The clinical value of immittance testing in the identification of middle ear pathology in South African mineworkers

By

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Abstract

This study was conducted to determine the clinical value of immittance testing in the identification of middle ear pathology among South African mineworkers. Case histories, pure tone audiometric screening, otoscopy, tympanometry and acoustic reflex testing were administered to 177 workers at Harmony gold mine in Randfontein, South Africa, within the context of the mine's programme of medical surveillance for noise exposure.

Middle ear pathology was identified on the basis of a proposed middle ear screening protocol, which included medical history-taking, otoscopic examination, pure tone audiometry and immittance testing. A high prevalence of abnormal middle ear results was identified by immittance testing in the population of mineworkers. More than half of the population was positively identified with potential middle ear pathology.

The present study found that mineworkers who smoke or are subjected to second-hand smoke have higher incidence of abnormal outer and middle ear results. Otoscopic findings indicated that retracted tympanic membranes were the most common type of middle ear pathology among those identified, followed by scar tissue the tympanic membrane or an inflamed tympanic membrane, and dull tympanic membranes, all of which correlated with the findings of immittance testing.

A review of medical history should include information on any pathology indicating previous barotrauma. Screening for hearing disorders forms an essential part of medical surveillance in the deep mining industry. Mine medical staff was often found to be unfamiliar with middle ear barotrauma, which may influence decisions on referral and further assessment of barotrauma-susceptible individuals. The risk of barotrauma during vertical conveyance increases greatly where middle ear pathology is present, but it was found that mineworkers are not excluded from underground work where middle ear pathology is present, thereby exposing them to the risk of barotrauma. Mineworkers should be counseled regarding the consequences of middle ear pathology, and be encouraged to report problems, e.g. pain, suspected ear infection or tympanic membrane perforation, which they presently fail to do.

A greater prevalence of middle ear pathology was identified among subjects screened with the proposed immittance testing protocol than was found by conventional screening methods. The existing and proposed screening protocols used during the study are detailed and discussed, to evaluate findings and identify possible reasons for the differing prevalence of middle ear pathology determined by the two different screening methods.

Opsomming van studie

Die navorsingsstudie is uitgevoer om die kliniese waarde van immittansietoetsing in die identifikasie van middeloorpatologie te bepaal in Suid-Afrikaanse mynwerkers. Gevalsgeskiedenisse, suiwertoonsifting, otoskopie, timpanometrie en akoestiese reflekstoetsing is uitgevoer op 177 goudmynwerkers binne die konteks van Harmony goudmyn in Randfontein, Suid Afrika, se gehoorkonserveringsprogram.

Middeloorpatologie is geïdentifiseer op die basis van 'n voorgestelde middeloorpatologiesiftingsprotokol wat die afneem van 'n gevalsgeskiedenis, 'n otoskopiese ondersoek, suiwertoontoetsing en immittansietoetsing insluit. Die resultate van die studie het 'n hoë prevalensie van middeloorpatologie in die populasie mynwerkers getoon. Meer as die helfde van die mynwerkers is positief gediagnoseer met middeloorpatologie.

Daar is ook bevind dat rokers en passiewe rokers aanduidend meer vatbaar is vir middeloorpatologie. Met die otoskopiese ondersoek is bevind dat 'n teruggetrekte timpaniese membraan, die algemeenste patologie is wat geïdentifiseer is by die populasie proefpersone, gevolg deur letsels op die timpaniese membraan, inflammasie van die timpaniese membraan of 'n dowwe timpaniese membraan. Dit stem ooreenstem met die bevindinge van immittansietoetsing.

Siftingtoetse vir oorpatologie vorm 'n integrale deel van die gehoorkonserveringsprogram in die goudmyn industrie. Die afneem van 'n gevalsgeskiedenis moet inligting oor vorige episodes van barotrauma insluit. Die myn se mediese personeel het min begrip getoon van middeloor barotrauma, wat gevolglik besluite mag beïnvloed aangaande verwysing en verdere toetsing van individue wat vatbaar is vir barotrauma. In gevalle waar middeloorpatologie teenwoordig is, neem die risiko van barotrauma toe tydens vertikale mynvervoer. Dit is kommerwekkend dat sulke werkers normaalweg nie uitgesluit word van ondergrondse werk nie en dit stel hul gevolglik bloot aan die risiko van barotrauma. Mynwerkers behoort berading te ontvang aangaande die gevolge van middeloorpatologie en moet aangemoedig word om

probleme soos oorpyn, moontlike oorinfeksie of timpaniese membraan perforasie aan te meld, wat huidiglik nie geskied nie.

‘n Hoër voorkoms van middeloorpatologie is onder werkers, wat met die voorgestelde metode wat immittansietoesting insluit, geïdentifiseer, as met die konvensionele siftingsprosedures. Die bevindinge is geëvalueer en die moontlike redes vir die verskille in die voorkoms, soos geïdentifiseer met die twee verskillende siftingsprotokolle, is aangetoon.

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Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
ANSI	American National Standards Institute
ASLHA	American Speech Language and Hearing Association
Cc	Cubic centimetres
COMRO	Chamber of Mines Research Organization
DaPa	Deca pascal
dB	Decibel
DME	Department of Minerals and Energy
HIV	Human Immunodeficiency Virus
HL	Hearing level
HPD	Hearing protection device
Hz	Hertz
kHz	Kilohertz
ml	Milliliters
n.a	No author
n.d.	No date
NUM	National Union of Mineworkers
OH	Occupational health
OHP	Occupational health practitioner

OMP	Occupational medical practitioner
PTT	Pure tone threshold
SOC	Superior olivary complex
TM	Tympanic membrane
WCC	Workmen's Compensation Commissioner
WHO	World Health Organization

CHAPTER 1 Introduction and background

The aim of this chapter is to provide a background and rationale for the present study, by examining the issues of epidemiology and prevalence of middle ear pathology, complications of middle ear pathology and the value of identifying middle ear pathology. The research problem is defined, and the chapter also outlines the structure and content of subsequent chapters.

1.1 Epidemiology of middle ear pathology

Results from a study of middle and external ear disorders among underground coal miners showed a high prevalence of middle ear and ear canal abnormalities (Hopkinson, 1981:4). Furthermore, hearing loss and particularly noise-induced hearing loss (NIHL) is one of the most serious health risks confronting the South African mining industry. Another form of hearing loss and associated middle ear pathology that is common, but not so well recognized, is that caused by sudden intense forms of energy from explosions, blasts or changes in atmospheric pressure in the workplace (Workmen's Compensation Commissioner, 2001:5). A review of previous research in the South African mining industry has indicated that workers are subjected to rapid pressure changes during vertical conveyance between surface and ultra-deep workings and presents a significant risk of barotrauma among susceptible individuals. Walling (2000:1) indicated that pressure changes within the ear could result in barotrauma if the normal function of the Eustachian tube is compromised. The non-compressible middle ear cavity makes the ear susceptible to damage from these ambient pressure changes (Harril, 1995:2). Middle ear pressure is governed by Boyle's Gas Law. During descent, as ambient pressure increases, the volume of gas-filled spaces decreases unless internal pressure is equalized. Equalization can be achieved through deliberate swallowing actions and/or movement of the lower jaw to open the Eustachian tubes and admit outside air into the middle ear cavities. If the pressure is not equalized by a larger volume of gas, the space will be filled by tissue engorged with fluid and blood (Newton, 2001:2). The existence of such medical conditions that creates a likelihood of acute illness, is of particular concern to the mines' employers (Department of Minerals and Energy, 2001:1).

HIV rates and its relation to ear disorders are also cause for concern in the mining industry. The Minister of Minerals and Energy, Phumzile Mlambo-Ngcuka, released the figures of HIV levels in the gold mining industry in South Africa on August 13, 2003 (News24, 2003:1). Rates are estimated at 30% in the gold mining industry. This correlates with Anglo Gold's press release on April 2002, which indicated HIV prevalence levels of 25% to 30% amongst the company's 44000 South African employees. This reflects levels similar to the range of prevalence of the virus throughout South Africa. Minister Mlambo-Ngcuka further reported HIV rates at 20% to 24% in the platinum industry and 15% and 17% in the coal, while it is 8% to 11% in the diamond industry. Estimates from the National Institute of Health (Zuniga, 1999:1) indicate that as many as 75 percent of adults with AIDS experience auditory dysfunction as a result of opportunistic infections or treatment with drug combinations that are potentially ototoxic. Yet, while hearing loss and other speech and language disorders that occur as a direct or indirect consequence of HIV-infection are common, there appears to be little awareness among medical professionals about the serious effects of these disorders on people living with HIV/AIDS (Zuniga, 1999:1).

Medical personnel should recognize that HIV may cause two kinds of hearing losses, namely sensorineural and conductive hearing loss (Zuniga, 1999:1). Sensory neural loss is a dysfunction of the cochlea and/or auditory nerve that often results in patients' inability to hear or distinguish softer sounds that unaffected individuals are able to hear. Thus, the speech that they hear is often distorted. Some of the more common causes of cochlea and auditory nerve disease are cytomegalovirus (CMV), cryptococcosis, bacterial meningitis, toxoplasmosis, syphilis, and herpes zoster (Zuniga, 1999:4). In conductive hearing loss, otologic infection affects the pinna, the outer ear, external auditory canal, tympanic membrane, and the ossicles behind the tympanic membrane. Medical personnel will find that the most common cause of conductive hearing loss in the HIV population is otitis media. There is also a higher incidence of otitis media in HIV-infected individuals than in those who are not HIV-infected. In addition to the routine causes of otitis media in the general population, there has been a higher incidence of nasopharyngeal polyps and subcutaneous cysts in patients with HIV disease compared to the non-infected population. These nasopharyngeal masses can occlude the Eustachian tube and block ventilation, which can contribute to the development of chronic otitis media. Surgical removal of the polyps and cysts is usually indicated. Mastoiditis can also cause conductive hearing loss and can be treated with antibiotics and surgery (Zuniga, 1999:4). Otitis externa, an infection of the cartilaginous portion of the external auditory canal, is another common cause of conductive hearing loss. It is often found in patients with Kaposi's sarcoma lesions of the outer ear, and in patients with herpes zoster. Symptomatic treatment includes antibiotics (oral and ear drops) and steroid eardrops (Zuniga, 1999:5). Salzer (1996:2) also related HIV to neurotologic manifestations. He reported that otologic complaints are common in HIV/AIDS patients and include hearing loss (62%), otalgia (50%), otorrhea (31%), vertigo (15%) and tinnitus (15%). In another study performed by Professor Strauss (2001) of the Audio-Digest Foundation, 45% of HIV-positive patient had significant otologic abnormalities, while 57% of AIDS patients had abnormalities. The study demonstrated that otologic manifestations are seen often in HIV patients.

The development of middle ear pathology are also linked to environmental risk factors and include poverty, overcrowding, inadequate housing, poor hygiene, poor nutrition and exposure to air pollution (WHO and CIBA, 2000:2). In developing countries, mineworkers may be simultaneously exposed to workplace hazards, an unsafe/unhealthy housing environment, and to pollution in the general environment (WHO, 1997:2). The prevalence of aural disease is therefore related to poor social conditions, as evident from findings by a team of doctors where active ear disease was present in more than one-third of subjects living under the most desperate social situations (Socio-Economic Factors, 1990:2). This problem is particularly common in the poorer communities of developing countries (WHO and CIBA, 2000:4). In 1996 the National Union of Mineworkers (NUM) expressed concern over poor working and living conditions of mineworkers. This organization’s statistics indicated that 90 per cent of mineworkers were living in overcrowded hostels close to the mine, and that health standards were poor. They also indicated that mineworkers contracted illnesses on a daily basis, and there had been an increase in poverty among mineworkers (NUM, 2001:3). The workplace is where most people spend the greatest portion of their time (WHO, 1997:2), and the impact from the workplace can be compounded when employees live close to the workplace. The Greater Johannesburg Metropolitan Council (2000:2) issued a warning that people living in areas close to industrial and mining areas suffer more from respiratory diseases associated with air pollution. Ear-, nose- and throat diseases head the list of diseases related to air pollution in South Africa. Ear-, nose- and throat diseases also coincided with conditions of poverty among local communities, creating a cycle of occupational and environmental health hazards.

The International Labour Organization (2003:2) has also identified hazards in mineworkers' working conditions. Underground workers, operators of drilling and blasting machines, stone crushing equipment, conveyer, compressors, steam boilers, air receiver, gas cylinders and acetylene generators are in danger of being exposed to dusts, gases, fumes, dirty conditions, respiratory diseases, barotrauma and other ear injuries. The South African mining industry presently has a labour force in excess of 350 000 workers, indicating that environmental hazards are a threat to a significant proportion of the South African population.

1.2 Complications of middle ear pathology

Middle ear pathology is a major public health problem in many countries around the world, with middle ear diseases and their sequelae causing substantial economic and social costs (WHO and CIBA, 2000:2). Mineworkers with neglected middle ear pathology can cost the company a minimum of R5284.58 per patient (De koker, 2003a:27). Taking appropriate preventative action such as early identification of middle ear pathology may greatly reduce medical expenses (De Koker, 2003a:27).

Research in the South African mining industry has recommended screening for the prospective identification of barotrauma susceptible individuals before appreciable damage is incurred. Barotrauma is the tissue damage that occurs when a gas-filled body space (e.g. middle ear, lungs) fails to equalize the internal pressure to accommodate changes in ambient pressure (WebMD Corp., 2001:2; Newton, 2001:2). Rapid changes in air pressure during vertical transportation of mineworkers may result in perforation of the tympanic membrane or inner ear barotrauma (Slaughter and Quinn, 1992:2; Franz, 2001:27), followed by oedema of the middle ear mucosa, and even bleeding into the middle ear (Walling, 2000:1). Figure 1.1 provides an illustration of resultant barotrauma. Divers are also a population that is exposed to rapid changes in air pressure and resultant barotrauma (Ornhagen, 2004:1). Blockage of the outer ear canal during descent will cause the ear drum to bulge outwards when the middle ear is pressure equilibrated. The diver can not feel the direction and interpret the pain in the ear as an insufficiently pressure equilibrated middle ear and force even more air into the middle ear, which might rupture the ear drum. The blockage could be caused by a tight hood preventing the entrance of water or air from filling the outer ear canal on descent. In inexperienced divers diving without hood the blockage can be caused by a hydroscopic swelling of accumulated cerumen that becomes a "cerumen obturata" (Ornhagen, 2004:1). The feeling of fullness and later the pain will be followed by a rupture of a vein resulting in pressure equilibration by blood that fills the middle ear, which makes the pain go away, or the rupture of the ear drum. The rupture is painful, but afterwards the diver most often report very little until a possible infection has developed. If the Eustachian tube is closed, and wrong equilibration technique is used, the round window may rupture (Ornhagen, 2004:1). Paaske, Staunstrup, Malling and Knudsen (1991) reported on the strain on the tympanic membrane caused by rapid pressure changes in divers. An assessment of the strain on the tympanic membrane caused by diving was performed using impedance measurement in 21 untrained young men going through a scuba-diving training programme. Tympanometry was carried out just before and after diving. The results showed a significant increase in middle ear compliance on diving. The increase in compliance was significant at different depths, was transient, and fell to the initial level between the dives. We conclude that the strain exerted on the tympanic membrane and middle ear from barotrauma due to rapid pressure changes results in a reversible impairment of the recoiling capacity of the elastic fibrils of the tympanic membrane. This transient increase in compliance, we think, is the first measurable change in elasticity of the tympanic membrane. If barotrauma continue the changes could be irreversible. Depending on the extent and location of damage, hearing loss may be temporary or permanent (Harril, 1995:2). Other findings indicate that the risk of barotrauma would be greatest among individuals with a chronic predisposing medical condition involving the ear or the upper respiratory tract (which is anatomically associated with the ears). Scarring on the tympanic membrane as a result of previous barotrauma, middle ear infection or damage caused by a foreign object would render it more susceptible to rupture, as the interface between the scar tissue would constitute a weak point in the membrane (Franz, 2001:2). Slaughter and Quinn (1992:2) clearly demonstrated the phenomenon of individual susceptibility to barotrauma.

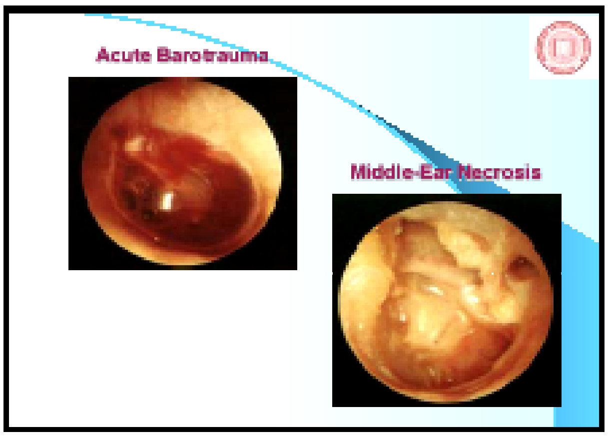

Figure 1.1: Example of acute barotrauma (Indiana University, 2003:2)

Where an unacceptable risk of barotrauma is demonstrated, risk-based medical examinations (RBME) would provide information necessary for the valid exclusion of such individuals from ultra-deep areas. The preceding discussion may give the impression that barotrauma would only be a concern in ultra-deep operations, but there are clear indications that barotrauma is already a problem at current underground mining depths (Franz, 2001:1).

The risk of barotrauma can be controlled by identification and management of high risk individuals (Franz, 2001:171). Early diagnosis and proper management can improve outcomes for many conditions that have established associations with occupational or environmental factors (Boehlecke and Bernstein, 1992:7). It is essential that the health practitioner be sufficiently aware of all relevant environmental factors to which the patient is exposed, and considers the individual's medical history (Boehlecke and Bernstein, 1992:7). Diagnosis of barotrauma is initially based on careful history. If the history indicates ear pain or dizziness that occurs after vertical conveyance, barotrauma should be suspected (Bentz and Hughes, 2002:2). The case history may reveal ear discomfort or pain in one or both ears, slight to severe hearing loss, sensation of fullness or stuffiness in ears, dizziness, nose bleed, middle ear pain (Kacker, 2001:2). The diagnosis may be confirmed through ear examination, as well as hearing and vestibular testing (Bentz and Hughes, 2002:2). Otoscopic examination may show a slight outward bulge or inward retraction of the eardrum. If the condition is severe, there may be blood behind the eardrum. Severe barotrauma might be difficult to distinquish from ear infection (Kacker, 2001:2). However, when diagnosis has been confirmed, ear barotrauma can be classified in a grading system (Harril, 1995:2). The grading scale is from zero to five. Grade 0 is when patient experiences symptoms of middle ear barotrauma and no physical findings are present. Grade I is when the presence of tympanic membrane injection can be seen. Grade II has injection as well as hemorrhage within the tympanic membrane. Grade III includes gross hemorrhage and Grade IV includes gross hemotympanum. Grade V includes the presence of a tympanic perforation (Harril, 1995:2).

The external ear canal can also be a source of middle ear barotrauma if a closed space is created between the outer rim of the concha bowl and the tympanic membrane. The closed space may be due to a cerumen impaction, earplugs or external otitis. As an individual descends, ambient pressure will increase, causing a net negative pressure gradient between the external ear canal obstruction and the tympanic membrane. The obstructing plug is then forced deeper into the external ear, resulting in a tympanic hemorrhage or perforation. The patient typically experiences extreme pain as the descent phase begins, despite an ability to clear the middle ear (Harril, 1995:2).

Factors that would lead to a decrease in Eustachian tube function include recent upper respiratory infections, uncontrolled nasal allergy, nasal polyposis, and deviated nasal septum (Harril, 1995:2). Congestion of the Eustachian tubes or their blockage by inflammation or swelling of surrounding tissue can cause a failure to equalise incrementally during underground descent. The level of pressure in the middle ear becomes different from that outside the ear drum, and excessive pressure differences then cause barotrauma (Franz, 2001:2). Nasal problems may lead to inflammation of the Eustachian tube openings (Hoffman, 1996), and if workers suffer from congestion caused by allergies, colds, HIV or upper respiratory infection, barotrauma becomes more likely (WebMD Corp., 2001:1). Untreated ear disease could result in the aggravation of acute conditions or development of debilitating chronic ones, in either instance extending the recovery period and absence from duty. The complications of middle ear pathology could thus have a lasting effect on the workers' health and productivity (Franz, 2001:173).

1.3 Value of identifying middle ear pathology

Identifying hearing disorders forms an essential part of medical surveillance in the mining industry. The Mine Health and Safety Act (1996) requires the employer to establish and maintain a system of medical surveillance for all employees exposed to known health hazards, to identify and respond to occupational diseases and injuries (Department of Minerals and Energy, 1996:19). In addition, appropriate health education, health and safety training, early detection and treatment of illnesses provide for the health and safety of employees in a mining environment. The importance of early detection is further highlighted by concerns that the risk of barotrauma among workers could increase as mining depths are extended to a depth of 5000m. Harmony Occupational Health Department (2000:3) stated that the Occupational Medical Practitioner (OMP) conducting the medical examination should be satisfied that no disease is present that could be aggravated by further exposure to underground mining conditions or present an unacceptable health risk to the individual. Any disorders detected during medical surveillance examinations must be acted upon by the OMP, either by direct treatment or by appropriate referral. Treating middle ear problems is best done by addressing the cause (WebMD Corp., 2002:3). Workers suffering from conditions that prevent the equalization of pressure differences (e.g. occluded Eustachian tubes) should be excluded from work in deep level areas until their condition has been resolved (Franz, 2001:7). Therefore early identification of such conditions is essential.

The identification of individual workers in need of audiological and otological services has mainly involved pure tone testing and otoscopic examinations. Immittance measurements have also been widely employed for the identification of middle ear pathology in children and adults (American Speech Language and Hearing Association, 1990:18). If the purpose of screening is also to identify persons with middle ear pathology, acoustic immittance screening measurements should be included in the test battery (American Speech Language and Hearing Association, 1993:29). ASHLA also recommended that the screening protocol should include otoscopic examination of the external ear canal, medical history taken for otological abnormalities, pure tone screening and acoustic immittance measurements. Early Identification of such conditions relies to a large extent on the accuracy of diagnostic tools and procedures available for this purpose.

Risk-based medical examination should focus on ears given their greater vulnerability to pressure variations in South African goldmine workers (Franz, 2001:172). Franz (2001:172) reported on the use of immittance testing for the identification of middle ear pathology in South African mining populations affected by barotrauma. He advised that immittance testing should be included in examinations to quantify aspects that are considered subjectively during an otoscopic examination (Franz, 2001:172). The value of immittance testing lies in its ability to evaluate ear drum compliance and provide an indication of any middle ear pathology, e.g. damaged or scarred ear drum, as well as abnormalities in the middle ear ossicles or the Eustachian tube. Franz (2001:172) has further motivated the use of immittance testing in the mining industry by noting that the tympanometer is able to generate a test report immediately and can be linked to a computer for record-keeping and data management purposes. Franz (2001:172) noted that accurate otoscopic interpretations rely on the knowledge and skill of the examiner, implying the likely need for an ear-, nose- and throat specialist. In contrast, tympanometry does not require the same level of expertise and the results are quantitative, thus enabling the use of pre-determined action referral level (Franz, 2001:172). It can thus be argued that tympanometry may reduce the medical costs associated with unwarranted referrals to ear- nose- and throat specialists in the mining industry. Franz (2001:172) recommended that medical history-taking and tympanometry should be included in middle ear screening practices in the South African mining industry.

There is some controversy regarding the efficacy of visual inspection (otoscopy) in screening for outer and middle ear disorders in all age groups, as the skill and experience of clinicians vary considerably (American Speech Language and Hearing Association, 1993:31). It can therefore be anticipated that the more subtle visual indications of middle ear disorders will be detected by some screening programs and not by others (American Speech Language and Hearing Association, 1990:18). Furthermore, the reliability of historical information provided by the person being screened has yet to be demonstrated (American Speech Language and Hearing Association, 1993:31). Pure tone screening audiometry is the last suggested component of the proposed screening protocol. The findings of Eagles, Wishik and Doefler (1967) (in American Speech Language and Hearing Association, 1990:19), showed that pure tone screening audiometry is inadequate for detecting all medically significant otological diseases. The Chamber of Mines Sub-Committee on Hearing Conservation (COMRO, 1988:40) and the Department of Minerals and Energy (2001:11) both suggested the use of medical histories, otoscopic examinations, and pure tone screening audiometry, but immittance testing (tympanometry and acoustic reflexes) was viewed as an optional procedure.

Clinical data on screening techniques, including the ASLHA guidelines of 1990 and a document prepared by the British Society of Audiology (Cooper and Lightfoot, 2000:1), have shed new light on the outcomes of such screening strategies and recommended certain audiometric procedures to screen for hearing impairment and middle ear disorders. Recommendations have also been made for pure tone screening procedures to be supplemented with otoscopy and immittance testing as additional components (American Speech Language and Hearing Association, 1993:29). A review of previous audiological research has indicated that an identification programme that incorporates history-taking, visual inspection, pure tone testing and acoustic immittance measurements is the most effective means for identifying individuals in need of audiological and otological intervention (American Speech Language and Hearing Association, 1993:34). The above statement might suggest the incorporation of case history-taking, otoscopy, pure tone air conduction and immittance testing can be of value in screening for middle ear disorders in the mining industry.

Acoustic reflex testing, together with tympanometry, constitute immittance testing. The diagnosis of some forms of middle ear pathology like otitis media, is difficult using medical history and otoscopy. Immittance measures may, therefore, be helpful in the diagnosis and follow-up of middle ear pathology (Van Balen, Aarts and De Melker, 1999:117). Over the past 30 years, immittance testing methods have evolved from a specialist procedure to a fundamental and routine method of audiological evaluation (Wiley, 1997:116). There is no better, quicker, or less expensive audiological procedure for assessing the status of the middle ear, cochlea, eighth nerve and lower auditory brainstem than a comprehensive immittance (impedance and/or admittance) assessment (Hall and Mueller, 1997:177). Research has shown that acoustic immittance meters can be useful in diagnosing perforations of the tympanic membrane, even those too small to be detected by experienced examiners during ordinary otoscopy (Martin, 1994:194). The clinical utility of tympanometry is in measuring the mobility of the tympanic membrane and associate middle ear ossicles, and in providing an estimate of middle ear pressure (American Academy of Otolaryngology, 2000). Immittance testing is a very straightforward test procedure, which requires no special patient preparation (Evergreen Speech and Hearing Clinic Inc, 2002:4). It also provides important clinical information regarding the condition of the middle ear system (Petrak, 2001:2).

When a hearing loss is present, tympanometry may be used to determine whether the loss includes a conductive component and, if so, its cause (Smith and Evans, 2000:57). The acoustic reflex is particularly sensitive to conductive hearing loss, as losses as small as 5 dB to 10 dB are sufficient to abolish it (Alford, 2001:4). The tympanogram can provide useful information where other diagnostic methods are not feasible, for example when visualization of the tympanic membrane is difficult (Patient Evaluation, 2001:4). Middle ear function can be classified into three categories on the basis of the tympanogram's configuration (Alford, 2001:4). It may reflect a normal mechanism; an abnormally compliant middle ear (as seen in ossicular dislocation or erosion, or loss of elastic fibres in the tympanic membrane), or indicate a stiff middle ear system, as in otosclerosis or chronic middle ear disease.

