personal factors (WHO, 2002). Concepts of how body structure and function, activities and participation (in daily life situations) can be influenced by health conditions (such as HI), personal factors (e.g. gender, age, social background) and environmental factors (e.g. social attitudes) are explained. The ICF framework allows for a description of all difficulties experienced by an individual. Goals and solutions specific to an individual can accordingly be formulated to promote the alleviation of individual difficulties and optimal participation in activities considered to be limiting.

Exchanging information with others is an important aspect of everyday life and can be seriously impaired in individuals presenting with HI. Difficulties in communication may lead to a reduction in an individual's quality of life. The impact of HI, irrespective of the age at which the HI develops, is experienced by individuals with HI and their family at different levels including functional, educational, social, emotional and economic levels.

Functional impact.

A study conducted in 2003 measures individuals older than 53 years (N = 2688) functioning in all activities of daily living (ADL) and instrumental ADL (IADL) (Dalton et al., 2003). ADLs measured included more global functioning in activities that are a part of everyday living, such as walking across a small room and getting from a bed to a chair.

Although it was found that HI may not be a direct cause of reduction in these activities for this group of participants, difficulty with these tasks still remain for individuals with HI, demonstrating that HI accompanies the general frailty and decline that occur with aging. IADLs measures included functioning in more subtle activities, such as shopping for personal items, taking care of personal finances and communication. It was also found that those individuals presenting with a moderate to severe HI had reduced abilities and functioning in these areas (Dalton et al., 2003).

Educational impact.

Hearing plays an important and central role in language, cognitive, social, emotional and academic development. Important elements of language development occur within the first two years of a child's life. Speech and language development is at greatest risk for an individual with a HI and may also develop at a later stage in life (Kelly & Teplin, 2003). Children with HI are shown to often have a delay in grammar, vocabulary and concepts in both receptive and expressing language development (Robbins, 2006; Northern & Downs, 2003). With the ability to read and write being based on a good foundation of language acquisition, HI may typically interfere with the development of literacy skills. Other significant aspects include problems with phonemic awareness, which can result in reading delays, poor attention skills, difficulty following directions/instructions, delayed social skills, difficulty hearing in the presence of noise, difficulty localizing sound, poor organizational skills, fatigue and decreased background knowledge (WHO, 2013).

It is disconcerting to note that most children with a HI finish high school with a grade 3-equivalent reading level (Robbins, 2006). This may further impede job placements as well as studies post high school (Dalton et al., 2003).

Social and emotional impact.

Research has shown that among the older population with hearing loss, there appears to be limited access to services. Additional exclusion from communication results in a significant impact on these individuals' everyday life. This exclusion causes further possible feelings of loneliness, isolation and frustration (WHO, 2013).

Economic impact.

In developing countries, children with HI rarely receive any schooling and adults with HI also have a much higher unemployment rate (WHO, 2013). Among those who are employed, a higher percentage of people with HI are in the lower grades of employment compared to individuals who are in the general workforce (WHO, 2013). Improving access to education and vocational rehabilitation services, as well as raising awareness especially among employers, should decrease unemployment rates among adults with hearing loss (WHO, 2013).

In addition to the economic impact of hearing loss at an individual level, hearing loss substantially affects social and economic development in communities and countries (WHO, 2013). HI within the adult population is the second highest contributing factor to the years lived with disability [YLD] (Ullauri et al., 2011). Disability-adjusted life year (DALY) is a widely used summary measure of population health in the assessment of disease burden. It represents the incident number of healthy life years lost due to diseases or disability. Countries are beginning to calculate national DALYs to assess and monitor their community's health and to set priorities and programmes within their health facilities. The WHO uses the above to estimate prevalence, births, deaths as well as specific causes of death (WHO, 2014a). Often, a large number of diseases and conditions are overlooked and

underestimated as they appear not to be as dramatic as other conditions; HI is often one of these conditions.

HI is rated the 15th leading cause of burden of disease for all ages and is projected to be the 7th leading cause of burden of disease for all ages by the year 2030 (WHO, 2014a). This demonstrates the global need for attention to HI as well as the need for ear and hearing health services worldwide.

Epidemiology of Hearing Impairment

Epidemiology is the study of the distribution, incidence, possible control of diseases and other factors relating to health states or events. Epidemiology aids in the understanding of the causes and patterns of illness and health related issues (U.S. Department of Veterans Affairs, 2014). Various methods can be used to carry out epidemiological studies, but all methods should be based on a particular population followed over a period of time. The fundamental distinction is the study of incidence versus prevalence and the various epidemiological study designs differ in the way in which information is drawn from the population (Pearce, 2012).

Determining prevalence.

Prevalence studies are more practical than incidence studies in that they measure the prevalence of a disease at a particular point in time in addition to the population burden of disease. Information is physically collected by the researcher in order to obtain information on disease prevalence (Pearce, 2012). Worldwide, countries are encouraged to conduct random sample, population-based prevalence and cause surveys of HI and auditory pathology. The benefits of utilising such surveys is that it allows for the collection of accurate information on the size of the problem. It, in addition, provides an overview of the main causes of HI and auditory pathology. Baseline data is thus provided to assist all

stakeholders to prioritize and plan for services as well as allocate resources. Lastly, information obtained from surveys allows for comparisons of prevalence among areas and countries (Ullauri et al., 2014; WHO, 2012b).

WHO Ear and Hearing Disorders Survey. The WHO Ear and Hearing Disorders Survey (WHO, 1999) was designed as a measure to determine the prevalence of auditory pathology and HI. It has been widely used to determine prevalence of HI and to date, data published from at least 15 surveys in 11 different countries and regions have been published (Ullauri et al., 2011). One of the strengths of using this survey is that it allows for the generation of standardized data and comparisons between countries (Ullauri et. al., 2011; Stevens et al., 2011). In addition, prevalence data makes it possible to determine the burden of disease as well as assist with planning, determination of priorities, economic analysis and raising awareness. By using a standardised measure, results can be used at local and national levels and collated for regional and global levels (WHO, 2012b).

Prevalence of Hearing Impairment

Global prevalence.

When the prevalence of DHI was first estimated in 1985, it was estimated that 0.9% of the world's population presented with a DHI (Olusanya et al., 2014). By 1995, 10 years later, this number increased by more than 100% to 2.1% of the world's population presenting with a DHI. Merely 13 years later in 2008, the estimated global prevalence of DHI was 10% (Oishi & Schacht, 2011). The distribution of DHI at that time was reported to be 1.4% for children aged 5-14 years, 9.8% for females older than 15 years and 12.2% for males older than 15 years (Stevens et al., 2011). It is well-known that the incidence to HI increases with age. A 3% prevalence rate was reported for individuals between the ages of 20 and 35 years, but that increased to 11% between 44 to 55 years with a significant increase to 43% for those

between the ages of 65 and 85 years (Lasak, Allen, McVay & Lewis, 2014; Cruickshanks, Wiley & Tweed 1998), which supports the suggestions that the most common cause of HI is age-related HI, i.e. presbycusis (65 years and older).

The most recent global prevalence data indicates that there is an estimated 360 million individuals worldwide who present with HI, which is 5.3% of the world's population (WHO, 2012a). It has been reported that 78 million of those affected are living in developing countries (WHO, 2012a). The majority of individuals with HI (328 million) are adults older than 15 years of age. Of these individuals, 183 million are male and 145 million female. Approximately one-third of individuals over the age of 65 years are affected and this prevalence is seen to be the highest in South Asia, Asia Pacific and Sub-Saharan Africa (Olusanya et al., 2014; WHO, 2012a).

It is evident that DHI is unequally distributed across the world (WHO, 2012a). A comparison between prevalence rates in high-income regions to lower-income regions, suggests DHI to be nearly double to that seen in high-income areas (WHO, 2012a) (Figure 1).

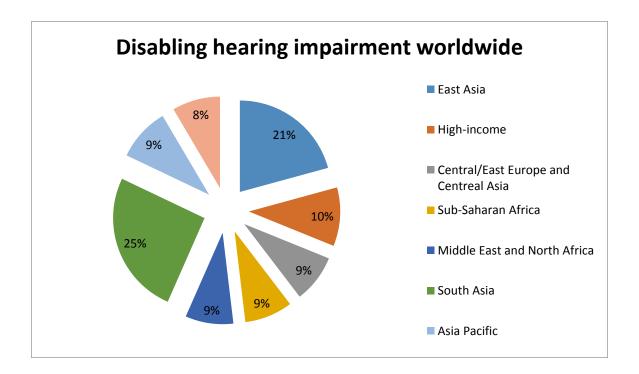


Figure 1. DHI across the world (WHO, 2012a)

There also appears to be a significant difference in prevalence rates for DHI for adults and children across regions (Grosse, 2007) (Figure 2). According to the WHO (IDP, 2011), the issues of prevention and management of HI are still of low priority in most developing countries. This could be due to the fact that too often, the identification of hearing loss in children is delayed as parents are unaware that newborn babies are able to undergo a battery of hearing assessments to detect such impairments. Similarly access to hearing health services may be limited (WHO, 2010; Madell, 1998).

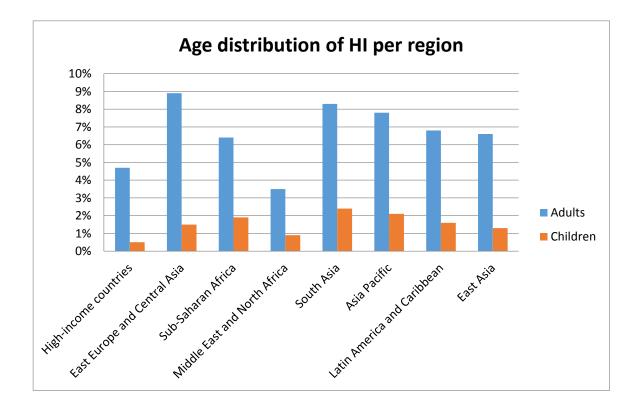


Figure 2. Prevalence of DHI in adults and children by regions (WHO, 2012).

The WHO Ear and Hearing Disorders Survey has been conducted in a number of countries including Brazil, China, Ecuador, India, Indonesia, Iran, Madagascar, Nigeria, Oman, Sri Lanka and Vietnam (WHO, 2013). Eighteen of these studies were conducted in high-income areas and 24 in middle- or low-income areas. Thirteen studies only reported on children and adolescents younger than 20 years of age, while 12 studies tested only the adult

population and 17 reported for participants of all ages. Data regarding hearing aid coverage was reported from eight studies, of which besides one country, the rest were from highincome areas (Stevens et al., 2011; WHO, 2013). The results indicated that the prevalence rates of DHI reportedly ranged from 2% to 9% of the population (Pascolini & Smith, 2009). The same growth in prevalence rate in comparison to age is seen worldwide.

Table 3

Comparative prevalence rates of moderate and severe hearing impairment between highincome and middle- and low-income areas (WHO, 2014a).

Age Group	High-income areas	Middle- and low-income areas
0-59 years	7.4 million	54.3 million
>60 years	18.5 million	43.9 million

National prevalence.

Prevalence data for HI and auditory pathology in South Africa is lacking. From recent reports, it is estimated that approximately 6 out of every 1000 infants born, are born with or develop a HI, three times higher than figures reported for developed countries (Olusanya et al., 2014; WHO, 2013). It can thus be inferred that between 9 and 18.2 infants are born daily with a HI (thus 3306 and 6612 annually) in South Africa (Swanepoel, Störbeck & Friedland, 2009). This figure is confirmed by Copley and Friderichs (2010) who reported that approximately 17 babies are born with or will develop HI every day in South Africa. This is in contrast to the rates of 2 to 4 infants born daily with a HI in developed countries (Attias et al., 2006). HI is considered the most prevalent congenital abnormality found in newborns and it is more than twice as prevalent as other conditions that are often screened for at birth, such as sickle cell disease, and hypothyroidism (Finitzo & Crumley, 1999). To date, no national surveys have been conducted, however surveys have only been completed at provincial or sub-national levels in South Africa.

Prevention of Hearing Impairment

Although hearing disability is usually experienced over a lifetime for some individuals, approximately half of the incidence of HI in all age groups could be prevented (Olusanya, Neumann & Saunders, 2014; WHO, 2006). Prevention can be done at three levels; primary, secondary or tertiary prevention (Olusanya et al., 2014).

Priority must be given to the primary prevention of HI, more specifically in low- and middle-income areas. Primary prevention prevents the occurrence of the disease due to other factors which may be leading to a HI. Such interventions may include interventions such as noise induced HI campaigns, immunizations against infections (e.g. rubella), treatment against otitis media and limiting, where possible, the use of ototoxic medication (WHO, 2006). This is particularly important in developing countries where health care is often scarce.

Secondary prevention includes actions that prevent a disease actually causing a HI, or to prevent a HI becoming a disability. These include screening for early detection, diagnosis and treatment of infections such as meningitis (WHO, 2006). Secondary prevention in addition includes the implementation of early hearing detection and intervention programmes for HI before six weeks of age as well as upon school entry. Evidence shows that early identification of HI may lead to substantial improvement in language and education, however late identification leads to poor remediation (WHO, 2006).

Finally, tertiary prevention is done to prevent the disability from becoming a handicap. This may include hearing amplification, aural rehabilitation, special education and accessibility (WHO, 2006).

The overall effectiveness of rehabilitation of a child with a HI is often complex. This is predominantly the case in developing countries where financial and human resources are scarce. The cost-effectiveness of the acquisition and maintenance of hearing amplification devices (e.g. hearing aids, cochlear implants and assistive listening devices) as well as aural rehabilitation in developing countries is a constant problem. In developing countries, only 20% of individuals with a HI who require amplification have access to hearing aids (WHO, 2013).

Ameliorating the effect and impact of HI can only be done with appropriate planning and resources. In order to appropriately plan for ear and hearing health services, accurate epidemiological data is required. Accurate prevalence data is important as it allows organisations and relevant governmental departments to plan and implement local, regional, provincial and national ear and hearing health care services.

Lack of Prevalence Data in South Africa

In the most recent census conducted in 2012, it was reported that nationally approximately 5% of the South African population have some kind of disability (Stats SA, 2012). The prevalence of HI was estimated at 20% of the reported disabilities. Thus, making HI the third highest reported disability after vision (32%) and followed by physical disability (30%). The distribution of HI according to race revealed that the white population presented with the highest prevalence of HI at 26%, followed by the African population (20%) and the coloured population (18%). The Indian/Asian population presented with the lowest prevalence of reported HI at 16% (Stats SA, 2012). Although these statistics were obtained via population-based census via self-reported questionnaires, they are still crucial to report on as this brings focus into HI being under- or over-report amongst populations. This in itself

then shows the need for more accurate screenings to be done and not purely relying on selfreported where the reliability is in question.

There is a dearth of information regarding the prevalence of HI in South Africa. A study conducted in the early 1990's reported that 13% of preschool children had undetected HI (Swart, 1996).

The fourth highest disability prevalence rate, 5.1%, was reported in the Limpopo Province (Stats SA, 2012). Limpopo is South Africa's northernmost province with an approximate population size of 5.4 million individuals, taking up 10.3% of South Africa's land area. Limpopo province is divided into five municipal districts and furthermore subdivided into 24 local municipalities. EMLM is a local municipality that makes up part of the Greater Sekhukhune District and consists of 30 wards, 104 villages and two towns, with approximately 60 200 households.