Normal reflexes can be present at normal threshold and sensation levels, and elevated reflexes can occur due to retrocochlear pathology. Elevated thresholds indicate loss of cochlear sensitivity or a VIII nerve disorder, while absent reflexes may reflect an abnormal middle ear system, severe loss of sensitivity, or a lesion in the VIII nerve or ipsilateral VII nerve (Alford, 2001:4). Immittance testing has the additional advantage of being objective, in that it requires no response from the subject and thereby negates attempts to influence results (as commonly occurs with conventional pure tone audiometry). Immittance screening to identify susceptible individuals could enable the immediate and positive identification of precipitating barotrauma injury and early-stage middle ear pathology. The medical surveillance system must provide information that the employer can use in determining measures to eliminate, control and minimize the health risks and hazards to which employees are or may be exposed (Department of Minerals and Energy, 1996:19). Emphasis should therefore be placed on the anticipation, recognition and evaluation of those hazards that could compromise the health, well being and safety of employees, and to formulate measures for their effective control (Department Minerals and Energy, 2001:1). Immittance testing offers a means of satisfying these requirements.

1.4 Problem statement

In developing the research design, the problem statement served as the point of departure (Mouton, 2001). Immittance testing is currently viewed as an optional middle ear screening procedure in the South African mining industry (COMRO, 1988:6). Stach (1998:177) has concluded that immittance audiometry is the best means for assessing outer and middle ear function and exclusion thereof may result in unidentified cases of middle ear pathology.

The study evaluated the potential for immittance testing to identify middle ear pathology and satisfy a fundamental requirement for limiting the incidence of middle ear pathology, i.e. the positive identification of susceptible individuals to enable focused risk control measures. Furthermore, the study evaluated the benefits and practicability of immittance testing within employers' medical surveillance programmes. Additional issues addressed include the relevance of otoscopy and guidelines for assessing and reporting symptoms. The benefits of early identification and management of susceptible individuals to prevent hearing impairment are also considered.

The above-mentioned issues were addressed to answer the research question: What is the clinical value of immittance testing in the identification of middle ear pathology in South African mineworkers?

1.5 Outlay of chapters

The chapters that follow present the details of the research study.

Chapter 1

The purpose of the first chapter is to provide an introduction and rationale for the present study. It provides an overview of the complications and epidemiology of middle ear pathology. The value of the identification of middle ear pathology is discussed and a problem statement is put forward. An outlay of chapters and definition of terminology are provided.

Chapter 2

Knowledge of theoretical underpinnings is essential in the identification of middle ear pathology. Chapter 2 provides an overview of the relevant anatomical structures of the middle ear. The middle ear mechanical system and impedance matching are discussed, as are methods for assessing the condition and function of the middle ear, with the focus on the clinical value of immittance testing.

Chapter 3

Chapter 3 presents a concise background of the methodology used during the present study, after which the aims, hypotheses, research design, explicit description of the population, sampling techniques, materials, apparatus and procedures are all discussed in detail.

Chapter 4

The aim of Chapter 4 is to present the results and to discuss them. Indications of significance, as determined by statistical analysis, will also be included. Additional value is derived from the findings through a process of interpretation relative to the theory, concepts and constructs presented in the earlier chapters.

Chapter 5

Conclusions and recommendations are presented in Chapter 5, based on present findings in relation to the initial background from previous research, their theoretical basis and possible implementation scenarios to address the problem statement, and the strengths and weaknesses of the study.

1.6 Definition of terminology

Barotrauma: tissue damage that occurs when a gas-filled body space (e.g. middle ear, lungs) fails to equalize the internal pressure to accommodate changes in ambient pressure (WebMD Corp., 2001:1; Newton, 2001:2).

Eustachian tube: a 3-4 cm tubular structure linking the ear with the throat and nose (Hoffman, 1996:2).

Health hazard: any physical, chemical or biological hazard to health, including anything declared to be a health hazard by the Minister (Department of Minerals and Energy, 1996:84).

Immittance testing: test procedures that use measures of the tympanic membrane compliance to determine normalcy of structures medial to the eardrum (Evergreen Speech and Hearing Clinic, 2002:3).

Normal hearing: hearing sensitivity to a level of 25 dB or below (Hoffman, 1996:2).

Medical surveillance: a planned programme of periodic examinations, which include clinical examinations, biological monitoring or medical tests of employees by an occupational health practitioner or an occupational medical practitioner, as contemplated in section 13 of the Mine Health and Safety Act (1996:85).

Occupational disease: any health disorder including an occupational disease as contemplated by the Compensation for Occupational Injuries and Diseases Act No. 130 of 1993 or the Mine Health and Safety Act No. 29 (1996:86).

Occupational health: a programme to ensure the health of workers that includes occupational hygiene and occupational medicine (Department of Minerals and Energy, 1996: 86).

Occupational health practitioner: a person who holds a qualification in Occupational Health and is registered with the South African Health Professions Council (Department of Minerals and Energy, 1996:86).

Occupational injury: any injury arising out of and during the course of a person's employment, Compensation for Occupational Injuries and Diseases Act No. 130 of 1993 (Mine Health and Safety Act, 1996).

Occupational medical practitioner: a medical practitioner who holds a qualification in occupational medicine or an equivalent qualification, and who is registered with the South African Health Professions Council, or a medical practitioner engaged in accordance with section 13(4) of the Compensation for Occupational Injuries and Diseases Act of 1993 (Mine Health and Safety Act 1996: 87).

Pneumatic otoscopy: a two-step procedure to evaluate the tympanic membrane that includes, firstly, visualization of the ear canal and eardrum with a light source and, secondly, observation of the tympanic membrane while very slight positive and negative pressure is applied to the sealed ear canal (Australian Department of Health and Aging, 2001:3).

Risk: the likelihood that occupational injury or harm to persons will occur (Department of Minerals and Energy, 1996:88).

Safety: the prevention of accidental loss (Department of Minerals and Energy, 1996:88).

Screening: the rapid application of tests or other procedures for the purpose of identifying pre-clinical disease (Community Practice Handbook and Logbook, 2001:26).

Screening test: a test performed for the purpose of identifying preclinical disease in a population or subgroup (Community Practice Handbook and Logbook, 2001:26).

Screening programme: systematic application of screening tests to an identified population or sub-population (Community Practice Handbook and Logbook, 2001:26).

Sensitivity: the number of diseased individuals detected by a test in relation to the number of diseased individuals in the population being screened expressed as a percentage (Community Practice Handbook and Logbook, 2001:27).

Specificity: the number of non-diseased individuals whose response to the test is negative in relation to the number of non-diseased individuals in the population, expressed as a percentage (Community Practice Handbook and Logbook, 2001:27).

Surveillance: the twin notions of careful observation and timely intervention (Community Practice Handbook and Logbook, 2001:27).

Tympanogram: a graphic representation of middle ear status and function (Wiley, 1997:141).

CHAPTER 2 Causes, identification and treatment of middle ear pathology

2.1 Introduction

This chapter provides a theoretical discussion of middle ear pathology and its identification. Relevant structures in the middle ear and the mechanical system of the middle ear are reviewed and an overview of clinical measures for assessing middle ear status is provided. The focus falls on immittance measures for its value in providing important clinical information regarding the condition of the middle ear system (Petrak, 2001:2).

2.2 Anatomy and physiology of the middle ear

An overview follows on the anatomy and physiology of a normal middle ear system. Knowledge on the close communication of the middle ear with the surrounding structures provides focused perspective on both the cause of middle ear disease and its complications (Stool, Mount and Medellin, 1996:3).

2.2.1 Tympanic membrane

A normal eardrum (Figure 2.1) is translucent, similar to ground glass, and is usually pearly grey in colour (Australian Department of Health and Aging, 2001:3). The total area of the tympanic membrane is approximately 0.5 cm² and it comprises three layers (Martin, 1994:221), despite being only 0.07 mm thick. The entire area of the membrane is richly supplied with blood, which is why it appears so red in the presence of infection. The tympanic membrane is a stiff (but flexible), diaphragm-like structure (Howard, 2003:2). The eardrum moves synchronously in response to variations in air pressures, which constitute sound waves. The drum's vibrations are transmitted through the ossicular chain to the cochlea (Howard, 2003:2). Embedded in the fibrous portion of the tympanic membrane is the malleus, the first and the largest of the three middle ear ossicles (Martin, 1994:221).

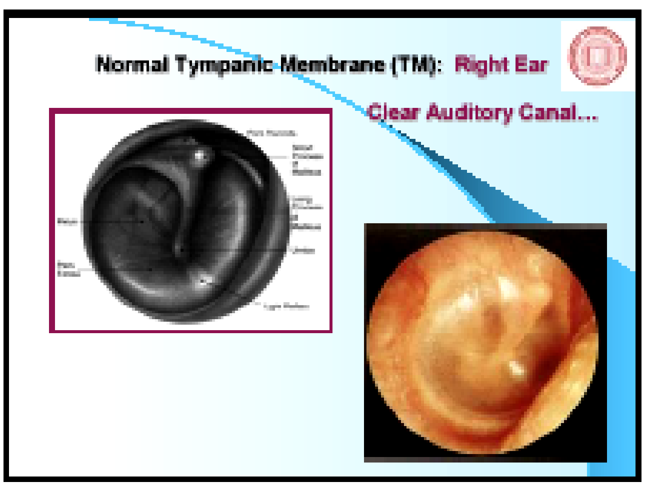

Figure 2.1: Normal tympanic membrane (Indiana University, 2003:1)

2.2.2 Middle ear cavity

An average adult middle ear cavity has the shape of a flattened sphere with a volume of approximately 2.8 cm³ and is filled with air (Martin, 1994:236). A thin layer of bone, which separates the middle ear from the brain, forms the roof of the cavity. The jugular bulb is below the floor of the middle ear cavity, and the carotid artery is behind the anterior wall. The lateral portion of the middle ear holds the tympanic membrane at the distal end of the ear canal. The space in the middle ear above the tympanic membrane is called the epitympanic recess. To accomplish the function of transmitting sound energy from the air-filled external auditory canal to the fluid-filled inner ear, the middle ear contains a set of three small bones called ossicles. They are the malleus (hammer), incus (anvil) and stapes (stirrup). The middle ear is connected to the nasopharynx via the Eustachian tube, which provides for pressure equalization between the middle ear and surrounding air (Martin, 1994:236). A graphic representation of the middle ear anatomy is provided in Figure 2.2.

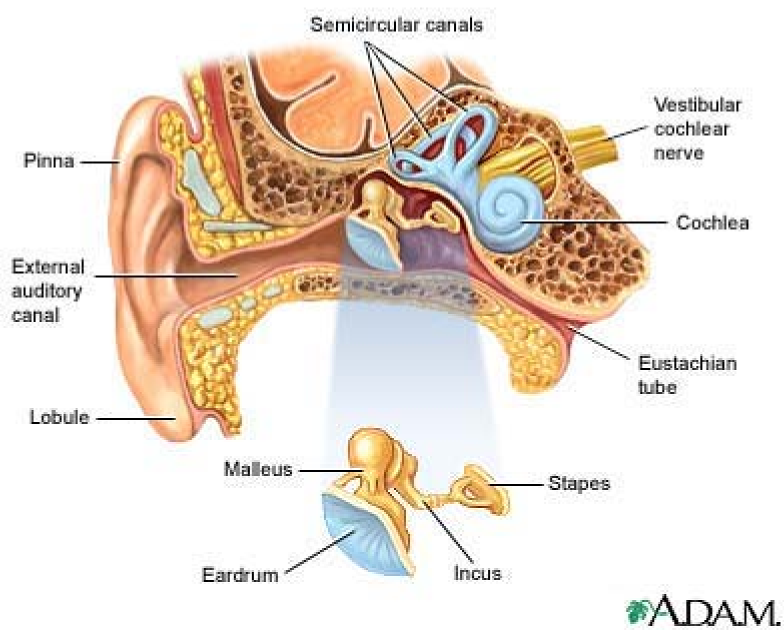

Figure 2.2: Middle ear anatomy (Hart, Greene, Juhn and Peckham, 2004:1)

2.2.3 Eustachian tube and its relation to middle ear pathology

In the adult, the Eustachian tube can be visualized as two truncated cones attached at their narrow ends (Hoffman, 1996:2). It runs from the middle ear to the nasopharynx and is between 31 mm and 38 mm in length. The normal Eustachian tube is collapsed when at rest, resulting in slight negative pressure in the middle ear. It opens during swallowing, sneezing, and yawning. The Eustachian tube has three functions: ventilation, drainage, and protection. When open, it allows ventilation of the middle ear and equalization of pressure differences between the middle ear and the atmosphere, and also drains the middle ear of unwanted secretions. When closed, it protects the middle ear from nasopharyngeal secretions and sound (Alford, 2001:2). Conditions such as colds or allergies can contribute to obstruction of the Eustachian tube by causing swelling of the lining and resultant fluid accumulation (Department of Otolaryngology, 2005:1). Eustachian tube dysfunction may lead to negative middle ear pressure associated with middle ear disorders (Wiley, 1997:67). A normal functioning Eustachian tube is essential for deep mineworkers in the equalization of middle ear pressure during vertical transportation (Franz, 2001:168)

2.2.4 Middle ear mechanical system and impedance matching

Impedance is defined as opposition to the flow of energy through a system (Bess and Humes, 1995:135). When acoustic energy strikes the ear drum of a normal ear, a portion of it is transmitted through the middle ear to the cochlea, while the remainder is reflected back out through the external ear canal. The reflected sound forms a wave travelling in an outward direction, which has an amplitude and phase determined by the resistance encountered at the tympanic membrane. The energy of the reflected wave is greatest when the middle ear system is stiff or immobile, as in pathologic conditions such as otitis media with effusion and otosclerosis. On the other hand, an interruption of the ossicular chain, as with a dislocated ossicle, will reflect considerately less sound back into the canal because reduced stiffness at the tympanic membrane allows most of the energy to pass through to the middle ear. The reflected energy wave, therefore, carries information about the status of the middle ear system, which is evaluated during immittance testing.

The reciprocal of impedance is admittance, i.e. an ear with high impedance has low admittance, and vice versa. Admittance describes the relative ease with which energy flows through a system, and the term “immittance” refers either to impedance or admittance data. Measurement of acoustic immittance at the tympanic membrane is an important component of basic hearing evaluations (Bess and Humes, 1995:136). In contrast, the Chamber of Mines Sub-Committee on Hearing Conservation (COMRO, 1988:40) and the Department of Minerals and Energy (2001:11) suggested medical history, otoscopic examination and pure tone air conduction audiometry to satisfy standards for hearing loss screening. Immittance testing (tympanometry and acoustic reflex testing) is described as optional. Given that immitance testing provides information on the status of the middle ear, including immittance testing into the mines' hearing screening procedures might prove useful.

2.3 Assessing middle ear condition and function

Structural changes in the outer and middle ears can cause functional changes and result in hearing impairment. Problems associated with the outer ear are usually related to obstruction or stenosis (narrowing) of the ear canal. The most common problem is an excessive accumulation or impaction of cerumen. When changes such as this occur, sound can be blocked from striking the tympanic membrane, and a loss in the conduction of sound will occur. The function of the tympanic membrane can also be reduced by either perforation or sclerotic tissue adding mass to the membrane. These changes result in a reduction in appropriate tympanic membrane vibration and a consequent loss in conduction of sound to the ossicular chain (Stach, 1998:173). The structural and functional changes that might occur in the outer and middle ear need to be identified to prevent the development of further pathology. History-taking, otoscopy, immittance testing and pure tone testing should be performed on mineworkers to diagnose a conductive hearing loss (RMA, 2004:5).

2.3.1 Case history

Before the audiologic examination begins, a case history is obtained from the patient. Questions regarding the nature of past and present hearing problems, other medical problems, and prior rehabilitative efforts are recommended (Bess and Humes, 1995:105). Minimum standards of fitness guide the occupational medical practitioner conducting the interview, who must be satisfied that no disease or impairment is present that could be significantly aggravated by further exposure or to present an unacceptable health risk to the individual (Department of Minerals and Energy, 2001:1). The Australian Department of Health and Aging (2001:3) states that the recording of an accurate and comprehensive medical history, forms the basis for any extra or special investigations that may be required, and should include date of onset of signs/symptoms of middle ear disease, previous treatment and degree of compliance with treatment regimes, as well as an assessment of environmental factors.

2.3.2 Otoscopy

The first step in the process of assessing the outer and middle ear function is inspection of the ear canal and the tympanic membrane. This is achieved with otoscopy. Otoscopy is simply the examination of the external auditory meatus and the tympanic membrane with an otoscope (Stach, 1998:174).

A general physical examination of the head and neck is fundamental and should include the nose and throat, with special attention to the ears and adjacent structures (Alford, 2001:3). Surgical scars, defects and congenital deformities should be noted (Alford, 2001:3), and the external ear canal should be carefully examined for cerumen, exostosis, evidence of infection, flaking, dry skin, and osteomas. The postero-superior area of the canal should be inspected for previous mastoid surgery or a cholesteatoma (Alford, 2001), and the tympanic membrane should be inspected for evidence of scars, perforations, tympanosclerosis and colour changes. The tympanic membrane's colour, translucence and resting position can be assessed during otoscopy (Australian Department of Health and Aging, 2001:2). Acute middle ear effusion makes the tympanic membrane appear amber, whereas chronic middle ear effusion makes it pale and dull. The area superior to the lateral process of the malleus might show evidence of a retraction pocket or attic cholesteatoma. An atrophic, retracted tympanic membrane is a sequala of middle ear infections (Alford, 2001:2). The appearance of the tympanic membrane is the first key to diagnosing middle ear disorders (College of Family Physicians, 2001:2). By being familiar with the appearance of a normal ear drum, the examiner will be able to immediately recognize signs of pathology in the middle ear (College of Family Physicians, 2001:2). It would thus seem important for medical staff performing the otoscopic examinations to be familiar with all signs of pathology for immediate identification.

Otoscopic examinations are subjective (Palmu, 2001:1), and it has been estimated that static otoscopy, even when performed by experienced personnel, can only predict otitis media with effusion in 50 per cent of cases. It may be necessary to remove wax or foreign material before an adequate view can be obtained. Furthermore, narrow or crooked ear canals can impede visual examination (Australian Department of Health and Aging, 2001:2).

The skill and experience of clinicians vary considerably, it is anticipated that the more subtle visual indications of middle ear disorder will be detected in some screening program but not in others (American Speech Language and Hearing Association, 1990:17). Nurses and/or audiometrists registered with the Department of Labour, perform otoscopic screening examinations the in the South African mining industry (RMA, 2004:5). The Western Cape HARK Project (2000:3) found that there is a need to provide additional training regarding hearing impairment, the effects thereof and its identification to other health professionals, particularly primary health care nurses. The need for training on the management of middle ear pathology has been widely called for. Medical staff needs to be proficient in the identification and referral of patients with suspected middle ear pathology. Three types of abnormality apparent from visual inspection should result in immediate referral, which includes structural defects of the pinna, head or neck (Franz, 2001:172). These indicate a wide variety of conditions, including abnormal position and/or structure of the external ear ranging from complete absence of the pinna and atresia of the ear canal to more subtle abnormalities such as mal-positioned pinnae and pre-auricular pits and tags. The presence of visually detectable structural defects may hide the presence of other otological abnormalities requiring medical attention. Ear canal abnormalities including inflammation, bleeding, effusion, excessive cerumen, tumours, or foreign bodies in the ear canal are also sufficient cause for referral. Ear drum abnormalities may be indicative of active middle ear disorders requiring immediate medical attention. Detection of these abnormalities by otoscopy requires considerable skill and experience, as in many cases the tympanic membrane may not be visible, even to an experienced clinician. Consequently, only the most obvious ear drum abnormalities are recommended as referral criteria in a screening program (American Speech Language and Hearing Association, 1990:17). Obvious inflammation, perforation and severe retraction of the tympanic membrane all constitute criteria for medical referral (American Speech Language and Hearing Association, 1990:17). Variable proficiency in the skill and training of the medical staff performing otoscopic examinations, would lead us to believe that otoscopy as a single procedure would not be comprehension enough in the identification of all forms of middle ear pathology. The diagnosis of some forms of middle ear pathology like otitis media, is difficult using medical history and otoscopy. Tympanometry may, therefore, be helpful in the diagnosis and follow-up of middle ear pathology (Van Balen, Aarts and De Melker, 1999:117).

2.3.3 Immittance testing

Following otoscopic inspection of the outer ear structures, the next step in the evaluation process should be to assess the function of the outer and middle ear mechanisms (Stach, 1998:174). Tympanometry is not a test of hearing, but rather a test of middle ear function, as it measures middle ear impedance to acoustic energy (Australian Department of Health and Aging, 2001:3). Together with otoscopy, an essential prerequisite for tympanometry, tympanometry provides quantitative information on the mobility of the tympanic membrane and middle ear structures (Smith and Evans, 2000:57; Franz, 2001:7). The acoustic reflex measurement is an indirect index of the status of the middle ear. It has a high sensitivity for the detection of middle ear pathology (Neumann, Upperkamp and Kollmeier, 1996:4). Tympanometry is increasingly included in auditory screening protocols (Fowler and Shanks in Katz, 2002:175). Results of 16500 auditory screenings performed over a five year period indicated that tympanometry significantly enhanced the effectiveness of screening for middle ear disorders (Fowler and Shanks in Katz, 1994:297). Screening audiometry, even in the primary care physician's office, has been given an additional boost with the advent of commercially available hand-held tympanometric devices. Other studies has cautioned that although tympanometry should be included as part of the screening program, mass one-time tympanometric screening may not be productive. Results of this research have shown that a one-time finding of an abnormal tympanogram is correlated with, but not a diagnostic indication of middle ear effusion and prevalence of middle ear effusion (Fowler and Shanks in Katz, 2002:184). Furthermore, more than one-half of all cases of otitis media with effusion may resolve spontaneously. This research suggests that only when tympanometric test results suggests middle ear pathology should the screening be followed up with more frequent screening to monitor the presence of fluid in the middle ear. Audiometric screenings are usually associated with pediatric populations, however, there is direct evidence to suggest that tympanometry is also a useful screening test for treatable hearing loss in adults (Fowler and Shanks in Katz, 2002:202).

From the preceding review, it is clear that tympanometry has a secure role in screening programs. The time has come for increasing the use of combinations of instrumentation, techniques, and clinical aural immittance measurements to most effectively describe middle ear function (Fowler and Shanks in Katz, 2002:202). Tympanometry and acoustic reflex measures are valuable adjunctive tools to aid diagnosis and follow-up of middle ear pathology. The use of immittance testing may improve diagnostic accuracy because it validates or refutes the clinician’s impression (Pichichero, 2000:2015).

2.3.4 Pure tone audiometry

The most commonly used test for evaluating auditory sensitivity is pure tone audiometry (Quinn, 2000:4), which is widely accepted as the most reliable measurement of hearing (Petrak, 2001:2). The main purpose of screening is to obtain reliable, frequency- and ear-specific hearing thresholds (Petrak, 2001:2), which are defined by ANSI (Quinn, 2000:4) as the minimum effective sound pressure level of an acoustic signal that produces an auditory sensation “in a specified fraction of trials”. Pure tones are well suited for testing auditory acuity, and signals can be delivered via air and bone conduction pathways. Pure tones are suitable test stimuli because of their utility and spectral specificity in evaluating cochlear elements. If a loss occurs as a result of changes in the outer or middle ear, it is considered a loss in the conduction of sound to the cochlea, or a conductive hearing loss. To diagnose a conductive loss, pure tone air thresholds need to be obtained together with pure tone bone thresholds (Stach, 1998:179).

In the South African mining industry employers are required by law to establish a system of medical surveillance of all employees exposed to noise at or above the noise-rating limit (Mine Health and Safety Act, 2001:12). All industrial workers exposed to an equivalent noise exposure of 85 dB (A) to 105 dB (A), should undergo routine audiometric examinations to identify hearing loss as early as possible (SANS 10083:2004). Eagles, Wishik and Doefler (1967) (in American Speech Language and Hearing Association, 1990:17) also recommended that identification audiometry should be included in all screening protocols. The Mine Health and Safety Act (2001:12) also states that the employer ensure that a baseline audiogram is recorded for all new employees; conduct periodic audiogram; conduct an exit audiogram for every employee whose employment is terminated or transferred to another workplace in respect of which audiometric tests are not required. Utilizing audiometry as part of industrial hearing conservation programs can identify hearing loss in individuals before they notice it themselves. Early diagnosis and intervention is the key to prevention of occupationally related hearing loss (Department of Occupational Health & Environmental Medicine, 2003:2).

2.4 Assessment of middle ear function using immittance measures

A thorough understanding of the basic principles of aural acoustic immittance measurements and identification audiometry is essential for competent design and execution of a screening protocol (American Speech Language and Hearing Association, 1990:19), which should include tympanometry to provide important clinical information regarding the condition of the middle ear system (Petrak, 2001:2).

Immittance audiometry has proved to be a sensitive indicator of middle ear function, thereby permitting a direct assessment of middle ear disorders. It is important to note that a middle ear disorder can exist with or without a significant air-bone gap (Stach, 1998:259). Immittance testing is significantly more sensitive to middle ear pathology than the assessment of air-bone gaps (Stach, 1998:259). Current clinical practice argues for carrying out immittance testing first, before pure tone audiometry. If all immittance measures, tympanometry, static immittance and ipsi- and contra-lateral acoustic reflexes, are normal, then whatever hearing loss is determined is sensorineural in nature. In fact, if an air-bone gap exists, then either air conduction thresholds or bone conduction thresholds are not accurate. Many clinicians will not bother testing bone conduction if all immittance measures are normal. This is a reasonable practice, since the weakest link in this chain is bone conduction audiometry. If immittance measures are abnormal, the next clinical question is whether the middle ear disorder is causing a conductive hearing loss, which can then be addressed by air and bone conduction audiometry (Stach, 1998:260). There is agreement in the literature that immittance measures should form part of the diagnosis of middle ear pathology.

2.4.1 Electro-acoustic immittance instruments

Immittance instruments measure the sound pressure reflected by the tympanic membrane to determine its mobility and impedance (which is partly controlled by the middle ear ossicles attached to it), thereby providing an objective assessment of middle ear status. The immittance probe has different-sized "plugs" to seal the entrance of the external ear canal (Patient Evaluation, 2001:3), and its tip has a pressure transducer to vary pressure in the ear canal from negative-to-ambient-to-positive. While the pressure is varied, a sound transmitter sends an energy wave to the tympanic membrane, which reflects some of the sound energy back to a microphone in the probe. Although instruments vary in the components measured and in the frequency of the probe tone, all instruments work on the same basic principle (Quillen, 2002:1). However, the most utilized device in any audiology or ototology facility is hand-held screening devices (Smith, 2004:2). These instruments offer a fast, non-invasive and cost effective method to assess the integrity and function of the middle ear. Immittance measures can also be conducted in less optimal conditions, as long as the ambient noise does not exceed 50 dB(A) (Smith and Evans, 2000:59).