Census data estimated that a total of 14 388 individuals presented with some form of disability in the EMLM. HI was reported by 2 351 (16.34%) individuals. As reported in the national prevalence information, HI in EMLM is also the third highest reported disability after vision and physical disability (EMLM IDP, 2011). Access to health care services in this rural area is limited. It has been confirmed that the demand for health services far exceeds the facilities that are currently available to the residents of the EMLM (EMLM Annual Report, 2011)

The South African government is aware of the vast challenges faced by the health system especially in rural communities. Rural communities make up 38% of South Africa's population (World Bank, 2012). Access to quality health care services in rural areas is limited due to a number of significant barriers in the rural context. These barriers include (i) geographic accessibility (distances to health care facilities, lack and expense of transportation

services); (ii) financial accessibility (high levels of poverty and unemployment); (iii) acceptability (health care services are often not accepted based on the social and cultural norms of the community accessing them), and lastly (iv) the availability of health care facilities (the inequitable distribution and shortage of healthcare facilities, under resourced facilities).

A relationship between poverty, unequal distribution of health care services and health outcomes is described by Eagar, Versteeg-Mojanaga and Cooke (2014). It is postulated that individuals living in rural contexts experience higher burden of diseases (both communicable and non-communicable diseases) and thus poorer health outcomes (Eagar et al., 2014).

Summary

Hearing health care services in the form of audiology services are almost non-existent in the remote and rural areas of Limpopo. In the EMLM audiological services are only offered at two hospitals. Additional access to audiological services was facilitated by the establishment of an audiology clinic in one of the villages. This is however wholly inadequate given the high rate of HI in the EMLM area as reported during the 2012 census.

The lack of epidemiological data on the prevalence of HI and auditory pathology in a rural community such as the EMLM negatively impacts on the availability of audiological services. Priorities for ear and hearing health care services can only be determined by documenting the needs of the community. Without relevant data on the type and extent of the problems encountered, the government is unable to allocate resources and improve on the services offered. In an attempt to illuminate the extent of HI and auditory pathology in rural areas of South Africa, the research study aimed to address the following research question: What is the current prevalence of ear and hearing disorders in the EMLM

area of Limpopo Province, South Africa. By highlighting the extent of HI and auditory pathology, it would allow the expansion of services based on evidence-based data.

Chapter 3: Methodology

Introduction

The purpose of this chapter is to provide a detailed description of the research aims, design and phases. The participant selection criteria and description will be discussed as well as the data collection equipment, measures and data collection procedures. Lastly, ethical considerations and aspects of validity, reliability and data analysis will be emphasised.

Research Aims

The main aim of this study was to obtain epidemiological data on the prevalence and distribution of auditory pathology and HI in the EMLM of the Limpopo Province.

The main aim was achieved by the following sub-aims:

- To determine the prevalence and distribution of HI in the EMLM.
- To determine the prevalence and distribution of auditory pathology in the EMLM.

Research Design

The research employed a quantitative, non-experimental, cross-sectional survey research design to achieve the aims of the study.

A quantitative research paradigm was chosen for the study as the primary objective was to determine how the measured variables are distributed, and how they relate to each other (Punch, 2003). Quantitative research involves specifying, observing and measuring data numerically (Cresswell, 2003). Additionally, this type of research reduces researcher bias (Gravetter & Forzano, 2003).

A cross-sectional survey research design, a non-experimental approach to research, was implemented for this study. In cross-sectional research, various groups of people are examined at one point in time (Salkind, 2009). A survey was conducted as it is versatile and efficient (Punch, 2003). The strengths of a cross-sectional survey research design are that conclusions about a population from the sample studied can be drawn and can thus provide inferences about the prevalence and distribution of HI and auditory pathology in the community of EMLM. It is also the most common research design used in prevalence studies. Limitations of a cross-sectional research design include measuring outcomes at one specific point in time, therefore not taking into consideration diseases that have a shorter duration time or changes in clinical practice over time (Jackson, 2012).

Research Phases

The research was conducted in three phases; the development, pilot study and main study phases. In the first phase of the study the research protocol was developed and permission obtained from the Department of Health and Social Development of the Limpopo Provincial, the Ndlovu Care Group as well as ward councillors to conduct the research study. The second phase, the pilot study, was important in refining the research protocol and data collection procedures. The final phase was the main study.

Context

The study was conducted in the EMLM, located in the Limpopo Province of South Africa. The EMLM forms part of the Sekhukhune District that is the second poorest district in South Africa. This district is one of the 13 points identified as requiring development (Integrated Development Planning [IDP], 2011).

The EMLM is predominantly a rural setting with limited access to municipal services such as water and sanitation. Only 33% of households have some access to piped water facilities. Of these households 3% have water within their house, 20% obtain water via a

yard tap and 10% use a communal standpipe. Waterborne sanitation is severely lacking in this area. Four percent of the households have access to waterborne sanitation services; 9% have access to pit latrines without ventilation and 3% have access to septic tanks. Electricity supply is much better as 94% of all the villages within the EMLM have access to electricity supply (EMLM Annual Report, 2011; IDP, 2014).

It is estimated that there is 60 200 households in the EMLM with an average household size of 4 individuals (IDP, 2014; Stats SA, 2011). The total estimated population size for the EMLM is approximately 249 300 individuals. Females make up the majority of the population at 54% (133 800). Fifty seven percent of the population is between the ages of 15 and 64 years, 36% is between the ages of 0 to 14 years, whilst 7% is older than 65 years of age (IDP, 2014; Stats SA, 2011).

The high unemployment rate in this area results in high levels of poverty. The lack of economic growth directly affects the employment rate. More than two-thirds of employable individuals (63%) are unemployed. The level of unemployment is more prevalent in the younger age groups. Due to the high levels of poverty and unemployment, most households depend on government grants as a means of income. It has been found that 24% of all households reported an average of household income between R 4 801 and R 9 600 per month whilst 38% of all households reported having no monthly income (EMLM Annual Report, 2011; IDP, 2014).

Education is a constant concern in this area as 46% of the adult population reported having received no schooling, whilst only 22% completed some secondary education and less than 1% completed higher education (EMLM Annual Report, 2011). In EMLM, there is currently only one further education and training college. There are 85 secondary schools, 115 primary schools and 126 pre-schools. Of these combined (pre-school to secondary

schools) schools, 58 have extremely limited infrastructure; more specifically no water, limited sanitation and no appropriate sporting facilities (IDP, 2014).

Residents of the EMLM have access to 18 health facilities which include 2 hospitals, 11 primary health care (PHC) clinics and 5 mobile clinics. Health care facilities are inadequate in addressing the health needs, as the EMLM should, considering the population, ideally have ten hospitals (IDP, 2014).

Pilot Study

Pilot studies are designed to test logistics and gather information prior to a larger study in order to improve the quality and efficiency of the research (Clark-Carter, 2012). A pilot study can reveal deficiencies in the design of a proposed research study or procedure. The results of the pilot study are then used to address these deficiencies before time and resources are consumed on large scale studies. A pilot study is normally small in comparison to the main study and therefore provides only limited information on the sources and magnitude of variation of response measures (Blessing & Chakrabarti, 2009).

Objectives.

The purpose of the pilot study was to test the sampling strategy, data collection procedures, suitability of equipment, logistics and timing of each part of the data collection forms.

Participant description.

A total of 40 participants from nine households were included in the pilot study. Households were selected from one ward and the average household size was 4.4 individuals. The majority of participants were female (n = 26; 65%). The mean age of participants was 17.6 years (Range: 1 month - 62.4 years; SD - 19.98).

Procedures.

The ward was randomly selected prior to arrival. The households were selected (as described in the main study) and potential participants given information about the study in their home language. Only participants that gave written consent and/or assent were included in the pilot study. Case history information was obtained separately from each participant in their home language. Thereafter, the same steps as outlined in the main study were followed and the measuring instruments completed with each participant. Data collected from these participants were not included in the main study.

Results and recommendations.

The pilot study assisted with refining the research measurement instruments and procedures. No changes were required with regard to the sampling strategy but some changes were made to the survey form, training programme for research assistants as well as the logistics. The following recommendations were implemented following the pilot study:

- *Survey form.* The changes to the test protocol were made whereby the repeat testing of 1 kHz was excluded. In the survey form the 'Action needed' section was expanded.
- *Research assistant training.* The role of the research assistants was expanded to also perform pure tone audiometry and AABR screening. The interpretation of test findings was however made by the researcher, a qualified audiologist.
- *Timing*. The estimated time spent at each household (with an average of four individuals per household) was one hour. Participants in the main study were informed of the time commitments prior to testing.
- *Logistics*. During the initial visits, the research team arrived at the household with all the audiological equipment. This was time consuming and in most cases impractical

as the houses are very small. The recommendation was that the research team would first approach the house to explain the purpose of the study and to determine the equipment needs (based on the ages of individuals in the household).

Main Study

Study sample.

Sampling method. A random multi-stage cluster sampling strategy, two-stage sampling, was utilised for the purpose of the research study. This type of sampling draws a random sample from blocks within the community on a map. A field team (audiologist and volunteer) then visits the clusters or blocks in the sample. This type of research design is useful when the selected clusters and population is widely dispersed and it is thus impractical to list as well as sample for all its elements (Hulley, Cummings, Browner, Grady & Newman, 2007).

The term cluster is defined as a collection of sampling units which form a natural grouping or community within the population (Johnson & Christensen, 2014). Clusters can be villages, settlements, municipal wards or census enumeration areas. The sample of households is then randomly selected from these clusters. Multi-stage sampling is used in a larger population and here the population is divided into large groups such as districts and the required number is selected by the probability proportional to size (PPS) method (Som, 1996).

The PPS method is guided by the likelihood of clusters or communities being selected to vary according to their size. The PPS procedure is self-weighted and no weighting is therefore required in the analysis (Som, 1996). PPS was chosen as with clustering, fewer units are required to make the sample. This consequently, positively improves the cost-

effectiveness of administering the survey and in addition controls for selection bias through random selection (Hulley et al., 2007).

For the current study, the first stage in the multi-stage sampling process was the random selection of the clusters, in this case municipal wards. A rural sampling frame was used in order to determine the proposed sample size. This resulted in the exclusion of all the wards where the two major towns are situated and wards with a large population. For the purpose of this study, five wards (wards 1, 7, 14, 27 and 29) were excluded from selection (See Table 4). Seven wards were randomly selected for inclusion in the study (Wards 2, 4, 6, 9, 17, 23 and 24). Ward 9 was included in the study although it has a large population size; it was the area closest to the main clinic and one of the hospitals. Logistically, some of the other areas were too remote for the research team to travel to.

Table 4

Wards	No of	Excluded	Included	
vv ai us	households	LACIUUCU	menuucu	
1	3180			
2	1250		\checkmark	
3	1548			
4	1288		\checkmark	
5	1997			
6	1558		\checkmark	
7	2854	\checkmark		
8	1428			
9	3053		\checkmark	
10	2056			
11	1224			
12	1975			
13	1284			
14	3821	\checkmark		
15	1895			
16	2163			
17	1297		\checkmark	
18	1533			
19	1861			
20	2831			
21	2421			
22	1178			
23	1646		\checkmark	
24	2363		\checkmark	
25	1705			
26	1280			
27	2580	\checkmark		
28	2050			
29	2906	\checkmark		
30	2027			
Total no of	60251			
households				

Total number of households per ward (Stats SA, 2011)

The second stage was the selection of households within the cluster which were identified using the PPS.

Sample size. The sample size (identifying frame) included 850 individuals (N = 850) from 357 households from seven clusters (See Table 4 and Table 5). The sample size is much smaller than the 1550 participants initially expected. The reason for the smaller sample size was the absence of many individuals (mostly males) in the selected households on the day of testing. These individuals were reported to be elsewhere due to work commitments. A small number of participants also refused to participate in the study. Reasons for this were time limitations or prior commitments in which they had to attend.

The sample size was based on the 10% estimated prevalence of disabling HI (Oishi & Schacht, 2011). The total population of the EMLM is estimated at approximately 249 300 living in approximately 60 200 households with an average household size of 4 individuals (Stats SA, 2011). The confidence interval is 95%. The 95% confidence interval precision is within 3.4%, thus making it fairly precise.

Selection of households. In order to determine which households were to be visited, the total number of households from the randomly selected wards were added and divided by the total number of households to be tested. Thus, indicating that the researcher should visit every 35th household in each of the selected wards. In order to ensure that the measure of PPS is applied, the total number of households in each selected ward was divided by 35 in order to determine how many households that was to be visited in each ward (See Table 5).

Table 5

Ward	Total no of households	No of households visited	
2	1250	36	
4	1288	37	
6	1558	45	
9	3053	87	
17	1297	37	
23	1646	47	
24	2363	68	
Total	12 455	357	

Number of households visited per ward

Replacement of households due to refusal. In cases where the households selected declined participation in the study, the research team went to the household to the left of the household that refused. If this household also refused, the team went to the household to the right of the household targeted initially.

Participants.

Inclusion and exclusion criteria. All individuals living in the specific household selected who gave consent and/or assent to participate in the study were included in the research.

Households were excluded if they had visitors on the day of testing. This was done to prevent skewing of data as only specific households were visited as per the methodology. Households were also excluded if the individuals within the household, or the research team felt in any way uncomfortable or threatened.

Participant description. Of the total number of participants tested, 60.71% (n = 516) were female and 39.29% (n = 334) were male. The mean age of the participants was 27.9 years (Range: 1 month – 94.5 years; SD - 22.28).

Measuring Instruments and Equipment.

Measuring instruments. Two data collection forms were used in this study, the WHO Ear and Hearing Disorders Survey (WHO, 1999) and a self-developed case history form.

WHO Ear and Hearing Disorders Survey (WHO, 1999). This form was used to determine the prevalence of HI and auditory pathology in the EMLM. This survey is widely used to determine prevalence of HI with data published from at least 15 surveys in 11 different countries and regions (Ullauri et al., 2011). The use of this survey form allows for the generation of standardized data to compare results among various surveys and areas (Ullauri et. al., 2011).

A survey is the preferred type of data collection for this research study as it anticipates identifying attributes of a large population from a smaller group of individuals and generalising this data across the entire population (Creswell, 2003).

The WHO Ear and Hearing survey consists of five sections completed by the research team (See Appendix A). A brief description of the survey is presented in Table 6.

Table 6

Description and rationale for the WHO Ear and Hearing Survey components

Section	Description	Rationale
Demographic information	Name, age and gender	To determine the prevalence of HI and auditory pathology
		at an age and gender level.
Hearing examination	< 3.11 years: OAEs and AABR.	To determine the prevalence of HI and auditory pathology
	>3.11 years: Assessment of air conduction thresholds	of individuals in the EMLM.
	bilaterally 0.5 kHz, 1 kHz, 2 kHz and 4 kHz.	
Basic ear assessment	Otoscopy and tympanometry	To determine middle ear functioning and any outer and
		middle ear pathologies that could contribute to HI.
Cause of auditory pathology	This will be determined once all the components of	To aid in suggesting appropriate recommendations and
or HI	the survey are completed.	referrals.
Recommendations/Referrals	For additional testing or management, i.e. medication	To assist in decreasing the impact HI may have on
	or hearing aids, etc.	individuals and to control any diseases found as well as to
		determine future planning of health services required.