Normally, a single low-frequency tone is delivered (e.g. 220 Hz), and the ear drum's compliance is plotted for various air pressures to produce a tympanogram. The instrument automatically generates a graph and a test report, which can be stored in a linked computer for record-keeping and data management purposes, and printed on an associated plotter (Franz, 2001:6). A tympanogram indicating pathology can result from impacted cerumen; eardrum perforation; canal stenosis, or a false positive result may occur in the event of incorrect probe placement (Australian Department of Health and Aging, 2001:2).

Specifications for aural acoustic immittance measurements are described in ANSI S3.39–1987 (Der, 2001:1). The purpose of this standard is to ensure that acoustic-impedance or acoustic-admittance measurements will be substantially the same for a given ear when these measurements are obtained with any instruments that meet the specifications and tolerances outline in this standard, and when comparable test conditions prevail. Der (2001:1) further explains that acoustic immittance machines are categorized into specific types according to its features and capabilities, similar to how audiometers are categorized. Those devices that offer the greatest number of features and capabilities are classified as type one and the most basic devices are categorized as type four. A type one device are generally more precise that a type two or three. It is important to note that contralateral acoustic reflex is not available on all screening immittance instruments (School Health, 2004:2). There are however, mandatory characteristics and features acoustic immittance devices must have in order to meet ANSI S3.39 standards. It is also the manufacturers' responsibility to indicate the accuracy and limitations of their device, as well as the limitations with regards to the atmospheric pressure and altitude above sea level in which the device will operate. Ambient temperature and barometric pressure are also important variables that affect the measurement of acoustic immittance. Since these variables are likely to change on a periodic basis due to environmental conditions, it is important that audiologists calibrate their machines for changes in these conditions, on a daily basis prior to use (Der, 2001:1).

There is some direct evidence to support positive tympanometry results as a reliable indicator of middle ear pathology in children (Australian Department of Health and Aging, 2001:3). A study to evaluate correlations between tympanometry and pure tone results from 581 children between three and ten years of age confirmed a high positive-predictive value for hearing impairment in children with type B tympanograms. Children with a flat tympanogram were 78.6 per cent more likely to have a hearing loss greater than 25 dB, as quantified by pure-tone audiometry, and it was found that the positive-predictive value of immittance testing is even higher for younger children. The researchers suggested that tympanometry could be used to screen younger children (age three and younger) with otitis media and effusion for hearing impairment, without the need for pure-tone testing, because the procedure is easily applied and produces valid results, even where the tester is relatively inexperienced (Australian Department of Health and Aging, 2001:3). Meaningful otoscopic assessments rely on the experience, knowledge and interpretational skills of the examiner, implying the likely need for an ear, nose- and throat specialist or medical practitioner. In contrast, tympanometry does not require the same high level of interpretational skills and the results are quantitative, thereby enabling the use of pre-determined action and referral levels (Franz, 2001:6). In a study performed by (Green, Culpepper, De Melker, Froom, Van Balen, Grob and Heeren, 2000:3) a coordinator trained several physicians in the otoscopic examination of the ear, the use of a screening immittance meter and tympanogram interpretation. The results of the study indicated that there is high agreement in the interpretation of tympanograms between experts and primary care physicians. Green et al. (2000) recommended that interpretation of tympanograms by primary care physicians could be used with confidence. These results may suggest that with proper training of occupational health personnel may result in successful utilization of immittance testing in medical surveillance screening. Another study performed by Butler and MacMillan (2001:3) confirmed an 80% sensitivity and specificity for tympanometry.

2.4.2 Main components of immittance testing

Three basic measurements commonly make up the basic acoustic immittance test battery (Bess and Humes, 1995:105). These are tympanometry, static acoustic immittance and acoustic reflex testing.

2.4.2.1 Static admittance/compliance

This procedure measures the height of the admittance-magnitude tympanogram, relative to the tail value (American Speech Language and Hearing Association, 1990:19). Static admittance can be used as an objective parameter for categorizing the tympanogram on the basis of its shape (American Speech Language and Hearing Association, 1990:19). The amplitude of the tympanogram gives additional information about the compliance or elasticity of the middle ear system. A stiff middle ear (e.g. ossicular chain fixation) yields a tympanogram with a shallow amplitude plot indicating high impedance, while an ear with an interrupted ossicular chain (e.g. dislocation) produces a tympanogram with a steep plot, indicating low impedance. If the middle ear space is filled with fluid, the stiffened tympanic membrane reflects most of the sound wave back to the probe, yielding a flat tympanogram that indicates low compliance. If the middle ear is filled with air at a pressure equal to atmospheric and the ear drum and ossicles are intact, some of the energy delivered by the probe is absorbed by the tympanic membrane, ossicles and inner ear structures, resulting in a tracing that indicates normal compliance. Any disruption of the ossicles or flaccidity in the tympanic membrane will cause a large portion of the energy to be absorbed, and the tracing will display an abnormally steep slope and high peak, indicating high compliance (Patient Evaluation, 2001:2).

2.4.2.2 Equivalent ear canal volume

Ear canal volume is conventionally subtracted from measures of total aural admittance, to yield an estimate of middle ear admittance referred to as compensated admittance. Estimates of ear canal volume are routinely included in tympanometry conducted using commercially available instruments (Fowler and Shanks in Katz, 2002:180). This provides information about the volume of air medial to the probe, and is obtained by measuring admittance at high-positive or high-negative ear canal pressure. Ear canal volume generally ranges between 0.5 ml for babies; 0.8 ml to 1.0 ml for children and 1.5 ml to 1.8 ml for adults, with larger volumes among geriatric patients. Volume measurements greater than these suggest tympanic membrane perforation or a patent pressure equalization tube (Quinn, 2000:4), while lower ear canal volumes indicate occlusion of the ear canal by cerumen or other material (Patient Evaluation, 2001:2).

2.4.2.3 Tympanometric peak pressure

Tympanometry reflects the mobility of the middle ear when air pressure is varied from +200 daPa to -400 daPa (Quinn, 2000:4). A normal tympanogram for an adult has a peak pressure point between –50 daPa and +50 daPa, indicating that the middle ear functions optimally at or near ambient pressure (Fowler and Shanks in Katz, 2002:184). Peak pressure below the normal range suggests malfunction of the middle ear pressure-equalising system, attributable either to Eustachian tube dysfunction, or to early or resolving chronic otitis media or acute otitis media. Tympanometric peak pressure has frequently been recommended as an indicator of middle ear pathology and as a criterion for medical referral (Margolis and Heller, 1987:3), as the normal relationship between air pressure changes and changes in immittance is frequently altered in the presence of middle ear pathology (Tavartkiladze, 2003:1).

2.4.2.4 Acoustic reflex testing

Acoustic reflex threshold is defined as the lowest intensity that elicits a middle ear contraction (Bess and Humes, 1995:138). Measures of acoustic reflex have been used in screening and diagnostic protocols for middle ear disorders (American Speech Language and Hearing Association, 1990:19). The reflex involves two small muscles in the middle ear that are functionally related to the middle ear transmission system, specifically to the ossicular chain. The tensor tympani muscle is attached to the wall of the Eustachian tube and the upper margin of the malleus' manubrium. It is innervated by cranial nerve V, the Trigeminal, and contracts during a "startle response". This involuntary contraction of the tensor tympani muscle draws the malleus inward thereby stiffening the ossicular chain and, in turn, the tympanic membrane. The resulting tensing of the tympanic membrane along its lateral surface increases acoustic impedance and, hence, decreases acoustic admittance. A further decrease in acoustic impedance results from the inward movement of the tensor tympani, which reduces middle ear volume thereby increasing middle ear pressure.

The second middle ear muscle, the stapedius, originates at a small bony canal adjoining the facial canal and attaches to the head of the stapes. It is innervated by the motor or stapedial branch of cranial nerve VII, the facial nerve. The stapedius muscle can contract in response to an acoustic stimulus of sufficient intensity and duration, or a non-acoustic stimulus. Functionally, contraction of the stapedius pulls the stapes downwards and away from the oval window, the interface with the inner ear. As the head of the stapes is drawn back, its anterior base is tilted towards the tympanic cavity, resulting in a stiffening of the ossicular chain and a corresponding decrease in acoustic admittance at the lateral surface of the tympanic membrane. The reduction in acoustic admittance is a result of the stiffened middle ear transmission system, which is time-locked with the activating stimulus, thereby providing the basis for clinical measurements of stapedius muscle response (Wiley, 1997:78).

Contraction of the stapedius muscle is normally bilateral, i.e. if the stapedius muscle in one ear contracts, so will the stapedius muscle in the opposite ear. Hence, the stapedius muscle reflex can be measured for either ipsilateral or contralateral stimuli. With ipsilateral stapedius reflex measurements, a reflex activating stimulus (RAS) is presented to the same ear in which acoustic immittance changes are being measured. With contra-lateral stapedius reflex measurements, an activator is presented to one ear (the stimulus ear), while acoustic immittance changes are measured in the opposite ear (the probe ear). Response of the stapedius to an ipsilateral activator is slightly stronger than to a contralateral activator. Neurologically, the primary ipsilateral acoustic pathway involves the cochlea, cranial nerve VIII, ventral cochlear nucleus, superior olivary complex, facial motor nucleus, and the motor (stapedius) branch of cranial nerve VII (the facial nerve, which innervates the stapedius) (Wiley, 1997:78). Therefore an abnormality at any of these areas will result in absent or abnormal reflexes.

The acoustic reflex threshold is defined as the lowest intensity level at which a middle ear immittance change can be detected in response to sound (Stach, 1998:270). Each measure is evaluated in isolation against normative data and then in combination to determine the pattern (Stach, 1998:274). Measuring the acoustic reflex provides information about the integrity of the entire auditory system up to the level of the superior olivary complex (SOC) in the brainstem, and also the motor branch of the facial nerve. Acoustic reflex thresholds are classified as normal, absent, recruited or elevated. The reflex threshold is deemed normal if the reflex occurs at a sound level between 70 dB and 90 dB, abnormal-with-recruitment if the reflex occurs below 70 dB, and abnormal-elevated if it only occurs at levels greater than 90 dB (Wiley, 1997:86).

This sensitive and objective tool has been used to identify the presence of fluid in the middle ear, to evaluate Eustachian tube and facial nerve function, to predict audiometric findings, to determine the nature of hearing loss, and to assist in diagnosing the site of auditory lesion. This technique is considered particularly useful in the assessment of difficult-to-test persons, including malingerers (Tavartkiladze, 2003;2). It is exceedingly sensitive to middle ear disorders. Only a 5 dB to 10 dB air-bone gap is usually sufficient to eliminate the reflex when the reflex probe is in the ear with conductive loss (Stach, 1998:274).

Although threshold measures are valuable, interpretation of the absence or abnormal elevation of an acoustic reflex threshold can be difficult because the same reflex abnormality can result from a number of pathologic conditions. It is for this reason that the addition of uncrossed reflex measurement, tympanometry, static immittance and other tests is important in reflex threshold interpretation (Stach, 1998:272). Kemaloglu, Sener, Beder, Bayazit and Goksu (1999:1) considered that tympanometry and acoustic reflexes provide complimentary data to each other, which would be particularly important for screening studies and that they are good tools for confirmation of clinical impression, particularly for less experienced clinicians. When acoustic reflex information is used in conjunction with tympanometry, it serves to substantiate further the existence of a middle ear disorder (Tavartkiladze, 2003:1). The American Academy of Audiology

(1997:2) also confirmed that aural acoustic immittance measures are well-suited for middle ear screening and may improve the sensitivity of middle ear screening.

2.5 Classification and analysis of tympanograms

Over the years, various classification systems for a single component (admittance or impedance), low probe-tone frequency (226 Hz) have been proposed (Fowler and Shanks in Katz, 2002:177). Jerger's system, which dates from 1970 (Fowler and Shanks in Katz, 2002:177), is simple and clinically popular, because ears can be classified into three basic groups on the basis of the tympanogram's configuration (Alford, 2001).

Type A: peak compliance occurring at or near atmospheric pressure, indicating normal pressure in the middle ear. Type A is divided into three subgroups:

- Type A: normal, symmetrical shape, indicating a normal mechanism
- Type Ad: deep curve with a tall peak, indicating an abnormally compliant middle ear, as seen in ossicular dislocation or erosion, or with loss of elastic fibres in the tympanic membrane
- Type As: shallow curve indicating a stiff or non-compliant middle ear system, as in otosclerosis or chronic middle ear disease

Type B: no definite peak, with little or no variation in impedance over a wide range of pressures, often secondary to the presence of non-compressible fluid in the middle ear (otitis media), tympanic membrane perforation or obstructing cerumen. As for a type B tympanogram with normal ear canal volume (0.8 cm^3 to 2.0 cm^3) as in otitis media, no compliance peak is obtained at +200 daPa to -400 daPa. Type B tympanogram with a large ear canal volume (larger than 2.0 $cm^{3)}$ as in the presence of patent pressure equalization tubes or perforated tympanic membranes, an open exchange of air occurs between the ear canal and thus, any contraction of the stapedius muscle cannot be measured. Type B with small ear canal volume (smaller than 0,8 cm^3) suggests a patent pressure equalization tube (Campbell and Mullin-Derrick, 200322).

Type C: peak compliance significantly below zero, indicating negative pressure (sub-atmospheric) in the middle ear cavity that is often associated with Eustachian tube dysfunction or middle ear effusion (Alford, 2001:1).

Immittance measurements employ very straightforward testing procedures, as no special patient preparation is required (Evergreen Speech and Hearing Clinic, 2002:2). Tympanometry provides important clinical information regarding the condition of the middle ear system (Petrak, 2001:2), and a high concordance in interpretation of tympanograms by physicians has been demonstrated, with high specificity and moderate sensitivity (Palmu, 2001:2). In addition, the positive-predictive value, crucial to appropriate clinical decisions, was shown to be excellent. Tympanometry is useful in assessing the risk of otitis media developing from a respiratory infection (negative middle ear pressure increases the risk of secondary infection occurring within the next three weeks), and in improving the diagnosis of ear infections (Australian Department of Health and Aging, 2001:2).

Tympanometry may be of value in the mining industry. It is an objective test, which requires no response from the subject. It thereby eliminates the possibility of attempts to influence results, as in the case of conventional pure tone audiometry, during routine screenings for occupational hearing loss. Screening to identify susceptible individuals could enable immediate and positive identification of predisposing factors, such as previous barotrauma and early-stage middle ear pathology, with considerable savings in time and expense over conventional examination methods (Franz, 2001:6). Van Balen, Aarts and De Melker (1999:1) concluded that tympanometry is a reliable diagnostic instrument in general practice. Their study found that 61% of the general practitioners handled the tympanometer faultlessly. The overall inter-observer agreement was moderate to substantial. With respect to the gold standard 74% of the general practitioners had a satisfactory to almost perfect agreement. These results were achieved after instruction and training. Longer practice produced no significant improvement in the agreement and the classification of tympanograms was satisfactory. Audiometricians are able to perform hearing screening in the mining industry (SANS

10083, 2004:1). This research study suggests that audiometricians who are trained and instructed by audiologists might be able to perform tympanometric screening in the mining industry. Saunders and Locke (1998:1) also reported on the value of tympanometry in documenting middle ear function in barotrauma-susceptible divers. Tympanometry complimented otoscopic findings and identified retracted tympanic membranes and decreased mobility. Tympanometry may also reveal fluid in the middle ear, perforated ear drum, impacted ear wax, scarring of the tympanic membrane, ossicular chain disarticulation and a tumor in the middle ear (Ford, 2001:2). In cases of acute middle ear infection, immittance testing can confirm the presence of commonly coinciding effusion, and is a mandatory procedure for confirming acute otitis media in clinical studies. Immittance testing may also be useful for identifying infections that can be treated by expectant follow-up without antibiotic treatment (Palmu, 2001:2). Tympanograms can be interpreted with confidence and provide quality data for research purposes (Institute for Healthcare Improvement, 2001:1), and can reduce the cost of providing health care by preventing unnecessary referrals (Thunderbay District Health Unit, 2001:2).

Immittance testing for diagnosis of middle ear disorders is not regarded as the gold standard (Wiley, 1997:1). For unequivocal diagnosis, a surgeon's report based on myringotomy is more widely accepted. Myringotomy is a surgical procedure with or without general anesthesia involving a small incision in the tympanic membrane to ascertain whether fluid is present in the middle ear cavity. This can be done via aspiration with a fine needle (Nozza, Bluestone, Kardatzke and Bachman, 1994:1). However, the specialized nature of this procedure makes it unfeasible for general application, compelling many researchers to rely on immittance testing to identify middle ear disorders. Otoscopy is often used to validate the tympanometry findings but, irrespective of otoscopic or myringotomy confirmation, the results of many studies have shown that the sensitivity and specificity of immittance measures depend most of all on the variables measured and evaluation criteria used (Nozza, Bluestone, Kardatzke and Bachman, 1994:1). A primary rationale for the clinical use of acoustic immittance measures is that they are sensitive to middle ear disorders, even in persons who display little or no functional hearing loss (Wiley, 1997:1). Due to the fact that the acoustic reflex is absent in the presence of middle ear pathology, screening for presence or absence of the acoustic reflexes may reduce the number of false positive medical referrals associated with “wide” tympanograms accompanied by normal static admittance (American Academy of Audiology, 1997:2).

Early identification of middle ear pathology may limit the treatment costs associated with neglected middle ear pathology including surgical intervention. Previous findings indicate that individuals with chronic or temporary predisposing medical conditions are subjected to an increased risk of barotrauma (Franz, 2001:27). If workers suffering from middle ear pathology are temporarily excluded from work in deep-level areas, those with neglected middle ear pathology will be unavailable for longer periods, implying a need for their replacement, or assigning the patient’s duties to others. State and Federal agencies in the USA require effective medical surveillance programmes, and most compensation underwriters also advocate effective hearing conservation programmes, imposing higher premiums on employers who fail to adequately protect workers from hearing loss. An effective hearing conservation program promotes good labour relations because employees can see that management is concerned, which often translates to improved quality and productivity (Suter and Franks, 1990:5). Appropriate preventive measures, including monitoring by immittance testing could reduce future claims for hearing-related complaints and middle ear barotrauma. The research was conducted to define the research question: Should immittance testing be included as a preventative measure in the hearing conservation programmes of the mining industry?

2.6 Summary

This chapter has considered the theoretical aspects of identifying middle ear pathology. Relevant structures and the mechanical system of the middle ear were reviewed, and an overview was provided of clinical measures for assessing middle ear function and condition. The measures of assessment included history-taking, otoscopy, immittance testing and pure tone audiometry. Focus was placed on the components of immittance measures and the importance of the procedure for the clinical practice of audiology.

CHAPTER 3 Research methodology

This chapter presents the aims of the research study, the research design, hypothesis, material and apparatus for the selection of subjects, gathering, recording and analysis of data.

Research is the systematic process of collecting and analysing data, to develop information that enhances understanding of the phenomenon being investigated. The methodology controls the study, dictates how data are gathered and arranged them in terms of logical relationships, defines an approach for refining and developing the raw data to provide useful information and, finally, yields conclusions that lead to an expansion of knowledge or its more beneficial application (Leedy, 2001:8).

3.1 Aims of the research

The main aim of this study was to investigate the clinical value of immittance testing for the identification of middle ear pathology among South African mineworkers. In order to fulfill the principle aim, the following sub-aims were used:

3.1.1 To determine the prevalence of middle ear pathology as identified by conventional methods using the case history, otoscopy and pure tone air conduction testing.

3.1.2 To determine the prevalence of middle ear pathology using immittance testing.

3.1.3 To determine any discrepancies in the results

3.2 Research design

This section provides the overall structure of procedures followed, describes the data collected and the analytical measures applied. In designing the investigation, the research question was used as the point of departure (Mouton, 2001:4). The question to be answered was whether immittance testing should be incorporated into employers' medical surveillance programmes.

A literature review provided a better understanding of the research problem. There are many unidentified cases of middle ear pathology in mineworkers. The best means of screening for middle ear pathology is immittance testing and is not utilized in the mining industry. The research design was constructed to determine the prevalence of middle ear pathology as identified by conventional methods and by using immittance testing. The research outcomes further needed to determine any discrepancies in these results.
Two groups of subjects were included in the study. The first group of subjects were five members of the medical staff and the second group of subjects were 177 gold mineworkers. Medical staff was included to provide qualitative information on the identification of middle ear pathology. Gold mineworkers were included as subjects to provide quantitative and qualitative information to fulfil the principle and sub-aims. Middle ear pathology was identified by comparing results from medical histories, questionnaires, otoscopy, pure tone screening and immittance testing. Data were summarized in terms of prevalence and frequency counts, and inferences were drawn regarding the prevalence of middle ear pathology in the population of mineworkers (Leedy, 2001:196).

An experimental research component was employed to determine whether results from conventional middle ear screening procedures and those from the proposed method differed. Conventional screening procedures in medical surveillance programmes consisted of three components: medical history-taking, otoscopic examinations and pure tone screening audiometry. The proposed method for screening had the additional fourth component of immittance testing, the additional variant introduced to the screening protocol. The outcomes of screening by conventional procedures were compared with those from the proposed method, to determine which protocol was the most effective in identifying middle ear pathology. Each subject's otoscopy and case history results were directly compared with his immittance results to evaluate the effectiveness otoscopic examinations and case histories, and additional information on middle ear pathology was provided by the questionnaires. Digotome scales (yes/no answers) and lickert scales (multiple answers) were then used to extract and organize information from subjects for analysis by means of computer-based statistical software (Levin, 2003).

The formulation of guidelines for incorporating immittance testing into medical surveillance systems required a qualitative research component, provided for by means of two sets of questionnaires. Questionnaires were designed for medical staff and mineworkers to solicit closed- and open-ended responses as a source of descriptive data (Leedy, 2001:159). These provided information on the nature of middle ear pathology, the environment in which screening procedures were performed, and contributed to an evaluation of the proposed screening methods.

Variables were controlled to ensure the study's internal validity, and precautions were taken to eliminate other possible factors (Leedy, 2001:103). Internal validity was ensured by following the same procedures for the proposed screening methods and the currently used conventional procedures, with the exception that one single variant was introduced i.e. immittance testing. The study was constructed so as to select and screen the same people, in the same time frame and within the same context for both conventional and the proposed screening procedures. Rosenthal's experimenter's expectancy effect has been taken in consideration during the administration of questionnaires to medical staff and mineworkers, by ensuring that examiners are independent and not associated with occupational activities at the mine (Chow, 1994:89). All workers were informed during signing of the consent form that their identity will remain anonymous and all information confidential. Furthermore, questionnaires to mineworkers were administered in Fanakalo with the assistance of an interpreter, where comprehension of English was limited. External validity of the study was enhanced by using a representative sample of the daily mineworker population. The 177 subjects were randomly selected from a common pool of mineworkers attending Certificate of Fitness evaluations.

3.3 Subjects

This section describes and clarifies the criteria and procedures of the selection of subjects.

3.3.1 Criteria for the selection of subjects

By prescribing criteria and insisting on standards, the researcher could control the type of data admitted and regulate the conditions under which the research effort proceeded (Leedy, 2001:97). Criteria were set for the selection of the medical staff and mineworkers. The criteria are depicted in table 3.1 and further delineated thereafter.

Table 3.1: Criteria for the selection of subjects

Medical staff	Mineworkers
Performs periodic fitness evaluations at the mine's Occupational Health Centre	Underground gold mineworkers
Signed consent	Signed consent
-	Normal pure tone screening results

3.3.1.1 Medical staff

- Occupation:

The first group of subjects were selected from a group of medical staff who performs periodic fitness evaluations at the mine's Occupational Health Centre. Medical staff was incorporated as subjects to provide qualitative information on the identification of middle ear pathology. Medical staff included registered nurses and audiometrists (RMA, 2004:14).

- Signed consent:

Signed consent was required from subjects participating in research procedures.

3.3.1.2 Mineworkers

- Occupation:

The second group of subjects were selected from underground gold mineworkers. Gold miners were studied because they work at underground depths as great as 5 000 m. It provided an opportunity to observe the effects of rapid pressure changes during vertical conveyance to and from deep-level workings and hence, the greater risk of middle ear pathology from, amongst others, barotrauma (THRIP, 1999:3).

- Pure tone screening results

Only mineworkers with normal pure tone screening results were included in the study. The average pure tone air conduction values for 500 Hz, 1000 Hz, 2000 Hz, 3000 Hz and 4000 Hz were required to be ≤25 dB. Normal hearing was prescribed because the mine's conventional screening procedures do not provide for referral of such individuals for diagnostic audiology, which includes immittance testing. In many instances middle ear pathology causes measurable hearing loss, which if sufficient, results in referral for diagnostic audiometry and immittance testing. However, it is possible for middle ear pathology to occur without appreciable hearing loss, in which case, the identification of middle ear pathology relies entirely on history-taking and the otoscopic skills of occupational health staff.

- Signed consent:

Signed consent was required from subjects participating in research procedures.

3.3.2 Description of subjects

- The first group of subjects consisted of five medical personnel at the Occupational Health Centre of a goldmine in Randfontein, South Africa. They were employed at the mine in their current position for longer than five years. They were familiar with periodic hearing screening procedures.
- The second group of subjects consisted of 177 gold mineworkers from a population of 200 mineworkers that visit the centre each day. Statistical analysis showed the sample size to be representative of the population of mineworkers to determine the prevalence of middle ear pathology in mining populations (Levin, 2003). The mineworkers were mainly unskilled males between 18 and 55 years of age who performed under ground duties.

3.4 Apparatus and material

3.4.1 Apparatus and material for the selection of subjects

- Results from pure tone audiometry were used for the selection of mineworkers. A Tremetrics RA-600 computerized audiometry system and headsets were used for pure-tone screening tests in Metalair test booths. The audiometer was calibrated prior to the study on November 30, 2001, in accordance with SABS 0154-1:1996 (Appendix I). The test environment consisted with a room in compliance with specifications of SABS 0182:1998. The Everest Software package was used and automatically calculates and categorized hearing thresholds. The audiogram printout indicated the Category 1, 2, 3A or C. Category 1 subjects were selected as it represented normal hearing (COMRO, 1988:107).
- No material or apparatus were used for the selection of medical personnel.

3.4.2 Apparatus and material for the gathering of data

The apparatus and material used to obtain the research data were as follows.

3.4.2.1 Questionnaires

Questionnaires are reported to be 70% to 80% accurate for identifying patients with hearing abnormalities (Mulrow and Lichtenstein, 1991:2). The scope of an interview should incorporate information on otitis media, ototoxic medication, head injuries and barotrauma (SAIOH, 2003:3).

Two different questionnaires were used for medical staff and mineworkers. The first questionnaire was administered to medical staff (Appendix H). The questionnaire obtained qualitative information relating to the incidence of middle ear pathology, the effectiveness of otoscopic examinations and medical surveillance/referral procedures, as well as medical personnel's knowledge of middle ear pathology and barotrauma. The format of the questions included multiple-choice and open-ended questions.