Self-developed case history form. The self-developed case history form (See Appendix B) was completed in the participants' home language prior to any audiological testing. The following sections were included in the case history form: Highest level of education obtained, job status and medical history (which included non-communicable diseases, trauma, medication/treatment and other).

Table 7

Section	No. of questions	Type of questions	Information obtained	Rationale
Identifying information	4	Closed ended	Participant date of birth, gender, address, and ward number.	Obtain identifying information regarding participant date of birth, gender and ward as per the research aims.
Qualification and work experience	2	Closed ended	Highest education obtained, and employment status.	According to participants in a study conducted, obtaining information regarding educational level is considered important information when conducting a case history interview. This is particularly seen in rural areas and may contribute to the lack of number of participants completing school or studying further in a tertiary institution (Huang, 2009). Factors which affect this is how many years of formal schooling was attended by the participant as well as work experience such as employed, unemployed, pensioner etc. (Shipley & McAfee, 2008).
Medical history (adult vs. child)	4	Open and closed ended	Non-communicable diseases, trauma, treatment/medication and other additional information.	Obtaining medical history aids the audiologist to determine the starting point for understanding clients, the problems they may have experienced or are experiencing, and any difficulties they are facing (Shipley & McAfee, 2008). This assists in determining the "at-risk" clients and helps in making an informed diagnosis.

Description and rationale for the self-developed case history forms

Audiological measures, protocol and equipment.

The various audiological measures (protocol), norms and equipment used are presented in Table 8.

Table 8Audiological measures, equipment and norms

Measure	Equipment	Rationale	Norms
Infection Control	• Ultracide disinfectant	Infection control is the management of the environment for the purpose of minimizing or potentially eliminating risks of possible cross-contamination and the potential	N/A
		of spreading diseases. It is the teams' ethical responsibility to administer the infection control guidelines within the context of the environment for both adults and children (Bankaitis & Kemp, 2008).	
Otoscopic examination	 Welch Allyn Otoscope Speculae Ultracide disinfectant 	Otoscopy is utilized as a general examination of the external ear and tympanic membrane using an otoscope (Martin & Clark, 2009; Diefendorf, 2009).	Ear canal free from cerumen and/or foreign objects with a visible, pearly grey tympanic membrane and a cone of light present.
Tympanometry	 Titan Portable Screener Tympanometer Tympanometry probe tips Ultracide disinfectant 	Tympanometry was done to establish the functioning of the middle ear. Pressure is sent through the middle ear therefore measuring the mobility of the tympanic membrane. Tympanometry using a 226 Hz probe tone was used for individuals > 6 months of age, whilst a 1000 Hz probe tone was used for infants < 6 months. Research has found that conventional tympanometry may produce outcomes which are erroneous, such as poor sensitivity and producing different shaped peaks (for example, double peaks) when testing infants < 6 months. The differences between infants 6 months and younger as opposed to adults may be due to the	Infants (< 6 months): Traces are recorded as normal or abnormal. If the trace appears in the upward direction, this is considered a positive peak and is considered normal. If the trace is going in the opposite direction, i.e. downwards, this is considered a negative peak and is regarded as abnormal (Baldwin, 2006; Kei et al., 2003).

differences in acoustic energy transmissions through the
middle ear. Furthermore, research indicates that infants
6 months and younger's middle ear is mass-dominated
as opposed to adults which is stiffness-dominated (Kei
et al., 2003) For high frequency tympanometry, the
ECV value is disregarded.

Children (> 6 months – to 10 years): Middle Ear Pressure: -150 to 50 daPa; Static Compliance: 0.25-1.0 5 cm³; Ear Canal Volume: 0.3-0.9 mmho. Adults: Middle Ear Pressure: -150 to 50 daPa; Static Compliance: 0.2-2 cm³; Ear Canal Volume: 0.28-1.8 mmho (Keefe & Feeney, 2009; Margolis, 1997).

Measure	Equipment	Rationale	Norms
Pure tone audiometry	 AS608 Screening 	Air conduction is designed to evaluate the whole	Refer to tables 1 and 2
(air conduction)	Audiometer	auditory pathway (from the outer ear right through to	
	• Headphones	the brain) to establish the thresholds of hearing. When	
	• Response button	sound is sent via the earphone, the hearing threshold	
	• Survey response	(sensitivity) can be evaluated in each ear separately	
	form	(Welling & Ukstins, 2013b).	
		Instructions were given to individuals and four	
		frequencies tested bilaterally; 1000 Hz, 2000 Hz, 4000	
		Hz, and 500 Hz. Testing began with familiarisation,	
		using a test tone of 1000 Hz at 40 dBHL if the	
		participant was assumed to have normal hearing (based	
		on the case history information). If the participant was	
		suspected to have a HI, threshold testing began at 70	
		dBHL (Hall & Mueller, 1997).	
Otoacoustic	OtoRead Portable	DPOAEs were conducted on children aged birth to 3.11	Pass /refer criteria: The signal to
Emissions (OAEs)	OAE	years. OAEs provide a physiologic means of assessing	noise ratio should be at least 6 dB

Moosuro	Fauinmont	Dationala	Norma
			2012)
			clinic within 4-6 weeks (WHO,
			should be arranged at their local
			cannot be tested and a screening
			no OAE on one ear, the infant
			and a 'pass'. If an infant obtained
			this indicated a 'refer' for both ears
			both ears, an ABR was used and
			had no OAE response on one or
			classified as a 'pass'. If an infant
			'pass' bilaterally, this was then
			al., 2012). If an infant obtains a
			as a 'refer' (De Conde Johnson et
		• 12 frequency region. 2 5 km2.	absent and thus, will be classified
		 F2 frequency region: 2-5 kHz. 	greater than 30 dB, OAEs will be
		 Frequency ratio (f2/f1): 1.22 	In individuals with a cochlear HI o
		• Stimulus intensity: L1 65 dBSPL and L2 55 dBSPL	(JCIH, 2007).
		measured at 2f1-f2 for each	must pass for an overall pass result
		• Stimulus type: two primary pure tones, response	minimum of three test frequencies
	alonnootunt	The test protocol for DPOAEs (JCIH, 2007) include:	automatically be displayed. A
	disinfectant	affected by conductive hearing loss (Hall, 2000).	test, a pass or refer result will
	• Ultracide	pathological middle ear system and is, therefore,	dBSPL. At the completion of the
	• OAE probe tips	preneural auditory function. It is further sensitivity to a	(minimum response level of -5 to -

Measure	Equipment	Rationale	Norms
Automated Auditory	Maico MB11	ABR allows one to detect retrocochlear pathology	A pass or refer criteria is obtained.
Brainstem Response	• Conducting gel	including the abnormalities along the auditory pathway	When a 'pass' result is received, it
(AABR)	Alcohol swabs	beyond the cochlea, including the auditory nerve and	is suggestive of an absence of a
		various structures of the auditory brainstem. AABRs are	sensorineural hearing loss (Stach,

		commonly used in the "hard-to-test" population as it	2010). Typically, when a response
		requires no responses from the individual (Newman & Sandridge, 2007). The presence of a response (pass) or the absence of a response (refer) is determined by using a 0.1 msec click stimulus type and an intensity of 35 dBnHL. A relatively high stimulus rate is used, thus minimising test time (Mason, 2002). The suggested rate is anything faster than 30 clicks per second (Mason, 2002). The suggested stimulus level is in the range of 35 dBnHL to 50 dBnHL (Mason, 2002).	is present at 30 dBHL – 40 dBHL, the child is said to have hearing within normal limits at the frequency range of 1000 Hz to 4000 Hz.
OAE and	OtoRead Portable		Both tests were conducted on
Tympanometry	OAE		children from birth to 3.11 years of
Protocol	• OAE probe tips		age. The results were recorded on
	• Titan Portable		the survey form. If a refer result
	Screener		for either of the tests were obtained
	Tympanometer		children were referred to the
	• Tympanometry		Ndlovu Wits Audiology clinic or
	probe tips		Philadelphia hospital for further
	• Ultracide		assessment. If an overall pass
	disinfectant		result was obtained no referrals
			were required.

Research team.

The research team consisted of the researcher and three research assistants. The researcher was a qualified audiologist with two years' experience in the public health care sector. The research assistants were members from the Elandsdoorn community. The research assistants all completed Grade 12, and had previous experience in interpreting and conducting research through their involvement with a non-governmental organisation. They all had previous experience as volunteers in the audiology clinic.

Training of research assistants. All research assistants were trained in a four-hour training session prior to data collection. The training covered the following areas: (i) purpose of the study; (ii) how to approach households; (iii) obtaining informed consent; (iv) use and biologic calibration of equipment; (v) accurate completion of the data collection forms; (vi) infection control, and (vii) reviewing the maps of the areas where data collection took place. The research assistants were provided with a manual outlining the aspects addressed during training (Appendix C). This manual is based on the WHO Ear and Hearing Disorders Survey Protocol (WHO, 1999).

Two of the research assistants used in the study had previous training and experience in performing hearing screening prior to their participation in the data collection for the current study. All research assistants signed confidentiality agreements after training and prior to data collection.

Data Collection Procedures

Once ethical clearance was obtained and permission granted by the Ndlovu Care Group and the Limpopo Department of Health and Social Development, data collection commenced.

Community entry.

The community were informed of the study by announcing the research project on Moutse FM, the local radio station. Permission was sought from ward councillors and tribal authorities (e.g. village chiefs) prior to entry into the selected wards.

Entry into households.

The research team visited each household as described in the study sampling procedure. If permission was granted to enter the household, individuals in each of the selected households were presented with the participant information sheet. The study was explained to the individuals and they were required to give consent and/or assent to the study. For individuals aged 18 and younger, a parent or guardian signed consent on their behalf, with them signing their own assent form.

Testing Procedure.

The test protocol for individuals older than 4 years of age is presented in Figure 3 and children younger than 4 years of age are presented in Figure 4. Sound level measurements were taken prior to testing.

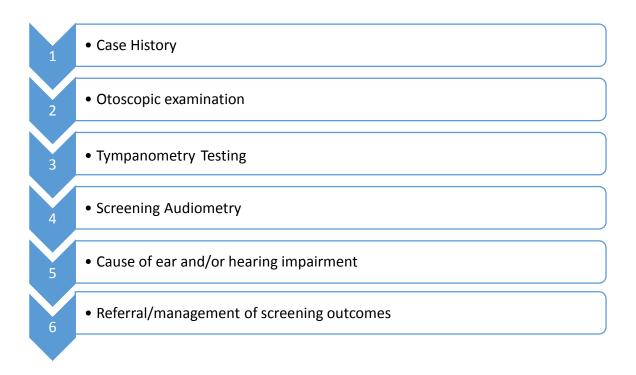


Figure 3. Test protocol: > 4 years and older.

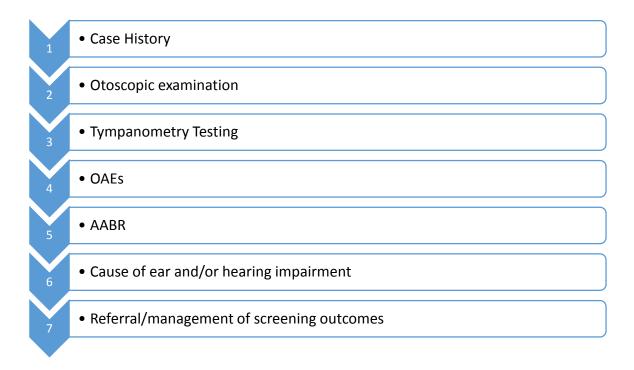


Figure 4. Test protocol: 0 - 3.11 years

Monitoring of environmental noise.

Precautions were taken to minimize the interference of noise such as utilising TPH earphones. Additionally, if noise became too loud to continue testing, testing was paused until noise levels decreased. Furthermore, if noise levels became too excessive to complete any testing, individuals were then tested in the vehicle transporting the research team to various households.

Screening levels.

Although this study was aimed at screening for hearing impairment and auditory pathology, categorization of participants according to degrees of hearing impairment was done by threshold testing for air conduction only. This enabled the researcher to breakdown the results found into various categories and compare these results with previous statistics provided or with other studies done internationally.

Management of screening outcomes.

Management of the screening outcomes depended on the results, cause of ear disease and/or degree of HI. If a referral was indicated, individuals were referred to the appropriate institutions (e.g. closest clinic or hospital).

Data management.

Results were recorded on the relevant measuring instruments. Data was encoded according to data definitions on a password-protected Excel spreadsheet. Once printed, data was stored in a locked cupboard, which only the researcher had access to.

Ethical Considerations

Ethical principles as outlined in the Declaration of Helsinki (World Medical Association [WMA], 2013) were adhered to during this study.

Ethical clearance.

Ethical clearance was obtained from the Human Research Ethics Committee (Medical) of the University of the Witwatersrand (Protocol number: M130238) (Appendix E). Permission was granted by the Limpopo Department of Health and Social Development for the research study to be conducted in EMLM (Appendix F) as well as from Ndlovu Care Group Chief Operations Officer (Appendix G).

Once all clearance and permission was obtained, the team of research assistants were explained the basic principles and concepts of the study, signed the confidentiality form as well as was given a training programme as to how to complete the survey (including assessment and analysis of the methods involved in the research study).

Informed consent.

An information pamphlet (see Appendix D) was presented at each household explaining the team and the study, its' goals as well as the information pertaining to study. After the team had explained the study, each member of each household was provided with written information to allow for informed consent or assent to become a participant in the study. All individuals who were 18 years and older were required to sign the consent form if they wished to participate in the study. Participants under the age of 18 required a parent or legal guardian to sign the consent form for them and those aged between 7 and 18 years of age were additionally required to sign an assent form stating that they wanted to participate in the study.

Confidentiality.

Data gathered from the individuals did not include any identifying information. Instead of disclosing any names and breaching confidentiality, participant numbers were used to represent each participant while analyzing data, thus allowed for participant confidentiality.

Autonomy.

The principle of autonomy recognizes the rights of individuals to self-determination. This is rooted in society's respect for individuals' ability to make informed decisions about personal matters (WMA, 2013). This principle was applied through individuals' choice to agree or decline participation once the purpose, methods, any possible conflicts of interest, the anticipated benefits and potential risks of the study were explained. Their right to withdraw from the study without any negative consequences was also explained.

Beneficence.

The term beneficence refers to actions that promote the well-being of others. In the medical context, this means taking actions that serve the best interests of patients (WMA, 2013). Individuals that participated in the study were afforded the opportunity to obtain information regarding their hearing status, that due to limited audiological services in the Limpopo Province they would not have otherwise received.

Non-maleficence.

The principle of non-maleficence is to do no harm to the patient by providing treatments that have adequately been tested that they do in fact "do no harm" (WMA, 2013). Referrals recommended by the research team were made taking the participants' best interests into consideration.