The second questionnaire was administered to the mineworkers (Appendix C). The questionnaire contained questions on previous ear or hearing related complaints, particularly conditions relating to the middle ear (e.g. infection or barotrauma). Questions included both multiple-choice and open-ended questions.

3.4.2.2 Medical history form

Case history data was captured and collated using a purpose-designed form (Appendix D). Information was gathered on the mineworker's previous or current episodes of middle ear related diseases and treatments for allergies e.g. hay fever, otitis media, diabetes, asthma, ear operations, ear trauma, tympanic membrane perforations, colds or flu and hearing loss.

3.4.2.3 Screening audiometer

Pure tone air conduction screening tests were performed on mineworkers, using a Tremetrics RA-600 computerized test system with Everest computer software to record results. The Tremetrics RA-600 test system is a fully automatic group hearing screening device (Tremetrics, 2005:1). An operator sets up eight subjects in eight sound booths and tones are presented by the computer system. The subjects respond and thresholds captured automatically by the system. The Everest software manages the audiometry records by automatically transferring and storing audiogram data (Everest Audio, 2005:1). Metalair test booths were used. The system was calibrated prior to research testing on 30 November 2001 in accordance with SABS 0154:1996.

3.4.2.4 Otoscope

Otoscopic examinations were performed on mineworkers using a hand-held battery-powered Heine Beta K180 otoscope (Figure 3.1).

Figure 3.1: Heine Beta K180 otoscope (Stethoscope.com:1)

3.4.2.5 Immittance meter

Immittance measurements employed a calibrated Grason-Stadler GSI 38 AUTO TYMP (Figure 3.2). The calibration certificates are presented in Appendix J.

Figure 3.2: GSI 38 Auto tymp (Madison Products, 2004:1)

3.4.3 Apparatus and material for the recording of data

3.4.3.1 Questionnaires

Separate questionnaires were administered to medical staff (Appendix H) and to mineworkers (Appendix C). For both questionnaires the researcher circled the corresponding answer's number in the answer box and wrote the number in the box to the right of the question which is indicated by a "V" in front.

3.4.3.2 Medical history form

The mineworkers' medical files were used for retrieving information on their medical history. Specific information was requested by the researcher and systematically recorded on the questionnaire. The format of the questionnaire enabled the researcher to circle the corresponding answer's number in the answer box and write the number in the box to the right of the question, which indicated by a "V" in front (Appendix D).

3.4.3.3 Screening audiogram

A Tremetrics computerized audiometry system automatically conducted tests, recorded results and provided a printout indicating audiometric category, the basis for prospective subjects' inclusion in immittance testing. The Tremetrics RA-600 test system is a fully automatic group hearing screening device (Tremetrics, 2005:1). An operator sets up eight subjects in eight sound booths and tones are presented by the computer system. The subjects respond and thresholds captured automatically by the system. The Everest software manages the audiometry records by automatically transferring and storing audiogram data (Everest Audio, 2005:1).

3.4.3.4 Otoscopic recording form

Data obtained through otoscopy was marked on the form in Table 3.2 and then used for statistical analysis. The data included otoscopic findings for the pinna/mastoid, ear canal and tympanic membrane.

Table 3.2: Middle ear pathology findings during otoscopic examinations (Govender, 1998:59; Hawke & McCombe 1995:1; Hoffman, 1996:1; WebMD, 2001:2)

Outer ear (pinna/mastoid)	YES	NO
Malformations, specify:	1	2
Traces of scars	1	2
Pinna tenderness	1	2
Mastoid tenderness	1	2
Growths, specify:	1	2
Ear canal		
Foreign object in ear canal	1	2
Bleeding	1	2
Swelling	1	2
Wax plug	1	2
Otitis externa	1	2
Red/irritated	1	2
Scratching marks in ear canal	1	2
Appear eczema-like	1	2
Growths, specify	1	2
Abnormal shape of canal, specify:	1	2
Tympanic membrane		
Retracted	1	2
Outward bulge	1	2
Red	1	2
Tympanic membrane		
Otitis media	1	2
Discharge	1	2
Fluid behind ear drum	1	2
Perforation, specify (small/big)	1	2
Light reflex absent	1	2
Grommets in place	1	2
Dull	1	2
Infected	1	2
Scar tissue on ear drum	1	2
Air bubbles behind ear drum	1	2
Blood behind ear drum	1	2

3.4.3.5 Immittance test report

Immittance measurements employed a Grason-Stadler GSI 38 AUTO TYMP (Figure 3.2) and calibrated on 14 March 2002 prior to the study (certificates in Appendix J). Probe tips were immersed in Milton's hygiene solution after each test. The results of immittance testing, including tympanograms and ipsilateral acoustic reflexes, were printed automatically in the form of a strip chart for each ear. An example of the display format is presented in Figure 3.3, indicating test mode, parameters for the test and the results. The typical tympanogram recorded first the ear canal volume (EVC) in cm3, the left (L) or right (R) ear, compliance (cm^3) and middle ear pressure (daPa). A typical acoustic reflex printout indicates ipsilateral (I) or contralateral (C) reflex elicitation, frequency and reflex threshold (NR indicated No Response and NT indicated No Test).

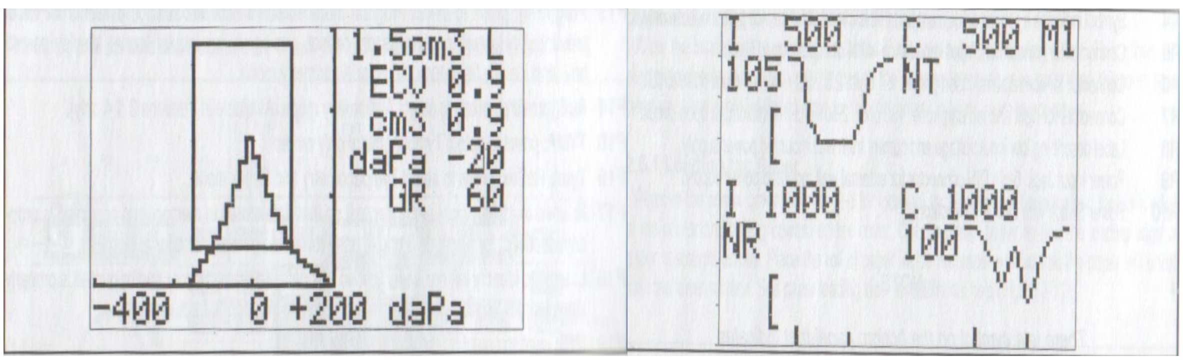

Figure 3.3: Display format for tympanometry and acoustic reflex tests

3.4.4 Apparatus and material for the analysis of data

A Stata Version 7 statistical software package was used for data analysis, to incorporate univariate procedures (including t-tests and chi-square tests), and stepwise multiple-regression modelling (Levin, 2003).

3.5 Procedure of methodology

This section presents the means of collecting and interpreting data.

3.5.1 Pilot study

The researcher felt the need to do a brief exploratory investigation, or pilot study, to try out particular procedures, measurement instruments and methods of analysis (Leedy, 2001:116). The pilot study provided an excellent way to determine the feasibility of the study. A convenience sampling method was used in the selection of medical staff and mineworkers. The first type of subject for the preliminary examination was one member of the medical staff performing Certificate of Fitness evaluation at the mine's Occupational Health Centre. Only medical personnel who gave consent were included in the study. The second group of subjects was taken from the list of underground gold mineworkers that undergo their periodic Certificate of Fitness evaluations at the mine's Occupational Health Centre. Only mineworkers who gave consent and with normal pure tone screening results, were included in the study.

A questionnaire was administered to one member of the medical staff (Appendix G) to obtain information on otoscopic examinations, barotrauma and middle ear treatment procedures. The questionnaire was administered by appointment in English by the researching audiologist. Rosenthal's experimenter's expectancy effect has been taken in consideration during the administration of questionnaires to medical staff and mineworkers, by ensuring that examiners are independent and not associated with occupational activities of the mine (Chow, 1994:89). All workers were informed during signing of the consent form that their identity will remain anonymous and all information confidential.

A separate questionnaire was used for two mineworkers (Appendix C, D, E and F) to identify individuals with previous ear or hearing related complaints, particularly conditions relating to the middle ear (e.g. infection or barotrauma). Questionnaires were administered in Fanakalo with the assistance of an interpreter, where comprehension of English was limited (Appendix B).

The pilot study performed on both questionnaires, provided estimation of how much time it took to gather and process data. The questionnaire to medical staff took approximately ten minutes to complete. The questionnaire to mineworkers took approximately 20 minutes to complete. The researcher was of the opinion that medical staff and mineworkers showed good comprehension of consent forms and questionnaires. No adjustments or format changes were necessary.

All relevant information was extracted from two mineworkers' previous medical reports for use as supplementary data, and information provided by workers during previous medical history interviews was confirmed. Data were captured and collated using a purpose-designed form (Appendix D). The pilot study indicated that workers' files were easily accessible to complete the above-mentioned form.

Pure tone air conduction screening tests were simultaneously performed by an audiometrist who manages the Tremetrics RA-600 and Everest software systems, and results were recorded. Each worker was seated inside a test booth to limit the effects of background noise. The thresholds for pure tone air conduction were determined, categorized and printed out. The pilot study confirmed that workers were familiar with this procedure. Normal pure tone air conduction screening tests were set as criteria for subject inclusion.

The audiologist performed otoscopic examinations on two of the pilot study's subjects on the same day as otoscopic examination by medical staff. The recording form and relevant references are included with the questionnaire in Appendix E, and a summary of possible middle ear pathology to be identified is presented in Table 3.2. In both screening protocols, otoscopic examinations were investigated. It included pathological conditions in the outer ear (pinna/mastoid), ear canal and the tympanic membrane. The results of otoscopic examinations were captured on the otoscopic findings form in Table 3.2. The pilot study confirmed that the otoscopic findings form were comprehensive and easy to use. No revisions were necessary.

The same subjects were used during the conventional screening procedures and the proposed middle ear screening procedures. The conventional and proposed hearing screening procedures were performed within 24 hours of each other on the same subjects. Tympanograms were performed and repeated until stable repeated measures were obtained (Wiley, 1997:11). The tympanogram were then recorded and printed out. Results were captured on a tympanometry record form (Appendix F), and the tympanogram printout (Figure 3.3) was evaluated and classified by the audiologist according to criteria given in Table 3.6. Tympanograms were interpreted and classified. Type A tympanograms were considered normal and, hence, such results were taken as PASS. Type As, Ad, B and C tympanograms were indicative of possible middle ear pathology and were taken as REFER (Govender, 1998:51; Martin, 1994:178; Hall and Mueller, 1997:199). Volume measurements for normal ears should fall within the range of 0.8 to 2.0 ml and, accordingly, results outside this range were taken as REFER. Ipsilateral acoustic reflexes were performed and repeated until stable repeated measures were obtained (Wiley, 1997:11). Reflexes were then recorded, printed out, interpreted and classified. Ipsilateral acoustic reflex thresholds at 500 Hz, 1 000 Hz, 2 000 Hz and 4 000 Hz were taken as PASS if they occurred at a level 70 dB to 90 dB above the corresponding pure tone threshold (Martin, 1994:182). Those that were absent, elevated or indicated recruitment were taken as REFER.

The pilot study indicated that the ideal time frame for conducting the research testing was during waiting times between Certificate of Fitness assessments. Instructions during immittance testing were clearly understood. The recording length of these tests was approximately seven minutes. In cases where abnormal results we obtained, immittance testing was repeated to confirm results. Immittance testing produced highly repeatable results as indicated by cross-correlation analysis (Levi and Werner, 1998:2). The interpretation form was sufficient and easy to use.

The audiologist's findings with regards to case history and otoscopy, were correlated with those of medical staff. Current conventional screening procedures applied in employers' medical surveillance programmes, includes medical history, otoscopic examinations and pure tone screening audiometry. For workers with normal hearing, medical personnel rely solely on otoscopy to identify middle ear pathology such as otitis media and perforated tympanic membrane, in which case the individual is referred. The additional measure of immittance testing was applied by the researcher, including tympanometry and acoustic reflex tests. Otoscopic examination results were taken as a PASS if no abnormalities were present and as a REFER if one or more relevant symptoms were identified. Tympanograms were interpreted and classified according to criteria listed in Table 3.6 (Govender, 1998:51; Martin, 1994:178; Hall and Mueller, 1997; Campbell and Mullin-Derrick, 2003). The table shows that a type A tympanogram is considered normal and, hence, such results were taken as PASS. Type As, Ad, B and C tympanograms are indicative of possible middle ear pathology and were taken as REFER. Table 3.6 also indicates that volume measurements for normal ears should fall within the range of 0.8 ml to 2.0 ml and, accordingly, results outside this range were taken as REFER. Ipsilateral acoustic reflex thresholds at 500 Hz, 1 000 Hz, 2 000 Hz and 4 000 Hz (Table 3.7) were taken as PASS if they occurred at a level 70 dB to 90 dB above the corresponding pure-tone threshold (Martin, 1994:182). Those that were absent, elevated or indicated recruitment were taken as REFER.

The number of mineworkers with pass and refer results from conventional screening procedures were compared and correlated with corresponding results from the proposed procedures, to determine which protocol was most effective in identifying middle ear pathology. Each subject's otoscopy and case history results were directly compared with his immittance results to evaluate the effectiveness otoscopic examinations and case histories. Additional information on middle ear pathology was provided by the questionnaires. Digotome scales (yes/no answers) and lickert scales (multiple answers) were then used to extract and organize information from subjects for analysis by means of computer-based statistical software (Levin, 2003). The statistician used a Stata Version 7 statistical software package for data analysis, to incorporate univariate procedures (including t-tests and chi-square tests), and stepwise multiple-regression modelling (Levin, 2003). Univariate procedures were used to assess the significance of individual coefficients, specifically testing the null-hypothessis (Allison, 1999:33). Stepwise multiple regression, also called statistical regression, was used in the explanatory phase of the research (Allison, 1999:33).

3.5.2 Procedures for the selection of subjects

Prospective subjects (medical staff and mineworkers) were located at the mine's Occupational Health Centre. Permission was obtained from mine management and the occupational health practitioner at the mine's Occupational Health Centre.

The audiologist made appointments with medical staff on a day and time of their choice as not to interfere with their duties. Only medical staff involved with audiological services was included in the study. Medical staff agreeing to participate was requested to sign an informed consent form (Appendix G). Five out of the five subjects agreed to participate. The following information was incorporated into the consent form:

- The parties involved in the research investigation
- The purpose of the research testing
- Procedures of the research testing were delineated
- Participants' confidentiality were guaranteed
- Voluntary participation was confirmed

The Health Centre summoned approximately 200 mineworkers at the same time of day. This resulted in long waiting times before their Certificate of Fitness evaluations were performed and provided an ideal time frame in which to execute the research testing. Thus, a convenient sampling approach was adopted at the time of selection. Prior to commencing with the actual gathering of data, the audiologist requested of the workers who were willing to participate, to sign a consent form (Appendix A). Of the 200 mineworkers that attended the certificate of fitness evaluations, 177 were selected. The 23 subjects excluded from the study refused participation. The consent form was administered in Fanakalo, with the assistance of an interpreter, where comprehension of English was limited (Appendix B). The purpose of the research was fully explained to prospective subjects, and a statement was read aloud by the translator who informed them of their right to decline participation without any negative consequences. If the worker declined participation, the research form was repeated to the next prospective workers. If the worker has consented to participate he was asked to sign or make a mark in the space provided to indicate that he has been given the information and understands it. Once consent was given the worker was provisionally accepted as a participant, subject to the findings of subsequent pure tone screening conducted during the course of the same working day.

The occupational health staff performs history-taking, otoscopy and pure tone screening as part of the annual fitness evaluations. These results were all recorded in the participant's file. Audiometric category based on pure tone screening was the next criterion for subjects' inclusion in the study. Pure tone averages were automatically calculated by the Everest computer software to determine audiometric category. The Schilling hearing loss categorizations system was used to classify screening results into five categories: Category 1, 2, 3a, 3b, and 3c (Everest Audio, 1998:34).

Table 3.3: Schilling's categorization of hearing thresholds
(COMRO 1988:112)

Age in years	**Sum of hearing levels (dB)**			
	Referral level (dB)		**Warning level (dB)**	
	Low1	**High2**	**Low1**	**High2**
≤24	60	75	45	45
25-29	66	87	45	45
30-34	72	99	45	45
35-39	78	111	48	54
40-44	84	123	51	60
45-49	90	135	54	66
50-54	90	144	57	75
55-59	90	144	60	87
60-64	90	144	65	100
≥65	90	144	70	115

Hearing thresholds were summed for each ear over the low frequencies of 500, 1 000 and 2 000 Hz, and over the high frequencies of 3 000, 4 000 and 6 000Hz. The four sums were then compared with norms (Table 3.3) to determine audiometric category (COMRO 1988:107). The Schilling categories used were:

Category 1: Summated hearing levels did not fall into Category 2 or 3 as defined below and, thus, were considered normal.

Category 2: Summated hearing levels for either ear equaled or exceeded the warning level, but did not equal or exceed the referral level.

Category 3a: Summated hearing levels for either ear equaled or exceeded the referral level for low or high frequencies, or for both.

Category 3b: The difference between summated hearing levels for the two ears exceeded 45 dB for low frequencies, or exceeded 60 dB for high frequencies.

Category 3c: Summated hearing levels for either ear, for either low or high frequencies, showed an increase of 30 dB in comparison the individual's most recent available audiogram.

Results from these assessments were placed in employees' medical files, and employees were sent to the audiologist for subject selection and research testing on the same day. The audiologist reviewed the results in employees' files, and only workers with Category 1 (normal) audiograms were accepted as subjects for immittance testing. The outcomes of all measures allowed a binary decision regarding the presence or absence of middle ear pathology (COMRO, 1988:107). Hearing loss was excluded from the selection procedures for middle ear screening. Malingering (hearing loss exaggerators) is a common occurrence in the mining industry, ranging from 8% to 30% (Cooper and Lightfoot, 2000:1). Inaccurate results would influence the accuracy of research outcomes.

3.5.3 Procedures for the gathering of data

Data was collected in a form that could be easily converted to numerical indices. The procedure for the collection of data is described in this section.

3.5.3.1 Questionnaires

Data was gathered from the questionnaire to medical staff by using multiple-choice and open-ended questions intended to supplement any results obtained by middle ear pathology screening. It was administered in English by the audiologist to five of the medical staff, who is involved with middle ear screening in the mining industry. It took approximately ten minutes to complete each questionnaire. Rosenthal's experimenter's expectancy effect has been taken in consideration during the administration of questionnaires to medical staff, by ensuring that examiners are independent and not associated with occupational activities of the mine (Chow, 1994:89). The medical staff was informed during signing of the consent form that their identity will remain anonymous and all information confidential.

Instructions and history taking should be administered in a language best understood by the client (SAIOH, 2003:1). Questionnaires to mineworkers were therefore administered in Fanakalo (the most commonly used language on this mine), with the assistance of an interpreter. Questionnaires were formulated to provide information on workers' previous episodes of middle ear pathology and susceptibility to barotrauma, as well as their occupation, overall medical history and ear/hearing-specific history, which the audiologist recorded with assistance from the interpreter. Data from the questionnaire were obtained through the use of multiple-choice and open-ended questions intended to supplement and analyse any findings of middle ear pathology. The questionnaire was completed in approximately twenty minutes. Rosenthal's experimenter's expectancy effect was ensured during the administration of questionnaires to mineworkers, by ensuring that examiners are independent and not associated with occupational activities of the mine (Chow, 1994:89). All mineworkers were informed during signing of the consent form that their identity will remain anonymous and that all information is confidential. The mineworkers questionnaire included questions on the following aspects: Annual flu vaccinations; smoking habits; sanitary living conditions; current conditions of colds, flu, asthma, diabetes or allergies (e.g. hay fever); ear cleaning habits; comfort of hearing protectors. History of ear infections was investigated further with regard to reporting symptoms, referral for medical treatment, medical follow-ups and resultant absence from work. Questions were also directed to gain more information on barotrauma susceptibility. This included symptoms during transportation in the cage, which includes ear pain, dizziness/vertigo (head spinning), nausea or vomiting, headaches, diminished hearing, bleeding ear, fullness in ear, techniques for relieving ear discomfort during case transportation. Questions were also directed towards current pathology experienced. This included incidence and timeframe of ear infection, ear discharge, ear pain, tinnitus, fullness in ear, and vertigo. Previous history of ear operations and trauma to ears were included. The questionnaire was composed from Alford (2001); American Speech Language Hearing Association (1990:17-24); College of Family Physicians (2001:3); Franz (2001:1-10); Cruicshanks, Klein, Wiley, Nondahl and Tweed (1998:1715-1719).

3.5.3.2 Medical history

All information on previous middle ear pathology was extracted from workers' previous medical reports for use as supplementary data, and information provided by workers during previous medical history interviews was confirmed. Data were captured and collated using a purpose-designed form (Appendix D). Information was gathered on previous or current episodes of diseases and treatments for allergies e.g. hay fever, otitis media, diabetes, asthma, ear operations, ear trauma, tympanic membrane perforations, colds or flu and hearing loss.

3.5.3.3 Screening audiometry

Pure tone air conduction screening tests were simultaneously performed by an audiometrist, using a Tremetrics RA-600 computerised test system to record results (Tremetrics, 2005:1). Each worker was seated inside a Metalair test booth and fitted with headsets to limit the effects of background noise. Everest computer software automatically presents tones. The subjects respond and thresholds captured automatically recorded and categorized (Everest Audio, 2005:1). A hard copy is provided of the air conduction thresholds at 250Hz, 500Hz, 1000Hz, 2000Hz, 3000Hz, 4000HZ, 6000H and 8000Hz for both ears.

3.5.3.4 Otoscopy

Otoscopic examinations of each prospective subject were performed by the audiologist who conducted the otoscopic examination. A graphic representation of such otoscopic examinations is provided in Figure 3.4. The record form and relevant references are included with the questionnaire in Appendix E, and a summary of possible middle ear pathology to be identified is presented in Table 3.2. In both screening protocols, otoscopic examinations were performed. The otoscopic examination included identification of pathological conditions in the outer ear (pinna/mastoid): malformations; traces of scars; pinna tenderness; mastoid tenderness and growths. Examination of the ear canal included identification of foreign objects in ear canal; bleeding; swelling; wax plug; otitis externa; redness or irritation; scratching marks in ear canal; appear eczema-like; growths and abnormal shape of canal. The tympanic membrane included retracted ear drum; outward bulge; red; otitis media; discharge; fluid behind ear drum; perforation; light reflex absent; grommets in place; colour of the ear drum; infected; scar tissue on ear drum; air bubbles behind ear drum and blood behind the ear drum. The results of otoscopic examinations were captured on a form designed for that purpose (Appendix E).

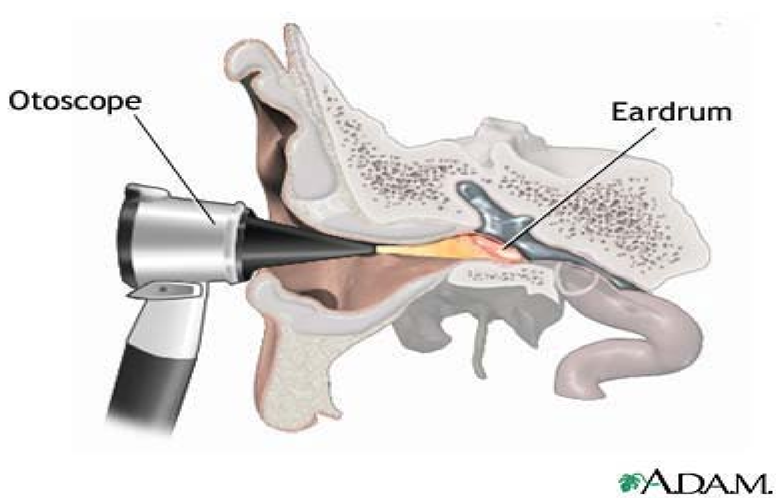

Figure 3.4: Representation of an otoscopic examination (Hart et al, 2004:3)

3.5.3.5 Immittance tests

The same group of mineworkers was used during the conventional screening procedures and the proposed middle ear screening procedures. The conventional and proposed hearing screening procedures were performed within 24 hours, during which time the mine does not allow the workers to leave the premises, and thus not exposed to occupational hazards. The audiologist performing the immittance testing selected an appropriate size probe tip in accordance with the subject's estimated ear canal size and confirmed that probe fit/seal and all instrument settings were correct. Tympanograms and ipsilateral acoustic reflexes were performed and repeated until stable repeated measures were obtained. Tympanograms and acoustic reflexes often produce variable results due to the manner and depth in which the probe tip is inserted in the ear canal (Wiley, 1997:11). Tympanograms and ipsilateral acoustic reflexes were then recorded for each ear at 500 Hz, 1 000 Hz, 2 000 Hz and 4 000 Hz and printed out. Results were captured on a tympanometry record form (Appendix F), and the tympanogram printout (Figure 3.3) was evaluated and classified by the audiologist according to criteria given in Table 3.6. Values of 0.3 cm^3 to 1.75 cm^3 at –50 to +50 daPa were classified as normal Type A tympanograms. Measurements smaller than 0.3 cm^3 at –50 daPato +50 daPa were classified as Type As and indicated a stiff middle ear system consistent with otosclerosis. Classification: Type Ad were measurements larger as 2,5 cm^3 and a middle ear pressure of –50 daPa to +50 daPa indicated a flaccid middle ear system, consistent with eardrum flaccidity/ossicular disarticulation and classified as Type Ad. As for a type B tympanogram with normal ear canal volume (0.8 cm^3 to 2.0 cm^3) as in otiitis media, no compliance peak is obtained at +200 daPa to -400 daPa. Type B tympanogram with a large ear canal volume (larger than 2.0 $cm^{3)}$ as in the presence of patent pressure equalization tubes or perforated tympanic membranes, an open exchange of air occurs between the ear canal and thus, any contraction of the stapedius muscle cannot be measured. Type B with small ear canal volume (smaller than 0.8 cm^3) suggests a patent pressure equalization tube or perforation of tympanic membrane (Campbell and Mullin-Derrick, 2003:2). Tympanograms with values of 0.3 to 1.75 cm^3 at -51 to -400 daPa, were classified as Type C and is consistent with Eustachian tube malfunction. Tympanometry also provides a measure of ear canal volume. The equivalent ear canal volume is a measure of the equivalent volume of air in front of the measurement probe (Margolis and Heller, 1987:197). This section was included in Table 3.6 as equivalent ear canal volume is sensitive to tympanic membrane perforations that are accompanied by middle ear mucosa. Volume values were accepted as normal between 0.8 cm^3 to 2.0 cm^3 for adults (Margolis and Heller, 1987:198).

Information from the subject's medical records was recorded on a summary form (Appendix D), including medical history, employment history, working environment and the results of physical examinations, otoscopic examinations and pure tone air conduction tests conducted by occupational health personnel. A scoring form was then completed for each subject by the audiologist, recording all observations under the relevant headings (outer ear, external meatus and tympanic membrane). Where pathology was identified, detailed observations were recorded and used for qualitative analysis (Appendix E). These finalized test procedures for identifying middle ear pathology and the acquisition of relevant data for comparison and evaluation of the existing and proposed screening protocols.

3.5.4 Procedures for the recording of data

3.5.4.1 Questionnaires

The questionnaires were administered to the medical staff and answers systematically recorded on the questionnaire. The format of the questionnaire enabled the audiologist to circle the corresponding answer's number in the answer box and write the number in the box to the right of the question, which is indicated by a "V" in front. The statistician then entered the number written in this box into the Stata Version 7 statistical software package for statistical analysis. The questionnaires to medical staff included questions on the following:

- Specifications of the person who performed otoscopic examination;
- Frequency of performing otoscopic examinations as a standard procedure during medical surveillance;
- Symptoms of pathology in the outer, middle and inner ear noted during routine otoscopic examinations;

- Comprehension of the term “middle ear barotrauma”;
- Frequency of performing preventative counselling to barotrauma susceptible individuals;
- Incidence of training susceptible individuals pressure equalizations techniques when going underground to prevent barotrauma;
- Incidence of providing training on pressure equalization techniques to prevent barotrauma;
- Frequency of patients reporting suspected ear infection to medical staff;
- Frequency of patients undergoing treatment in the event of confirmed middle ear pathology;
- Frequency of follow-up treatment middle ear pathology;
- Personnel’s opinion of their proficiency in dealing with middle ear pathology.

The questionnaires were administered to the mineworkers and the answers were systematically recorded on the questionnaire. The same recording procedure was followed for the administration of the questionnaire to medical staff and to mineworkers. The interpreter circled the corresponding answer in the answer box and wrote the number in the box to the right of the question, which was indicated by a “V” in front. The statistician entered the number written in this box into the Stata Version 7 statistical software package for statistical analysis (Levin, 2003). The questionnaires to medical staff included questions on the following:

- Personal information on the subject’s age, occupation, work location
- Frequency of undergoing annual flu vaccinations
- Frequency of exposure to cigarette smoke
- Exposure to unsanitary conditions
- Presence of middle ear related pathology
- Use of foreign objects to relieve itching in the ear canal
- Comfort of wearing different types of hearing protectors
- History of middle ear pathology
- Tendency of reporting suspected ear infections to medical staff
- Referral, treatment and follow-up outcomes
- Performing underground duties in the presence of middle ear pathology

- Symptoms of discomfort during vertical transportation
- Corrective actions taken during discomfort
- Counseling obtained on preventive techniques during vertical transportation
- Current symptoms related to barotrauma
- Previous ear-related surgical procedure

3.5.4.2 Medical history

The mineworkers' medical files were used for retrieving information on their medical history. Specific information was requested by the researcher and systematically recorded on the questionnaire. The researcher circled the corresponding answer in the answer box and wrote the number in the box to the right of the question, which is indicated by a "V" in front. The statistician entered the number written in this box into the Stata Version 7 statistical software package for statistical analysis (Levin, 2003). The audiologist obtained information from mineworker's medical files (Appendix D). The following information was extracted:

- History of middle ear pathology and treatment for allergies, otitis media, diabetes, asthma, ear operations, ear trauma, tympanic membrane perforations, cold or flu and hearing loss.
- Presence of current ear pathology noted by the medical staff. It included otitis media, ear trauma, tympanic membrane perforation, cold or flu and other outer and middle ear pathologies.

3.5.4.3 Screening audiometry

A Tremetrics computerised audiometry system with eight Metalair test booths were used for pure tone screening tests, and were calibrated prior to the study (Appendix I), in accordance with SABS 0154: 1996. This system automatically conducted tests, recorded results and provided a printout indicating audiometric category, the basis for prospective subjects' inclusion in immittance testing. The air conduction thresholds were recorded at 500Hz, 1000Hz, 2000Hz and 4000Hz for both ears (Table 3.4).

Table 3.4: Recording form for pure tone air conduction screening results

Ear (R/L) and test frequency (Hz)	HL (dB)
Right ear	
500Hz	dB
1 000 Hz	dB
2 000 Hz	dB
4 000 Hz	dB
Left ear	
500 Hz	dB
1 000 Hz	dB
2 000 Hz	dB
4 000 Hz	dB

3.5.4.4 Otoscopy

Otoscopic examinations were performed by occupational health staff and by the audiologist, using hand-held battery-powered Heine Beta K 180 otoscopes. Data obtained through otoscopy was marked on the form in Table 3.5 and then used for statistical analysis.

Table 3.5: Middle ear pathology findings during otoscopic examinations (Govender, 1998:59; Hawke & McCombe 1995; Hoffman, 1996; WebMD, 2001)

Outer ear (pinna/mastoid)	YES	NO
Malformations, specify:	1	2
Traces of scars	1	2
Pinna tenderness	1	2
Mastoid tenderness	1	2
Growths, specify:	1	2
Ear canal		
Foreign object in ear canal	1	2
Bleeding	1	2
Swelling	1	2
Wax plug	1	2
Otitis externa	1	2
Red/irritated	1	2
Scratching marks in ear canal	1	2
Appear eczema-like	1	2

Ear canal		
Growths, specify	1	2
Abnormal shape of canal, specify:	1	2
Tympanic membrane		
Retracted	1	2
Outward bulge	1	2
Red	1	2
Otitis media	1	2
Discharge	1	2
Fluid behind ear drum	1	2
Perforation, specify (small/big)	1	2
Light reflex absent	1	2
Grommets in place	1	2
Dull	1	2
Infected	1	2
Scar tissue on ear drum	1	2
Air bubbles behind ear drum	1	2
Blood behind ear drum	1	2

3.5.4.5 Immittance tests

Immittance measurements employed a calibrated Grason-Stadler GSI 38 AUTO TYMP (Figure 3.2), using appropriately sized re-usable probe tips in accordance with subjects' ear canal size (calibration certificates in Appendix J). Probe tips were immersed in Milton's hygiene solution after each test. Tympanograms and ipsilateral acoustic reflexes were performed for each ear and repeated until stable repeated measures were obtained (Wiley, 1997:11). The results of immittance testing, including tympanograms and ipsilateral acoustic reflexes, were recorded in the form of a strip chart for each ear. An example of the display format is presented in Figure 3.3, indicating test mode, parameters for the test and the results. These were classified according to type of tympanogram, i.e. Type A, As, Ad, B or C; and ear canal volume measurements (Table 3.6). Tympanogram classification and interpretations were recorded on the test result form, with acoustic reflex thresholds noted as Normal, Absent, Elevated or Recruited (Table 3.7 and Appendix F). Contraction of the stapedius muscle is normally bilateral, i.e. if the stapedius muscle in one ear contracts, so will the stapedius muscle in the opposite ear. Hence, the stapedius muscle reflex can be measured for either ipsilateral or contralateral stimuli (Wiley, 1997:78). Only the ipsilateral acoustic reflex values were gathered. With ipsilateral stapedius reflex measurements, a stimulus is presented to the same ear in which acoustic immittance changes are being measured. Response of the stapedius to an ipsilateral activator is slightly stronger than to a contralateral activator and thus important for screening purposes (Wiley, 1997:78).

Table 3.6: Recording form for tympanometric results

(Govender, 1998:51; Martin, 1994:178; Hall and Mueller, 1997:212; Campbell and Mullin-Derrick, 2003:2)

Findings	Outcome
Type A NORMAL Compliance 0,3 cm^3 to 1,75 cm^3 Middle ear pressure –50 daPa to +50 daPa Ear canal volume 0.8 cm^3 to 2.0 cm^3	**Pass**
Type As STIFF MIDDLE EAR SYSTEM CONSISTENT WITH OTOSCLEROSIS Compliance <0,3 cm^3 Middle ear pressure –50 da Pa to +50 daPa Ear canal volume 0.8 cm^3 to 2.0 cm^3	**Refer**
Type Ad FLACCID MIDDLE EAR SYSTEM CONSISTENT WITH EARDRUM FLACCIDITY/OSSICULAR DISARTICULATION Compliance >2,5 cm^3 Middle ear pressure –50 daPa to +50 daPa Ear canal volume 0.8 cm^3 to 2.0 cm^3	Refer
Type B CONSISTENT WITH OTITIS MEDIA No Compliance Peak Middle ear pressure +200 daPa to -400 daPa Ear canal volume 0.8 cm^3 to 2.0 cm^3 CONSISTENT WITH PATENT EUSTACHIAN TUBES OR PERFORATED TYMPANIC MEMBRANE No compliance peak Middle ear pressure +200 daPa to -400 daPa Ear canal volume >2.0 cm^3 CONSISTENT WITH PATENT EUSTACHIAN TUBE OR PERFORATED TYMPANIC MEMBRANE No Compliance Peak Middle ear pressure +200 daPa to -400 daPa Ear canal volume <0.8 cm^3	Refer
Type C CONSISTENT WITH EUSTACHIAN TUBE MALFUNCTION Compliance 0,3 cm^3 to 1,75 cm^3 Middle ear pressure -51 daPa to -400 daPa Ear canal volume 0.8 cm^3 to 2.0 cm^3	Refer
Volume 0,8 cm^3 to 2,0 cm^3	Pass
<0.8cm3 or >2.0cm3	Refer

Hearing thresholds for 500 Hz, 1 000 Hz, 2 000 Hz and 4 000 Hz from the subject's air conduction screening test were noted (Table 3.4) and used to calculate the status of ipsilateral acoustic reflexes at a given frequency. If the value of the acoustic reflex threshold was 70 dB to 90 dB above the pure tone threshold (PTT) the acoustic reflex was recorded as normal. The acoustic reflex was recorded as absent if no response was found, elevated is acoustic reflex threshold was elicited at 90 dB above the pure tone threshold for that frequency and recruited if the reflex threshold was below 70 dB above the pure tone threshold (Wiley 1997:84).

Table 3.7: Classification of the acoustic reflex measures
(Gelfand in Katz, 2002:211-218; Stach, 1998:270 & Wiley 1997:86)

Status of ipsilateral acoustic reflex at given test frequency (Hz)	YES	NO
500 Hz		
Normal: 70-90 dB above PTT	1	2
Absent: No Response	1	2
Elevated: >90 dB above PTT	1	2
Recruitment: <70 dB above PTT	1	2
1 000 Hz		
Normal: 70-90 dB above PTT	1	2
Absent: No Response	1	2
Elevated: >90 dB above PTT	1	2
Recruitment: <70 dB above PTT	1	2
2 000 Hz		
Normal: 70-90 dB above PTT	1	2
Absent: No Response	1	2
Elevated: >90 dB above PTT	1	2
Recruitment: <70 dB above PTT	1	2
4 000 Hz		
Normal: 70-90 dB above PTT	1	2
Absent: No Response	1	2
Elevated: >90 dB above PTT	1	2
Recruitment: <70 dB above PTT	1	2

3.5.5 Procedures for the analysis of data

Raw data were taken from immittance test printouts, otoscopy forms, medical records and questionnaires, with the latter used mainly to provide additional descriptive information. The conventional and proposed systems were used on the same subjects. The outcomes of all measures were used to determine the presence or absence of middle ear pathology, and categorize the result as “REFER” or “PASS”, respectively. The prevalence of middle ear pathology as identified by conventional methods was derived from the number of patients with either abnormal case history and/or otoscopy. The prevalence of middle ear pathology as identified by proposed methods were then determined. Mineworkers were classified as having middle ear pathology if one or more of the hearing screening procedures (case history, otoscopy, tympanometry or acoustic reflex testing) performed by the researching audiologist, indicated abnormal results. Abnormal results were further analysed by comparing the collective outcomes of the case history, otoscopy, tympanometry and acoustic reflex testing for the individual mineworker. The combined results that correlated as being pathological were then classified as indicating middle ear pathology. Discrepancies in results were investigated by comparing the prevalence rates for the individual and collective tests during the conventional and proposed middle ear screening procedures. The audiologist’s findings were correlated with those of medical staff. For workers with normal hearing, medical personnel rely solely on otoscopy and the case history to identify middle ear pathology such as otitis media and perforated tympanic membrane, in which case the individual is referred. The additional measure of immittance testing was applied by the researcher, including tympanometry and acoustic reflex tests, for which a pass or refer result was recorded and noted on a digotome scale (Levin, 2003). The number of mineworkers with pass and refer results from conventional screening procedures were compared and correlated with corresponding results from the proposed procedures, to determine which protocol was most effective in identifying middle ear pathology. Each subject’s otoscopy and case history results were directly compared with his immittance results to evaluate the effectiveness otoscopic examinations and case histories. Additional information on middle ear pathology was provided by the questionnaires. Digotome scales (yes/no answers) and lickert scales (multiple answers) were then used to extract and organize information from subjects for analysis by means of computer-based statistical software (Levin, 2003). The statistician used a Stata Version 7 statistical software package for data analysis, to incorporate univariate procedures (including t-tests and chi-square tests), and stepwise multiple-regression modelling (Levin, 2003). Univariate procedures were used to assess the significance of individual coefficients, specifically testing the null-hypothessis (Allison, 1999:33). Stepwise multiple regression, also called statistical regression, was used in the explanatory phase of the research (Allison, 1999:33).

Figure 3.5 illustrates conventional screening procedures applied in employers' medical surveillance programmes, including medical history, otoscopic examinations and pure tone air conduction screening audiometry. Where no abnormalities are found the employee is classified as fit for work in terms of hearing status. If otoscopy revealed pathology, the individual was referred for treatment, but still underwent pure tone screening. If significant hearing loss is indicated the employee is referred for diagnostic evaluation, which includes further investigation of hearing-related medical history, followed by otoscopy, immittance testing and diagnostic audiometry. Diagnostic audiometry includes pure tone air and bone conduction. The employee's hearing fitness is then reviewed by the Occupational Health Medical Practitioner, based on the audiologist's findings.

Figure 3.6 illustrates the proposed screening protocol evaluated by the present study, which differs from current practice in that it includes immittance testing in additional to the current procedures. The flow of assessment in the proposed middle ear screening procedure is as follows: First, the mineworkers provide case history information on hearing related matters. This is followed by an otoscopic examination. Patients with abnormal otoscopic results are referred for further investigation. Patient with normal otoscopic results proceed to screening immittance testing. Patients with abnormal immittance results are referred for further investigation. Patients with normal immittance test results proceed to pure tone testing. Patients with hearing loss are sent for diagnostic audiometry, which includes a diagnostic audiogram, otoscopy and diagnostic immittance testing. The patient's results are then reviewed for hearing fitness.

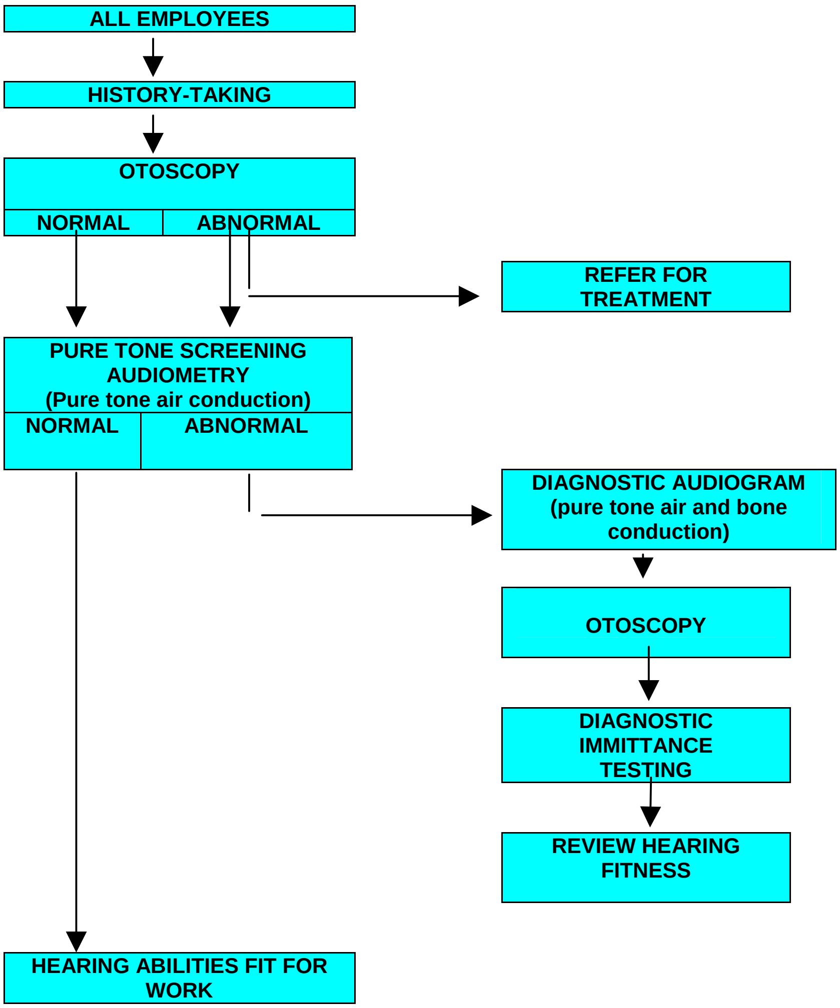

Figure 3.5: Flow chart of the conventional screening medical surveillance system (Revised from COMRO, 1988:46)

Patients with normal hearing thresholds are classified as fit for work. However, it is possible for middle ear pathology to occur without appreciable hearing loss, in which case, the identification of middle ear pathology relies entirely on history-taking and the otoscopic skills of occupational health staff. Normal pure tone results were thus set as criteria for the inclusion of mineworkers in the study. It is anticipated that if immittance testing is more sensitive to middle ear pathology, it can be expected to yield a higher incidence of referrals. This was assessed in terms of relative prevalence, through quantitative comparisons of outcomes from the current and proposed screening protocols. Otoscopic examination results were taken as a PASS if no abnormalities were present and as a REFER if one or more relevant symptoms were identified. Tympanograms were interpreted and classified according to criteria listed in Table 3.6 (Govender, 1998:51; Martin, 1994:178; Hall and Mueller, 1997; Campbell and Mullin-Derrick, 2003). The table shows that a type A tympanogram is considered normal and, hence, such results were taken as PASS.

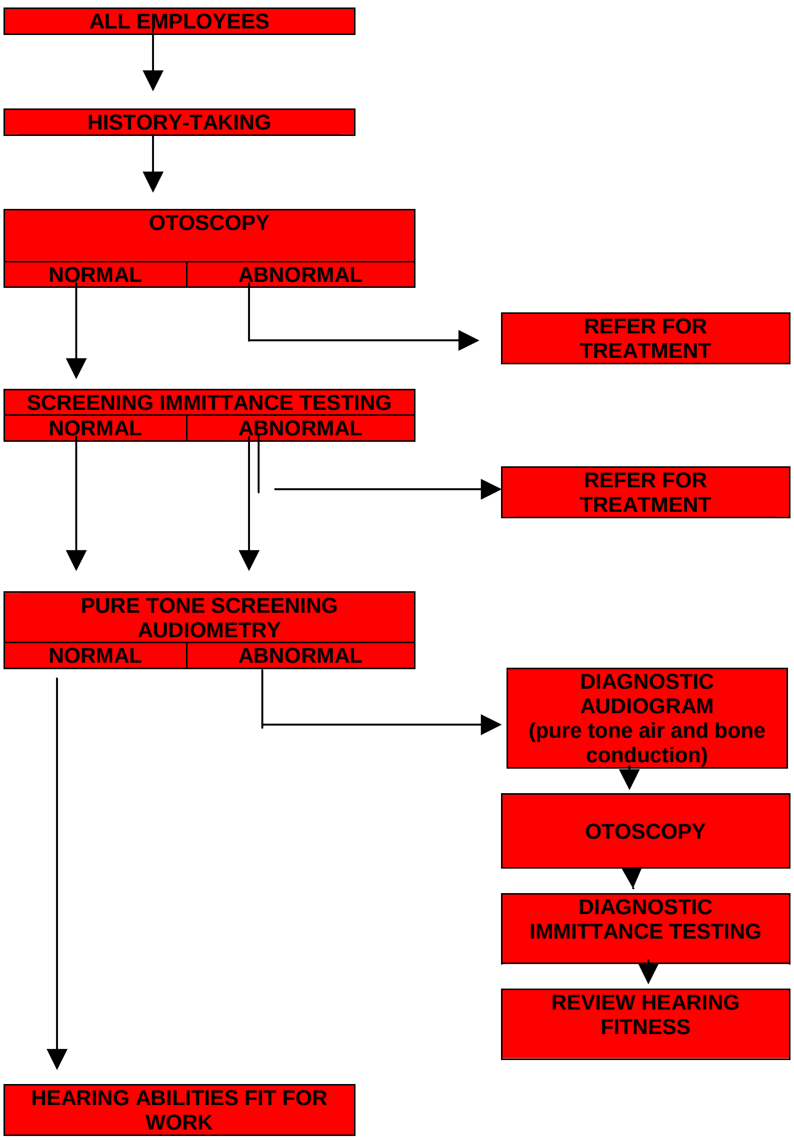

Figure 3.6: Flow chart of the proposed medical surveillance system

(Revised from COMRO, 1988:46)

Type As, Ad, B and C tympanograms are indicative of possible middle ear pathology and were taken as REFER. Table 3.6 also indicates that volume measurements for normal ears should fall within the range of 0.8 ml to 2.0 ml and, accordingly, results outside this range were taken as REFER. Ipsilateral acoustic reflex thresholds at 500 Hz, 1 000 Hz, 2 000 Hz and 4 000 Hz (Table 3.7) were taken as PASS if they occurred at a level 70 dB to 90 dB above the corresponding pure-tone threshold (Martin, 1994:182). Those that were absent, elevated or indicated recruitment were taken as REFER.

Outcomes from existing hearing screening procedures (otoscopy and pure tone screening) as conducted by occupational health staff were compared with outcomes from the proposed protocol (incorporating conventional and immittance testing procedures), to evaluate relative effectiveness in identifying middle ear pathology. The hearing screening procedures for both protocols were performed on the same day.

CHAPTER 4 Results and discussion

This chapter presents and discusses results obtained during experimental testing. The clinical value of immittance measures for the identification of middle ear pathology is evaluated. Results are systematically discussed according to the aims of the research study. Findings are presented in the form of graphs and tables, immediately followed by an interpretative discussion.

4.1 The prevalence of middle ear pathology as identified by conventional methods

The first aim of the research was to determine the prevalence of middle ear pathology as identified by conventional methods. The conventional methods only included medical history, otoscopic examinations and pure tone air conduction screening audiometry. Mineworkers with hearing loss are referred for further investigation without exception.

Thus only mineworkers with normal pure tone screening results were included in the study. The case history obtained from medical records included questions on current and previously suffered illnesses and treatment for allergies e.g. hay fever, otitis media, diabetes, asthma, ear operations, ear trauma, tympanic membrane perforation, cold or flu and hearing loss (Appendix D).

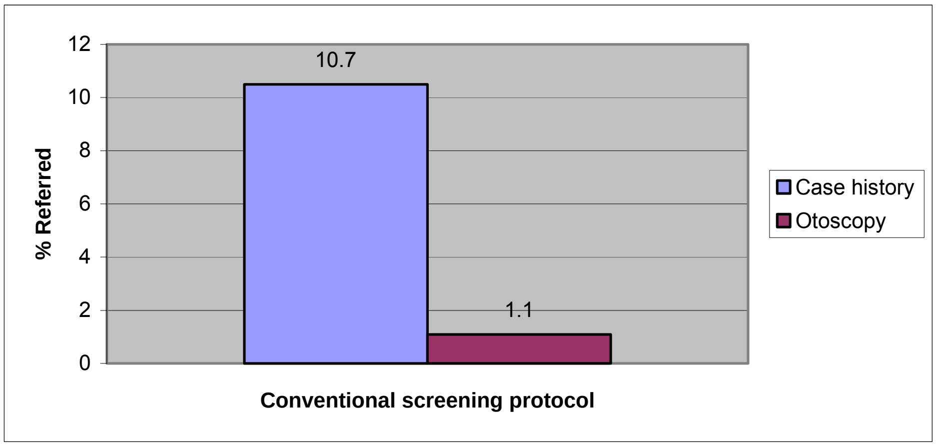

Figure 4.1: Referral rates for the conventional screening protocol

During conventional procedures, a total of 21 subjects out of 177 subjects (11.8 per cent) were referred for suspected middle ear pathology. Figure 4.1 demonstrates the percentage of subjects referred for suspected middle ear pathology during conventional procedures. The case history was the first component, and OHP referred 19 subjects (10.7%). Otoscopy was the second component in the conventional screening protocol, performed by the OHP. Abnormal outer ear results were identified by otoscopy in two out of 177 subjects (1.1%). Among the 158 subjects (89.3%) for whom OHP-recorded case histories found no history of middle ear pathology, five subjects (3.1%) were subsequently referred for further investigation on the basis of otoscopy findings. Among the 19 subjects (10.7%) who presented with a history of middle ear pathology, six subjects (31.6%) were referred for further investigation on the basis of otoscopic findings. The case history and otoscopic findings correlated in six subjects (31.6%). For workers with normal hearing, medical personnel rely solely on otoscopy and the case history to identify middle ear pathology. American Speech and Hearing Association (1989) recommended that identification of middle ear pathology during case histories or visual inspections represent grounds for immediate medical referral. However, false negative screening by incorporating only case histories and otoscopic examinations may occur. The value of the case history is unquestioned by most physicians. However, physical otoscopic examination is perceived as being of lesser value due to the intrinsic uncertainty and variability of the clinician's physical diagnostic skills (Fitzgerald, 2003). Barnett (2002) noted that cross-cultural communication during case history-taking may influence the accuracy of information obtained. This statement suggests that the language barrier that exists in the South African mining industry may influence the accuracy of the information obtained during case history-taking. Most OHP is not fluent in the mineworkers' language, namely Fanakalo (De Koker, 2003b).

In summary, the first aim of the research determined an 11.9% prevalence rate among mineworkers for suspected middle ear pathology, as identified by conventional methods.

4.2 Determine the prevalence of middle ear pathology with immittance testing

The second aim of the research was to determine the prevalence of middle ear pathology by incorporating immittance testing in the screening procedures.