Justice.

The principle of justice is concerned with the fair and equitable distribution of benefits and burdens to the individuals in society, and how the rights of various individuals are realized (Feinsod & Wagner, 2008). This study was designed to obtain information regarding the prevalence of HI and auditory pathology in the EMLM area. The results of this study will be used to improve service delivery in the EMLM to ensure that appropriate services are offered to individuals diagnosed with HI and auditory pathology.

Reliability and Validity

Reliability.

Reliability involves addressing the consistency of measures (Shoukri, 2010; Newman & Benz, 1998). In order to establish reliability, inter-rater reliability was determined. Inter-rater reliability is established if test results are consistent when more than one person administers the test (Shipley & McAfee, 2008). A qualified audiologist with two years' experience acted as inter-rater and accompanied the research team on 100% of the visits. The inter-rater completed the same data collection forms as the research team during these visits and the inter-rater reliability determined.

In order to calculate the percentage of inter-rater agreement (A) was the observed agreement (O) divided by the possible agreement (P), thus $A = O/P \ge 100$ (Bordens & Abbott, 2008). There appeared to be no items of disagreement between the inter-rater and assistant administering the test. The inter-rater agreement was thus 850/850 items which yielded a high degree of agreement of 100% (Bordens & Abbott, 2008).

Validity.

Validity estimates how well a study measures what it intends to measure (Newman & Benz, 1998). For the current study, validity was ensured through: i) internal validity; ii) face validity; and iii) content validity.

Internal validity refers to the extent to which a specific research design has excluded all possible hypotheses which could possibly explain the variation of the dependent variable. To obtain high internal validity, a research design should control as many extraneous variables as possible (Bless, Higson-Smith & Kagee, 2007; Silverman, 2000). In this study, internal validity was ensured through the calibration of equipment. Calibration of equipment ensures accurate functioning and thus the validity of the results. The audiological equipment was calibrated prior to data collection in accordance to calibration standards prescribed by the South African Bureau of Standards (SABS 0154-1; 0154-2). In addition, daily biological calibration based on the evaluation of the hearing threshold of a person with normal hearing was done (at 500 Hz, 1 kHz, 2 kHz and 4 kHz. If there was a shift of greater than 5 dB from the baseline measure at one or more frequencies tested, this is typically indicative of the need for calibration of the equipment (Roeser, Eccles & Sameroff, 2000). Daily listening checks were also performed to ensure that the equipment was free from distortion and interfering signals.

Furthermore, internal validity is controlled through known bias from the sample frame. The sample frame that was included in this study appeared to be largely free from known bias in that the inclusion and exclusion criteria as well as sampling techniques allowed for the participants to be different ages, gender and from different educational backgrounds.

Face validity ensures that a test appears to measure what it originally claims to measure. As face validity is not enough to ensure validity as it is based on appearance and judgment and not actual outcomes, content validity was also included (Shipley & McAfee,

2008; Goodwin, 2010). Face validity was established by using a validated questionnaire in the form of a case history form (Appendix B) (Goodwin, 2010).

Content validity refers to the completeness of a test. A valid test battery will represent from the whole spectrum of areas to be tested (Shipley & McAfee, 2008). This was established by completing a pilot study prior to the main study to ensure that the test battery and protocol represented various areas which required testing.

Quality Control

The following quality-control measures, as prescribed by the WHO (1992) were taken into account to minimise non-random errors (coverage errors, observational errors and processing errors):

- Clear and detailed training manuals (adapted from the WHO, 1999) were developed for use by the research team.
- The research team was trained under actual field conditions, in all aspects of their duties.
- Team members were encouraged to sign each survey form and enter their staff number upon completion of filling in each form to encourage good work.
- Inter- and intra-observer variation were measured and quantified. This was done at the beginning and at several various points during the survey, the performance of the team members were assessed by comparing team members testing the same subject, as well as on different occasions.
- Validation of the tests used was carried out and their sensitivity and specificity were measured.

- All audiometric equipment was calibrated regularly. Calibration was done by a laboratory at the beginning and end of the study and on a biological, weekly basis by the team members using self-calibration against their own hearing thresholds.
- Regular feedback regarding performance and possible refresher training was provided by the researcher as required.

Data analysis

Data were documented on the measuring instruments and encoded by the researcher according to data definitions. All data was computerised for statistical analysis with Windows Excel. Results were analysed utilising a variety of statistical procedures, as listed in table 9 and displayed in tables and figures in the results section of this report.

Table 9

Statistical Analysis Completed

Statistical procedures	Rationale and application to the study
 Descriptive statistics Measures of central tendency e.g. mean median and mode Measures of variability e.g. range and standard deviation (SD) 	This type of data was useful for initial analysis of results where one number is provided in an attempt to give readers a sense of the "average" or "typical" values in a distribution (Rubin, 2013; Salkind, 2009; Holt & Walker, 2009). Measures of variability provide additional information such as the extent to which data are clustered together or scattered apart. Frequency patterns (Rudestam & Newton, 2001) are found in the data as well as assists in organising and summarising information (Gravetter & Forzano, 2003).
Binomial proportion confidence intervals	A binomial distribution applies when an experiment has been repeated a fixed number of times, each trial of the experiment has two possible outcomes and the probability for success is the same for each trial, thus making them statistically independent (Albright, Winston & Zappe, 2011). A 95% confidence interval is applied which indicates that 95% of the times that the procedure for constructing the confidence interval is employed (Albright et al., 2011).

Summary

This chapter described the methodology of the research. It included the aims of the study and provided a description of the research design and phases. This was followed by a description of the pilot study and main study. The main study was discussed with respect to cluster and participant selection criteria and description. A description of the measures and equipment used was also provided. Lastly, data collection procedures employed in the current study as well as reliability, validity, ethical considerations and data analysis were discussed.

Chapter 4: Results and Discussion

Introduction

In this chapter the results of the study will be presented and discussed. Demographic information on the sample population will first be presented, followed by the results of the study in relation to the aims, namely the prevalence and distribution of HI and auditory pathology within the EMLM of the Limpopo Province.

Distribution of Participants per Cluster

Participants were selected from seven clusters in the EMLM. Table 10 depicts the population number in the cluster as well as the number of individuals selected with a specific breakdown of gender and age (adult vs. paediatric) included in the study.

Table 10

Donulation		No of participants				
Cluster Population – size*	Ν	Iale	Fe	male	Total	
	SIZE	Adult	Paediatric	Adult	Paediatric	
2	5000	20	21	42	18	101
4	5150	21	22	43	19	105
6	6230	31	21	69	23	144
9	10 000	38	43	79	43	203
17	5180	6	21	40	8	75
23	6580	24	18	37	8	87
24	9450	29	19	62	25	135
Total	47 590	169	165	372	144	850

Distribution of participants per cluster (N = 850)

*Census 2011

Demographic Information of the Sample Population

In total, 850 individuals (N = 850) were included in the study (See Table 11). The majority of participants were 15 years and older (63%; n = 536).

Table 11

Age Groups	Male		Female		Total	
(in years)	N	%	n	%	N	%
0 to 3.11	41	12.28	22	4.26	63	7.41
4 to 14.11	128	38.32	123	23.84	251	29.53
15 to 64.11	148	44.31	317	61.43	465	54.71
>65	17	5.09	54	10.47	71	8.35
Total	334	100	516	100	850	100

Distribution of participants by age and gender (N=850)

More females (60.7%; n = 516) than males (39.3%; n = 334) participated in the study. The difference found in the gender proportion could be attributed to the fact that in rural communities men are more likely to work in more urban areas where the likelihood of finding employment is higher (Food and Agriculture Organisation, 2014). As migrant workers, men only return home once a month, over long weekends or holidays.

Most of the individuals tested were in the 15 to 64.11 years age group (54.71%; n = 465). This is however representative of the age distribution in the EMLM as the age group of 15 to 64.11 years presents 57% of the EMLM population (IDP, 2014).

Educational status.

Educational status was obtained from participants as part of the demographic case history questionnaire. Twenty nine percent (n = 247) of the participants attended pre-school, primary or high school (See Table 12). Of the participants that were older than 18 years of age, the majority completed some form of secondary education (40.24%). Only a minority (10.82%; n = 92) did not receive any form of schooling. This figure is much lower than the figures reported in the IDP (2014) that stated that 45.7% of the EMLM population has received no schooling. Only 3.53% of the participants (n = 30) received some form of higher education in contrast to the figures reported in the IDP (2014) indicating that a larger number of individuals, 11.9% of the EMLM population reportedly completed some form of higher education.

Table 12

Educational status	Total		
Educational status	п	%	
Not of school going age e.g. infants	52	6.12	
Pre-school	57	6.71	
In school	190	22.35	
Primary education	85	10	
Secondary education	342	40.24	
Tertiary education	30	3.53	
Did not attend school	92	10.82	
Special schools	2	0.24	
Total	850	100	

Educational status of participants (N=850)

There are a total of 115 primary schools (+/-3 per ward); 85 high schools (1 per ward) and only one college that offers further education and training (FET) in the form of certificate and diploma courses (IDP, 2014). There are no universities located in this area.

Employment status.

It was further evident that in this sample, participants older than 15 years of age (n =

536), were mostly unemployed, indicating that of almost half of the population surveyed,

43.4%, is unemployed (See Figure 5).

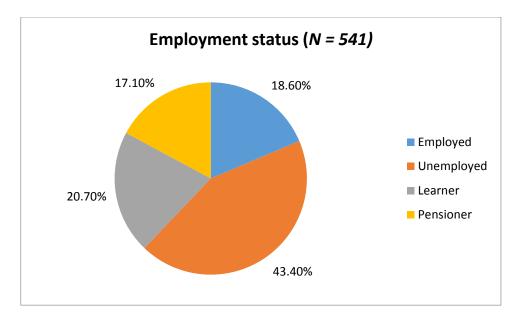


Figure 5. Employment status of participants older than 15 years of age.

Significant medical history.

Information pertaining to significant medical history was obtained from all participants as part of the demographic case history questionnaire. Of the total participants, 13.6% (n = 116) reported significant medical history factors (See Table 13).

Table 13

Condition	T	otal
(as reported by participants)	n	%
HIV/AIDS (reported)	13	11.21
Tuberculosis (TB)	2	1.72
Cancer	2	1.72
Hypertension (HPT)	69	59.48
Diabetes	17	14.66
Respiratory	12	10.34
Cerebrovascular accident (CVA)	4	3.45
Otitis Media Externa (OME)	3	2.59
Epilepsy	2	1.72
Mental Retardation	3	2.59
Developmental Delay	1	0.86
Down Syndrome	1	0.86
Psychosis	1	0.86
Cerebral Palsy	2	1.72
Measles	1	0.86
Total	116	100

Significant medical history obtained from the participants (N=116)

Hypertension. Hypertension was prevalent in 59.45% (n = 69) of the participants. Significantly more females (84.06%; n = 58) than males (15.94%; n = 11) presented with hypertension. The average age of individuals who reported hypertension was 61.11 years. Of the reported hypertension cases, 52.17% (n = 41) presented with some form of HI (Figure 6). Slight HI was detected in 24.64% (n = 17) of the cases, whilst a DHI was detected in the remainder of the cases. Moderate HI was detected in 18.84% (n = 13), whilst 7.25% (n = 5) in this group presented with a severe HI. Only 1.45% (n = 1) presented with a profound HI.

In 2.9% (n = 2) of the cases where individuals presented with hypertension,

additional ear pathologies were noted based on a 'refer' result for tympanometry, otoscopy or both.

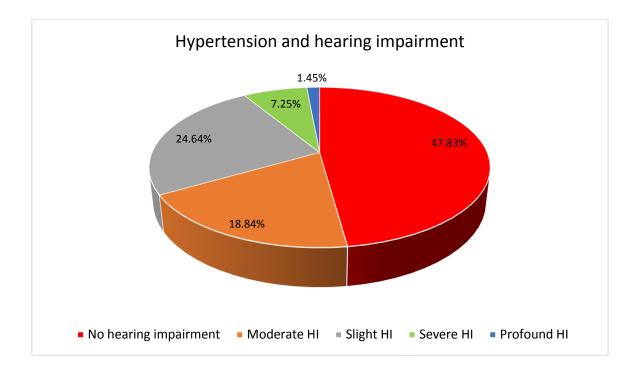


Figure 6. Hypertension and HI.

In a recent South African study, Solanki (2012) found a HI prevalence rate of 5% in individuals diagnosed with cardiovascular disease. Research has confirmed that chronic hypertension is linked to the development of HI (Duck, Prazma, Bennett & Pillsbury, 1997). It is postulated that hypertension enhances noise-induced malfunctioning in cochlear function and the development of histological cochlear damage (Duck et al., 1997).

Ototoxicity. A significant number of participants (14.76%; n = 17) were on potentially ototoxic treatment for HIV/AIDS, tuberculosis (TB) and cancer (Table 13). Thirty-five percent (n = 6) of these individuals presented with a DHI. This indicates that individuals on the abovementioned medication are at high risk of developing a HI due to ototoxic medication (Whitehorn et al., 2014).

The IDP (2014) reported that there are no specific prevalence levels for HIV/AIDS reported in EMLM, however if the country's prevalence is 24.8% for those with HIV/AIDS, there will be a significant stress for the poor communities such as the EMLM area. The low

report rate of this however could be due to the lack of knowledge regarding the ototoxic medication used as well as the individuals under reporting during the case history section in the survey

Prevalence and Distribution of Hearing Impairment

The first sub aim of the study was to determine the prevalence and distribution of HI in the EMLM.

Ambient noise was measured with a sound level meter immediately prior to testing. The mean level of ambient noise measured during testing was 55.53 dBA. A *t*-test for independent samples did not show a statistically significant relationship between the level of ambient noise during testing and the different degree of HI in this study.

The results indicate that 19.88% (95% CI: 0.15% - 0.21%) of the population tested presented with some degree of HI (ranging from slight to profound) (Table 14). Of these individuals 25.58% (95% CI: 0.21% - 0.28%) were female and 17.66% (95% CI: 0.16% - 0.26%) male. The highest prevalence of HI was in the > 65 year age group with 74.65% (95% CI: 0.62% - 0.83%) presenting with some degree of HI.

Table 14

Proportion (%) of individuals with HI by WHO age group categories (N = 191)

Age Group	Ν	fale	Fe	male	Т	otal
(years)	%	CI	%	CI	%	CI
0 - 14.11	13.61	0.09-0.17	14.48	0.08-0.22	14.01	0.12-0.21
15 - 64.11	16.22	0.12-0.27	22.08	0.21-0.31	20.22	0.14-0.23
> 65	70.59	0.47-0.90	75.93	0.62-0.85	74.65	0.62-0.83
Total	17.66	0.16-0.26	25.58	0.21-0.28	19.88	0.15-0.21

The degree of HI was further classified as slight or disabling. The prevalence of slight HI (26 - 40 dB) was 10.95% (95% CI: 0.09%-0.14%), whilst 8.94% (95% CI: 0.08% -

0.12%) presented with a DHI (HI greater than 40 dB and classified as moderate, severe or profound). The prevalence of moderate HI was 5.88% (95% CI: 0.05%-0.125%); for severe HI 2.24% (95% CI: 0.01%-0.03%) and for profound HI 0.82%.

Table 15

Age Group	п	U	npairment 40 dB)	_	DHI 40 dB)
(years)	-	%	CI	%	CI
0-3.11	63	0	0	1.01	0.01 0.05
4-14.11	251	6.77	0.04-0.11	1.91	0.01 – 0.05
15-64.11	465	12.04	0.1-0.17	7.96	0.06-0.11
>65	71	28.17	0.26-0.53	46.48	0.36-0.53
Total	850	10.94	0.09-0.14	8.94	0.08-0.12

Proportion (%) of individuals (by age group) with HI (N = 850)

The prevalence rate of 8.94% obtained in the current study is significantly higher than the global estimate of 4.2% (Beria et al., 2007). It is also the highest prevalence rate when compared to the other developing countries where the prevalence rate ranged from 4.7% (Southern Vietnam) to 7.8% in Northern Vietnam. The prevalence rate in Nigeria, a sub-Saharan African country, is 7.6% (WHO, 2008; Mathers, Lopez & Murray, 2006; Beria et al., 2007).

The 8.94% prevalence rate is also much higher than the figures reported by the EMLM IDP in 2011. An 8.94% prevalence rate suggests that approximately 21 445 individuals living in EMLM present with a HI, which is almost ten times more than the 2 341 reported in the EMLM IDP (2011), thus suggesting an under reported rate of a hearing disability.

The age group 65 years and older presented with the highest prevalence of DHI at 46.48% (95% CI: 0.36% - 0.53%). Age related HI, or presbycusis, is found in approximately

40% of the population (Jung & Bigelow, 2004). It has also been reported to be more prevalent in the male population (Jung & Bigelow, 2004). This is in contrast to the findings of the current study where females in this age group presented with the highest prevalence of HI. Other studies are inconclusive regarding specific patterns of gender differences in ageassociated HI. It has been found that women have better hearing at higher frequencies than men and there appears to be gender reversal in which women, as they age, have a poorer capacity to hear at lower frequencies than men do (Beria et al., 2007; Sharashenidze, Schacht & Kevanishivili, 2007; Murphy & Gates, 1997; Zakzouk, 1997; Pearson et al., 1995). Despite previous research, most which was conducted more than a decade ago, the current research study found that females presented with a higher prevalence rate of HI than males. This could be due to having more female participants included in the study than males; however the definite reason is unknown.

The high prevalence rate of HI in the EMLM highlights the need for hearing screening in rural areas and the importance of early detection and intervention. Promoting access to relevant hearing health services available for the older population (such as hearing aids) is essential in addressing the impact of HI in this age group. Similar results were reported in a study conducted by Stevens et al. (2011) where high prevalence rates among the adult population were found predominantly in low-income sub-Sahara Africa areas. Furthermore, it was also found that the childhood onset of HI was also higher in this region than others (Stevens et al., 2011). It has been hypothesised that the high prevalence rate could partially be due to impacted cerumen as well as otitis media (Stevens et al., 2011).

Proportion of paediatrics with pass/refer. Due to the nature of the screening measures used for children 0 - 3.11 years of age, it was not possible to differentiate between the degrees of HI. Instead, this population presented with either a 'pass' or 'refer' result. A pass result indicated that the children presented with normal middle ear and outer hair cell

functioning.

Only 37.5% (n = 21) of the children obtained a refer result (Table 16). More male children (21.4%; n = 12) than female children presented with a refer result.

Table 16

Proportion of children (by gender) with a pass and refer test result (N=56)

]	Male	Fe	emale	Т	'otal
	n	%	n	%	n	%
Pass	23	41.07	12	21.42	35	62.5
Refer	12	21.4	9	16.07	21	37.5
Total	35	62.5	21	37.5	56	100

According to the WHO (2012b) the prevalence rate for HI is 1.7%, in both male and female children. This is similar to the prevalence rate reported by Grosse (2007) who found that 1.8% of children did not pass the final screening assessment. These prevalence rates appear to be the highest in south Asia (2.2%) followed by Sub-Saharan Africa (1.9%), with a marked difference in the prevalence rates in high-income countries (WHO, 2012b; Stevens et al., 2011).

Interestingly, it has been found that in most regions, prevalence of HI in children often decreases as parent's literacy rate increases (WHO, 2012b). In the current study, it is evident that of the participants older than 18 years of age, only 40.24% completed secondary school, and 10.82% did not attend any schooling at all. The prevalence rate of DHI for children from birth to 14.11 years as found to be 1.9%, only slightly higher than the rates reported by WHO (2012b) and Grosse (2007).

Prevalence and distribution of auditory pathology

The second sub aim of the study was to determine the prevalence and distribution of auditory pathology.

Auditory pathology included impacted cerumen, foreign bodies, acute otitis media as well as underdetermined causes. The total prevalence of auditory pathology is 27.53% (95% CI: 0.26%-0.32%) (Table 17). Females presented with the highest rate of auditory pathology at 29.07% (95% CI: 0.18%-0.32%). The age group 65 years and older presented with the highest auditory pathology rate of 76.06% (95% CI: 0.65%-0.85%).

Table 17

Age group	Ν	fale	Fe	male	Т	otal
(years)	%	CI	%	CI	%	CI
0 - 15	20.71	0.15-0.29	25.52	0.19-0.35	22.93	0.19-0.27
15 - 64.11	25	0.18-0.33	22.4	0.19-0.27	23.22	0.20-0.31
> 65	70.59	0.41-0.90	77.78	0.64-0.88	76.06	0.65-0.85
Total	25.15	0.28-0.39	29.07	0.18-0.32	27.53	0.26-0.32

Ear disease found according to the WHO age group categories (N = 234)

A breakdown of the type of auditory pathology found is presented according to age group and gender in Table 18. Undetermined cause of auditory pathology made up the largest percentage of auditory pathology reported (52.14%) followed by impacted cerumen (36.32%) and otitis media (8.97%). Those individuals that presented with an 'Undetermined cause' were classified as undetermined if the participant presented with a HI but the cause of the auditory pathology was not determined.

Table 18

		Cer	umen		reign dies	Otitis	media		ermined ause	Т	otal
Age group (years)	Gender	n	%	N	%	n	%	N	%	n	%
	Male	1	0.42	0	0	6	2.56	1	0.42	8	3.42
0-3	Female	1	0.42	0	0	3	1.28	0	0	4	1.71
	Total	2	0.85	0	0	9	3.84	1	0.42	12	5.12
	Male	19	8.12	1	0.42	2	1.56	5	2.14	27	11.54
4 - 14.11	Female	20	8.55	3	1.28	6	2.56	4	1.71	33	14.10
	Total	39	16.6	4	1.71	8	3.42	9	3.84	60	25.64
	Male	17	7.26	0	0	3	1.28	17	7.26	37	15.81
15 - 64.11	Female	20	8.55	1	0.42	1	0.42	49	20.94	71	30.34
	Total	37	25.81	1	0.42	4	1.71	66	28.20	108	46.15
	Male	0	0	0	0	0	0	12	5.13	12	5.13
> 65	Female	7	2.99	1	0.42	0	0	34	14.53	42	17.94
	Total	7	2.99	1	0.42	0	0	46	19.66	54	23.08
Tota	ıl	85	36.32	6	2.56	21	8.97	122	52.14	234	100

Types of auditory pathology found according to WHO age group categories (N = 234)

Impacted cerumen was found to have the second highest rate (36.32%) in this population. This is high if compared to a recent population-based survey conducted in Brazil where it was found that between 8.4% and 13.7% of their participants presented with impacted cerumen (Ullauri et al., 2011). Of the individuals in the current study presenting with cerumen, 13.79% also presented with a HI and were thus referred for cerumen management as well as further diagnostic audiometric testing.

Otitis media was found to be the third most common auditory pathology (8.97%) in this population. Previous population based studies did not include additional testing procedures to confirm otitis media, however, in this current study, tympanometry tests were performed on every participant in the study to confirm the presence or absence of otitis media. When comparted to the WHO (2001) being 7.9%, the prevalence rate found in this current study appears to be slightly higher. However, this rate seems considerably higher when compared to other studies conducted by the Indonesian Eye and Ear Health Survey (not using the WHO protocol), which was 2.6% to 5.7% (Hendarmin, 1997). When taking into account risk factors that are commonly found in developing countries, this prevalence rate appears quite low as children in developing countries are found to be at higher risk due to having lower immune systems, lack of hygiene and living in crowded households (Copley & Friderichs, 2010; Paradise & Bellizia Neto, 2009). Otitis media can be prevented if well treated and managed, especially from an early age.

When comparing results with other countries and studies (Sri Lanka 9%, Myanmar 8%, Brazil 6.8%, Vietnam 5-7.8%, India, 6% and Oman 2%) (Beria et al., 2007), results vary by a vast amount when considering the above mentioned otitis media results. One hypothesis for this could be due to the fact that results rely on visual examination of the external ear canal for otoscopic examination and results are therefore subjective.

The above results indicate that nursing staff at local health care facilities should be appropriately trained in ear health as they are the first line of referral in this community. The 'Primary ear and hearing care' training package developed by the WHO (2006) is a good example of a training package to ensure that health care workers can identify and appropriately manage auditory pathology such as impacted cerumen and otitis media. It is imperative that health care workers are further empowered to inform the community about the prevention of auditory pathology and the potential complications thereof (Clark, 2008).

Need for ear and hearing services.

Thirty one percent (n = 261) of the individuals tested required further action to be taken following the screening (Table 19). This percentage takes into account those individuals that require further testing to confirm diagnosis and medical management for otitis media.

Action	N	Iale	Fer	nale	Т	otal
needed	п	%	n	%	N	%
Yes	99	37.93	162	62.07	261	30.7
No	235	39.9	354	60.1	589	69.3
Total	334	39.29	516	61.06	850	100

Distribution of participants in need of ear and hearing services (N = 261)

The distribution of action needed is outlined in Table 20. Participants who received a 'yes' result for action needed received referrals to either the hospital or PHC clinics for a range of services. These included referrals for medical management, allied medical services (such as physiotherapy, occupational therapy and speech therapy), diagnostic audiometry and cerumen management. Participants who received a 'no' results in action needed, did not require any additional referral or testing and passed the screening assessment.

Table 20

Distribution of action needed in the population with ear or hearing disorder (N = 261)

Action needed	n	%
Diagnostic audiometry	134	51.34
Cerumen management	56	21.45
Medical management	18	6.9
Audiology (HA Services)	1	0.38
Diagnostic and cerumen management	36	13.79
Diagnostic and medical management	8	3.07
Other	8	3.07
Total	261	100

Of all the individuals screened, 30.7% (N = 261) required further referrals of which the majority (62.07%) were females. Most of the participants primarily required diagnostic audiometric testing to determine type and degree of hearing loss (51.3%; n = 134). This was followed by 21.5% (n = 56) of the participants requiring cerumen management. Medical management for acute otitis media was needed by 6.9% (n = 18). The 'other' category included referrals for other health services such as physiotherapy, occupational therapy and speech therapy.

It is evident that there is a need for more extensive ear and hearing health services in the EMLM. Ear and hearing health services are only available at the two hospitals in the area. In the two main state hospitals found in the EMLM area, there are only four allocated speech therapists and audiologists (two at each hospital), thus suggesting that these individuals need to provide services for approximately 249 300 individuals that might present with HI (T. Hlabangwane, personal communication, 2015). The type of services available to individuals with HI is however limited as access to audiological equipment for comprehensive audiological assessment is hampered by lack of funds for the repairs and maintenance of equipment as well as provisioning of hearing aids.

The key to the implementation of context- and need- specific audiological services lies in the availability of accurate epidemiological information on prevalence of HI and auditory pathology such as current study.

Summary

The overall prevalence of disabling HI (> 40 dB) in this rural population is 8.9% (95% CI: 0.08% - 0.12%). The age group 65 years and older presented with the highest prevalence of HI at 74.65% (95% CI: 0.62 - 0.83). The prevalence of auditory pathology is 27.53% (95% CI: 0.26 - 0.32) with undetermined causes, impacted cerumen and otitis media occurring most often.

Chapter 5: Conclusion and Implications

Introduction

This chapter contains an overview of the rationale for the study as well as a summary of the findings. The limitations, strengths, recommendations as well as implications of the study will then be presented. The recommendations, guided by the limitations of the study, will be discussed in relation to policy, clinical and practise implications.

Summary of findings

The main aim of this study was to determine the prevalence and distribution of HI and auditory pathology in the EMLM area in the Limpopo Province, South Africa.

The prevalence of HI in EMLM is 19.88% and the DHI 8.95%. The female population presented with a higher prevalence of 25.58% (95% CI: 0.21%-0.28%) than males who had a prevalence of 17.66% (95% CI: 0.16%-0.26%). Furthermore, the age group of >65 years presented with the highest HI prevalence rate of 74.65% (95% CI: 0.62%-0.83%).

The prevalence rate of auditory pathology is 27.53% (95% CI: 0.26%-0.32%). The female population presented with the highest prevalence rate of 29.07% (95% CI: 0.18%-0.32%) than the male population who had a prevalence of 25.15% (95% CI: 0.28%-0.39%). Again, the >65 year age group presented with the highest prevalence rate of auditory pathology of 76.06% (95% CI: 0.65%-0.85%). Undetermined causes, impacted cerumen and otitis media were the most prevalent causes of auditory pathology.

Evaluation of the study

Study strengths.

- This study is the first epidemiological study aimed at obtaining the prevalence data on HI and auditory pathology in a rural context in South Africa.
- The use of the WHO Ear and Hearing Disorders Survey (WHO, 1999) allowed for comparisons to be made to other contexts; locally, nationally and globally using a standard tool.
- The inclusion of members from the community in which the study was conducted as research assistants facilitated the researchers' entry into the community and households. The research assistants were familiar with the areas in which data was collected, they understood the customs and practices of the community and acted as cultural brokers during the study. Their ability to communicate with the participants in their home language limited misunderstandings.
- The members of the research team remained constant during the study. This increased the consistency in conducting the screening and reliability of the study.
- As data collection took place on weekends the research team had more access to households than would have been the case if data collection took place during the week. The fact that testing was done in the household, increased the sample size as individuals were not required to travel to a central venue to participate in the study.
- Unlike a number of other prevalence studies, tympanometry was performed and that allowed for the identification of middle ear pathology.

• The researcher gained first-hand experience in the challenges faced by outreach teams when offering mobile services in remote areas such as geographical constraints (e.g. distance) and inaccessible roads.

Study limitations.

- The sample size was small when compared to other prevalence studies however the sampling strategy employed allowed for the generalisation of findings to the population of the EMLM.
- The disproportionate distribution of gender is a limitation of the study. More females were included in the study due to the migrant nature of male residents work commitments.
- Ambient noise levels often impacted on the duration of testing. At times environment became too noisy and testing had to be paused until it was at acceptable levels. The source of the noise was mostly children playing around the area, animal sounds (roosters, cows and goats), cars and wind noise.
- Community activities such as weddings and funerals mostly take place over the weekend and are attended by all community members (especially in the more remote areas). On these occasions, most households were empty and alternative households had to be selected.