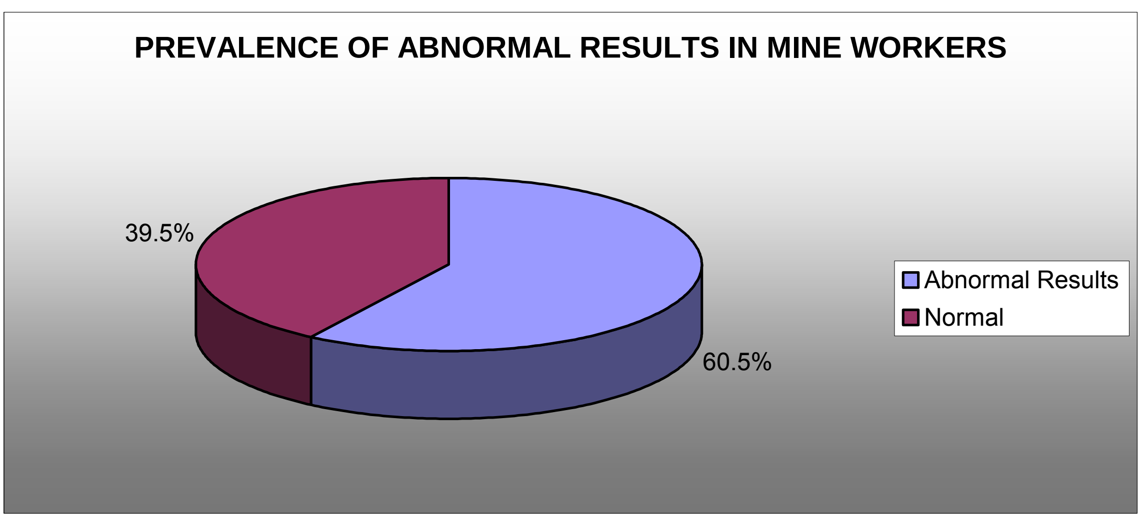

Figure 4.2: Prevalence of abnormal results among mineworkers

Figure 4.2 indicates the prevalence of abnormal outer and middle ear results as identified by proposed middle ear screening procedures, incorporating immittance testing. Mineworkers were classified as having middle ear pathology if one or more of the hearing screening tests (case history, otoscopy, tympanometry or acoustic reflex testing) performed by the researching audiologist, indicated abnormal results. Abnormal results were found in 107 out of the 177 mineworkers (60.5%) studied. It corresponds with results from a study of middle and external ear disorders among underground coal miners in the USA (DHHS, 1981:17). Case history questionnaires administered by the researching audiologist during the proposed screening protocol identified otological abnormalities in 21 subjects (11.8%), in comparison with 19 out of 177 subjects (10.7%) from OHP-recorded case histories. Although the reliability of historical information from patients is often questionable (American Speech Language and Hearing Association, 1993:31), the questionnaires administered by the researching audiologist and OHP yielded corresponding results.

Otoscopy administered during the proposed screening protocol, identified otological abnormalities in 88 subjects (49.7%), in comparison with two subjects (1.1%) from the OHP-recorded otoscopy. A possible explanation for the discrepancies in these results have been provided by Gelfand (1997:2) who noted that otoscopic examinations could be very subjective and its reliability depends on the skill and experience of the examiner. It has been demonstrated by Wormald, Browning and Robinson (1995:2) that a structured teaching method could improve skill and accuracy in performing otoscopic examinations. Unlike conventional training that usually involves observation and repeated exposure to patients, this method incorporates multimedia presentations of pathological ears together with formal instruction. In their study, Wormald et al. (1995:2) reported that the error rate fell from 44% to 21% for trainees taught using structured teaching methods. It is essential to perform case histories in association with otoscopic examinations to confirm middle ear pathology. Many infections of the external ear are asymptomatic and the patient would thus not report symptoms to the examiner (Quinn, 2001). Otoscopy also facilitates the identification of conditions of the pinna, concha, external auditory canal and of the middle ear (Sullivan, 1997:2).

Immittance measures incorporated tympanometry and acoustic reflex testing. Abnormal tympanometric results (type Ad, As, B or C tympanograms) were found in 48 out of 177 of subjects (27.1%), which compared favourably with a prevalence of 23.4 per cent among coal miners, also based on tympanometry (Hopkinson, 1981:17). Acoustic reflex testing revealed higher identification rates. Reflexes were abnormal (absent, elevated or recruited) in 153 subjects (86.4%) during the present study. Although Alford (2001:3) reported that the acoustic reflex is particularly sensitive to conductive hearing loss, and that losses as small as 5 dB to 10 dB are sufficient to abolish acoustic reflex thresholds, their ability to detect middle ear disorders were found to be limited in this study. In evaluating middle ear pathology, the acoustic reflex is an indirect index of middle ear status, which can be more directly assessed by means of tympanometry. Furthermore, use of acoustic reflex measures in isolation may result in an unacceptably high incidence of false positives for referral tool (American Speech Language and Hearing Association, 1990:19). The opposite is also true that by only looking at tympanometry or acoustic reflexes in isolation some patient might be missed (American Speech Language and Hearing Association, 1993:29). The abnormal results found in 107 out of the 177 mineworkers (60.5%) were further analysed. The collective outcomes of the case history, otoscopy, tympanometry and acoustic reflex testing for the individual mineworker were compared and only the combined results that correlated by being pathological, were classified as indicating middle ear pathology. Further analysis indicated that in 30 out of the 107 subjects (28%) were identified with middle ear pathology. Based on the statement of the American Speech Language and Hearing Association (1990:19) it is possible that 77 of the 107 mineworkers (72%) may have presented with false positive results and possible over-referral. It is thus recommended that the case history be supplemented with pure tone screening procedures, otoscopy and immittance testing as additional components (American Speech Language and Hearing Association, 1993:29).

The high prevalence of abnormal middle ear results among mineworkers (28%) may be attributed to their exposure to environmental risk factors such as poverty, overcrowding, inadequate housing, poor hygiene and nutrition, as well as environmental and occupational exposure to air pollution, including dust (WHO and CIBA, 2000:3). Explosions, blasts, or changes in atmospheric pressure in the workplace constitute additional risk factors (Workmen's Compensation Commissioner, 2001:5). Results of the present study correspond with a study from 1990 (Socio-Economic Factors, 1990:2), which found active ear disease in more than one-third of individuals from poor communities in developing countries. The subjects here did not necessarily have active ear disease. Convergence of multiple risk factors, as can occur in the case of mineworkers, appears to create the potential for negative synergies between social, economic, environmental and occupational risks to human health. The present study also found that mineworkers who smoke or are subjected to second-hand smoke have higher incidence of abnormal outer and middle ear results, i.e. 89 out of 141 smokers (62.9%) versus 14 out of 36 non-smokers (47.2%). These findings are supported by the research of De Beyer (2001:2), who confirmed that tobacco use might cause ear infections, emphysema, bronchitis, respiratory infections and compromise (cough, wheezing, etc), asthma and greater susceptibility to Tuberculosis. Smokers are also 1.69 times as likely to have hearing loss as non-smokers, which provides further evidence of the detrimental effects of smoking on the hearing system (Cruickshanks et al., 1998:3).

In summary, the results from the second aim indicated that there was a high prevalence of suspected middle ear pathology among mineworkers, as identified by the proposed middle ear screening procedures. Correlating results were obtained during case history-taking by OHP and the researching audiologist. A greater number of subjects with suspected middle ear pathology were found during acoustic reflex testing than with tympanometry.

4.3 Investigate discrepancies in the results

The third aim of the research study was to investigate discrepancies in middle ear screening results.

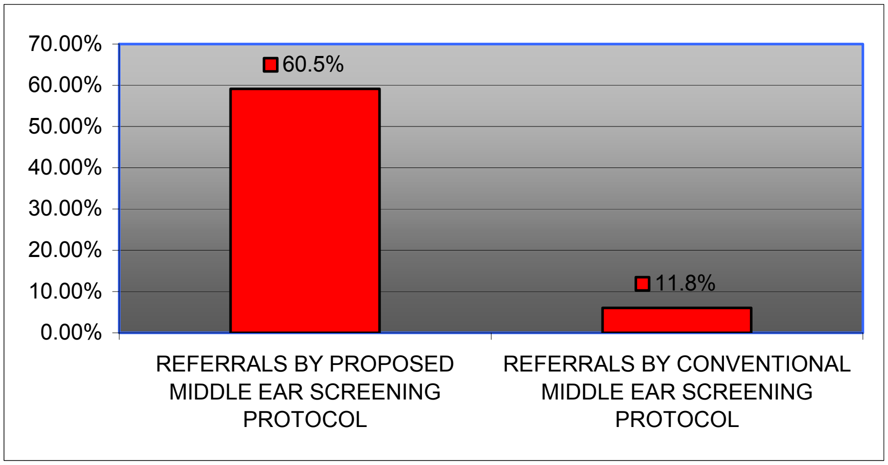

Figure 4.3: Discrepancies between conventional and proposed methods for middle ear screening

Clear discrepancies in identification rates were observed between the existing and proposed middle ear screening protocols, as indicated in Figure 4.3. Conventional procedures referred a total of 21 subjects out of 177 (11.8%) based on case histories and otoscopic examinations. The proposed screening protocol incorporating case

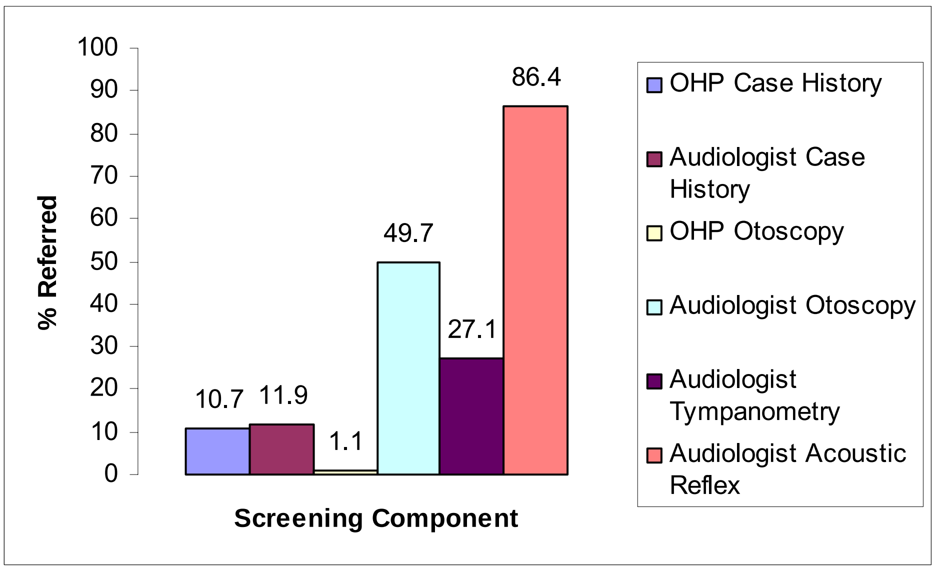

Figure 4.4: Comparison of referral rates for existing and proposed screening protocols

histories, otoscopy and immittance testing referred 107 out of 177 subjects (60.5%). The case history and otoscopy correlated in six subjects during the conventional screening procedures. During the proposed screening procedures the case history, otoscopy and immittance measures correlated in 30 subjects. Statistical analysis of these results indicated that an additional 24 mineworkers (80%) were identified with middle ear pathology by incorporating the proposed screening procedures. This might indicate that current middle ear screening methods employed at the mines are insufficient due to the omission of immittance testing (Wiley, 1997:116), and that the suggested use of immittance testing, in addition to otoscopy and pure tone screening, may be a better means of identifying middle ear pathology. The diagnosis of some forms of middle ear pathology like otitis media, is difficult using medical history and otoscopy. Tympanometry may, therefore, be helpful in the diagnosis and follow-up of middle ear pathology (Van Balen, Aarts and De Melker, 1999:117). Tympanometry and acoustic reflex measures are valuable adjunctive tools to aid diagnosis and follow-up of middle ear pathology. The use of immittance testing may improve diagnostic accuracy because it validates or refutes the clinician's impression (Pichichero, 2000:2015). Referral rates from the existing and proposed screening protocols were compared and are illustrated in Figure 4.4.

As part of the proposed middle ear screening protocol the researcher obtained a medical history from the mineworkers (Appendix C). Occupational health personnel identified middle ear pathology with the case history in 19 subjects (10.7%) and 21 subjects (11.9%) were identified by the audiologist. There were thus no significant discrepancies between the outcomes of case histories conducted by occupational health personnel and those conducted by the researching audiologist.

Otoscopy was the second component in both the conventional and the proposed screening protocol, performed by the OHP or the audiologist, respectively, depending on which protocol was applied. Both protocols were performed within 24 hours on the same subjects. The examination included observation of pathological conditions of the outer ear (pinna/mastoid): malformation; traces of scars; pinna tenderness; mastoid tenderness and growths. Examination of the ear canal included identification of foreign objects in ear canal (Figure 4.11); bleeding; swelling; wax plug; otitis externa (Figure 4.8); redness or irritation; scratching marks in ear canal; appear eczema-like; growths (Figure 4.5) and abnormal shape of canal. Examination of the tympanic membrane included observation of the retracted ear drum (Figure 4.13); outward bulge; colour; otitis media (Figure 4.7); discharge; fluid behind ear drum; perforation (Figure 4.6); the presence or absence of the light reflex; grommets in place; dull; infected; scar tissue on ear drum; air bubbles behind ear drum and blood behind the ear drum. When performed by the audiologist, otoscopy identified abnormal outer ear results in 88 out of 177 subjects (49,7%), in contrast with two subjects (1,1%) when performed by OHPs. Almost midway between these two values are the findings of Hopkinson (1981), which identified 19 per cent of coal miners as having middle ear disorders. The variance among these findings may support the contention that the skill and experience of the clinician greatly influence the sensitivity and, hence, effectiveness of otoscopic examinations (American Speech Language and Hearing Association, 1993:31), and that subtle visual signs of pathology may go undetected in some cases (American Speech Language and Hearing Association, 1990:19).

Table 4.1: Incidence of abnormal results in otoscopic examinations

Outer ear (pinna/mastoid)	**Incidence %**
Traces of scars	1.1
Malformations	0.5
Pinna tenderness	0
Mastoid tenderness	0
Growths	0
Ear canal	
Red/irritated	6.1
Wax plug	5.5
Foreign object in ear canal	1.1
Bleeding	1.1
Scratching marks in ear canal	1.1
Appear eczema-like	1.1
Swelling	0
Otitis externa	0
Growths	0
Abnormal shape of canal	0

Tympanic membrane	
Retracted	16.4
Scar tissue on ear drum	11.6
Red	11.1
Dull	5
Air bubbles behind ear drum	2.8
Infected	1.1
Light reflex absent	0.6
Outward bulge	0
Otitis media	0
Discharge	0
Fluid behind ear drum	0
Perforation	0
Grommets in place	0
Blood behind ear drum	0

Prevalence data for abnormal outer ear results were obtained from the otoscopic screening results for 177 mineworkers performed by the audiologist. A summary of the incidence of abnormal results is provided in Table 4.1. Traces of scars were found in two subjects (1.1%) and pinna malformations were found in one subject (0.5%).

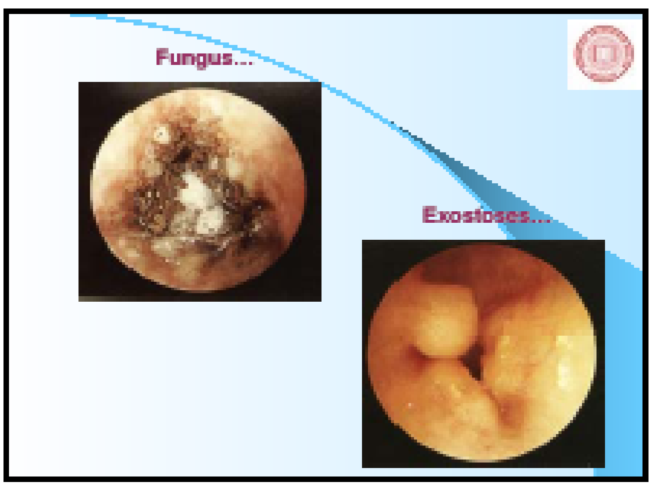

Figure 4.5: Outer ear canal growths (Indiana University, 2003:2)

It is important to identify fungus and exostoses (Figure 4.5) (examples of outer ear canal growths) during otoscopic examinations. None of these abnormalities were found in the study.

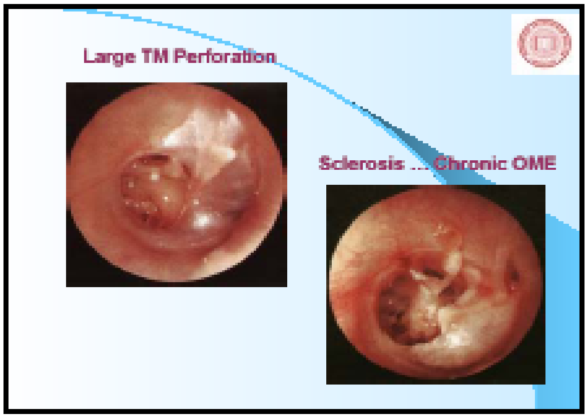

Figure 4.6: Tympanic membrane perforation & otitis media (Indiana University, 2003:2)

Tympanic membrane perforations and otitis media were also not identified in any subjects (Figure 4.6).

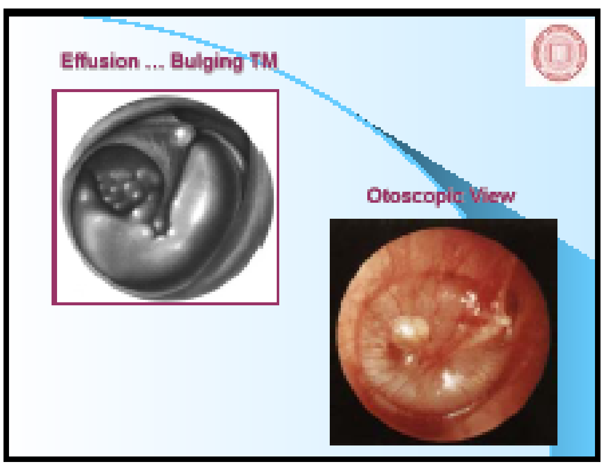

Figure 4.7: Otitis media with effusion (Indiana University, 2003:2)

The otoscopic examiner should also be able to recognize otitis media with effusion (Figure 4.7). No incidences of otitis media with effusion were identified in the study.

Figure 4.8: Otitis externa (Kavanach, 2004:1)

Figure 4.8 indicates otitis externa and was not identified as such by the examiner. However, observable signs of otitis externa may include swelling and reddening of the ear canal (Berger, 2003:2). As illustrated by Figure 4.9 red/irritated ear canals were identified in 6.1% (11 out of 177) mineworkers suggesting symptoms of otitis externa. Otitis externa occurs most often in the summer months, when people are frequenting swimming pools and lakes. Continually exposing the ear canal to moisture may cause significant loss of cerumen. The delicate skin of the ear canal, unprotected by cerumen, retains moisture and becomes irritated. Without cerumen, the ear canal stops being appropriately acidic, this allows bacteria the opportunity to multiply. Thus, the warm, moist, dark environment of the ear canal becomes a breeding ground for bacteria (Smith, 2004:1).

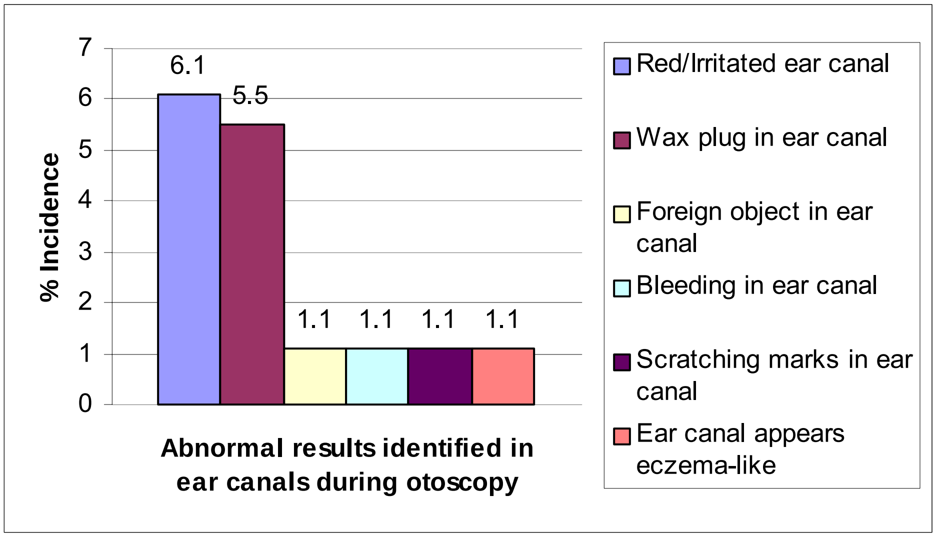

Figure 4.9: Incidence of abnormal results in the external ear canal during otoscopic examinations

Figure 4.9 illustrates that red/irritated ear canal and wax plugs were the most common abnormalities found in the external auditory canal. Two mineworkers (1.1%) had bleeding canals and another two (1.1%) appeared eczema-like. Eczema can occur in the auditory canal, causing dry, red, scaly and itchy skin (Pillinger and Crisp, 2004:2). The incidence of otitis externa in the general population is related to environmental or seasonal conditions, being more prevalent when temperature and humidity are elevated (Berger, 2003:2). Otitis externa affects about five out of 10 000 people, mostly teenagers and young adults (WebMD Corp., 2001:2). Hearing protection devices has been documented as a causative agent for infections of the ear canal, particular in the case of earplugs (Berger, 2003:2). The use of earplugs can increase the temperature and humidity in the canal, creating the potential for skin abrasion or local trauma, remove cerumen, and provide a vehicle for the introduction of organisms into the canal (Berger, 2003:2). Prior to issuing hearing protection devices the clinician should examine the ear canal to identify any medical or anatomical conditions, which might interfere with or be aggravated by the use of the hearing protector. If such conditions are present, hearing protectors should not be worn until medical consultation and/or corrective treatment can be obtained, or the suspected problem has been shown not to constitute a problem

(Berger, 2003:2). In underground mineworkers, switching from a premoulded vinyl plug to a foam plug decreased the incidence of canal irritation (Berger, 2003:3). Canal irritations can also arise due to the use of poor fitting or inappropriate hearing protection devices, omission of a "break-in period" for new users, or the use of worn hearing protection devices whose once resilient parts are no longer soft and flexible (Berger, 2003:3). Another common cause of otitis externa is excessive cleansing and scratching of the ear canal. This not only removes the protective ceruminous layer and creates itching, but may also result in trauma or abrasion, which further breaches the skin's protective layer. In patients with otitis externa, 63% to 87% reported cleaning their ear canals with cotton swabs, matches, fingernails, or the like (Berger, 2003:3). Other predisposing factors for otitis externa may include allergies to chemicals, dermatitis, chronic draining middle ear infections, excessive cerumen (which can trap water in the canal), and systemic conditions that lowers the body's resistance, such as HIV/AIDS (Berger, 2003:3).

Figure 4.10: Impacted cerumen in the ear canal (Hawke, 2004:2)

The appearance of the outer ear, ear canals and tympanic membranes were assessed. Impacted cerumen occurred in 5.5% (10 out of 177) of mineworkers and needed to be removed by medical staff (Figure 4.10). This finding correlates with the DHHS (1981:17) study, which identified impacted cerumen as prevalent among the coal mineworker population. The external ear canal can also be a source of middle ear barotrauma if a closed space is created between the outer rim of the concha bowl and the tympanic membrane (Franz, 2001:168). The closed space may be due to a cerumen impaction as found in 5.5% of mineworkers. As an individual descends, ambient pressure will increase, causing a net negative pressure gradient between the external ear canal obstruction and the tympanic membrane. The obstructing wax is then forced deeper into the external ear, resulting in a tympanic hemorrhage or perforation (Franz, 2001:168). Identification of impacted cerumen with otoscopy is of great importance in preventing barotrauma. The patient typically experiences extreme pain as the descent phase begins, despite an ability to clear the middle ear (Harril, 1995:2). Ceruminous glands continuously produce cerumen. The secretions mix with keratin debris produced by the migration of epithelial cells, in the external meatus (Rodgers, 1997:3). Cerumen protects and waterproofs the meatal skin and is slightly acidic, thereby providing antibacterial and antifungal properties (Rodgers, 1997:3). It is gradually moved towards the entrance of the auditory canal by the action of muscles used in chewing and talking, and by surface migration. Hooper (1991:38-9) points out that people seem to be unaware that wax is necessary to protect the external auditory meatus and view its presence as a sign of poor personal hygiene. Such public misperception contributes to the high incidence of impacted cerumen and resultant amount of syringing performed (Sharp, Wilson and Ross, 1990:3). Cotton swabs are used in an attempt to remove ear wax, however this frequently pushes wax further into the canal and causes it to become impacted (Webber-Jones, 1992). If cerumen production is excessive, or if an obstruction prevents it moving towards the entrance to the auditory canal, the canal may become blocked with wax that hardens over time. People with large amount of hair in their ears, or who work in dusty or dirty atmospheres, such as mineworkers, have a higher incidence of excessive wax accumulation (Beare and Myers, 1998:3). A patient with recurring build-up and plugging of excess cerumen may be taught to use a prescribed non-irritant softener regularly. Through education, patients will develop an understanding of how to prevent ear problems, recognizing the first signs of recurrence, and will therefore seek treatment sooner (Rodgers, 1997:2).

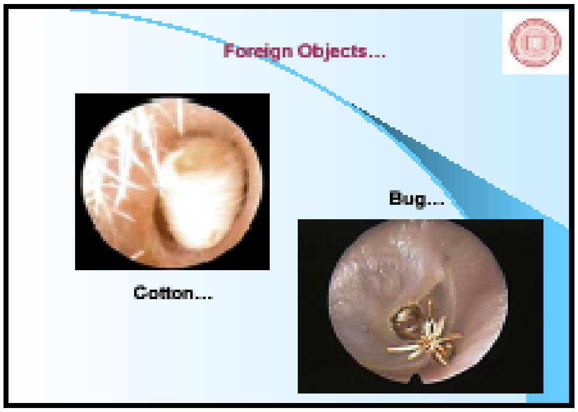

Figure 4.11: Foreign objects in the outer ear canal (Indiana University, 2003:2)

Foreign objects were found in two out of 177 subjects (1.1%). Figure 4.11 indicates some examples of objects, namely cotton and insects that was found in the ear canal. Foreign bodies are sometimes inserted into the external canal and may become lodged. Alternatively, insects or debris may be blown into the ear (Beare and Myers, 1998: 1160).