Implications of the study

The results obtained from this study have yielded significant implications for planning for ear and hearing services in the EMLM and would guide practice and clinical services.

Practice.

The need for ear and hearing health care services in the EMLM has been highlighted with this study. The expansion of the limited services currently available is of utmost importance. This can be done through establishing a variety of outreach services to the more remote villages in the area. These services must however be adequately resourced with a range of robust audiological equipment (including otoscope, immitance measures, audiometer, and OAEs) to ensure that HI and auditory pathology can be detected. Testing should ideally be done in a sound-treated environment thus the use of mobile booths are suggested. The mobile booths should be mounted on robust vehicles with high ground clearance (e.g. four wheel drive vehicles) as most of the gravel roads are inaccessible to normal vehicles.

Health care workers at all levels (PHC nurses, community health workers and health promoters) should be trained on the identification and prevention of ear and hearing problems. A valuable resource is the training package 'Primary ear and hearing care' developed by the WHO in 2006. Training can be offered at a basic, intermediate and advanced level. Once trained, support should be available to trained individuals in terms of referral sources once they have identified potential ear and hearing problems.

Clinical.

This study highlighted the need for more extensive health prevention and promotion campaigns on ear and hearing health to decrease the burden of disease. The strategies outlined by Olusanya et al (2014) provide a road map for the prevention of HI. The authors further describe activities for the primary and secondary prevention of hearing loss across different groups, disorders and risk factors (including prenatal and peri- and neonatal ages, as well as childhood and adulthood).

75

In the EMLM the first priority should be the early detection and prompt management of HI in the adult population through audiological screening and referral for diagnostic assessment. Resources should also be available for the provisioning of hearing aids and aural rehabilitation to this age group.

Another priority is the identification and monitoring of ototoxicity. Primary prevention should include raising awareness in medical personnel regarding the rational and prescribed use of ototoxic drugs. This is especially relevant in a community with a high rate of HIV/AIDS and TB. Health education on appropriate practices and early recognition of disease and HI should for part of the secondary prevention of ototoxicity.

The implementation of newborn hearing screening programmes is also recommended. At a primary prevention level, health education should be provided to pregnant mothers and should include personal hygiene, nutrition and the avoidance (where possible) of ototoxic medication. A secondary prevention strategy would be early hearing detection of HI through newborn hearing screening at clinic level.

The expansion of well-coordinated and closely monitored comprehensive audiological services that provide easy access to the community of the EMLM cannot be overemphasized. As government structures lack the capacity to implement such services, public-private partnerships and humanitarian outreach programmes to this area should be encouraged (Olusanya et al., 2014).

Recommendations for future research

Future research can be completed to refine, replicate, and expand on the current study in various, in-depth ways which can allow for further generalisation to similar contexts. The following suggestions for future research will contribute to governmental policy

76

development as well as provide important information in the area of HI and auditory pathology.

It is recommended that this study be replicated in other rural communities in all provinces so as to obtain a more comprehensive impression of the prevalence of HI and auditory pathology in South Africa.

It is also important to more specifically determine the prevalence of middle ear pathology and management thereof in this population.

It would also be valuable to describe the community members' awareness and knowledge of audiology and causes of HI as the prevalence of HIV/AIDS and TB is high. The prevalence of HI in individuals receiving medication for these conditions will provide an indication of the extent of ototoxic HI in this community.

It would be useful to document the number of individuals experiencing HI due to noise exposure at workplaces and the knowledge of the risks of noise induced HI.

The effectiveness of and access to current audiological and otological service within the EMLM community at hospital and clinic level should also be explored.

Conclusion

Individuals with HI are as much a part of the future of the country as those who present with normal hearing. The implementation of effective programmes for the prevention and promotion of ear and hearing health services will facilitate the active and equal participation of these individuals among their hearing peers to contribute to change, influence and direct the future of South Africa.

77

Summary

This final chapter provided a summary of the findings of the study. A critical review of the strengths and limitations identified in the execution of this study as well as practical recommendations for future research were provided. This chapter concluded with a review of the implications arising from the study.

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Appendices

Appendix A: WHO Ear and Hearing Survey

The second s			WHO Ear a	nd Hearing Di	sorders Exan	nination Fo	orm		
Ward		Household		Total persons per		Person number		Sex	
Date				household		Age in		-	
(dd/mm/y)	L	DOB		Age in years		months		Name	
				B. HEARING	XAMINATIC)N			
(I) Hearing As	sessment for c	hildren (birth	to 3y11m)	D. HEARING					
		Pass	Fail	Not done		Pass	Fail	Not done	
1. OAE Test 2. AABR	Right Right				Left Left				_
2.75101	ngrit								Tymps not
3. Tympanometry	Right	A:	В:	C:	Left	A:	B:	C:	done: R / L
4. Equipment					Tympanomet				Specify:
number	OAE:		ABR:		ry:				
(II) Audiomet	ny lAgo Avora	and over)							
1. Ambient no	ry (Age 4 years bise		7						
Equipment Au	udiometer								
2. 'aring Thi	resholds Right (dBHL)	Frequency	Left (dBHL)						
] 1KHz							
		2KHz		_					
		4KHz 500Hz		-					
	L	1 230/12	L						
				C. BASIC EAR	ASSESSMEN	т			
			light		ļ	Left			
I. Ear Pain	N: N=No; Y=Yes;	Y: N/A=Not aske	N/A:		N:	Y:	N/A:	_	
II. Auricle	N=INO; T=Tes;	M:	N/S:	-					
			111/3.		N:	M:	N/S:	7	
	N=Normal; M		n; N/S=Not se		N:		N/S:		
	ar Canal	=Malformation	n; N/S=Not se Right	en	l	Left			
			n; N/S=Not se	N/E:	N:		N/S:	_	
	ar Canal 1. Normal 2.	Malformation	n; N/S=Not se Right Y:	en N/E:	N:	Left Y:	N/E:		
	ar Canal 1. Normal 2. Inflammation	N:	n; N/S=Not se Right Y: Y:	n/E:	N:	Left Y: Y:	N/E:		
	ar Canal 1. Normal 2.	Malformation	n; N/S=Not se Right Y:	en N/E:	N:	Left Y:	N/E:		
	ar Canal 1. Normal 2. Inflammation 3. Wax	N:	n; N/S=Not se Right Y: Y:	N/E: N/E: N/E:	N:	Left Y: Y:	N/E:		
III. External E	ar Canal 1. Normal 2. Inflammation 3. Wax 4. Foreign Body	=Malformation N: N: N: N: N:	n; N/S=Not se Right Y: Y: Y: Y: Y:	N/E: N/E: N/E: N/E:	N: N: N: N:	Left Y: Y: Y: Y: Y:	N/E: N/E: N/E: N/E:		
	ar Canal 1. Normal 2. Inflammation 3. Wax 4. Foreign Body 5. Otorrhoea	=Malformation N: N: N: N: N:	n; N/S=Not se Right Y: Y: Y: Y:	N/E: N/E: N/E: N/E:	N: N: N: N:	Left Y: Y: Y: Y: Y: Y:	N/E: N/E: N/E: N/E: N/E:		
III. External E	ar Canal 1. Normal 2. Inflammation 3. Wax 4. Foreign Body	Nalformation N: N: N: N: N: N: N: N: N:	n; N/S=Not se Right Y: Y: Y: Y: Y: Y:	N/E: N/E: N/E: N/E: N/E: N/E:	N: N: N: N:	Left Y: Y: Y: Y: Y:	N/E: N/E: N/E: N/E:		
III. External E	ar Canal 1. Normal 2. Inflammation 3. Wax 4. Foreign Body 5. Otorrhoea	Nalformation N: N: N: N: N: N: N: N: N:	n; N/S=Not se Right Y: Y: Y: Y: Y: Y: Y: Y: Y:	N/E: N/E: N/E: N/E: N/E: N/E:	N: N: N: N:	Left Y: Y: Y: Y: Y: Y:	N/E: N/E: N/E: N/E: N/E:		
III. External E	ar Canal 1. Normal 2. Inflammation 3. Wax 4. Foreign Body 5. Otorrhoea	Nalformation N: N: N: N: N: N: N: N: N:	n; N/S=Not se Right Y: Y: Y: Y: Y: Y: Y: Y: Y:	N/E: N/E: N/E: N/E: N/E: N/E:	N: N: N: N:	Left Y: Y: Y: Y: Y: Y:	N/E: N/E: N/E: N/E: N/E:		
III. External E	ar Canal 1. Normal 2. Inflammation 3. Wax 4. Foreign Body 5. Otorrhoea	Nalformation N:	n; N/S=Not se Right Y: Y: Y: Y: Y: Y: Y: Y: Y:	N/E: N/E: N/E: N/E: N/E: N/E:	N: N: N: N:	Left Y: Y: Y: Y: Y: Y:	N/E: N/E: N/E: N/E: N/E:		
III. External E	ar Canal 1. Normal 2. Inflammation 3. Wax 4. Foreign Body 5. Otorrhoea 6. Fungi 1. Perforation	Nalformation N:	n; N/S=Not se Right Y: Y: Y: Y: Y: Y: Y: Y: Y: X: N/E= Not exa	N/E: N/E: N/E: N/E: N/E: N/E:	N: N: N: N:	Left Y: Y: Y: Y: Y: Y: Y:	N/E: N/E: N/E: N/E: N/E:		
III. External E	ar Canal 1. Normal 2. Inflammation 3. Wax 4. Foreign Body 5. Otorrhoea 6. Fungi	Nalformation N:	n; N/S=Not se Right Y: Y: Y: Y: Y: Y: Y: Y: Y: X: N/E= Not exa	N/E: N/E: N/E: N/E: N/E: N/E:	N: N: N: N:	Left Y: Y: Y: Y: Y: Y: Y:	N/E: N/E: N/E: N/E: N/E:		
III. External E	ar Canal 1. Normal 2. Inflammation 3. Wax 4. Foreign Body 5. Otorrhoea 6. Fungi 1. Perforation 2. Duliness or Retraction 3. Red and	Nalformation N:	n; N/S=Not se Right Y:	N/E: N/E: N/E: N/E: N/E: N/E:	N: N: N: N:	Left Y: Y: Y: Y: Y: Y: Y: Y:	N/E: N/E: N/E: N/E: N/E:		
III. External E	ar Canal 1. Normal 2. Inflammation 3. Wax 4. Foreign Body 5. Otorrhoea 6. Fungi 1. Perforation 2. Dullness or Retraction 3. Red and bulging	Nalformation N:	n; N/S=Not se Right Y: Y: Y: Y: Y: Y: Y: Y: Y: Y:	N/E: N/E: N/E: N/E: N/E: N/E:	N: N: N: N:	Left Y: Y: Y: Y: Y: Y: Y: Y: Y:	N/E: N/E: N/E: N/E: N/E:		
III. External E	ar Canal 1. Normal 2. Inflammation 3. Wax 4. Foreign Body 5. Otorrhoea 6. Fungi 1. Perforation 2. Dullness or Retraction 3. Red and bulging 4. Normal	Nalformation N:	n; N/S=Not se Right Y: Y:	N/E: N/E: N/E: N/E: N/E: N/E: N/E: N/E: N/E: N/E:	N: N: N: N:	Left Y: Y: Y: Y: Y: Y: Y: Y: Y: Y: Y: Y:	N/E: N/E: N/E: N/E: N/E:		
III. External E	ar Canal 1. Normal 2. Inflammation 3. Wax 4. Foreign Body 5. Otorrhoea 6. Fungi 1. Perforation 2. Dullness or Retraction 3. Red and bulging	Nalformation N:	n; N/S=Not se Right Y: Y: Y: Y: Y: Y: Y: Y: Y: Y:	N/E: N/E: N/E: N/E: N/E: N/E:	N: N: N: N:	Left Y: Y: Y: Y: Y: Y: Y: Y: Y:	N/E: N/E: N/E: N/E: N/E:		

PREVALENCE OF HEARING IMPAIRMENT AND AUDITORY PATHOLOGY IN LIMPOPO

V. Middle Ear			i			
	1. Normal	Y:	Y:			
	2. Otorrhoea	Y:	Y:			
	3. Not					
	examined	Y:	Y:			
			1			
VI. Others	Specify:					
	specity.			<u> </u>		
VII. Additiona	al information					
	1. How long has the person					
		ood (0-14years)				
	Since old age	ood (15-59years) e (60years+)				
	Uncertain	2 (00) cuisty				
	No difficulty					
	Not asked					
	2. Does any relative of the p	person have difficluty heari	ng? Brother or sister			
	No . Yes		 Child of subject 			
	Uncertain		 Parent of subject 			
	Not asked		Grandparent			
			and the second			
	D.	CAUSE OF EAR DISEAS	E AND/OR HEARING IMP.	AIRMENT		
		Right Left				
Normal ear						
Normal heari I. Ear Disease						
I. Edi Disease	1. Wax					
	2. Foreign Body					
	3. Otitis externa					
	4. Acute otitis media					
	 Chronic otitis media Serous (with effusion) 					
	7. Dry perforation of TM					
II. Infectious I			ā.			
	Specify:					
III. Genetic Co						
IV. Non-Infec	Specify: tious Conditions					
	Specify:					
V. Undetermi		2 E E				
VI. Other	Specify:					
vi. Other	Specify:					
		E. AC	TION NEEDED			
Y=Yes		Y:				
I. No action n	eeded					
II. Action nee	ded					
	1. Referral for medical mar	nagement to:	Clinic Hospital			
	2. Referral to hospital for:		OT PT	ST Audiology]	
	6. Diagnostic audiometry					
	7. Cerumen management					
	7. Cerumen management 8. Others					
	7. Cerumen management		J			
	7. Cerumen management 8. Others					
	7. Cerumen management 8. Others Specify:					
Any additiona	7. Cerumen management 8. Others					
Any additiona	7. Cerumen management 8. Others Specify:					
Any additiona	7. Cerumen management 8. Others Specify:					
Any additiona	7. Cerumen management 8. Others Specify:					
Any additiona	7. Cerumen management 8. Others Specify:					
Any additiona	7. Cerumen management 8. Others Specify:					
Any additiona	7. Cerumen management 8. Others Specify:					

97

Appendix B: Self-developed Case History Form

Ward number:

Household number:

Participant number: Address: Participant name:

DOB:

Case History Form

Participant number: Date of completion (of form):

Sex: Male / Female

Highest education obtained:

Year	Yes	Year	Yes
Grade 1		Grade 8	
Grade 2		Grade 9	
Grade 3		Grade 10	
Grade 4		Grade 11	
Grade 5		Grade 12 (matric)	
Grade 6		Diploma (specify)	
Grade 7		Degree (specify)	
Other (specify):			

Job status:

Job	Yes	Job	Yes
Employed		Student	
Unemployed		Housewife	
Baby		Pensioner	
Learner		Other	

....

Do you have a hearing difficulty/problem? YES/NO. If YES, for how long?
 Have you ever had a hearing test before? YES/NO. If YES, when?

3. Have you ever used a hearing aid? YES/NO.

ADULT	CHILD (0-14 years)
Non-Communicable Diseases	Non-Communicable Diseases
 Stroke/CVA 	 Diabetes
 Hypertension 	 Respiratory difficulties (asthma)
 Diabetes 	Cardiovascular diseases
• Smoker (current/history)	
Respiratory difficulties (asthma)	
 Alcohol abuse (current/history) 	
 Drug abuse (current/history) 	
N N	
Trauma	Trauma
• Traumatic Brain Injury (e.g. Motor vehicle accident, falls, assault, etc.)	 Traumatic Brain Injury (e.g. Motor vehicle accident, falls, assault, etc.)
 Head and Neck Trauma (e.g. Gun 	 Head and Neck Trauma (e.g.

Medical History (check all that apply)

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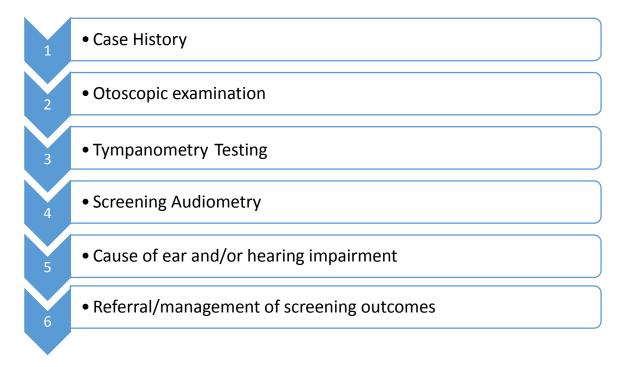
shot wounds, stabbings, assault, etc.)	Gun shot wounds, stabbings, assault, etc.)
Medications/Treatment	Medications/ Treatment
Cancer	Cancer
TB Medication (how long: Type: MDR/XDR)	TB Medication (how long: Type: MDR/XDR)
 ARTs (are you part of the HAART programme at Ndlovu- Tempelman) 	ARTs (are you part of the HAART programme at Ndlovu-Tempelman)
Other	Other
Noise exposure (current/history)	Noise exposure
Syndrome (specify)	Syndrome
• Rubella	Rubella
Head and neck structural abnormalities	 Head and neck structural abnormality
Malaria	Pre-term baby
External ear abnormality	External ear abnormality
Ear canal abnormality	Ear canal abnormality
• Ear pain	• Ear pain
Discharge from ears	Discharge from ears
Otitis média	Otitis media
•	• Malaria
•.	Measles
	Mumps

Appendix C: Research Assistants Manual

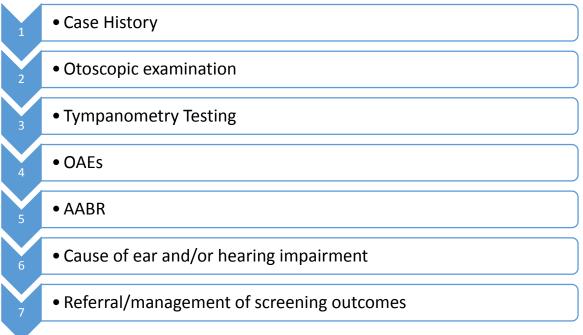
Aims of the study

- To provide a source of information for prioritisation, programme planning and resource allocation
- To provide baseline data for comparison with similar surveys to measure changes in the problem and measure effectiveness of interventions
- To provide information enabling determination of the costs of deafness and hearing impairments and the costs and benefits of prevention
- To provide accurate and standardised data that can be used to compare the prevalence and causes of hearing impairment between countries and regions who have use the same survey standards.
- To provide information for planning of health services and resources.
- To provide baseline data for future research studies.

A flow diagram of the test protocol for participants older than 4 years of age:



A flow diagram of the test protocol for participants from birth to 3 years, 11 months:



Case History Form

Case history is important in order to gain background knowledge of the participant's hearing status. It is vital that case history be performed in order to identify potential factors that may have affected and may still affect the client's hearing status. Obtaining case history information is vital to establishing a rapport with the participant's as well as caregivers, and understanding what they expect from the testing procedure, thereby aiding in the process of reporting audiological results.

A 'Case History Form' is to be filled out for every participant who gives consent and assent to the study. For DOB (date of birth), please fill out in the following order: dd/mm/yy. Under the headings "Highest education obtained', 'Job status' and 'Medical History', please tick in the columns on the right for the ones that apply to that participant.

'Highest education obtained': this indicates the highest level of schooling that the participant attended or achieved. If the participant is a child, indicate the grade they are currently in. if the child is in something other than what is listed, write this under 'Other'.

'Job status': indicates whether the participant is currently employed at that specific point in time. If the participant does not relate to any of the suggested job status, please write this in 'Other'.

'Medical History': please fill out the appropriate section for either an adult (older than 15years) or child (birth to 14 years). If you are filling in the form for a child under 15 years, please ask the parents or respective guardian the questions regarding the child.

- ARTs: Antiretroviral Treatment
- Cardiovascular diseases: diseases affecting the heart
- Noise exposure: anyone exposed to loud noises for a long period of time, e.g. DJ's, workers with loud machinery etc.
- Rubella:

• Otitis media: ear infections

Automated ABR Protocol (AABR)

Recordings of the AABR will either indicate the presence of a response (pass) or the absence (refer) at the screening intensity level of the stimulus.

- 1. Test Environment: should be as quiet as possible to achieve satisfactory environmental conditions.
- 2. Electrode contact impedance: This should be below specified levels.
- 3. Electrode location: The location of recording electrodes is similar to that employed in conventional ABR testing.
- 4. Stimulus
- Type: Typically a click stimulus generated by an electrical pulse of 100µs pulse duration with alternating polarity.
- Rate: Relatively high stimulus rates are employed to minimise test time (typically faster than 30 clicks per second).
- Level: The screening level of the click stimulus is typically in the range of 35dBnHL to 50dBnHL.
- 5. Waveform analysis:

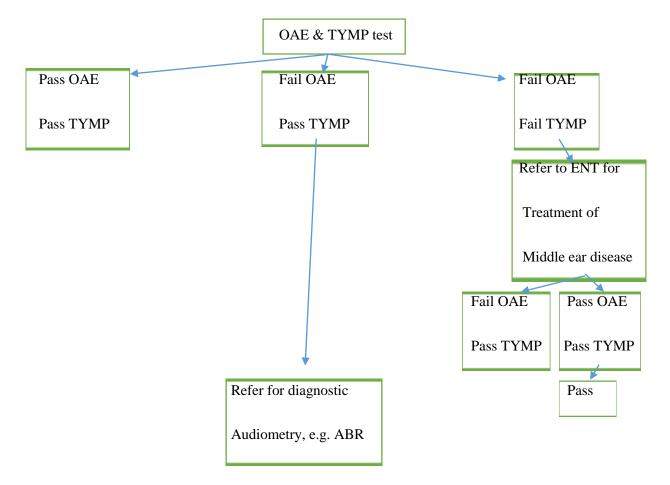
The screening test on each ear will indicate a pass or refer depending on whether or not a response is present. Occasionally, a re-test decision may be recommended if the result is marginal or if the test conditions are unreliable. The pass or refer will be indicated for each ear separately so that the referral for further testing can be initiated using either unilateral or bilateral referral criteria.

Tympanometry

- High-frequency (1000Hz) tympanometry:
 - For children from birth to 6 months
 - Ear canal volume should be disregarded as it will not be precise
 - o Positive peak is seen when the waveform is up and indicates normal
 - o Negative peak is seen when the waveform is going downwards
 - If there is a positive and negative peak, the trace should be classified as positive (i.e. normal)
 - A flat peak is considered abnormal
- Low-frequency (226Hz) tympanometry will be used.
 - For children older than 6 months
 - The trace should have a single sharp peak
 - Double peak can be seen when there is scarring on the ear drum, but should be repeated to exclude artefacts
 - Rounded or wide peaks should be repeated
 - Middle ear pressure (horizontal axis): -20 to +20daPa
 - \circ Compliance: 0.3 to 1.6cm³
 - Ear canal volume (ECV): 0.4 to 1.0cm³

OAE Testing flow chart OAE test: try attempt 3 attempts of the test Pass on both ears No OAE response on 1 or both ears No OAE on 1 ear Send baby home Arrange screen at clinic in 4-6weeks Refer both ears Pass Refer both ears Pass Refer both ears Pass

OAE and Tympanometry testing flow chart



Calibration

This is done to ensure that the audiometer is working properly and will produce accurate results. The audiometer needs to be calibrated regularly. These should be calibrated as follows:

- Daily self-calibration: testing your own hearing thresholds; if out by 5dB equipment requires calibration from the company and equipment should not be used on the day of testing
- Ensure batteries are at full strength

Hearing test

- Adults should be examined before children so that children are less frightened by the procedures
- Audiometry should be performed without removing occluding wax or foreign bodies and the results recorded

When you walk into a household, explain to the family why you are there and what you will be doing. Give the, the consent/assent form and ensure that they understand everything. If there are children present under the age of 18 years, a parent or guardian needs to sign this form on their behalf. If consent/assent is given, i.e. the individuals WANT to be part of the study, you may continue onto Case History. If any members DO NOT want to be part of the study, researchers must still fill in section A. CENSUS of the form.

Below is the basic outline of the survey form with the main sections highlighted:

A. CENSUS	
B. HEARING EXAMINATION	
(Age Birth to -3 years 11	(Age 4 years and older
months)	
C. BASIC EAR ASSESSMENT	D. CAUSE OF EAR DISEASE
	AND/OR HEARING
Additional information	IMPAIRMENT
	E. ACTION NEEDED

Section A needs to be filled in by a literate person. *Section B* needs to be completed by someone with audiometric skills to handle equipment and careful observation of behavioural responses of children. *Section C, D and E* should be completed by a person with experience of work as ENT or health workers with higher level specialist ENT training.

The form must be completed according to the coding instructions. The form is designed so as to be easy to fill in by marking the boxes and giving further information where indicated.

Small boxes for the right (R) and/or left (L) ear should be ticked only if the condition indicated exists. If it does not exist, leave the small box blank. Larger boxes require a number to be inserted.

In sections C, D and E, when the category says "**specify**", a detailed description or opinion of the examiner should be stated here.

2. Age determination

It is important to ensure that the individual's age in years is as accurate as possible. In individuals who do not have a birth certificate or who do not know their own age, it may be necessary to try and get the individual to think of a prominent local or national event whose year of occurrence in known.

SECTION B: HEARING EXAMINATION

In a household, adults should be examined **before** children so that children are less frightened by the procedures.

If occluding wax, foreign bodies or pus is present, audiometry should be performed **without removing** it and the results recorded in the boxes in Section B. this is in order to measure the actual level of disabling hearing impairment.

B.I. Hearing Examination for Children (birth to 3y11m)

- 1. OAE Test: pass/refer
- 2. AABR: pass/refer
- 3. Tympanometry:
 - a. High-frequency (1000Hz) tympanometry:
 - i. For children from birth to 6 months
 - b. Low-frequency (226Hz) tympanometry will be used.
 - i. For children older than 6 months

B.II. Audiometry (age 4 years and older)

<u>Pure Tone audiometry</u> is performed for all individuals who are 4 years of age and older. The system and method must be uniform throughout each survey. The hearing examination procedure should be carefully explained to each person. (*Although every effort should be made to use pure tone audiometry in children aged 4 years and older, if a child up to age 9 years cannot be tested this way, the questions given above for can be used*).

- 1. **Ambient Noise:** The testing must be performed in as quiet a room as possible. Ambient noise is recommended not to exceed 40dBA measured by a sound level meter. The level of ambient noise should be recorded in the box B.II.1. Even if ambient noise is higher than 40dBA hearing testing should continue and the results, including the level of ambient noise, should still be recorded in the boxes.
- 2. **Calibration**: the audiometer needs to be calibrated regularly to ensure its reliability. Portably audiometer should be calibrated as follows:
 - a. Daily self-calibration.
 - b. Regular audiometric calibration. Ideally every month.
 - c. Regular battery testing to make sure these are at full strength.
- 3. **Testing Procedure**: the person who is being tested should be seated with his/her back to the control panel and examiner. Each ear should be tested separately, the right ear first. The headphones should fit well. Each time the subject hears the sound, he/she has to respond to the tester by raising a hand.
- 4. **Hearing Thresholds (500, 1, 2, 4KHz):** it is important to be sure that the subject hears some sound and can hear and understand the test. Therefore, the presentation of sound at the start of the test should be at 60dBHL at 500KHz. If there is no response to this sound, increase in 10dB steps until the subject responds to the sound. Once the subject has heard a sound, the threshold of hearing should be established by decreasing thresholds by 10dB steps and increasing by 5dB steps until the threshold is established by subject, confirming thresholds

on 3 consecutive occasions. These thresholds should be established in the same manner at 2 and 4KHz.

SCREENING EXAMINER'S REMARKS: The option of the examiner why the examination could not be completed satisfactorily. The reasons should be recorded.

SECTION C: BASIC EAR EXAMINATION

C.I. Ear Pain: If the subject/parent/guardian reports any ear pain related to the external ear, ear canal or mastoid region, this should be recorded in the box with a $\sqrt{}$.

C.II. Auricle:

- 1. **Malformation:** if the auricle has evidence of sinuses, unusual shaped cartilages or is very small or missing, mark the appropriate box with a $\sqrt{}$.
- 2. Auricle Normal: Mark the appropriate box with a $\sqrt{}$ if the auricle is of normal appearance without any evidence of sinuses or pits. If it appears unusual or abnormal or is missing, leave the appropriate box blank.

C.III. External Ear Canal:

- 1. Inflammation: Mark the appropriate box with a \sqrt{i} if there is any redness or tenderness of the ear canal.
- 2. Wax: mark the appropriate box with a \sqrt{i} if unable to view the ear canal because of wax either soft or hard.
 - a. **Removed**: mark the appropriate box with a $\sqrt{}$ if the wax was removed by any member of the team.
- 3. Foreign Body: mark the appropriate box with a $\sqrt{}$ if there is an obvious foreign body in the ear canal. If identifiable, please describe what it is in "Special Examiner's Remarks".
 - a. **Removed**: Mark the appropriate box with a \sqrt{i} if object is removed from ear canal by member of the team.
- 4. **Otorrhea**: if there is evidence of any pus, mark the appropriate box with a $\sqrt{}$ for the appropriate ear.
 - a. **Removed**: if the ear canal has been cleaned by a member of the team so that the ear canal is visualised, mark the appropriate box with a $\sqrt{}$. If the ear was not touched, leave the box blank.
- 5. **Fungi**: Mark the appropriate box with a $\sqrt{}$ if there is any evidence of a fungal infection.
- 6. Normal: Mark the appropriate box with a √ if the ear canal is present and has no abnormalities. If there is an abnormality not listed above in C.III 1-5, record it is C.VI Others, and leave this box blank.
- 7. Not seen: If the external ear canal cannot be seen for any reason, mark the appropriate box with a $\sqrt{}$.