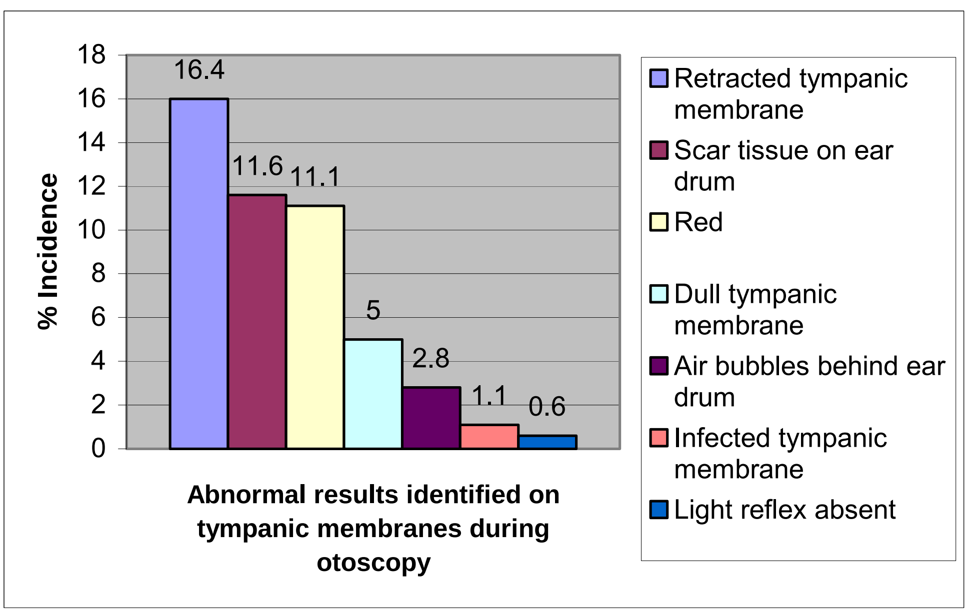

Figure 4.12: Incidence of abnormal results found on the tympanic membrane during otoscopic examinations

Figure 4.12 provides an overview of the abnormal results found on the tympanic membrane during otoscopic examinations. Retracted tympanic membranes had the highest prevalence rate among the types of middle ear pathologies identified with otoscopy, followed by scar tissue on the tympanic membranes and red tympanic membranes. Absence of the light reflex on the tympanic membrane was indicated as the least prevalent abnormality.

Changes in the colour of the tympanic membrane, which is normally shiny, translucent and pearly grey, may indicate and infection of the middle ear (Cook, 1998:2). Otitis media may result in a red tympanic membrane, while serous otitis media may cause it to be dull or retracted (Cook, 1998:2).

Figure 4.13 : Retracted tympanic membrane (Hawke, 2004:2)

Figure 4.13 indicates retraction of a tympanic membrane. If the Eustachian tube is blocked completely, air in the middle ear is gradually reabsorbed and a vacuum will form, pulling the ear drum inward. The blockage may be due to several conditions, but most commonly it stems from nasal congestion occurring with an upper respiratory infection. If changes in air pressure are great, such as vertical transportation, the pressure might cause bleeding in the middle ear and/or rupture of the tympanic membrane (The Eardrum, 2004:2). Retracted tympanic membranes were found in 29 mineworkers (16.4%). Tympanometry confirmed retracted tympanic membranes in 11 out of the 29 mineworkers (39.7%) and acoustic reflexes were absent in 10 of the 29 mineworkers (34.4%). Tympanometry and acoustic reflexes corresponded well in the identification of retracted tympanic membranes. It can thus be concluded that immittance testing is of value in the identification and prevention of barotrauma. Risk of barotrauma would be greatest among susceptible individuals and, accordingly, it would be appropriate to adopt a conservative criteria level and include immittance testing in risk based assessments (Franz, 2001:168). Red tympanic membranes were observed in 20 cases (11.1%). Abnormal tympanograms were found in four out of the twenty mineworkers (20%) identified with red tympanic membranes. Acoustic reflexes confirmed middle ear pathology in 6 of the 20 mineworkers (30%). Nine subjects (5%) had dull tympanic membranes that may be indicative of active ear disease and in need of medical intervention. Middle ear pathology was confirmed by abnormal tympanometry in two out of the nine mineworkers (22.2%) identified with dull tympanic membranes. Normally the tympanic membrane is smooth and unmarked. Previous infections and/or perforations cause scar tissue on tympanic membranes (Cook, 1998:2).

Figure 4.14: Scarring of the tympanic membrane (Kavanach, 2004:1)

Figure 4.14 indicates scarring on the tympanic membrane. Prerequisites for its formation appear to be infection and healing (Pensak and Adelman, 2004:2). Scarred tympanic membranes were identified in 21 mineworkers (11.6%) and middle ear pathology was confirmed in six out of the 21 mineworkers (28.6%) identified with scarring. Ten out of the 21 mineworkers (47.6%) presented with absent acoustic reflexes. Scarred tympanic membranes contributed to the second highest incidence of abnormalities identified with the otoscopic examination. The findings of this study correlate with the DHHS (1981:17) study, which indicated that retracted tympanic membranes and scar tissue on tympanic membranes were common among the coal mineworker population. The existence of scarring in the tympanic membrane as a result of previous barotrauma, middle ear infection or damage caused by insertion of a foreign object would render the ear drum more susceptible to rupture, as an interface between scar tissue and normal tissue constitutes a weak point in the membrane (Franz, 2001:27). Given that middle ear barotrauma would be most likely among the most susceptible individuals, it would be appropriate to adopt a conservative approach in the mine's medical surveillance program. This indicates that prospective identification of permanently susceptible individuals is a fundamental prerequisite to controlling the risk of barotrauma.

No tympanic membrane perforations were observed during the otoscopic examinations. Quinn and Ryan (2002:3) noted that the tympanic membrane is much more frequently traumatized than the middle or inner ear, but usually to a less serious degree. Annual incidence rates of traumatic perforations vary between 1.4 and 8.6 per 100 000 in the general American population. Young men are more commonly found to have perforation injuries. In industrial communities, hot welding slag and sudden changes in air pressure are occasionally encountered as the culprits for tympanic membrane injuries.

Data obtained from the questionnaire administered to mine medical staff performing the otoscopy, indicated that they are not familiar with the term middle ear barotrauma. Insufficient knowledge may influence referral and further investigation of barotrauma susceptible individuals. The risk of barotrauma is increased in cases where middle ear pathology is present during vertical transportation. The results indicated that mineworkers work underground in some cases when potential middle ear pathology is present. The questionnaires also indicated that mineworkers are in need of counselling on the consequences of middle ear pathology. It is evident from the data obtained that mineworkers do not report suspected ear infections or tympanic membrane perforations to medical staff in all cases. Occupation health personnel were also not able to identify these individuals with the otoscopic examinations. These are factors influencing the effectiveness of middle ear screening programs.

Data obtained from the questionnaire administered to mineworkers, further indicated that 149 out of 177 mineworkers (84.1%) scratch their ear canals with foreign objects. The epithelium lining the external auditory canal is thin and easily damaged. An abrasion is easily and frequently produced by scratching the ear with foreign objects (Hawke and McCombe, 1995). However, otoscopic examinations identified abrasions of the outer ear canal in two mineworkers (1.1%). This study found abraded external auditory canals and impacted cerumen in external auditory canals. These are the results of self-cleaning with foreign objects. This finding suggests that workers feel a need to clear dirt, debris, and cerumen from their canals, but they cause minor damage to their canals when doing so. Hearing protectors may also cause abrasions. It was determined that 24 out of 177 mineworkers (13.3%) complained that their hearing protectors are painful to wear.

The questionnaire further indicated that 141 mineworkers (79.6%) smoked or were exposed to passive smoking. Smoking increases the risk of upper respiratory tract infections (Franz, 2001:7). Data from the study indicated that 89 out of 141 smokers (62.9%) were referred for treatment of middle ear pathology, making them more susceptible to middle ear pathology than non-smokers. Additional information from the questionnaire revealed that 14 out of 177 (8.1%) mineworkers received annual flu vaccinations and nine out of 177 mineworkers (5.1%) suffered from flu. There is an association between colds and flu and the risk of middle ear barotrauma and workers should be counselled in the risks of upper respiratory tract infections (Franz, 2001:6). WHO and CIBA (2000) identified overcrowding, inadequate housing, poor hygiene, poor nutrition and exposure to air pollution as risk factors for the development of middle ear pathology. Data obtained from the study revealed that 10.92% (19 out of 177) of mineworkers do not live in sanitary, clean conditions and thus, poses a treat to their health.

The researcher further determined the feasibility of immittance testing in the mining industry by considering the time factors and costs associated with untreated middle ear pathology. It took the researcher an average of three minutes to prepare the subject (instructions and probe size selection) and four minutes on average to perform tympanometry and ipsilateral acoustic reflexes on both ears. Adding immittance testing to the hearing screening protocols will lengthen the screening process with approximately seven minutes. The Health Centre summons approximately 200 mineworkers per day. It can thus be concluded that the total screening process for these number of workers will be lengthened by approximately 23.3 hours. The proposed screening procedure is still a lengthy procedure in comparison to conventional procedures but the benefits make it worthwhile. An attempt to analyze the potential cost of neglected middle ear pathology is structured in the following way (De Koker, 2003a:27):

Lost production:

An example of how lost production can be estimated is as follows (De Koker, 2003a:27). A 30 meter panel of mining area worked on by rock drill operators involves a production cost of R79 000.00 per day. With one of 16 workers absent it amounts to R4937.50 lost production per day.

Lost shifts: The same example of rock-drill operators again taken in determining the cost of lost shifts. Rock drill operators are usually category four workers earning on average R2260.00 per month. That is R113.00 per day.

Transport costs: Transport of workers to Occupational Health Centres and Hospitals costs Harmony Goldmine R70000.00 per month (West Rand operations) (De Koker, 2003a:27). On average 584 workers are transported during a month. It thus costs R3500.00 per day per 29 workers. Thus R120.68 per workers transported.

Ear-, nose- and throat specialist referral: If attempts at treating middle ear pathology by the nurse or medical doctor were unsuccessful, a worker is often referred to an ear-, nose- and throat specialist. Lost shift (R113.00), lost production (R4937.50), transport (R120.68) and ENT consultation (R113.40), amounts to R5284.58. From the above it can be seen that without taking any surgery costs into consideration the mineworkers with neglected middle ear pathology can cost the company a minimum of R5284.58 per patient extra. Taking appropriate preventative action such as early identification of middle ear pathology utilizing immittance testing, may greatly reduce the medical expenses the company incurs. Utilizing tympanometry in hearing screening reduces the cost to the health care system in terms of referrals to physicians for suspected hearing problems (Thunderbay District Health Unit, 2001:3)

In summary, the third aim of the research study determined that the proposed middle ear screening method identified more individuals with suspected middle ear pathology than conventional methods. Acoustic reflexes, tympanometry and otoscopy performed by the researching audiologist produced the highest number of referrals. Retracted tympanic membranes followed by scar tissue on tympanic membranes presented with the highest incidence during otoscopic examinations. These abnormalities are indicative of previous episodes of middle ear barotrauma and/or susceptibility to barotrauma. Occupational health personnel demonstrated insufficient knowledge on middle ear barotrauma and mineworkers do not report incidences of pathology. These findings suggest that barotrauma susceptible individuals may not be identified.

CHAPTER 5 Conclusions and recommendations

This chapter presents a summary of the findings and conclusions of immittance measures for the identification of middle ear pathology and its implications for future research studies.

5.1 Conclusions

The researcher has formed research questions and hypotheses about what may be discovered based on the main aim and its attendant sub-aims. The question to be answered through the research was whether immittance testing should be incorporated into medical surveillance programmes. The design was based on the main research hypotheses: if immittance testing is incorporated into middle ear screening procedures together with history-taking, otoscopy and pure tone audiometry, a higher incidence of abnormal outer and middle ear results were expected to be identified. The nullhypothesis formulated was: if immittance testing is omitted from middle ear screening procedures and only history-taking, otoscopy and pure tone audiometry is used, then a lower incidence of middle ear pathology will be found. A causal relationship was expected to occur (Byrne, 1998:15) within the experimental research design (Leedy, 2001:234). Data were collected and analysed in order to prove or reject these hypotheses. Middle ear pathology was identified by comparing results from history-taking, questionnaires, otoscopy and immittance testing. Data were summarized with percentages and frequency counts, and inferences were then made regarding middle ear pathology in the population of mineworkers (Leedy, 2001:196).

Clear discrepancies in identification results were obtained from conventional middle ear screening procedures within employers' medical surveillance programmes and the proposed method of middle ear screening. An experimental research component was employed in delineating discrepancies in identification results obtained from conventional middle ear screening procedures and the proposed method for middle ear screening. The conventional hearing screening procedures followed in medical surveillance programs had three components: medical history-taking, otoscopic examinations and pure tone screening audiometry. The researcher's proposed method of hearing screening in medical surveillance programs had four components: medical history-taking, otoscopic examinations, pure tone screening audiometry and immittance testing. Current screening methods for middle ear pathology in medical surveillance systems are not sufficient. The suggested method of history-taking, pure tone audiometry, otoscopy and immittance testing identified more workers in possible need of medical attention and counselling than conventional procedures. The conventional screening protocol fails to identify all cases of middle ear pathology by excluding immittance testing (Wiley, 1997:116).

A high prevalence of abnormal middle ear results was identified by immittance testing in the population of mineworkers. More than half of the population was positively identified with potential middle ear pathology. There was substantial agreement between the finding of abnormal otoscopy and abnormal immittance testing results. By itself, acoustic reflexes were not useful in identifying potential middle ear pathology, since the reflex results were inconsistent by being absent in some cases, including normal middle ears. The presence of acoustic reflexes may be influenced by the age of a person, the presentation mode (ipsi- or contralateral) and the probe frequency (Hall and Mueller, 1997:211). In adults with normal hearing and normal tympanograms, acoustic reflexes may be absent at 4000Hz in 3.7% of cases, but at 1000Hz only 0.3% of reflexes may be absent (Hall and Mueller, 1997:211). There are also variations in contralateral measurements, with contralateral more absent than ipsilateral (Hall and Mueller, 1997:212). Hall and Mueller (1997:211) noted that up to 6% of contralateral acoustic reflexes might be absent at 4000Hz in normal hearing individuals and normal tympanograms. It is recommended that acoustic reflexes be used to rule out significant middle ear pathology by clarifying questionable tympanograms (Earscan, 1997:3). The literature suggests that the cross-check principle be applied in the interpretation of acoustic reflexes and tympanograms.

There is a high prevalence of middle ear pathology in the mineworker population. Emphasis should be placed on anticipation, recognition and intervention thereof (Department of Minerals and Energy, 2001:1). By incorporating immittance testing into screening procedures rapid interventions can reduce the risk of further impairment and enhance the overall well being of mineworkers. Early identification of middle ear pathology may also lead to substantial savings in time and expense, particularly treatment costs associated with neglected middle ear pathology and surgical interventions, as compared with current methods of identification and medical surveillance. More frequent recommendations for further follow-up such as diagnostic audiometry, medical referral, educational referral and counselling are also possible.

Findings indicate that individuals with chronic or temporary predisposing medical conditions would be subjected to an increased risk of barotrauma (Franz, 2001:6). Workers suffering from middle ear pathology are temporarily excluded from work in deep-level areas. Individuals with neglected middle ear pathology are excluded from work for longer periods of time and this implies the necessity for substitute workers, or the sub-delegation of the involved patient's work-related responsibilities. Federal and state occupational health agencies require effective medical surveillance programs by law (Suter and Franks, 1990:5). Most employee compensation carriers also advocate effective hearing conservation programs, and companies that do not protect their employees from hearing loss may find their premiums rising. A good hearing conservation program promotes good labour relations because employees know that management is concerned, and this type of concern may translate to improved productivity and product quality (Suter and Franks, 1990:5). Taking appropriate preventive action with monitoring immittance testing will greatly reduce the risk of future claims such as barotrauma. The company benefits from reduced worker compensation payments and medical expenses.

5.2 Critical evaluation of study

Research involving patients in clinical settings have certain unavoidable limitations due to the ethical constraints imposed upon a clinical researcher (Mitchell and Jolley, 1988 in De Koker, 2003a:27). The use of two different examiners provided some indication of the fact that the outcome of otoscopy could vary depending on the examiner. The use of more examiners with different degrees of experience would have provided a clearer picture of the range of variability that could be expected. This was particularly important in view of the finding that otoscopy was highly dependent on the skill of the examiner (American Speech Language Hearing Association, 1990:22). The inclusion of a larger sample of mineworkers would also have provided a clearer picture of the prevalence of middle ear pathology and discrepancies in identification results during the investigated middle ear screening protocol. The influence of another person performing immittance testing on the same population would also have been valuable.

The interpretation of acoustic reflexes as absent, elevated or recruited is also applicable to sensory-neural losses (Gelfand in Katz, 2002:217). It must be noted that a recruiting result is only applicable to a cochlear disorder (Gelfand in Katz, 2002:218). The combined use of tympanometry and acoustic reflex testing can help differentiate a middle ear disorder from a cochlear problem (American Speech Language Hearing

Association, 1990:19). This differential principle has not been applied in interpreting the results.

5.3 Recommendations

The findings of this study reiterate that screening programmes can and must be evaluated. Protocols should be based on data that demonstrate that individuals identified through screening have better medical outcomes than those not screened (American Speech Language Hearing Association, 1995:26). This should be done using randomised, controlled clinical trials. Program costs can be estimated and direct monetary costs of screening can be computed.

Several authors have identified the need for immittance results to be interpreted in conjunction with those of other otologic test procedures (Smith & Evans, 2001:57). Immittance testing should be included in the conventional middle ear screening protocol, together with history-taking, otoscopy and pure tone audiometry. Conventional pure tone audiometry, case history and otoscopy is already in place in the mining industry and is stipulated as the basis for evaluating possible middle ear pathology. Implementation of immittance testing would place additional demands on employers' medical surveillance systems, but would provide significant benefits beyond what is already in place. Referrals of individuals identified with potential middle ear pathology through an effective screening program allows for early medical diagnosis and consequent interventions. The risk of further impairment is also reduced.

A lack of local middle ear pathology prevalence data required that results of the present study be evaluated against data from overseas populations in different mining industries, which cannot be regarded as representative of South African mineworkers, in terms of ethnicity, demographics and other socio-economic factors. This creates a fundamental obstacle to deriving generalized prevalence results for mineworkers in South Africa. Consideration should be given to developing prevalence data for middle ear pathology in all areas of the South African mining industry.

Prevalence data is needed on barotrauma and the value of immittance testing as part of screening procedures in the identification of barotraumas susceptible individuals. This information will reiterate the need for timely, comprehensive middle ear screening programmes. It is crucial for future enhancements in employers' medical surveillance programmes. In the interim, the most important action on the part of employers would be to implement measures aimed at the prevention of middle ear pathology. Individuals with chronic predisposing middle ear conditions, should at least, be advised to be vigilant for signs of barotrauma susceptibility and symptoms of their underlying medical condition. Mineworkers should also be counselled regarding the risk of aggravating their condition, with extreme cases referred for specialist evaluation to enable a participative decision regarding fitness for ultra-deep areas (Franz, 2001:7). In some instances, surgically implanted grommets may offer a viable means of controlling the risk of middle ear barotrauma. In addition to draining purulent discharge from the middle ear, thus helping to clear an infection, grommets can provide for the equalisation of middle ear pressure differences, irrespective of Eustachian tube function (Franz, 2001:7). Acute illness involving the upper respiratory tract can render normally healthy workers temporarily susceptible to the risk of barotrauma. To counter seasonal increases in the incidence of influenza and resultant risks, the prophylactic vaccination of workers should be considered. Provision should also be made for the administration of antibiotics to treat secondary infection where flu does occur, and the availability of medicinal preparations to control symptoms that could increase the risk of barotrauma (Franz, 2001:7).

Behaviour-based control strategies are recommended to reduce the risk of middle ear pathology. These strategies require the promotion of rational, risk-based modifications in behaviour among workers and supervisors. Of primary importance would be the need for affected individuals to report any pressure-related problems to supervisors and medical personnel. Accordingly, employee awareness of the barotrauma hazard and knowledge of relevant signs and symptoms would be prerequisites to a behaviour-based control strategy, as would workers' awareness of their state of health supervisors should encourage workers to report any problems, as failure to do so could results in aggravation of acute conditions or development of debilitating chronic ones, in either instance extending the recovery period and absence from duty. Accordingly, the culture of early reporting should be developed, to enable early treatment and prevention of complications that could have lasting impact on workers' health and productivity (Franz, 2001:7).

Counselling techniques should incorporate explanations and demonstrations of practical means for coping with pressure changes, particularly middle ear equalisation techniques, with provision for workers to practice these techniques under supervision of a suitably competent person. In addition, workers should be made aware of the risks created by inappropriate behaviour, including the use of earplugs or holding one's breath during vertical conveyance, and failure to report medical problems. The increased risks of upper respiratory tract infections posed by smoking, and the dangers of using certain medications in hot, humid areas (especially without medical supervision) are other issues that should be addressed during workers' education and training. While education and training would be required for all employees exposed to significant variations in barometric pressure, special attention should be given to those identified as susceptible during risk-based medical examinations. Additional requirements would be to regularly reinforce workers' awareness of the hazards associated with middle ear pathology and their training in coping strategies, particularly during seasonal increases in the incidence of colds and flu, and to ensure that employees are cognisant of reporting procedures (Franz, 2001:7).

There is a present lack of knowledge on the different pathologies in need of identification during otoscopy. The skill and experience of the individual performing the otoscopic inspection will vary considerably and it is anticipated that more subtle visual evidence of middle ear disorders will be detected in some screening programs and not in others (American Speech Language Hearing Association, 1990:17). Thus, the extent to which a screening procedure yields consistent outcomes in repeat assessments is essential in confirming the inter-test reliability of this screening procedure. There is a need for more experienced otoscopic testers. It is an important factor to be considered in the successful implementation of a middle ear pathology screening programme.

Immittance testing, as part of a mine's middle ear screening programme, does hold promise for early identification of middle ear pathology. Where applied, the training of OHP would best be done by the consulting audiologist. An immittance testing room should not exceed ambient noise levels of 50dB. A specially treated environment is thus not necessary. The cost of a screening immitance instrument (NT 10 mini tymp) is presently estimated at R14000 plus VAT. No additional staff would be required, since the test procedure is very quick. Immittance testing also holds promise for industrial hearing screening by audiometrist. Test results should be used to identify existing employees who require counseling to avoid further pathology e.g. barotrauma susceptible individuals and referral for treatment. In addition, the results of immittance testing should be used along with those from conventional screening to ensure the targeting of appropriate middle ear pathology intervention measures.

5.3.1 Recommendations for further research

The prevalence of middle ear pathology is poorly documented in South Africa. A subject for further research would be to determine the prevalence of middle ear pathology in certain groups within the population of mineworkers. The effect that AIDS have on these prevalence statistics needs to be investigated.

Deep mine workers are exposed to the risk of barotrauma through vertical conveyance (Franz, 2001:1). This study has emphasized the clinical value of immittance testing. However, the role of immittance testing in screening individuals susceptible to barotrauma is yet to be demonstrated. Statistics is also needed on the prevalence of barotrauma in the South African deep mining population. Authors of the Guide Hearing Impairment (2003) expressed their concern that routine screening for hearing deficits of working-age adolescents and adults is usually limited to those in high-risk occupations involving exposure to excessive noise levels. Among older persons, however, in whom the rate of hearing impairment is high, recommended screening methods for detecting hearing deficits have included written patient questionnaires, clinical history-taking and physical examination, audiometry and simple clinical techniques designed to assess for the presence of hearing impairment (Davis, Stephens and Rayment, 1992:3). Reported hearing sensitivities and specificities have been 70% to 100% using pure tone audiometry as the reference standard, but there are inadequate data on interobserver variability (Mulrow et al., 1991:3). Self assessment questionnaires are reported to be 70% to 80% accurate for identifying patients with hearing deficiencies defined by pure tone audiometry (Mulrow et al., 1991:3). These screening tests have not been fully evaluated, and are thus recommended for further research (Davis et al., 1992:3).

The observations made in this investigation strongly suggest that it would be worthwhile to study “ear hygiene” among workers in industry. This study found abraded external auditory canals and impacted cerumen in external auditory canals. These are the results of self-cleaning with foreign objects. This finding suggests that workers feel a need to clear dirt, debris, and cerumen from their canals, but they cause minor damage to their canals when doing so.

Acoustic immittance testing holds promise for the future in that it could enable the early identification of middle ear pathology in the mining industry. It is therefore recommended that these procedures only be implemented once guidelines have been developed for the incorporation of immittance testing into medical surveillance systems. In the interim, it is proposed that acoustic immittance tests be considered as an optional medical surveillance technique. Where applied, an audiologist should train technicians. Test results should be used to identify susceptible individuals to enable immediate and positive identification of predisposing factors, such as previous barotrauma and early stage middle ear pathology, and counseling to avoid further degeneration. In addition, the results of the acoustic immittance testing should be used along with those from conventional screening to ensure the use of appropriate hearing conservation measures.

5.4 Chapter summary

This chapter presented the data from the research investigation in a summarized form. The clinical value of middle ear screening procedures were investigated using univariate procedures and stepwise multiple logistic regression modelling. These findings were then critically discussed in the context of previous research.

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APPENDIXES

Appendix A: Immittance testing participation consent form (English)

This form is to be administered to selected workers before their participation in immittance testing by the Audiologist.

Read the following to each prospective subject, pausing to answer any questions:

Phumlani Occupational Health Centre has agreed to co-operate with the SIMRAC research team and investigate specific tests for early identification of middle ear pathology before it becomes serious and causes problems. Results from the study will be useful in deciding whether modifications should be made to conventional testing procedures and enhance early identification of middle ear problems, in order to improve workers' health and safety. The study have been approved by the Responsible Occupational Health Medical Practitioner on the basis that workers who agree to participate remain unanimous and the results will be used to help protect workers against middle ear pathology.

If you agree to participate, we will ask you some questions about you, your job, and ear problems you might have. For example, you will be asked whether you experience ear pain during transportation from underground. It will take approximately three to five minutes.

Your ears will be visually examined. A light will be used to look in your ears for any pathology. The estimated time is one to two minutes. Then your ears will be automatically tested without requiring a response from you. The examiner will place an ear tip in your ear, which is connected to a machine. You will hear peep-peep sounds but you don't need to respond. The estimated time is 5 minutes. Your participation will now be completed. The information test results obtained through your participation will then be used to determine the effectiveness of identifying middle ear pathology. We want to find the best way of identifying middle ear pathology.

Your test results will be kept confidential, and only you and the research team will see them.

We will explain how each test is done, show you the results and explain what they mean. Some of the tests will be done more than once, to double-check on the results.

We will keep your name and information in strict confidence, and not tell the mine or the managers anything about you or your test results.

Your participation in this study is voluntary. Whether you decide to take part or not, it will not affect your job in any way. Your participation in this study will be helpful to all workers who are working underground. We ask you to decide for yourself whether you want to participate, and if you have some questions that need to be answered before you decide, please ask them.

Will you help us with the research? (YES or NO)
If NO, ask the next worker.
If YES, ask worker to sign or make a mark in the space below to indicate that he has been given the information and understands it. Then record the other details.

……………………………………………………………………………………………………

I have been told about the study and I have been given the chance to ask questions about it and my participation. I also understand that if I have any questions at any time, they will be answered, and that if I am not satisfied with the answers I can withdraw from the study.

Name:………………………………………
Company number:………………………..
Date:………………………………………..

Appendix B: Immittance testing consent form (Translated)

Lo form kalo sivumelano kalo jopisana

Lo form lo yena jopisiwa lapha kalo munye basebenzi lo yena tesitiwa Immittance testing kalo msetshi kalo mandlebe (audiologist).