C.IV. Ear Drum:

- 1. **Perforation**: If there is evidence of a perforation, mark $\sqrt{}$ in the appropriate box.
- 2. **Dullness or retraction**: If the ear drum is dull or retracted and the light reflex is poor, mark the appropriate box with a $\sqrt{}$.
- 3. **Bulging and red**: If there is evidence that the ear drum is tense and bulging and the drum mucosa appears red, mark the appropriate box with a $\sqrt{}$. (These signs, when seen together with ear pain are indicative of the condition Acute Otitis Media).

- 4. Normal: If there is a good view of the Tympanic Membrane (ear drum) and it appears normal, mark with a $\sqrt{}$ in the appropriate box.
- 5. Not seen: If the ear drum cannot be seen for any reason, mark the appropriate box with a $\sqrt{.}$

C.V. Middle Ear:

- 1. **Otorrhea**: If, on otoscopy, there is definitely otorrhea within the middle ear, mark the appropriate box with a $\sqrt{}$.
- 2. Normal: On examination with a perforation, if there is evidence that the middle ear is not inflamed and the malleus handle is in the correct position, mark the appropriate box with a $\sqrt{.}$
- 3. Not seen: If the middle ear cannot be seen for any reason (including because the drum is intact), mark the appropriate box with a $\sqrt{}$.

C.VI. Others: Mark the appropriate box with a $\sqrt{}$ if there is any other abnormal finding related to any part of the ear or mastoid region and specify these findings in the space provided.

Normal Findings: On examination, if the auricle, ear canal, tympanic membrane and middle ear appear normal, mark a $\sqrt{}$ is the appropriate box. If there is any abnormality or doubt, leave the box blank.

C.VII. Additional Information:

- 1. *For subjects who report or who are reported to have deafness or hearing impairment*, tick the appropriate box according to how long the subject has had difficulty hearing.
- 2. *For all subjects*, tick the appropriate boxes according to whether any of these first degree relatives have difficulty hearing.

SECTION D: CAUSE OF EAR DISEASE AND HEAIRNG IMPAIRMENT

Normal ear and normal hearing: If there are completely normal findings for the ear and for hearing, mark the appropriate box with a $\sqrt{}$. Otherwise, leave blank. The **definition of normal hearing**, for the purposes of this section, is that either in section B.II no hearing threshold box is marked as 26dBHL or greater.

D.I. Ear Disease:

- 1. **Wax**: Tick the appropriate box only if occluding or impacted wax have been found (whether or not it has been removed).
- 2. **Foreign Body:** Tick the appropriate box if a foreign body has been found (whether or not it has been removed).

Algorithms

Algorithms are provided for the following diagnoses (D.I, 3 to 7). A diagnosis box in Section D should only be ticked if all of the listed criteria for that diagnosis have been found and all of the boxes in Sections B and C have been ticked or not ticked as listed below.

		Criteria
3. Otitis Externa	Pain	C.I
	Inflammation External Ear Canal	C.II.1
4. Acute Otitis Media	Pain	C.I
	Ear drum red and bulging	C.IV.3
	No perforation	not C.IV.1

PREVALENCE OF HEARING IMPAIRMENT AND AUDITORY PATHOLOGY IN LIMPOPO

5.	Chronic	No pain	not C.I
	Supportive Otitis Media	Otorrhea External ear canal	
		And/or otorrhea of middle ear	C.III.4 and/or C.V.1
		Perforation	C.IV.1
6.	Serious Otitis Media	No pain	not C.I
		No perforation	not C.IV.1
		Dullness or retraction	C.IV.2
		Fails hearing screen (<4yrs)	
		or	
		Hearing threshold >25dB for 1	B.I or B.II
		or more freq (4 yrs or older)	
7.	Dry perforation	No pain	not C.I
		Perforation	C.IV.1
		No otorrhea external ear canal	not C.III.4
		No otorrhea middle ear	not C.V.1

For Sections D.II to D.V., further information (by history and/or examination) should be obtained from those subjects who appear to have a hearing impairment or deafness, in order to attempt to determine the likely cause. The **definition of hearing impairment and deafness**, for the purpose of these sections is that in section B(I) no box is ticked 'Yes' and at least one box is ticked 'No', or that in section B(II) at least one hearing threshold box records a level of 26dBHL or greater, or that one of the boxes in section C.VII.1 has been ticked.

D.II. Infectious Diseases: Further information should be obtained (by questioning) from subjects with deafness or hearing impairment if there is any history of a particular infectious illness present prior to deafness. *For example*: Rubella, meningitis, chicken pox, herpes, syphilis, mumps, measles, TB, malaria, pneumonia, CMV.

D.III. Genetic Conditions: In subjects with deafness or hearing impairment consideration with further information should try to establish if there are any physical characteristics which are unusual and are observed on the subject.

For example:

Unusual physical characteristics common to subject and parents, e.g. colour of hair. Craniofacial or skeletal disorder, e.g. dwarfism, shape of ears, saddle nose. Changes in pigmentation. Any eye disorder, e.g. different colour pupil, blindness. Cardiovascular abnormalities. Endocrine disorders Other conditions such as Down's Syndrome. Close parental relationship (specify relationship).

D.IV. Non-Infectious Conditions: Further questions of those with a deafness or hearing impairment should be asked to establish whether there is any medical or occupational reason for this hearing loss. For example: diabetes, thyroid disease, pituitary disease, exposure to loud noise at work over a period of time, treatment with medication for either a short or long-term period for illness which appears to be related to the onset of the hearing loss, exposure at work to dangerous chemicals, any known neurological condition, recent pregnancy, presbycusis.

D.V. Undetermined or other cause: Tick the appropriate box if the subject has deafness or hearing impairment but the cause has not been determined.

SECTION E: ACTION NEEDED

This section is included in order to assess resource requirements. Therefore, the examiner should determine what action is needed according to what is best for the subject, whether or not that action is available for the population.

The examiner should then tick the appropriate box having considered all the information collected in the questionnaire.

E.I. No action needed: There is no obvious reason for further treatment.

E.II. Action needed:

- 1. Medication: Subject has an infection or metabolic condition that requires treatment.
- 2. **Hearing aid**: Subject has a significant hearing loss and the hearing requires amplification for day to day communication.
- 3. **Language/Speech rehabilitation**: There is obvious delay or abnormal speech which may be the result of hearing impairment and speech therapy might be able to improve speech.
- 4. **Special needs**: There is obvious developmental delay either physically or mentally which requires specialised help.
- 5. **Vocational training**: The subject has significant hearing loss without any physical limitations and requires help in seeking appropriate employment.
- 6. Surgery referral: Examination shows evidence of an infective process or significant middle ear effusion, and if surgical correction of this process would clear up infections and/or improve hearing, this should be marked as requiring **non-urgent surgery.**
- 7. : If the subject has a significant persistent temperature and evidence of cerebral involvement or evidence of active cholosteatoma in the middle ear region, the subject should be marked as requiring **urgent surgery**.
- 8. Refer for further diagnostic audiometry

Appendix D: Participant Information Sheet



SPEECH PATHOLOGY AND AUDIOLOGY SCHOOL OF HUMAN & COMMUNITY DEVELOPMENT FACULTY OF HUMANITIES UNIVERSITY OF THE WITWATERSRAND Private Bag 3, WITS, 2050

Tel: (011) 717 4577 Fax: (011) 717 4572



PARTICIPANT INFORMATION SHEET

Good day,

My name is Donna Pullen and I am doing my Masters at the Department of Speech Pathology and Audiology at University of the Witwatersrand in Johannesburg. We are conducting a research study to look at an evidence-based model for the inclusion of audiological services as part of integrated health, child and community care in rural South Africa.

I would like to invite you to participate in the research study, but before agreeing to participate, it is important that you read and understand the following explanation of the purpose of the study, the study procedures, risks, benefits and your right to withdraw from the study at any time. If you have any questions, do not hesitate to ask me. You should not agree to take part unless you are satisfied about all the procedures involved. If you decide to take part in this study, you will be asked to sign this document to confirm that you understand the study. You will also be given a copy to keep.

This research aims to get information on how many people present with hearing problems in Moutse. The research will also look at the services available to people with hearing loss and their families in this area. This information will be used to inform the government about the services that are required for people with hearing loss and their families in Elandsdoorn and other rural areas in South Africa.

If you agree to take part in the study, you will be requested to answer some questions to whether you have any problems with your ears and/or hearing. Hearing screening tests will also be done to see if you have any difficulties with your ears and hearing. The interview will take approximately 30 minutes to complete. Your participation in this study is entirely voluntary and you can decline to participate, or stop at any time, without stating any reason. If it is found that you need further hearing tests we will refer you to the relevant clinic or hospital for help.

All information obtained (e.g. personal data and the results of the hearing tests) will be kept strictly confidential. The results of the study will be made available to you and reported anonymously to government agencies and in scientific journals. These reports will not include any information that identifies you as a participant in this study. The questionnaires will be kept in a locked cabinet at the university and will be destroyed after five years.

If you need any further information in this regard or if you would like feedback on the results you are welcome to contact me at any time on my Cell: 072 685 8363 or e-mail: <u>pullen.donna@gmail.com</u> or <u>Karin.Joubert@wits.ac.za</u>.

Should you have any questions or concerns on your rights as a research participant or require any additional information you are welcome to contact the secretary of the Medical Ethics Committee at the University of the Witwatersrand, Anisa Keshav on 011 717 1234 or e-mail: Anisa.Keshav@wits.ac.za or the chairperson, Prof Cleaton-Jones on 011 717 2301 for additional enquiries.

Yours sincerely

Donna Pullen

PARTICIPANT INFORMED CONSENT FORM

I hereby consent to participate in the research project: "An evidence-based model for the inclusion of audiological services as part of integrated health, child and community care in rural South Africa". The purpose and procedures have been explained to me. I understand that my participation is voluntary and that I may choose to withdraw from the study at any time without negative consequences. I understand that my results will be kept confidential.

Participant

Printed Name

Date

Signature

RESEARCHER

I here within confirm that the above participant has been fully informed about the nature, conduct and risks of the research study on the "An evidence-based model for the inclusion of audiological services as part of integrated health, child and community care in rural South Africa"

Printed Name

Date

Signature

ASSENT FORM FOR PARTICIPATION IN THE STUDY

(For Participants between the ages 7 and 18)

Hello, my name is Donna Pullen.

I would like to invite you to participate in a study, which looks at hearing and communication difficulties in rural communities.

Why are we doing this study?

We would like to know how many people have hearing difficulties in your community and to help us understand how we can offer services to these people in your community.

What will happen in this study?

First, the person helping me will check my ears with a torch. After that she will use a special machine that will play a soft sound into my ear, and take a little bit of air out of my ear canal, and then put it back in again. Then I will put on earphones and listen for some beeps, and put my hand up every time I hear a beep.

Who is doing this study?

The person helping to check my hearing is Donna Pullen from the University of the Witwatersrand. She will answer any questions I have about the study. I can also contact her on 072 6858 363 if I need to.

Can anything bad happen to me?

No. There is nothing in this study that could cause anything bad to happen to me.

Could I get better by being in this study?

This study looks at my hearing abilities, and will not make me any better or worse. If they find that I have a hearing problem I will be referred to the clinic where they would be able to help me with this problem.

Who will know I am in the study?

Only my parents and the person helping to check my hearing will know that I am in the study. When the researchers write a report about the study, they will not use my name or say that I was in the study. My parents and I do not have to tell anyone I am in the study if we don't want to.

When do I have to decide?

I have a few days to decide, and have been asked to discuss it with my parent/guardian.

Can I change my mind?

Yes - I can change your mind at any time, and nothing bad will happen to me if I do.

If I put my name at the end of this form, it means that I agree to be in the study.

Printed name

Signature

Date

PARENTAL CONSENT FORM FOR PARTICIPATION IN THE STUDY

(For Participants under the age of 18)

I hereby consent for my son/daughter/guardian to participate in the research project. The purpose and procedures have been explained to me. I understand that my child/guardian's participation is voluntary and that either he/she or I may choose to withdraw from the study at any time without negative consequences. I understand that my child's results will be kept confidential.

Name of Participant:	
Name of Legal Guardian: (If participant is underage)	
Signature:	Date:

RESEARCHER

I here within confirm that the above participant has been fully informed about the nature, conduct and risks of the research study on the "Implementation of early hearing detection and intervention services in a rural community".

Printed Name

Date

Signature

Appendix E: Ethical Clearance



R14/49 Dr Karin Joubert

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M130238

<u>NAME:</u> (Principal Investigator)	Dr Karin Joubert
DEPARTMENT:	Speech Pathology & Audiology Umthombo Building
PROJECT TITLE:	An Evidence-Based Model for the Inclusion of Audiological Services as Part of Integrated Health, Child and Community Care in Rural South Africa
DATE CONSIDERED:	22/02/2013
DECISION:	Approved unconditionally

CONDITIONS:

SUPERVISOR:

APPROVED BY:

lletten

Professor PE Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 22/02/2013

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and ONE COPY returned to the Secretary in Room 10004, 10th floor, Senate House,

University. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. I agree to submit a yearly progress report.

Principal Investigator Signature

Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix F: Permission letter from Limpopo Department of Health and Social

Development

	DEPARTMENT OF HEALTH
Enquiries	es: Selamolela Donald Ref:4/2/2
Joubert	К
Universi	ity of Witwatersrand Johannesberg
Greeting	gs,
Re: An	Evidence-Based Model for the inclusion of Audiological Services as part of Integrated
Health,	, Child and Community Care in Rural South Africa.
1	The above matter refers.
2.	the second study is berefy granted
3.	Kindly be informed that:-
	 Further arrangement should be made with the targeted institutions.
	 In the course of your study there should be no action that disrupts the services.
	 After completion of the study, a copy should be submitted to the Department to serve as a
	resource.
	 The researcher should be prepared to assist in the interpretation and implementation of the study recommendation where possible.
	 The researcher should be prepared to assist in the interpretation and implementation of

18 College Street, Polokwane, 0700, Private Bag x9302, POLOLKWANE, 0700 Tel: (015) 293 6000, Fax: (015) 293 6211/20 Website: http/www.limpopo.gov.za

Appendix G: Ndlovu Care Group Chief Operations Officer Permission letter

HEAD OFFICE P.O. Box 1508, Groblersdal, 0470 Republic of South Africa



22 Witstinkhout Street Groblersdal 12 September 2012

TO WHOM IT MAY CONCERN

Re: Application to conduct Audiology Research: An evidence based model for the inclusion of audiological services as part of integrated health, child and community care in rural South Africa.

I hereby confirm that the Department of Speech Pathology and Audiology of the University of the Witwatersrand has permission to use the Ndlovu facilities for this research project.

Do not hesitate to contact me should you need further information.

Kind regards

Mariette Slabbert Chief Operations Officer Ndlovu Care Group

Tel: +27 (0) 13 262 9000 • Fax: +27 (0) 13 262 3498 • info@ndlovu.com • www.ndlovucaregroup.com NPO: 019-524-NPO • PBO: 930002417 • Reg no: IT 10961/99 • Vat Reg No 4300226059 Ndlovu Care Group: CEO Hugo Tempelman • COO Mariette Slabbert • FM Lourens Duvenhage Board of Trustees: Chairman: Prof Geert H Blijham Trustees: Ronald Vies, Lynn van der Elst, Dr Hugo Tempelman, Mariette Slabbert