Fundela lo msebenzi futhi linda izwa nokho phendula lo mebuzo ka yena :

Lo phumlani occupational health centre yena vumile lo ku jopisana nalo simrac span , kalo kuyenza lo
Phando kalo munye matest kalo tshetsha thola noko vimbela loku limala noko lo sifo kalo
Ndlebe lo yena vela phakathi kalo ndlebe (middle ear pathology), phambili yena yenza makhulu noko
Yena dala lo probleme lapha kalo msebenzi. Lo siphumo kalo phando lo, yena azi siza lo ku enza lo siqibo
Kalo faka lo machanges lapha kalo ndlela lo yena jopisiwa kalo matest nalo ku phakamisa lo mathuba
Kalo vimbela lo sifo lo kalo ndlebe (middle ear pathology) nalo ku phakamisa lo health and safety kalo basebenzi. Lo phando lo yena vumelilwe kalo dokotela kalo medical bereau kalo khusela noko qina lo makama kalo basebenziyena mfihlo futhi kalo siza vikela lo basebenzi lapha kalo sifo lo kalo ndlebe.

Skhathi lo msebenzi yena vuma jopisana na thina , thina azi buza lo mebuzo lapha kalo msebenzi maqondana na yena , lo jop ka yena , lo maprobleme kalo mandlebe ka yena lo yena khona,
Mzekelo,, " skathi lo khetshe yena yehla wena izwa lo buhlungu lapha kalo zindlebe na ?. Lo
Skathi kalo testi lo yena phakathi kalo mizuzu e mihlano kuphela.

Lo mandlebe ka wena yena azi tshekitshiya kalo ku khangeliwa kalo light phakathe ka lo ndlebe lo

Buka lo ku limala noko loku mosheka kalo ndlebe phakathe.wena azi yizwa lo peep-peep yena khala kodwa

Lo msebenzi yena azi phendula ,yena mamela kuphela.. Lo mniningwane nalo siphumo kalo

matest yena azi jopisiwa kalo thola lo ndlela lo yena lula futhi yena khona lo sqiniseko

Kalo sifo lo yena phakathi kalo ndlebe (middle ear pathology).

Lo siphulo kalo matest lo yena azi hlala yena mfihlo ka lo msebenzi , msetshi (audiologist)

nalo span kalo phando.. Azikho noko one muntu lo yena azi yazi kuthi ka bani lo ma test

Futhi ayikhona thinthana na lo jop ka wena.

Thina azi qaqisa zonke lo matest nalo ku khomba wena lo ma siphumo nalo kuthi yene yena khuluma

Lo matest lo munye yena azi yenziwa two skat kalo ku thola lo siqiniselo ka yena

lo matest lo , ayikhona nyanzeliwa lapha kalo msebenzi . Lo ku jopisana yena azi siza ka khulu lo basebenzi lo yena jopa mgodi . Skat wena khona mebuzo buza yena ..

Wena azi jopisana na mina?

YEBO

QHA

DATE____

Appendix C: Questionnaire for mineworkers

(To be completed by interpreter)

Industry number: ____________ V1 ☐☐☐☐☐☐☐☐☐☐ 1-10

Date 2002/ ____ / ____

Age ____________________ V2 ☐☐ 11-12

Mine ____________________

Level ____________________ V3 ☐☐☐ 13-15

Occupation ____________________

1. Do you go for annual flu vaccinations?

Yes	1	V4
No	2	

☐ 16

2. Do you smoke or does someone regularly smoke near you?

Yes	1	V5
No	2	

☐ 17

3. Do you live in clean sanitary conditions?

Yes	1	V6
No	2	

☐ 18

Do you currently suffer from the following:

	Yes	No			
Cold/Flu	1	2	V7	☐	19
Asthma	1	2	V8	☐	20
Diabetes	1	2	V9	☐	21
Allergies e.g. hay fever	1	2	V10	☐	22

5. Do you scratch your ears with foreign objects?

Yes	1	V11
No	2	

☐ 23

6. Are your hearing protectors painful to wear?

Always	1	V12
Sometimes	2	
Never	3	

☐ 24

7. What type of hearing protectors do you use?

	Yes	No			
Earplugs	1	2	V13		25
Earmuffs	1	2	V14		26
Custom-made	1	2	V15		27
None	1	2	V16		28

8. Any history of ear infections?

Yes	1	V17		29
No	2			

COMPLETE SECTION 8.1 TO 8.8 IF PATIENT ANSWERED YES TO QUESTION #8

8.1 Did you report suspected ear infections immediately to medical staff?

Always	1	V18		30
Sometimes	2			
Never	3			

8.2 Were you referred for medical treatment once you reported a suspected ear infection?

Yes	1	V19		31
No	2			

8.3 If medications were prescribed did you go back for medical follow-ups?

Yes	1	V20		32
No	2			

8.4 Did you keep your ear(s) clean and dry while healing?

Yes	1	V21		33
No	2			

8.5 How long did this ear infection continue?

For days	1	V22		34
For months	2			
For years	3			

8.6 Did you go underground with an ear infection present?

Yes	1	V23	☐	35
No	2			

8.7 Do you suffer from one of the following when transported in the cage?

	Always	Sometimes	Never			
Ear pain	1	2	3	V24	☐	36
Dizziness/vertigo (head spinning)	1	2	3	V25	☐	37
Nausea/vomiting	1	2	3	V26	☐	38
Head aches	1	2	3	V27	☐	39
Diminished hearing	1	2	3	V28	☐	40
Bleeding ear	1	2	3	V29	☐	41
Fullness in ear	1	2	3	V30	☐	42

If you experience ear discomfort, is discomfort relieved by yawning, swallowing or chewing?

Always	1	V31	☐	43
Sometimes	2			
Never	3			

8.8 Have you ever been taught or informed about techniques to prevent further damage to your ears when using the cage?

Yes	1	V32	☐	44
No	2			

If yes, please explain:

____

9. Do you currently suffer from one of the following problems?

	Yes	No			
Ear infection	1	2	V33	☐	45
Ear discharge	1	2	V34	☐	46
Ear pain	1	2	V35	☐	47
Tinnitus (ringing sound in ear, like a cricket)	1	2	V36	☐	48
Fullness in your ear	1	2	V37	☐	49
Vertigo (head spinning)	1	2	V38	☐	50

If yes to any one of the above, how long has this problem continued?

For days	1
For months	2
For years	3

V39 ☐ 51

10. Have you had any ear operations?

None	1
One	2
Two	3
Three	4
Four	5
Five and more	6

V40 ☐ 52

If yes, specify the reason for ear operation?

____

11. History of injury to ears?

Yes	1
No	2

V41 ☐ 53

If yes, when and what happened?

____

12. Have you ever experienced a bleeding ear after scratching with foreign object

Yes	1
No	2

V42 ☐ 54

Appendix D: Information from medical records

1. Has patient previously suffered from or had treatment for the following?

	Yes	No			
Allergies e.g. hay fever	1	2	V43		55
Otitis media	1	2	V44		56
Diabetes	1	2	V45		57
Asthma	1	2	V46		58
Ear operations	1	2	V47		59
Ear trauma	1	2	V48		60
Tympanic membrane perforation	1	2	V49		61
Cold or flu	1	2	V50		62
Hearing loss	1	2	V51		63

2. Any current ear pathology noted by the medical staff?

	Yes	No			
Otitis media	1	2	V52		64
Ear trauma	1	2	V53		65
Tympanic membrane perforation	1	2	V54		66
Cold or flu	1	2	V55		67
Other outer and middle ear pathologies, please specify	1	2	V56		68

Appendix E: Recording form for otoscopic findings

(To be completed by Audiologist)

RIGHT EAR					
OUTER EAR (pinna/mastoid)	**YES**	**NO**			
Malformations, specify:	1	2	V57		69
Traces of scars	1	2	V58		70
Pinna tenderness	1	2	V59		71
Mastoid tenderness	1	2	V60		72
Growths, specify:	1	2	V61		73
EAR CANAL					
Foreign object in ear canal	1	2	V62		74
Bleeding	1	2	V63		75
Swelling	1	2	V64		76
Wax plug	1	2	V65		77
Otitis externa	1	2	V66		78
Red/irritated	1	2	V67		79
Scratching marks in ear canal	1	2	V68		80
Appear eczema-like	1	2	V69		81
Growths, specify	1	2	V70		82
Abnormal shape of canal, specify:	1	2	V71		83
TYMPANIC MEMBRANE					
Retracted	1	2	V72		84
Outward bulge	1	2	V73		85
Red	1	2	V74		86
Otitis media	1	2	V75		87
Discharge	1	2	V76		88
Fluid behind ear drum	1	2	V77		89
Perforation, specify (small/big)	1	2	V78		90
Light reflex absent	1	2	V79		91
Grommets in place	1	2	V80		92
Dull	1	2	V81		93
Infected	1	2	V82		94
Scar tissue on ear drum	1	2	V83		95
Air bubbles behind ear drum	1	2	V84		96

Blood behind ear drum	1	2	V85	97

Comments/Other:____

____

LEFT EAR				
OUTER EAR (pinna/mastoid)	**YES**	**NO**		
Malformations, specify:	1	2	V86	98
Traces of scars	1	2	V87	99
Pinna tenderness	1	2	V88	100
Mastoid tenderness	1	2	V89	101
Growths, specify:	1	2	V90	102
EAR CANAL				
Foreign object in ear canal	1	2	V91	103
Bleeding	1	2	V92	104
Swelling	1	2	V93	105
Wax plug	1	2	V94	106
Otitis externa	1	2	V95	107
Red/irritated	1	2	V96	108
Scratching marks in ear canal	1	2	V97	109
Appear eczema-like	1	2	V98	110
Growths, specify	1	2	V99	111
Abnormal shape of canal, specify:	1	2	V100	112
TYMPANIC MEMBRANE				
Retracted	1	2	V101	113
Outward bulge	1	2	V102	114
Red	1	2	V103	115
Otitis media	1	2	V104	116
Discharge	1	2	V105	117
Fluid behind ear drum	1	2	V106	118
Perforation, specify (small/big)	1	2	V107	119
Light reflex absent	1	2	V108	120
Grommets in place	1	2	V109	121
Dull	1	2	V110	122
Infected	1	2	V111	123
Scar tissue on ear drum	1	2	V112	124
Air bubbles behind ear drum	1	2	V113	125

Blood behind ear drum	1	2	V114		126

Comments/Other:____

____

Appendix F: Recording form for the findings of immittance testing

(Paste print-out from immittance test results on this page)

SECTION 1: TYMPANOMETRY

RIGHT EAR			
TYPE A NORMAL Compliance 0,3 cm^3 to 1,75 cm^3 Middle ear pressure –50 daPa to +50 daPa Ear canal volume 0.8 cm^3 to 2.0 cm^3	PASS	1	V115 [ ] 127
TYPE As STIFF MIDDLE EAR SYSTEM CONSISTENT WITH OTOSCLEROSIS Compliance <0,3 cm^3 Middle ear pressure –50 da Pa to +50 daPa Ear canal volume 0.8 cm^3 to 2.0 cm^3	REFER	2	
TYPE Ad FLACCID MIDDLE EAR SYSTEM CONSISTENT WITH EARDRUM FLACCIDITY/OSSICULAR DISARTICULATION Compliance >2,5 cm^3 Middle ear pressure –50 daPa to +50 daPa Ear canal volume 0.8 cm^3 to 2.0 cm^3	**REFER**	3	
Type B CONSISTENT WITH OTITIS MEDIA No Compliance Peak Middle ear pressure +200 daPa to -400 daPa Ear canal volume 0.8 cm^3 to 2.0 cm^3 CONSISTENT WITH PATENT EUSTACHIAN TUBES OR PERFORATED TYMPANIC MEMBRANE No compliance peak Middle ear pressure +200 daPa to -400 daPa Ear canal volume >2.0 cm^3 CONSISTENT WITH PATENT EUSTACHIAN TUBE OR PERFORATED TYMPANIC MEMBRANE No Compliance Peak Middle ear pressure +200 daPa to -400 daPa Ear canal volume <0.8 cm^3	**REFER**	4	
TYPE C CONSISTENT WITH EUSTACHIAN TUBE MALFUNCTION Compliance 0,3 cm^3 to 1,75 cm^3 Middle ear pressure -51 daPa to -400 daPa Ear canal volume 0.8 cm^3 to 2.0 cm^3	**REFER**	5	

VOLUME (Right ear) 0.8cm3 to 2.0cm3	**PASS**	1	V116		128
<0.8cm3 or >2.0cm3	**REFER**	2			

LEFT EAR					
TYPE A NORMAL Compliance 0,3 cm^3 to 1,75 cm^3 Middle ear pressure –50 daPa to +50 daPa Ear canal volume 0.8 cm^3 to 2.0 cm^3	**PASS**	1	V117		129
TYPE As STIFF MIDDLE EAR SYSTEM CONSISTENT WITH OTOSCLEROSIS Compliance <0,3 cm^3 Middle ear pressure –50 da Pa to +50 daPa Ear canal volume 0.8 cm^3 to 2.0 cm^3	**REFER**	2			
TYPE Ad FLACCID MIDDLE EAR SYSTEM CONSISTENT WITH EARDRUM FLACCIDITY/OSSICULAR DISARTICULATION Compliance >2,5 cm^3 Middle ear pressure –50 daPa to +50 daPa Ear canal volume 0.8 cm^3 to 2.0 cm^3	**REFER**	3			
Type B CONSISTENT WITH OTITIS MEDIA No Compliance Peak Middle ear pressure +200 daPa to -400 daPa Ear canal volume 0.8 cm^3 to 2.0 cm^3 CONSISTENT WITH PATENT EUSTACHIAN TUBES OR PERFORATED TYMPANIC MEMBRANE No compliance peak Middle ear pressure +200 daPa to -400 daPa Ear canal volume >2.0 cm^3 CONSISTENT WITH PATENT EUSTACHIAN TUBE OR PERFORATED TYMPANIC MEMBRANE No Compliance Peak Middle ear pressure +200 daPa to -400 daPa Ear canal volume <0.8 cm^3	**REFER**	4			
TYPE C CONSISTENT WITH EUSTACHIAN TUBE MALFUNCTION Compliance 0,3 cm^3 to 1,75 cm^3 Middle ear pressure -51 daPa to -400 daPa Ear canal volume 0.8 cm^3 to 2.0 cm^3	**REFER**	5			

VOLUME (Left ear) 0.8cm3 to 2.0cm3	**PASS**	1	V118		130
<0.8cm3 or >2.0cm3	**REFER**	2			

SECTION 2: ACOUSTIC REFLEXES

PURE TONE RESULTS IN RIGHT EAR Pure tone threshold in right ear at 500Hz	dB	V119		131-132
Pure tone threshold in right ear at 1000Hz	dB	V120		133-134
Pure tone threshold in right ear at 2000Hz	dB	V121		135-136
Pure tone threshold in right ear at 4000Hz	dB	V122		137-138

RIGHT EAR					
	YES	NO			
Ipsi-lateral acoustic reflex normal at 500Hz (70-90dB above PTT)	1	2	V123		139
Ipsi-lateral acoustic reflex absent at 500Hz (No Response)	3	4			
Ipsi-lateral acoustic reflex elevated at 500Hz (>90dB above PTT)	5	6			
Ipsi-lateral acoustic reflex recruitment at 500Hz (<70dB above PTT)	7	8			
Ipsi-lateral acoustic reflex normal at 1000Hz (70-90dB above PTT)	1	2	V124		140
Ipsi-lateral acoustic reflex absent at 1000Hz (No Response)	3	4			
Ipsi-lateral acoustic reflex elevated at 1000Hz (>90dB above PTT)	5	6			
Ipsi-lateral acoustic reflex recruitment at 1000Hz (<70dB above PTT)	7	8			

Ipsi-lateral acoustic reflex normal at 2000Hz (70-90dB above PTT)	1	2	V125		141
Ipsi-lateral acoustic reflex absent at 2000Hz (No Response)	3	4			
Ipsi-lateral acoustic reflex elevated at 2000Hz (>90dB above PTT)	5	6			
Ipsi-lateral acoustic reflex recruitment at 2000Hz (<70dB above PTT)	7	8			
Ipsi-lateral acoustic reflex normal at 4000Hz (70-90dB above PTT)	1	2	V126		142
Ipsi-lateral acoustic reflex absent at 4000Hz (No Response)	3	4			
Ipsi-lateral acoustic reflex elevated at 4000Hz (>90dB above PTT)	5	6			
Ipsi-lateral acoustic reflex recruitment at 4000Hz (<70dB above PTT)	7	8			

PURE TONE RESULTS IN LEFT EAR Pure tone threshold in left ear at 500Hz	dB	V127		143-144
Pure tone threshold in left ear at 1000Hz	dB	V128		145-146
Pure tone threshold in left ear at 2000Hz	dB	V129		147-148
Pure tone threshold in left ear at 4000Hz	dB	V130		149-150

LEFT EAR					
Ipsi-lateral acoustic reflex normal at 500Hz (70-90dB above PTT)	1	2	V131		151
Ipsi-lateral acoustic reflex absent at 500Hz (No Response)	3	4			
Ipsi-lateral acoustic reflex elevated at 500Hz (>90dB above PTT)	5	6			
Ipsi-lateral acoustic reflex recruitment at 500Hz (<70dB above PTT)	7	8			

Ipsi-lateral acoustic reflex normal at 1000Hz (70-90dB above PTT)	1	2	V132	152
Ipsi-lateral acoustic reflex absent at 1000Hz (No Response)	3	4		
Ipsi-lateral acoustic reflex elevated at 1000Hz (>90dB above PTT)	5	6		
Ipsi-lateral acoustic reflex recruitment at 1000Hz (<70dB above PTT)	7	8		
Ipsi-lateral acoustic reflex normal at 2000Hz (70-90dB above PTT)	1	2	V133	153
Ipsi-lateral acoustic reflex absent at 2000Hz (No Response)	3	4		
Ipsi-lateral acoustic reflex elevated at 2000Hz (>90dB above PTT)	5	6		
Ipsi-lateral acoustic reflex recruitment at 2000Hz (<70dB above PTT)	7	8		
Ipsi-lateral acoustic reflex normal at 4000Hz (70-90dB above PTT)	1	2	V134	154
Ipsi-lateral acoustic reflex absent at 4000Hz (No Response)	3	4		
Ipsi-lateral acoustic reflex elevated at 4000Hz (>90dB above PTT)	5	6		
Ipsi-lateral acoustic reflex recruitment at 4000Hz (<70dB above PTT)	7	8		

Appendix G: Medical staff participation consent form

Please read the following before answering any questions:

Phumlani Occupational Health Centre has agreed to co-operate with the SIMRAC research team and investigate specific tests for early identification of middle ear pathology before it becomes serious and causes problems. Results from the study will be useful in deciding whether modifications should be made to conventional testing procedures and improve early identification of middle ear problems, in order to improve workers' health and safety. The study have been approved by the Responsible Occupational Health Medical Practitioner on the basis that employees who agree to participate remain unanimous and the results will be used to help protect workers against middle ear pathology.

Please mark the chosen answer on the questionnaire form with a cross (**X**)

Your answers to questionnaire will be kept confidential, and only you and the research team will see them.

We will keep your name and information in strict confidence, and not tell the mine or the managers anything about you or your answers.

Will you help us with the research? (YES or NO)

NO ☐

YES ☐

I have been told about the study and I have been given the chance to ask questions about it and my participation. I also understand that if I have any questions at any time, they will be answered, and that if I am not satisfied with the answers I can withdraw from the study.

Name:………………………………………………Date:………………………………………..

Occupation:…………………………………

Appendix H: Questionnaire to medical staff

1. Who performs otoscopy?

Doctor	1
Nurse	2
Audiometrist	3

V1 ☐ 1

2. Do you perform an otoscopic examination during medical surveillance?

Always	1
Most of the times	2
Some of the times	3
Never	4

V2 ☐ 2

3. Which of the following symptoms do you look for in otoscopic examinations?

OUTER EAR (pinna/mastoid)				
	Yes	**No**		
Malformations	1	2	V3 ☐	3
Traces of scars	1	2	V4 ☐	4
Pinna tenderness	1	2	V5 ☐	5
Mastoid tenderness	1	2	V6 ☐	6
Growths, specify:	1	2	V7 ☐	7
EAR CANAL				
Foreign object in ear canal	1	2	V8 ☐	8
Grommet in ear canal	1	2	V9 ☐	9
Bleeding	1	2	V10 ☐	10
Swelling	1	2	V11 ☐	11
Growths	1	2	V12 ☐	12
Wax plug	1	2	V13 ☐	13
Excessive wax	1	2	V14 ☐	14
Abnormal shape of canal	1	2	V15 ☐	15
Infection in ear canal	1	2	V16 ☐	16
Red/irritated	1	2	V17 ☐	17
Scratching marks in ear canal	1	2	V18 ☐	18
Appear eczema-like	1	2	V19 ☐	19
EAR DRUM				
Retracted	1	2	V20 ☐	20

Outward bulge	1	2	V21		21
Red	1	2	V22		22
Middle ear infection	1	2	V23		23
Discharge	1	2	V24		24
Fluid behind ear drum	1	2	V25		25
Perforation	1	2	V26		26
Light reflex absent	1	2	V27		27
Grommets inplace	1	2	V28		28
Dull	1	2	V29		29
Infected	1	2	V30		30
Scar tissue on ear drum	1	2	V31		31
Air bubbles behind ear drum	1	2	V32		32
Blood behind ear drum	1	2	V33		33

4. Is middle ear barotrauma one of the following:

Middle ear pathology caused by trauma with foreign object	1
Middle ear pathology due to sudden changes in atmospheric pressure	2
Middle ear pathology due to bacterial infection	3

V34 [ ] 34

5. Do you counsel susceptible individuals to prevent barotrauma? If always/sometimes, specify:

Always	1
Sometimes	2
Never	3

V35 [ ] 35

6. Do you teach susceptible individuals techniques when going underground to prevent barotrauma?

Always	1
Sometimes	2
Never	3

V35 [ ] 35

7. Do patients go underground when middle ear pathology is present?

Always	1
Sometimes	2
Never	3

V36 [ ] 36

8. Your opinion on the following aspects:

8.1 Patients immediately report suspected ear infection to medical staff

Always	1	V37 ☐ 37
Sometimes	2	
Never	3	

8.2 Patients immediately report suspected eardrum perforations to medical staff

Always	1	V38 ☐ 38
Sometimes	2	
Never	3	

8.3 All patients receive treatment when middle ear pathology is diagnosed

Always	1	V39 ☐ 39
Sometimes	2	
Never	3	

8.4 Patients receive one or more follow-ups when medication is prescribed for middle ear pathology

Always	1	V40 ☐ 40
Sometimes	2	
Never	3	

8.5 Do you feel you've been sufficiently trained and informed about middle ear pathologies?

Yes	1	V41 ☐ 41
No	2	

8.5.1 If you answered NO to the previous question, please specify the type of information needed on middle ear pathologies?

____

____

Appendix I: Calibration certificate for audiometer

AUDIOMETRIC CALIBRATION
&
TRAINING SERVICES
P.O.BOX 526 ALBERTON 1450

FAX - (011) 867-1479
CELL - 082 959 4904

A.C.T.S

COMPANY: HARMONY PHUMLANI
AUDIOMETER TYPE: TREMETRICS RA-600
HEADSETS SERIAL: LEFT C57905
BOOTH TYPE: I.A.C

DATE: 29-Nov-02
SERIAL No: 981573 BOOTH 8
RIGHT: C57906
SERIAL No:

CALIBRATION CERTIFICATION IN ACCORDANCE WITH SABS 0154-1 / 1996 @ 70 dB HL

FREQUENCY RANGE (Hz)	FREQUENCY ACTUAL (Hz)	RANGE SPL (dB)	LEFT SPL (dB)	RIGHT SPL (dB)
242 - 258	250	94 - 100		
485 - 515	500	80.5 - 86.5	83.7	83.5
970 - 1030	1000	74.5 - 80.5	77.3	78.0
1940 - 2060	2000	76.0 - 82.0	79.0	79.0
2910 - 3090	3000	78.5 - 84.5	81.6	81.6
3880 - 4120	4000	79.0 - 85.0	82.0	82.1
5820 - 6180	6000	81.0 - 91.0	85.8	85.8
7760 - 8240	8000	80.5 - 90.5	85.0	85.6

BOOTH CALIBRATION CERTIFICATION S.A.B.S. 0182 / 1998

FREQUENCY (Hz)	SABS 0182 MAXIMUM SPL	ACTUAL SPL A (dB)	ACTUAL SPL B (dB)
125	52.0		36.4
250	38.5		30.8
500	22.0		20.0
1000	24.0		20.0
2000	31.0		20.0
4000	37.0		20.0
8000	35.5		20.0

ACTUAL A = SPL WITH FAN ON
ACTUAL B = SPL WITH FAN OFF
*EXCEEDS S.A.B.S. 0182/ 1998 VALUES

ATTENUATOR LINEARITY @ 4KHZ

dB HL	dB SPL	ACTUAL SPL (dB)
110	122.0	
105	117.0	
100	112.0	111.9
95	107.0	106.9
90	102.0	101.8
85	97.0	96.8
80	92.0	92.2
75	87.0	87.1
70	82.0	82.1
65	77.0	77.0
60	72.0	72.1
55	67.0	67.2
50	62.0	62.1
45	57.0	57.0
40	52.0	52.2
35	47.0	47.3
30	42.0	42.3
25	37.0	37.2

BACKGROUND NOISE AT 4KHz: 20.00

EQUIPMENT	MODEL	SERIAL NUMBER	EQUIPMENT CALIBRATION
SOUND LEVEL METER	TYPE 1 CEL 414	3/0733046C	MAY 2002
OCTAVE BAND FILTER	CEL 296	3/0163964	MAY 2002
CALIBRATOR	CEL 284/4	11310746	MAY 2002
ARTIFICIAL EAR	BRUEL & KJAER, TYPE 4153	1329113	MAY 2002
PRESSURE MICROPHONE	CEL 186/3 R	0254	MAY 2002
FREE FIELD MICROPHONE	CEL 192/2 R	0139	MAY 2002
FREQUENCY ANALYSER	MAJORTECH MT-879	9706044562	MAY 2002

This certificate of calibration is valid for a period of one year from the date of calibration, subject to the exceptions below:

a) movement of the audiometer and/or its headsets from the calibrated site by road, rail or air;
b) misuse or negligent handling of the audiometer or its headsets;
c) repairs to the audiometer, including the replacement of the headsets.

Signature Of Calibration Official

CERTIFICATE NO: 1413

Appendix J: Calibration certificate for tympanometer

Certificate of Calibration

This is to certify that on AUGUST, 30 2002

GSI 38V2 AUTO TYMP

Serial Number : 989057

was calibrated by NS Clinical Technologies (Pty) Ltd.

The above instrument complies with:

- ☑ IEC 1027 : Instruments for the measurement of Aural acoustic Impedance / Admittance
- ☑ IEC 601 – 1 : Safety of Medical Electric Equipment

Calibration Officer: W. DE KLERK Signature: