

1. INTRODUCTION AND LITERATURE REVIEW

1.1 Noise and Noise Induced Hearing Loss

The South African Department of Minerals and Energy (2000) has defined noise as “sound that is deemed undesirable, either because it annoys, distracts or interferes with those hearing it, or because it has the potential to damage the hearing mechanism and cause hearing loss for those exposed to it”. This is a definition that is similar to the ordinary man’s common understanding of the word ‘noise’, but in addition it also encompasses the concept of the potential damaging effects of noise exposure. The damage that results from such excessive (harmful) noise is manifest as Noise Induced Hearing Loss (NIHL), which is the ‘disease’ of interest in this study.

Rand Mutual Assurance Limited (RMA – NIHL Synopses, 2004) provides an objective definition of excessive noise as follows:

- Noise which exceeds the maximum laid down by SABS 083 Standard of 1983.
- Noise exceeding 85dB (Average)
- Noise Exceeding N85 Noise Rating Curve.

Noise Induced Hearing Loss is therefore a term that refers to some acquired loss of hearing due to damage of the middle ear, as a result of exposure to excessive noise. It is also referred to as Noise Induced Hearing Impairment due to the fact that it results in some level of impairment of the natural ability to perceive the sound stimulus across a spectrum of frequencies that comprise the normal hearing-range for humans. In its 1997 report on Prevention of Deafness and Hearing Impairment the World Health Organization (WHO-PDH, 1997) listed as one of the key points that “Noise Induced Hearing Loss is an important public health priority because, as populations live longer and industrialization spreads, NIHL will add substantially to the global burden of disability”.

1.2 The Global and National profile of NIHL

NIHL is therefore a worldwide problem and has been recognized as such by the World Health Organization (WHO). As a result of this concern WHO has adopted the ‘Program for Prevention of Deafness and Hearing Impairment (PDH)’. One of the resolutions that was passed by WHO-PDH acknowledged the worldwide estimated prevalence of disabling hearing difficulty to be around 120 million. In that resolution WHO has urged member states to set up National Programs for prevention of deafness. Each National Program must set an integrated strategy using the WHO guidelines but taking into consideration the local objective conditions. The WHO-PDH also concluded that NIHL is the most prevalent irreversible industrial disease and the biggest compensable occupational disease. With more than 800 000 people employed in the late 1980s (Begley, 2003) the South African mining industry has always been the biggest single employer outside of government. It is widely known that NIHL occurs commonly in the mining industry because of widespread use of noisy machinery; also due to the fact that a major portion of the work in this industry is done in confined spaces such as the underground

reverberant workplaces together with treatment and refining plants that are often enclosed for security reasons.

The significance of NIHL in the South African mining industry can be demonstrated by the fact that one of the mining houses, Harmony (2004), submitted 799 Hearing claims for compensation during their 2004 financial year. Of these 490 were compensated. This is out of a total workforce of 53 000. Therefore 1.5 out of every 100 of their total number of employees were submitted for compensation and more than 60 percent of these were paid out. Another mining house, De Beers (2002), reported that NIHL was the single biggest occupational disease in their workforce. It is not surprising therefore that NIHL is now regarded as a high profile problem in the South African mining industry. The response of the government has been a quick succession of legislative controls that have been introduced recently.

1.3 SA government interventions

The South African Department of Minerals and Energy (DME) has made NIHL a priority in the mining industry. The promulgation of the Compensation for Occupational Injuries and Diseases Act (1993), also known as the COID Act, has enabled the subsequent regulation of NIHL through Instruction-171 **(2001)**. This regulation is currently in force in the mining industry. It simplifies the compensation mechanism related to NIHL and it is widely believed to bring fairness for workers who have acquired NIHL in the course of performing their work. According to Instruction-171 high-risk employees must have had a baseline audiogram test at the commencement of their employment, or at least by November 2003 if they were already employed by that date.

After November 2003 all employees with a Percentage Hearing Loss (PHL) amounting to a ten percent shift from baseline (or more) will have to undergo a diagnostic audiogram and a formal application for a compensation claim (on the basis of the COID Act) must be submitted. On top of this, all those that were found to have already lost ten percent of their normal hearing at the time of their baseline audiogram test must automatically be submitted for compensation, even without having to wait for any further shift of their PHL. This is expected to increase the number of claims and resultant payouts in the next couple of years. In 2001 the proportion of claims for hearing loss in the mining industry was 14 percent of all claims (SIMRAC 2001).

The overall effect of instruction-171 is that it punishes employers who allow the hearing ability of employees to deteriorate due to noise exposure while in their employ. This is achieved through financial liabilities relating to the compensation procedure, together with other sanctions that the DME may deem appropriate for non-compliant employers. The regulation must therefore be seen as part of an integrated strategy by the national government to fall in line with the WHO-PDH resolutions.

This integrated strategy has been complemented by the publishing of the DME's Hearing Conservation Guidelines **(2000)**. These are used by the different mining operations across the country to benchmark their in-house Hearing Conservation Programs. More recently the Inspector of Mines, which is a directorate within the DME, has published the DME's Code of Practice for an Occupational Health Program for Noise **(2003)**. Therefore through legislation,

regulations and guidelines a comprehensive framework for preventing NIHL has been developed by the South African government.

1.4 The response of the SA Mining Industry

The S.A. mining industry introduced Hearing Conservation Programs (HCP) in **1988** (COMRO User Guide No. 11). This was a voluntary and proactive initiative from the industry itself, through the Chamber of Mines, and it shows that as far back as 1988 the industry had already identified NIHL as a priority problem. The concern shown by the mining industry was due to recognition of the fact that labor-intensive methods, common to many mineral extraction and processing operations, were resulting in large numbers of people being routinely exposed to noise beyond the recognized safe limit. The generally acceptable standard regulation for safe limit in most countries is an average of 85 dB time-weighted over 8 hours, which is the standard normal working day. According to SIMRAC this is the maximum safe limit for the South African mining industry. It is also used as the reference value for maximum noise exposure in the DME's Code of Practice **(2000)**.

As further proof of the Mining industry's commitment to deal with the effects of noise hazard on their employees, MOHAC (which is a tripartite advisory body comprising employers' representatives, workers' representatives and government representatives) has adopted a set of milestones that are ultimately meant to eliminate NIHL in the workplace.

- After December 2008 the hearing conservation programs implemented by industry must ensure that there is no deterioration in hearing greater than 10% amongst occupationally exposed individuals.
- By December 2013 the total noise emitted by all equipment installed in any workplace must not exceed a sound pressure level of 110 dB (A) at any location in that workplace.

The milestones themselves are targeted at the various health and safety problems that are deemed to be a high priority by the industry. Therefore they include elimination of: Injuries & Fatalities, Silicosis and of course NIHL.

Subsequent to the 1988 Chamber of Mines Guidelines the HCP has been enforced by law through the Mine Health and Safety Act **(1995 chapters 9 & 11)**. This law was further regulated through the DME's Hearing Conservation Guidelines (2000). The application of these guidelines has been summarized by SIMRAC (2001, 197 – 211) and simplified into six elements as follows:

1. Risk assessment and occupational hygiene (OH) monitoring.
2. Education, motivation and training.
3. Noise control engineering
4. Administrative control measures
5. Personal protection
6. Medical surveillance that includes audiometry

Risk assessment and occupational hygiene (OH) monitoring for the noise hazard should follow a rational sampling strategy. There should be zoning of the work areas according their noise

levels. Noise levels are always expressed as a time-weighted average (TWA) calculated over eight hours, which is the normal daily shift for workers. SIMRAC (2001, 199) provides a practical classification, according to noise exposure levels, that must be used for noise-risk zoning of work areas (see Table 1.4a).

Table 1.4a: A summary of Noise-zoning of work areas and appropriate interventions

TWA(dB)	Exposure classification according to:	
	OH Regs	Risk factor (n), with significance of risk & required action
<82	-	0: Insignificant risk of NIHL. No action required
83-85	C	1: Potential risk of NIHL. OH monitoring of exposure levels
86-90	B	2: Moderate risk of NIHL. OH monitoring of exposure levels
91-95	B	3: Significant risk. Priority intervention and re-evaluation of risk
96-105	B	4: Unacceptable risk. Immediate intervention and re-evaluation of risk
>106	A	5: Extreme risk. Urgent intervention and ongoing re-evaluation of risk

Reproduced from SIMRAC (2001, pp199)

The other key aspect of occupational hygiene monitoring is the use of personal noise dosimetry. Dosimetry refers to the use of a noise-measuring device (called dosimeter) that is carried on the person who is being sampled for noise exposure. It gives an accurate and reliable measurement of exposure, since the worker carries it through the different noise zones that he would normally have to pass through during his normal working day. For reliability of this device there is a recommended calibration procedure that is based on an SABS standard (SABS 0259: 1990).

Education, motivation and training is the obligation of the employer if a significant risk exists. This element is a fundamental aspect to the success of the HCP. There are two areas of focus that must be addressed in training. The first one is to instill awareness of the noise hazard. The second one is to inform them and also give them a positive image of the risk control measures that are in place such as the use of protective equipment and undergoing routine medical surveillance. In this way you also empower them to be vigilant so as to recognize any risk that they could become exposed to during the course of their work. Therefore the employer creates an additional but powerful policing mechanism of the Risk Management procedure. In practical terms the training must start at induction and continue throughout the employee's stay in the company. It must also be targeted at all employees and at all levels; not just those who are routinely exposed to noise.

The next three elements are: noise control engineering, administrative measures and personal protection. The DME guidelines (2000) instruct that this is the order in which they should be prioritized in the implementation of HCP. The rationale is that in the first instance you must try to remove the source of noise i.e. noisy machinery. If that fails you then remove the worker from the noise. If that also fails then you try to stop the hazard from reaching the worker by protecting him with personal protective equipment (PPE) such as ear muffs, ear plugs, etc.

Noise control engineering means that the employer must change his machinery to that which emits safe levels of noise, preferably below 85dB. The practical problem of this requirement is that replacing equipment before the end of its intended lifespan is often expensive and is often not a viable option. The other problem is that even when some of the machines have reached the end of their lifespan the new and quieter options of replacement machinery are usually more expensive to buy but still not quiet enough to eliminate the risk i.e. the equipment is often less noisy but still carries the risk.

Administrative controls refer to those measures that can be used reduce the time that is spent by a given worker in the high noise areas. This could mean a carefully controlled rotation of the work schedules aimed at reducing the time that each worker spends in the high noise areas. In complex organizations that have big workforces arranging effective administrative controls impose an additional administrative burden, such as more paperwork and work scheduling exercises. It is common knowledge that engineering controls and administrative control are not often taken as priorities by most industries, such as the mining. The additional resources required to implement these measures are seen as a burden. Therefore PPE is the most widely used intervention.

According to the DME guidelines PPE should be regarded as a last resort that is available for use when engineering and administrative measures fail. Its intended role is to supplement the other risk control elements rather than being used as the primary control measure. However the ease with which this particular intervention can be implemented has made it the most widely used.

The last element of a HCP is medical surveillance and audiometry. Audiometry is the clinical measurement that is used to assess the impact of noise on the workers' hearing and therefore to evaluate the impact of all the measures aimed at controlling NIHL. Because it measures the outcome, i.e. the hearing ability of individual workers, it is therefore the key to the monitoring program since it is the ultimate indicator of HCP effectiveness.

An instrument called 'audiometer' is used to measure Pure-tone Air Conduction Threshold Hearing in decibels (dB) at seven different frequencies. It gives a binaural (both ears) measurement. The seven measured frequencies (in ascending order) are 0,5 kHz 1 kHz 2 kHz 3 kHz 4 kHz 6 kHz 8 kHz. This combination of frequencies makes up the SABS conventional standard (1998) for audiometric screening in South Africa. Audiometric testing is therefore the most widely used form of pre-employment screening for hearing ability in the South African mining industry. It is a specific measuring instrument. It is also a reliable and sensitive instrument in trained and experienced hands. SIMRAC (2000. pp 206) provides the minimum qualification that must be held by personnel conducting audiometric tests. It must be a person

registered with the Health Professions Council of South Africa as an audiometrist or hearing acoustician, or holding a certificate in audiometry issued by an institution recognized and approved by the DME.

Medical surveillance has a legal basis since MHSA and Occupational Hygiene Regulations contained in the DME guidelines (2003) oblige the employer to implement a mandatory code of practice and occupational hygiene monitoring. Section 13(1) of the MHSA requires the employer to establish and maintain an appropriate system of medical surveillance. According to the act the medical surveillance programs should be designed to provide the employer with information that enables the elimination, control or minimization of the hazard and associated risk. There is a requirement therefore for linkages to be established between the results of noise exposure determinations and records of medical surveillance. There is also a need for physical medical examination of individual employees that must include an otoscopic examination, but the principal criterion for assessing hearing status is the percentage loss of hearing (PLH), which is determined by the audiogram.

The audiogram is the report that is produced by the audiometer. Employers are only required to monitor hearing with a screening audiogram and this is contained in Instruction-171 (2001), a regulation of the COID Act (1993). The instruction further spells out the criteria for submission of compensation claims for eligible workers, as discussed earlier. The procedure requires that the workers whose screening audiograms make them eligible for submission must have a diagnostic audiogram performed by a qualified audiologist. This serves to confirm the results of the screening test and once confirmed a claim must be submitted to either the Compensation Commissioner or Rand Mutual Assurance Limited. Rand Mutual has historically handled most compensation claims relating to employees of the various Mining Houses for more than 100 years.

1.5 Compensation Claims

There are two acts of parliament that govern the handling and payment of compensation claims in South Africa.

- Compensation for Occupational Injuries & Diseases Act (COID Act, 1993). This is administered by the Department of Labour and it governs the compensation procedure for injuries and diseases in all industries.
- Occupational Diseases in Mines and Works Act (ODMWA, 1973). This is administered by the Department of Health and it covers a defined list of occupational diseases in the mining industry.

The compensation setup in S A is such that claims for compensation under the COID Act are handled by three main bodies, the Compensation Commissioner (a government agency) and two semi-independent mutual agencies (semi-independent because they work under licensing from the Compensation Commissioner). The Compensation Commissioner handles all occupational diseases from all industries except those from the mining and construction industries. Claims for these two industries mainly go to the two mutual agencies. Federated Employers Mutual has traditionally dealt with construction Industry claims while Rand Mutual has dealt with Mining Industry claims since 1893.

The proportion of work handled by Rand Mutual Assurance (RMA) out of the total population employed in the mining industry in 2003 was 345 000 out of 403 000. This means that the total population employed in the formal mining sector was 403 000 and of these 345 000 or 86% were insured with Rand Mutual (Begley, 2003). This means that Rand Mutual's statistics on occupational diseases and injuries are a fairly accurate reflection of the total mining industry's overall situation. According to RMA 2003 report (Begley, 2003) NIHL & acoustic trauma was the 2nd most common of all diseases and injuries with a total of 7 241 claims and R52,2 million in total claims paid out. By comparison the most frequent claims were those of injuries of the wrist and hand, which amounted to 10 648 claims with a total value of R18,5. These figures seem to justify the high profile that been given to NIHL by the mining industry in recent years.

Rand Mutual Assurance Limited (RMA, 2004) has defined Noise Induced Hearing Impairment as: The cumulative permanent loss of hearing exceeding a designated criterion i.e. 25dB, ISO standard averaged from the threshold level at 500, 1000, 2000, 3000Hz, always of the sensori-neural type which develops over months or years of hazardous noise exposure. The frequencies that are specified in this definition form part of seven frequencies that are routinely measured in a screening audiogram.

RMA always compare the audiograms that are submitted for compensation claims with that particular subject's baseline audiogram. Instruction – 171 compels employers of workers who are at risk, e.g. in mining industry, to do a baseline. Therefore a baseline audiogram is the key to assessment of compensation claims. The criteria for submission of claims (RMA, NIHL Gazette. 2004) are as follows:

- Employees whose PLH has deteriorated by more than 10% PHL from the baseline audiogram; or
- Employees who have more than 10% PHL and for whom no baseline is available

The claim must be accompanied by other supporting documentation that is used to assist in the assessment of the claim. This is aimed at proving that industrial noise is the most likely cause of the disease for the claim that is being submitted. The supporting documentation must include:

1. The claimant's service record
2. Occupational hygiene measurements proving that he worked in a high noise environment.
3. Medical opinion from the examining occupational medical practitioner or ENT-specialist. This should also comment on any ear pathology that may be present.
4. Two diagnostic audiograms that were conducted by a suitably qualified audiologist as specified in the DME code of practice (2003).
5. A copy of the baseline audiogram and the calculated PLH, if available.

In a telephonic conversation on 16 April 2005, Arthur Begley who is the medical director of RMA said "it is critical to distinguish between permanent NIHL and Temporary Threshold Shift (TTS) when assessing a claim". This refers to a reversible shift (deterioration) of hearing

ability that normally occurs soon after a person has been exposed to hazardous noise. Since RMA have defined NIHL as ‘cumulative permanent loss of hearing’ the concept of TTS must feature prominently in their assessment of claims for NIHL because they have to recognize it as one of the exclusions.

1.6 Temporary Threshold Shift

According to Cummings et al (1998) the immediate phenomenon which occurs when a sound is presented to the ear is that of somewhat elevating the threshold. Recovery is exponential with the shift from sounds up to 70 dB recovering fully within 0.5 of a second. This is called adaptation and it is the normal physiological response to sound stimulus. Different individuals have significant individual variations in the amount and length of adaptation. Cummings et al go to say that with increasing intensity and duration of sound (noise) the ear goes on to the phenomenon of physiological fatigue.

Physiological fatigue is synonymous with Temporary Threshold Shift. This is collaborated by the WHO report (WHO-PDH 1997, p11) which states that “above a certain minimum of frequency and intensity, the outer hair cells show signs of metabolic exhaustion with drooping of stereocilia. This correlates with the common phenomenon of temporary threshold shift, which recovers within a few hours.... even higher levels of sound lead to the collapse of the outer hair cell stereocilia, and the hair cell is eventually phagocytosed”. This statement also brings into focus the fact that it is the outer cells rather than the inner cells that get damaged in TTS, and eventually in NIHL. Cummings et al also state that in physiological fatigue, unlike the case with adaptation, recovery is slow and related to degree of fatigue. It lasts longer than two minutes with complete recovery in less than 16 hours. Shift is usually 30 dB or less.

An example of this phenomenon was demonstrated by Nassar (2001) in a study he conducted on an aerobic class in Manchester. In this study members of an aerobic class were exposed to noise of approximately 91dB for 60 minutes. Their pure tone threshold hearing was measured just before the exposure and repeated within 2 minutes of stopping the exposure. Members of the exposed group (unlike members of the control group) all showed significant TTS at all frequencies except at 1000 HZ.

A more severe form of TTS is pathological fatigue, which is also called long lasting fatigue. Here there is no complete recovery within 16 hours and the cut-off threshold shift is approximately 40dB, according to Cummings et al. This is a pathological phenomenon that is indicative of damage at cellular level and it is a precursor to Permanent Threshold Shift (PTS). PTS has a spectrum and in its more severe forms it is synonymous with NIHL. The less severe forms of PTS are more important to recognize because there are still opportunities for interventions that could prevent NIHL.

Concha-Barrientos et al (2004) state that “threshold shift is a precursor to NIHL, the main outcome of occupational noise Because hearing impairment is usually gradual, the affected worker will not notice changes in hearing ability until a large threshold shift has occurred”.

In Permanent Threshold Shift, therefore, there is an irreversible elevation of the auditory threshold with associated permanent pathological cochlea changes. This is another way of describing NIHL. It is common knowledge that the risk of injury and hearing loss increases with:

- Noise intensity
- Duration
- Number of exposures
- Individual susceptibility

These exacerbating factors are especially true for steady-state noise; which is the typical type of noise found in industrial settings such as mining. This is because in industrial settings the source of noise is machinery that generates noise by repetitive mechanical displacement of its components, which in turn generates energy that is transmitted to surrounding air. When this energy is transmitted through the air at frequencies below 20Hz it is perceived as vibration, according to SIMRAC (2001. pp 195). If the propagation frequency is 20Hz – 20 000Hz this energy is perceptible via the hearing sense as sound. Sound is regarded as noise if it has the potential to damage people's hearing. This is how the steady-state noise is generated, causing hazardous industrial noise.

1.7 Impact Noise versus Steady State Noise

The other form of noise is impact-noise and this typically occurs with activities such as blasting and gunshots. When these activities take place in industrial settings there is generally prior knowledge and proactive protective interventions. As a result, impact-noise is generally not a characteristic form of noise damage in industries such as mining. The damage that is caused by exposure to this type noise is however not of insidious onset and it may affect one ear more than the other. Therefore the typical characteristics of industrial NIHL, i.e. insidious onset and binaural nature (both ears), are often not seen in impact noise damage.

1.8 Consequences of NIHL

Concha-Barriento et al (2004) go on to list the possible consequences of NIHL, regardless of whether it is due to steady state noise or impact noise:

- Social isolation
- Impaired communication with co-workers and family
- Decreased ability to monitor the work environment (warning signals, equipment sounds)
- Increased injuries from impaired communication and isolation
- Anxiety, irritability, decreased self esteem
- Lost productivity
- Expenses for workers' compensation and hearing aids.

This list of consequences is collaborated by the US - National Institute for Occupational Safety and Health (NIOSH, 2001). These consequences are serious and this further strengthens the importance of this disease, and the ethical imperative to try and prevent it.

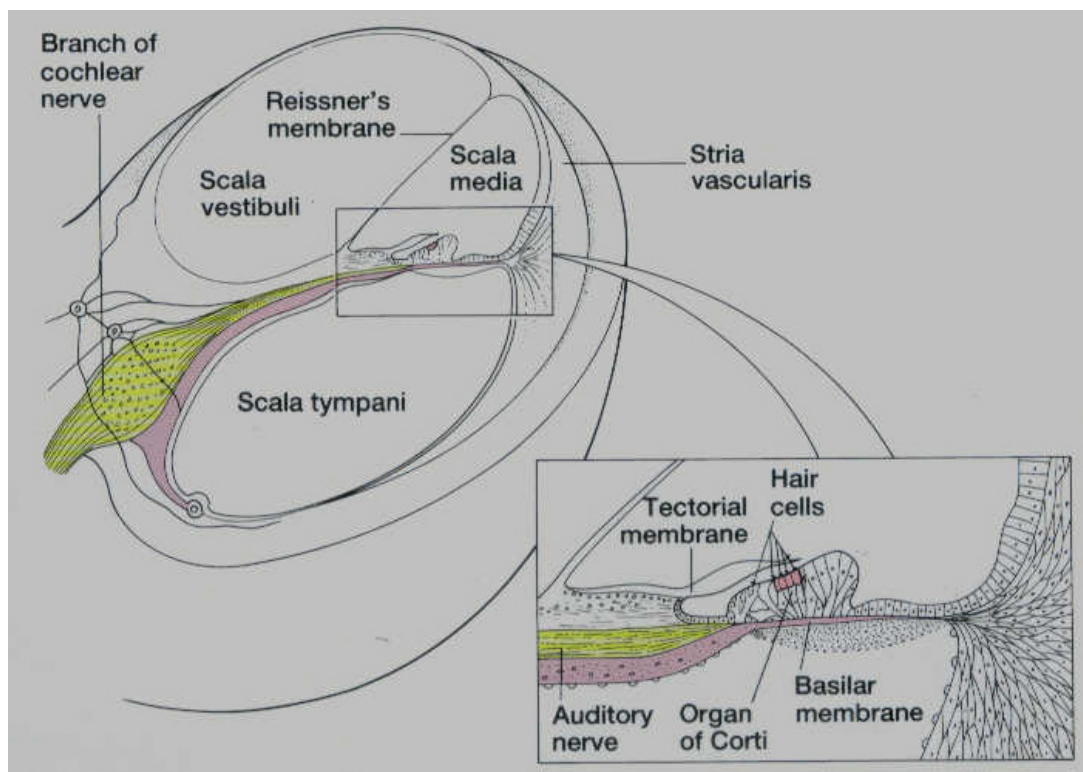
1.9 Changes at cellular level

The potential of NIHL to disrupt ordinary lives also justifies the research and other efforts that have been made in the last 20 years to try and understand it, with the ultimate goal of protecting the workers from getting this disease. It is appropriate therefore to look briefly at the sequence of events at cellular level that can lead to the development of Noise Induced Hearing Loss. Cummings et al list the correlates of NIHL (at cellular level) in the following order:

- Hair cell injury
- Cochlear vascular supply
- Auditory nerve and CNS changes
- Physiological changes
- Permanent changes

Figure 1.8a shows a schematic representation of the anatomy of the ear. It shows the anatomical relation of the hair cells to other vital tissues that are involved in the hearing mechanism.

Figure 1.8a: Cross sectional view of the cochlear in the middle ear

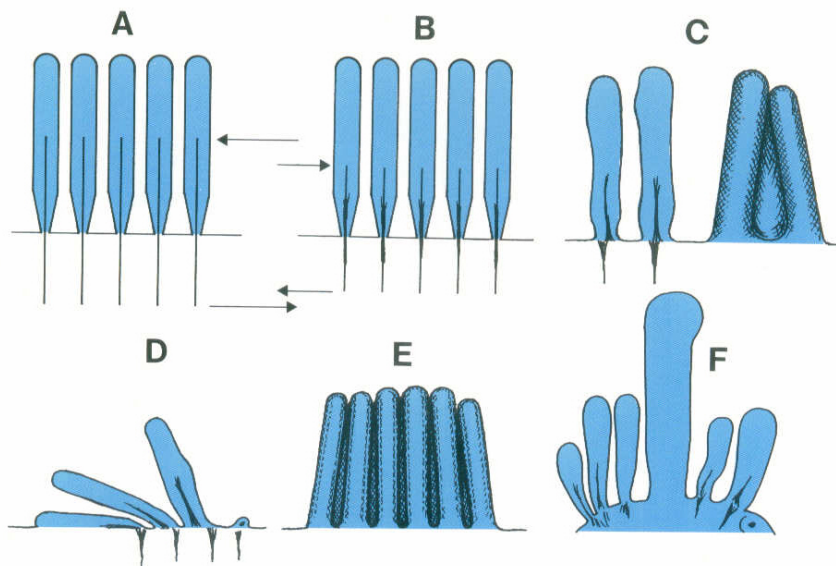


Copied from Cummings et al (3rd Edition, 1998)

In a lecture delivered to Diploma in Occupational Health students (April, 2004), McCulloch says the most significant change in the middle ear, during the progressive development of NIHL, is the damage of hair cells. Normal healthy hair cells are necessary for receiving sound impulses that are transmitted to the brain via the auditory nerve. Sound stimulus causes mechanical movement of the basilar membrane due to the acoustic resonance of this membrane resulting from the presence of sound waves in the middle ear. This will result in a 'brushing' effect on the hair cells due to the fact that they are anatomically located in close proximity to the tectorial membrane (see diagram). In this way the hair cells are stimulated so as to cause intracellular changes that result in an action potential of the adjoining auditory nerve. This is the normal mechanism by which the human ear perceives sound and it relies on a good supply of blood to all the structures involved.

The authors of the WHO-PDH (1997) report write that "the hair cells in the organ of Corti may be damaged directly by noise, or indirectly by very high levels of continuous sound which causes vasoconstriction of the vessels of the stria vascularis in the cochlea blood supply. This renders the hair cells relatively anoxic and thus secondarily damaged". This highlights the role of vascular factors in the pathogenesis of this disease. The nature of progressive damage that occurs is shown in figure 1.8b.

Figure 1.8b: Schematic representation of progressive damage that occurs in the hair cells due to the noise hazard.



Copied from Cummings et al (1998).

- A. Normal
- B. Shortening of central core
- C. Disorganized central filaments
- D. Shortening of core and rootlet
- E. Hair cell fusion
- F. Modified cell

The modified cells are phagocytosed and this leads to permanent impairment. The extent of impairment depends on the number of hair cells affected.

1.10 Clinical measurement for NIHL

In the USA the two bodies that set the standards for all matters related to occupational health are the Occupational Safety and Health Administration (OSHA) and National Institute for Occupational Safety and Health (NIOSH). OSHA is a government department under the Federal Government's Department of Labor. NIOSH is a specialized statutory body that researches, monitors and regulates on occupational health matters in the USA.

The OSHA's definition of the clinical measurement for the earliest changes of NIHL is "an average change in hearing from baseline levels of 10dB or more at frequencies of 2000, 3000 and 4000Hz". They call this the 'Standard Threshold Shift' (OSHA – STS, 1910.95), and they further spell out the standard procedure to be followed when it is detected in facilities that operate under US law.

The NIOSH on the other hand uses a different standard. They use the term Significant Threshold Shift (NIOSH – STS, 1999) for their clinical measurement of the earliest permanent changes. They define it as "a change of 15dB or more at any frequency from 500 through to 6000Hz from baseline levels that is present on an immediate retest in the same ear and at the same frequency". If this is positive they recommend another test within 30 days, which must be preceded by a quiet period of 14 hours.

Some research workers have described the very early changes that are manifest on pure-tone audiometric results. Studies conducted by McBride and Williams (2001) in England and Wales showed that the first sign was a dip or notch in the audiogram maximal at 4kHz with a recovery at 6 and 8 kHz. They go on to say that the notch broadens with increasing exposure, and may eventually be indistinguishable from changes of aging (prebycusis), where the hearing shows a gradual deterioration at the high frequencies.

The audiometric changes of prebycusis itself are described by Coles et al (2000). They describe the audiometric configuration of prebycusis as being similar to that of NIHL but without the recovery at 6 and 8 kHz. Typically this manifests as a high-frequency down-slope rather than the notch that is seen in NIHL (see appendix 2). The affected frequencies are more or less similar to those of NIHL.

McBride and Williams (2001) also describe how the earliest audiometric changes of NIHL occur within 2-5 years. These are the earliest detectable changes that do not result in functional impairment. According to these researchers a detectable non-reversible threshold shift at 4000Hz occurs as early as 2-5 years after initial exposure.

Coles et al also talk of the smallest hearing loss that can be measured in an individual with a reasonable degree of reliability. According to them this is considered to be 10 dB at 4 kHz. They go on to state the exact requirements to meet the definition of high frequency sensori

neural hearing impairment. Their view is that “it is when a single measurement of hearing threshold level (HTL) at 3, 4 or 6kHz, after any due correction for earphone type, is at least 10 dB greater than the HTL at 1 kHz or 2 kHz. This requirement essentially brings about the ‘notch’ that is seen on the audiogram”. It is worth noting that the criteria that are advanced by Coles et al have the stated objective of providing expert guidance for the British medico-legal establishment. An example of an audiogram that demonstrates the criteria advanced by Coles et al is provided in appendix 3. These criteria that were advanced by Coles et al are the exact same diagnostic criteria that have been used to define ‘disease’ for the purpose of this research project.

In summary, the criteria that are used to define ‘disease’ in this study are not in accordance with any publicly recommended method for South African standards.

But we will use the definition of ‘disease’ as advanced by Coles et al. The rationale for using this method is that it is fairly sensitive and it does have scientific basis, as argued elsewhere in this report.

It is also worth noting that this definition of the ‘earliest’ changes of NIHL overlaps with the OSHA definition of Standard Threshold Shift that was discussed earlier, even though the exact frequencies under consideration differ slightly. By comparison the OSHA definition of the earliest changes “is an average change in hearing from baseline levels of 10dB or more for the frequencies of 2000, 3000 and 4000 Hz”. Therefore they have included 2000 Hz and excluded 6000 Hz in what would otherwise be a similar definition.

In the same telephone conversation, of 16 April 2005, with Arthur Begley he also stated that the audiometric ‘notch’ at 4000Hz is a typical characteristic of NIHL, which weighs significantly in their assessment of claims. He goes on to say that even though it is not pathognomonic of NIHL, the presence of the notch at 4000Hz in an audiogram is such a strong association that one must consider NIHL to be at least one of the problems that are present in that particular worker’s audiogram. Therefore in the assessment of claims for NIHL, RMA look at the shift in Percentage Loss of Hearing (PLH) from baseline together with the presence of the audiometric notch at 4000Hz.

The scientific basis of the notch is that NIHL first affects the higher frequencies range of 3 KHz to 6 KHz. Only later and in more advanced forms does the loss of hearing spread to other (lower) frequencies. The dip or notch that appears on the audiogram is in fact just a manifestation of the downward shift in hearing ability that has already occurred in these higher frequencies.

The audiometric notch is therefore a typical feature of noise in NIHL and if present can be identified in the graphic presentation of pure-tone threshold pattern (see appendix 1). There is no universal agreement on the exact features of the audiometric notch. According to McBride (2001) “The main problem seems to be that there is no standard definition of an audiometric notch, so people tend to develop their own criteria”.

As a result, some researchers such as Mostafapour et al (1998) use consensus of three competent observers as a criteria for determining the presence or absence of the notch. These researchers measure the depth of the notch from the low frequency side of the graph. They also measure the exact frequency at the bottom of the notch to determine the exact expression of the notch i.e. 3, 4 or 6 KHz notch.

There is general consensus to the fact that the notch occurs typically at the 4 KHz frequency. McBride and Williams (2001) contend that when it occurs at 6 KHz, the notch is variable and of limited importance. They write: “the notch at 4 KHz is a well established clinical sign and may be valuable in confirming the diagnosis, the 6 KHz notch is variable and of limited importance”. Their view therefore is that the notch is only significant when it appears at 4 KHz. In his review article Touma (1992) also states that “the 4KHz notch is an important diagnostic sign of early NIHL”.

However, while agreeing that it occurs typically at 4KHz, others such as Seidman (1999) also state that the notch is significant when it occurs anywhere in the higher frequencies (3KHz – 6KHz) and not just at 4KHz.

In their article, which was written for the purpose of clarifying diagnostic standards for the British legal setup, Coles et al (2000) contend that such a notch is not pathognomonic of NIHL. To balance this view they go on to state that likewise the absence of such a notch does not preclude the presence of some NIHL.

For the purposes of this study the presence of the notch was taken as a dip of at least 10 dB in one of the following frequencies: 3, 4 or 6 KHz. The dip is measured on the lower frequency side of the notch. As part of the criteria for defining the notch (in this study) there must be some recovery at the high frequency side of the notch, especially at 8 KHz. This definition is consistent with that provided by many others such as Coles et al (2000), McBride and Williams (2001) and by Mostafapour et al (1998).

1.11 Purpose & objectives

This study was conducted against the background of the Noise Induced Hearing Loss being the most prevalent occupational disease presenting for compensation (in South Africa) according to Rand Mutual statistics as discussed above. As a result the mining industry, including the diamond mine that is the subject of this study, has implemented various control measures that are aimed at preventing NIHL. One of the keys to the success of these Hearing Conservation Programs is effective evaluation of their outcomes. This would entail the establishment of early detection mechanisms that are both specific and sensitive.

Therefore the purpose of the study is to use these fairly sensitive criteria to establish whether any additional loss of hearing has occurred in those workers that have continuously worked in high noise exposure areas during the period: 1999 – 2004 (inclusive). The study will also look at the effect of age on these workers.

In summary, the objectives of the study are:

- To measure the 5-year cumulative incidence of NIHL in high-risk workers.
- To measure the 5-year overall incidence of NIHL in low-risk workers.
- To measure the relative risk of NIHL in groups with high exposure and low exposure.
- To evaluate the effect of age on NIHL in both exposure groups.

The purpose of this study, therefore, was to establish if there had been additional incidence of NIHL in the exposed workers during the observation period of 5 years between 1999 and 2004, using the former as the take-off point or baseline and the later as the cutoff point for the timeline of observations.

2. PILOT STUDY AND ETHICS

2.1 Pilot Study

Accessibility of records:

Fifteen files were chosen at random from the filing cabinets to check the clarity of medical surveillance records and the presence of other information such as medical and occupational history. The quality of these records was found to be of sufficient standard to make it possible to conduct this study. This means that the filing system was found to be properly organized and the recording of patient records therein allowed easy access to audiometric records for the period 1999 – 2004. This process also tested the accessibility of patient files and this was found to be good.

Audiometer Calibration checks:

A possible shortfall of audiometry is poor calibration. As a result, part of the function of a pilot study that preceded the main research project was to check the reliability and validity of calibration of the audiometer. The purpose of this was to address the perceived risk that would be posed by unreliable original data. Therefore records of annual calibration certificates by legally authorized inspectors, for the duration of the time-line of this study, were checked and found to be in order. The keeping of annual calibration records is a requirement of section 13 of MHSA (1995). The procedure that is followed in conducting these calibrations was found to be in accordance with SABS 0154: 1996.

There is an additional written procedure for weekly biological calibration checks. Records of these weekly biological checks were also inspected. Biological checks are conducted weekly on a chosen individual who is a member of staff (the audiometrist in this case) by other members of the occupational health team to monitor the consistency of the machine's results. The rationale is that the weekly audiometric test results for one individual should not change significantly unless there is a technical error with the equipment. This assurance measure is meant to detect the early signs of technical errors that might compromise the mine's quality of original occupational health data. These records were found to be in good order and all calibration procedures were found to comply with the Department of Minerals and Energy's Code of Practice (2003).

2.2 Ethics approval and Employer permission

Ethics clearance was obtained from Ethics Research Committee of the University of Witswatersrand. Permission to use company records for the purpose of this research was first cleared with the Group Chief Medical Officer via a telephone discussion and the final written approval was granted by the mine's Senior Human Resources Manager.

3. METHODS (including study design & diagnostic criteria)

3.1 Study Design

This is an incidence study due to the fact that all study subjects were regarded as disease free at the beginning of the time line. Acquisition of 'disease' for these subjects was regarded a threshold shift in the relevant frequencies (defined elsewhere in this document under the heading: diagnostic criteria). In this way the subjects became 'cases'. This shift was in comparison with that particular individual's baseline audiogram, using 1999 as the baseline take-off point.

The setting is a South African diamond mine that uses underground methods of ore extraction. It is a retrospective cohort study that was conducted by doing a record review of the mine's occupational health records. It is the ideal study-design for medical conditions that may have a long latency period e.g. NIHL. In this type of study the problem of loss to follow-up, which can undermine prospective cohort studies, is easier to assess, quantify and control.

Stratification into high and low 'Time Weighted Average' noise exposure groups was done, based on the measurements used by the Occupational Hygiene Section (OHS) of the mine. OHS zone the various working areas according to noise risk assessment, based on the Department of Minerals and Energy guidelines (2003). Their procedure uses ISO 9612 (1997) in order to comply with these guidelines. The low risk group was used as the control group.

3.2 Methods

This is an underground mine that has undergone extensive underground infrastructural development in recent years, thus exposing some of the workers to high noise levels. A record review was done, using the mine's occupational health records

The criteria for being included in the study population were:

- Worked at the mine as full-time employees for the period: 1st January 1999, until 31st December 2004 (inclusive of both dates).
- Had uninterrupted yearly audiometric screening evaluation as part of the mine's medical surveillance program during that period from 1999 – 2004 (inclusive of both years).
- Age was equal to or more than 25-years at the time of their 2004 audiometric test.

The above population was further split into two groups according to exposure-risk. The high-risk group is the group whose work area has been measured to have a time-weighted-average (TWA) of more than 85 dB. The low-risk group comprises those whose work area has been measured to have a time-weighted-average (TWA) of less than 82 dB. These measurements are based on the classification of ‘high’ and ‘low’ risk areas as provided by the mine’s occupational hygiene section. Measurements are carried out in accordance with the criteria laid out by the Department of Mineral and Energy guidelines (2003), which in turn are in compliance with ISO 9612 (1997)

The mine has a policy of conducting annual screening audiograms for all employees that work inside the ‘high security area’ (which is a demarcated area where the actual mining activities take place). Even low risk employees who work in the “low security areas” undergo annual screening audiograms. For the purpose of this study only those that have presented themselves for these regular annual audiograms (without skipping a year) were included. Everyone who meets these criteria and was at least 25 years old at the time of 2004 audiogram has been included. Therefore no sampling was done as all eligible employees were included.

Data capturing was done with Microsoft Excel using Windows XP. An excel spreadsheet was used to collate original data from the employee records that are kept at the Mine’s occupational health centre.

Seven pure-tone hearing threshold records for each subject covering all the years 1999 – 2004 (inclusive) were retrieved from the patient’s file. This is an automatic report that is generated each year by the audiometer. The instrument that was used to measure the pure tone frequencies was the Mine’s standard audiometric measuring equipment, which consists of:

- Audiometer is an INTERACOUSTICS AS-216 MODEL
- Both earphones are TELEPHONICS TDH-39P MODEL
- This equipment is connected to a Dell Pentium III PC with a Microsoft keyboard and mouse.

For a given year each study subject’s pure tone thresholds were entered into the spreadsheet one below the other in alphabetical order, with each specific pure tone aligned to its separate unique column. A row on the spreadsheet therefore comprised all pure tone threshold readings (in ascending order of frequencies) for that given year for each particular employee. A column comprised threshold readings for the entire study population at that specific frequency for a given year.

The high and low risk groups were kept separate, but each year was captured on the same page, in order to enable comparison. Therefore there were a total of five data sheets/pages, each with data for both the high and low risk groups for that given year. Comparing results of different years therefore entails paging between the data sheets and comparing just the high and low risk groups within a given year entails scrolling up and down the same page.

The data thus collected was summarized in tables and graphs and entered onto EPI-INFO version-6 statistical software for statistical analysis. An incidence rate was calculated for the two exposure groups and expressed in ‘/1000 person years’. The z test was used to test if the difference that was observed in incidence rates between the two exposure groups is statistically significant.

3.3 Diagnostic criteria

In South Africa, currently there is no universally accepted general standard for parameters of the earliest changes of NIHL. The law, in the form of MHSA (1995), states that each employer must do a risk assessment and on the basis of that the employer must do what is reasonably practicable to protect employees from effects of health hazards such as NIHL. Therefore the law does not prescribe any course of action on the part of the employers, but they must be able to provide plausible justification for whichever course of action they choose. The owner of the business is ultimately accountable for the way health risks/hazards are managed in his business.

Hearing Conservation Programs have provided guidance, without prescribing, on what a reasonable standard for the earliest audiometric changes should be before one takes corrective intervention. As a result of this latitude some of the industries have arbitrarily set the warning level for ‘intervention’ at 1,5% shift in Percentage Hearing Loss (PHL) from the last screening audiogram. If this shift is noted to have occurred since the immediate previous audiogram an investigation of the workplace is commenced to identify the deficiencies that have resulted in such loss of hearing. This value is used just as a guide for the purpose of identifying early loss of hearing and it is convenient because modern audiometers, which are currently widely used by industry, calculate and print out the PHL automatically. The audiometrist is able to observe if the shift of 1,5% has occurred just by comparing the PHL of the current audiogram with the previous one.

The shift of 1,5% PHL is averaged over all frequencies and may not necessarily display the other features typically associated with early NIHL, e. g. a high frequency rather than low frequency shift and a dip on/around 4000Hz. However the criteria that are offered by Coles et al (above) for the earliest changes of hearing loss seem more likely to demonstrate these features. Therefore in the absence of a universally accepted reliable guideline this could be a reasonable standard to use, even in the South African setup.

It is worth noting that the weighting of the different frequencies in the calculation of percentage hearing loss, according to Rand Mutual (RMA tables, 2004), is in the ascending order of:

1. 4000 Hz
2. 3000 Hz
3. 500 Hz
4. 2000 Hz
5. 1000 Hz

This means that a shift at 4000 Hz will contribute the least to PHL than a similar shift at any of the other frequencies. Likewise a shift at 1000 Hz will contribute the most.

In view of these weightings, the suggestion of the threshold hearing level at 3000 or 4000 or 6000Hz being 10 dB more than that at 1000 and 2000 Hz as advanced by Coles et al. (2000) presents a criterion that is more likely to be observed even before a shift of 1,5% PHL occurs.

For this reason the clinical measurement that was used to define ‘disease’ for the purpose of this project is the one that was advanced by Coles et al, i.e. “when a single measurement of hearing threshold level (HTL) at 3, 4 or 6 KHz, after due correction for earphone type, is at least 10 dB greater than the HTL at 1 KHz or 2 KHz”. Since the same type of ear phone was used in all the tests conducted at the Mine during the period of observation, therefore no correction for earphones was necessary.

Phaneuf and Hetu (1990) described the early changes of NIHL by stating: “the first effect caused by noise generally results in a deterioration in hearing sensitivity at 4 KHz; if not at 4 KHz then either 3 KHz or 6 KHz”. Their views are therefore in line with the definition of disease that has been described above. The trend analysis and statistical testing of that trend was based on this very same definition of disease.

In addition to the above criteria a trend analysis of ‘notching’ and ‘down-sloping’ was done. This is because of the fact that these two phenomena have a strong association with NIHL as discussed elsewhere in this report. There is no universally accepted definition of audiometric notching in spite of it being regarded as a strong association with NIHL by writers such as Coles et.al. (2000), McBride and Williams (2001) and Mostafapour et.al. (1998). For the purposes of this study the presence of the notch was regarded as a dip of at least 10 dB in one of the following frequencies: 3,4 or 6 KHz. The dip is measured on the lower frequency side of the notch. As part of the criteria for defining the notch, in this study, there must be some recovery at the high frequency side of the notch, especially at 8KHz. This definition of the notch is consistent with those provided by many such as Coles et. al, McBride & Williams, and Mostafapour et. al.

Down-sloping is a descriptive name referring to a pattern that is sometimes seen on an audiogram. Coles et al describe it as a downward shift in the high frequencies without a recovery at 8 KHz. They also state that it is widely regarded as a sign of aging.

4. RESULTS AND DISCUSSION

4.1 Demographics and disease patterns

4.1.1 Study population

Table 4.1.1a: – Study population by sex and age

		High Risk	Low Risk
Population (number)	Total population	120	103
Sex by Percentage (%)	Males	100	65
	Females	0	35
Age by percentage (%)	25 – 34yrs	3	5
	35 – 44yrs	43	50
	≥45yrs	54	45

Table 4.1.1a is a summary of demographics of the study population. There are two important trends that were noted from this table:

1. There are no female subjects among the high risk employees.
2. The proportions of the different age categories are comparatively matched in both groups.

The total study population comprised 223 subjects. One hundred and twenty (120) of these were high risk employees, all of whom were men. One hundred and three (103) were low risk employees, comprising sixty seven (67) males and thirty six (36) females.

The reason for a relatively low population is twofold. Firstly the mine uses contractors widely but only the permanent employees were subject of this study. Permanent employees present a more stable population in terms of employee turnover. Therefore one is more likely to find an uninterrupted period of service among permanent employees than contractors, which is more suitable for the selection criteria of this study. Secondly those employees who did not submit themselves for the routine medical surveillance examination for at least 1year (i.e. skipped a year) were left out of the study. Approximately 25% of the total work population was eventually included in the study.

4.1.2 Age distribution

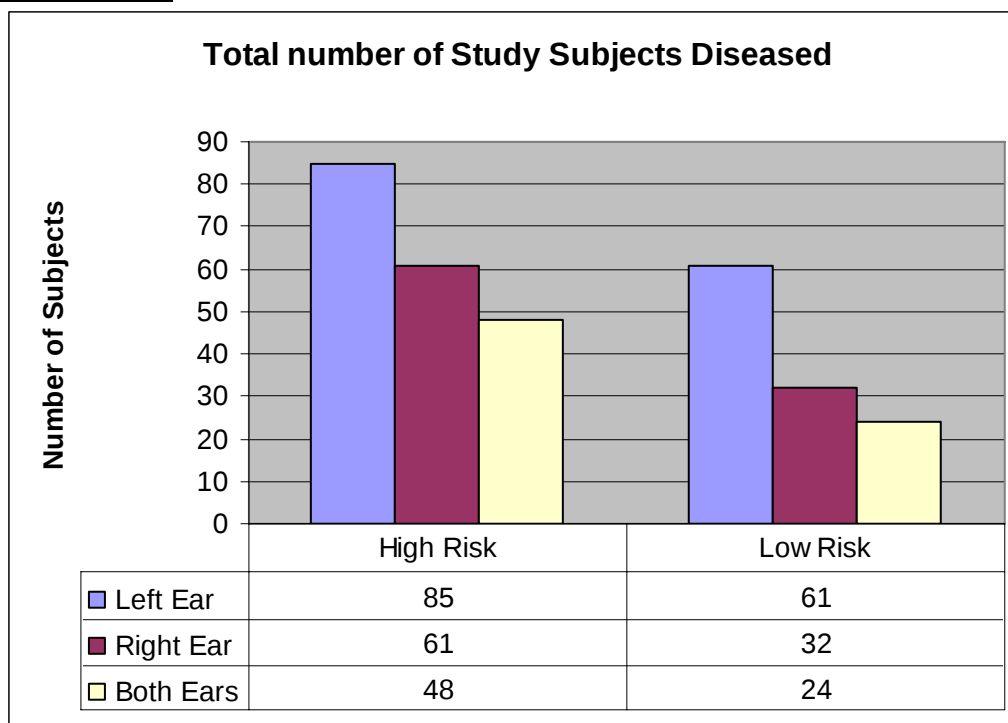
The age of each study subject at the time of the 2004 audiogram was used for age stratification. The maximum age for any subject can only be 60yrs, which is the maximum retirement age.

Table 4.1.1a also reveals that the population under observation is mainly an older population. Only 5% of the low exposure group and 3% of the high exposure group were less than 35yrs of age at the time of their 2004 audiogram.

There is a difference of 9% in the proportions of the ≥ 45 yrs age category between the two groups, more being in the high risk group. In the 35 – 44yrs category the difference is 7%, more being in the low risk group. The other 2% is made up in the 25 – 34yrs category. This represents the overall difference in the age distribution between the two risk groups and therefore the overall proportions of the three age categories are not vastly different between the two groups. This means that the impact of age as a confounder is minimized since there is no significant difference in the relative age distributions of the two risk groups. Considering that age is a significant possible confounder, the low risk group is thus a suitable control for age.

4.1.3 Subjects acquiring disease between 1999 and 2004

Graph 4.1.3a



The totals in Graph 4.1.3a represent the subjects that acquired the disease during the period of observation. The people with both ears simultaneously affected will automatically have been included in the groups with either the left or right ear affected, since they were not excluded when either of those groups was counted. This graph has been included to show the actual numbers of affected subjects but the analysis was done by means of percentages (proportions) as shown in Table 4.1.3a

Table 4.1.3a: – Percentage of diseased subjects - by Total population, Males and Females

	High Risk Subjects	Low Risk Subjects
Percentage of Total Population Diseased (%)	Left Ear 71	59
	Right Ear 51	30
	Both Ears 40	23
Percentage Males Diseased (%)	Left Ear 71	65
	Right Ear 51	37
	Both Ears 40	28
Percentage of Females Diseased (%)	Left Ear NA	47
	Right Ear NA	19
	Both Ears NA	14

It has already been stated that the definition of disease that was used for the purpose of defining the observations summarized in table 3 is: *When a single measurement of hearing threshold level (HTL) at 3 KHz, 4 KHz or 6 KHz, after due correction for earphone type, is at least 10 dB greater than the HTL at 1 kHz or 2 KHz.*

Table 4.1.3a shows that the proportion of high risk subjects that acquired the disease during the observation period is significantly higher than that of the low risk group. This is not surprising since noise is the hazard and the disease is the outcome of exposure to that hazard.

Another pattern that is evident from this table is that the left ear is almost always more commonly affected than the right ear. It is not immediately clear why this is so but it is a matter that is dealt with more fully later under ‘discussion’.

Looking at males alone shows that the proportion of diseased subjects in each exposure group generally follows the pattern already seen in the total population. There is a greater proportion of the high exposure group that has developed the disease in all forms i.e. disease of left, right or both ears.

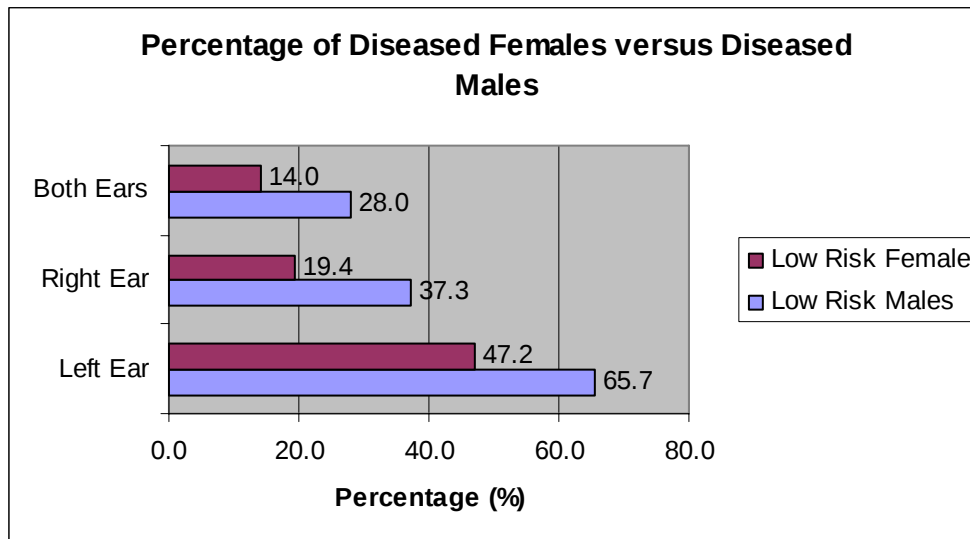
The comparison between the two exposure groups was not possible among the females because there are no females in the high exposure group. The general pattern of manifestation of

disease within the low risk females was however not different to that observed in males i.e. the order of frequency in descending order was: left, right and both ears.

Comparison of Males and Females:

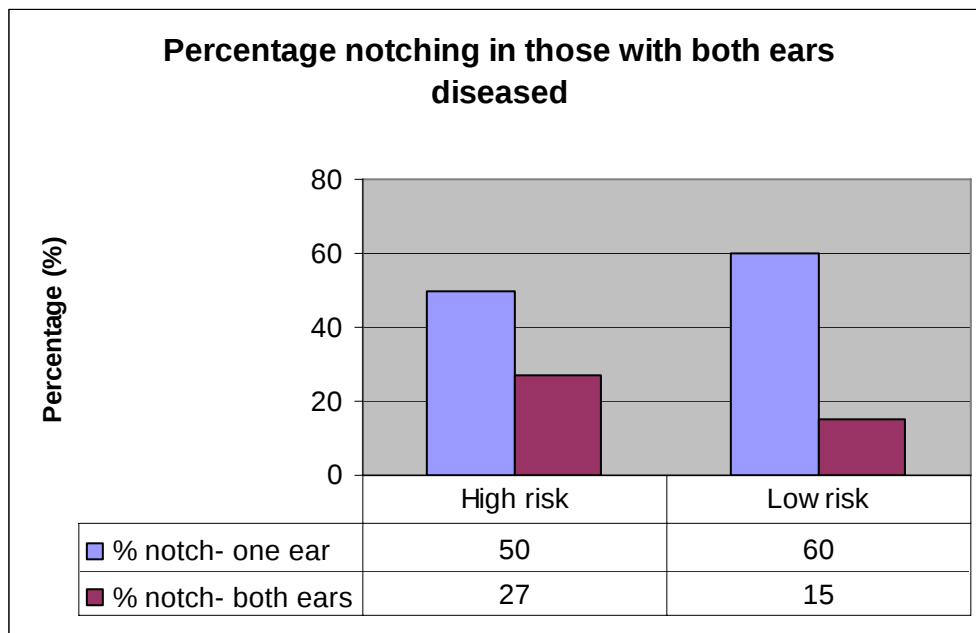
The exact proportions (Male versus Female) are shown in graph 4.1.3b. This is a direct comparison of males and females in the low risk exposure group and it shows that there was generally less occurrence of disease among females than in men.

Graph 4.1.3b:



4.1.4 Notching

Graph 4.1.4a:



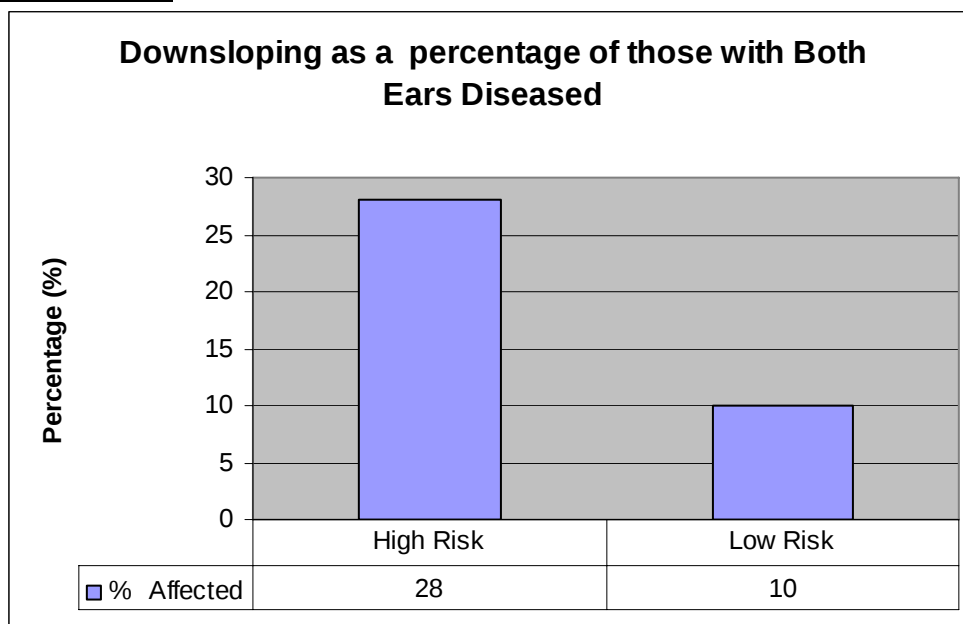
The subjects that have developed the disease (NIHL) in both ears were all analyzed to see if any of them displayed the phenomenon of Notching. The results are displayed in graph 4.1.4a. This shows that 50% of those with both ears diseased, in the high risk group, displayed a notch in at least one of the ears (monaural). The corresponding figure for the control group is 60%. However the rate of appearance of a notch in both ears (binaural) shows that relatively more people in the high risk group demonstrate this phenomenon, i.e. by a ratio of 27:15. In other words the relative rate of occurrence of the notch, simultaneously in both ears, was 1.9 times more among the high exposure group.

4.1.5 Age and Down-sloping

Table 4.1.5a: Percentage of subjects with downsloping for Left, Right and Both Ears - by Age category.

		High Risk grp		Low Risk grp
Percentage Diseased (by Age Category)	25 – 34 yrs	Left Ear	100	50
		Right Ear	100	33
		Both Ears	100	33
	35 – 44 yrs	Left Ear	61	57
		Right Ear	43	31
		Both Ears	29	22
	≥ 45 yrs	Left Ear	70	63
		Right Ear	52	30
		Both Ears	43	24

Table 4.1.5a shows the distribution of disease by age category in both exposure groups. The results of the 25 – 34yrs age groups could possibly be chance finding due to the low number of study subjects in this category i.e. four (4) and six (6) among the high and low exposure groups respectively. The overall trend in this table is **a** progressively increasing proportion of down-sloping with advancing age among the high exposure group compared to the low exposure group. In other words you are more likely to get down-sloping if you have both aging and noise exposure than if you have aging on its own.

Graph 4.1.5a

The two groups in the study population displayed a difference in the prevalence of downsloping as seen at the end of the observation time line i.e. 2004. This is shown in graph 4.1.5a. The graph shows that, in percentage terms, there are more subjects with downsloping among the high risk group than the low risk group.

Table 4.1.5b: Percentage of diseased subjects with downsloping – by Age Category

		High Risk grp.	Low Risk grp.
Down-sloping as Percentage (%) For each Age Category	25 – 34yrs	0	17
	35 – 44yrs	24	8
	≥45yrs	32	11

Table 4.1.4b shows down-sloping as a percentage of all disease cases by age category. It shows that down-sloping in this study population seems to affect a greater proportion of the diseased subjects with advancing age. This trend is seen in both age groups with the exception of the 25 – 34 age-group among the low risk group. However this can be ignored as the 17% is made up of one person out of a group of just six in this age category. By comparison there are fifty one people in the 35 – 44 age category and forty six in the ≥45 age category among the low risk group.

Therefore the 17% observed could again be a chance finding due to the small number of people in this age category. By the same token the 0% down-sloping among the high risk group (25 – 34yrs) could also be a chance finding since there were only four subjects in this category.

The table also shows that there is comparatively a greater proportion of down-sloping among the noise exposed group than those not exposed. This seems to suggest that just as the effects of noise exposure (i.e. NIHL) are greater in the exposed group so are the effects of aging (i.e. down-sloping) in that same group.

4.2 Aggregates and Means

Table 4.2a: Comparison of the 1999 and 2004 population mean threshold across each of the seven audiometric frequencies – High Risk Group

Table 4.2b: Comparison of the 1999 and 2004 population mean threshold across each of the seven audiometric frequencies – Low Risk Group

	0.5kHz		1kHz		2kHz		3kHz		4kHz		6kHz		8kHz	
	L	R	L	R	L	R	L	R	L	R	L	R	L	R
1999 Mean	5	5	7	7	9	9	14	13	18	17	25	23	23	18
2004 Mean	5	6	7	10	11	12	15	15	20	19	30	25	25	20
Mean shift	0	1	0	3	2	3	1	2	2	2	5	2	2	2

Table 4.2a

	0.5kHz		1kHz		2kHz		3kHz		4kHz		6kHz		8kHz	
	L	R	L	R	L	R	L	R	L	R	L	R	L	R
1999 Mean	5	6	5	5	8	7	10	9	12	13	20	17	17	13
2004 Mean	5	6	5	7	9	8	10	9	12	12	20	18	15	14
Mean shift	0	0	0	2	1	1	0	0	0	-1	0	1	-2	1

Table 4.2b

Population averages were used as another method to analyze trends in this study. Each individual's threshold hearing was taken at all seven frequencies of interest during 1999, i.e. at the beginning of the observation period. They were put on a Microsoft excel spreadsheet one below the other, added up and a mean was taken for each frequency. The same was done for the period of 2004 i.e. the end of the observation period. In this way it was possible to compare

the means for 1999 and 2004; and in a way compare what has happened to those means during the timeline of observation.

The 1999 mean was then subtracted from the 2004 mean to quantify the ‘mean shift’ at all seven frequencies. This was done in turn for each exposure group in order to compare the two groups. The results for each group are shown in figures 4.2a and 4.2b respectively. The overall observation was that of a consistently greater mean shift in the exposed group than the control group.

On its own this result does not indicate what has happened to individuals and therefore does not necessarily mean that individuals within the high exposure group were worse off than those in the control group. It does however point to the effects of the burden of noise exposure on the whole high exposure group and when taken in the context of the earlier results that showed the effects on individual subjects it should be regarded as a significant indicator of a worse outcome for the exposed group.

4.3 Statistical Testing

Table 4.3a: Incidence Rate of NIHL – in both Exposure Groups

	High Risk	Low risk
Total Population	120	103
Number Diseased	48	24
Person Years of Observation	517	459
Rate (/1000 Person Years)	92.8	52.3

The incidence rate for each exposure group (expressed /thousand person years) was entered into the Epi – Info statistical software and the results were as follows:

- $z = 5.844$
- this z value showed a $p\text{-value} < 0,05$

Since a $p\text{-value}$ of 5% was chosen as a significant $p\text{-value}$, this result means that the difference between the incidence rates is statistically significant. This means that the probability that the difference in incident rates, as large as that which was observed in this study, would have occurred by chance is less than 5%. As the null hypothesis states that any observed differences in the incidence rates are entirely by chance, we reject it.

The other method of statistical analysis was Relative Risk and this was found to be 1.77 (CI 1.06 – 2.75). This is another way of showing the strength of association between exposure and incidence of disease, since the CI is not wide and it also does not include 1.

5. DISCUSSION

5.1 Possible Bias

The population that was used in this study was not sampled as every eligible individual was included. However the possibility still remains that in not using every employee of the mine some unintended selection bias could have been introduced. There is a need therefore to examine the likelihood of this possibility with the purpose of addressing it in a scientifically plausible manner if there is a reasonably possible likelihood. To do such an assessment there is a need to go back to the eligibility criteria that were used earlier.

- Worked at the mine as full-time employees for the period: 1st January 1999, until 31st December 2004 (inclusive of both dates).

This is a fundamental criterion in this study because it establishes the time line for observation. It is unlikely that any one exposure group could be affected by this to an extent that differs to that of the other group.

- Age was equal to or more than 25-years at the time of their 2004 audiometric test.

Again this is not likely to affect the one group any differently to the other. This is because age is not a criterion for selection in the normal recruitment processes of the mine. The high risk group was mainly from the ‘production sections’ of the mine such as mining and the treatment plant. The low risk group on the other hand was mainly from the ‘services sections’ such as human resources, finance and administration. None of these sections emphasize age to any greater extent than the other in their staffing policies as they all conform to the uniform mine standard. Therefore no bias could have been introduced by the age criteria that were used. Table 4.1.1a provides further confirmation of this by showing how closely matched the age groups were between the two risk groups.

- Had uninterrupted yearly audiometric screening evaluation as part of the mine’s medical surveillance program during that period of 1999 – 2004 (inclusive of both years).

This is the one criterion that presents a realistic chance of introducing bias e.g. if the low risk population feel assured of their safety they may not have the motivation to comply with the routine medical surveillance as much as the high risk population who feel more at risk. In this way more low risk employees could have skipped a year or more without presenting for their

annual medical surveillance and audiogram, thus selecting out the ‘well’ employees from the low exposure group and leaving mainly the diseased ones as our controls.

This possibility was raised with both the occupational health nurse and the occupational health practitioner. They concurred in saying that they have ruled out this possibility through years of observation.

The main reasons they advanced were:

- All medical examinations were full examinations regardless of your risk status and therefore all employees tend to regard the annual examination as a valuable free health status ‘check-up’ that is seen in a positive light.
- It is the policy of the mine for all employees to undergo an annual medical examination regardless of risk status or age.
- Those that have skipped a year (and therefore were excluded from this study) only did so because of an imperfect booking system since employees have to get their appointment date from the occupational health nurse. There have been occasions when appointments were not scheduled as required due to the very high numbers of contractors who also have to go through the same system. Therefore the affected employees would not have been biased towards one or the other risk group.

The absence of bias makes the findings of this study to be generally applicable to the whole population of the mine, including those that did not meet all the above eligibility criteria. The matter of any findings being generalizable to other diamond mines will be discussed later under conclusions.

The other realistic source of bias follows from the question: What happens if you get NIHL? The relevance of knowing this is the fact that, should it be that these workers are removed and placed in low noise areas (or terminated) this would reduce the effect estimate. This would be an example of the ‘healthy worker effect’, and it is a well known source of bias in incidence studies. The bias would result from the fact that by being removed these workers would mask the real effect of noise exposure as measured by the number of cases that develop during the period of follow up. The effect of this was not quantified nor controlled for in this study, since the workers that missed any of their annual audiograms were excluded without establishing the reasons why they missed their annual tests. Should this be a significant factor in our study population it will have the effect of reducing the effect estimate among the high exposure workers.

The Mine’s policy is to relocate those that are affected by NIHL to lower noise areas, after the due process of counseling and investigation. This would bias the results by increasing the effect estimate among the low exposure group. The reason is that at the time of doing the record review their files would be counted in among the low exposure group whereas they may have previously belonged in the high exposure group at the beginning of the time line of observation, only to be relocated after developing NIHL. This was also neither quantified nor controlled for in this study and it may a possible explanation why there was a higher than expected incidence of NIHL among the low exposure group i.e. they acquired NIHL before

they were relocated to the low noise areas. The other possible reason for this relatively high incidence in this group is community acquired NIHL, even though this is a factor that is equally at play among the high exposure group as well.

It is however worth pointing out that the effect of these last two sources of possible bias has not detracted from what the study originally set out to do i.e. to show that high exposure workers did in fact end up with more cases of NIHL and low exposure workers ended up with relatively less cases. Therefore by having the effect of increasing the effect estimate among low exposure workers or/and reducing the effect estimate among high exposure workers one would expect these two factors to work in one direction i.e. that of narrowing the difference between the two exposure groups. The fact that the results presented above converge to a statistically significant difference between the two exposure groups serves to strengthen the overall goal of this study i.e. which is to show more incidence of NIHL among the high exposure group and less incidence of NIHL among the low exposure group.

The other type of possible bias that would have realistically affected this study is the phenomenon of transient threshold shift (TTS). To control for TTS one would have to ensure that the subjects in the high exposure group do their audiograms at least 16 hours after the last shift has ended, which is the maximum recovery period for TTS. The 16 hour rule is mandatory for baseline audiograms but not for routine annual tests. As these were routine annual rather than baseline audiograms, we will never know how many of those labeled as 'diseased' when they were in fact TTS. This will have increased the effect estimate for incidence in the high exposure group.

5.2 Trends for NIHL

Graph 4.1.3a demonstrates the fact that high risk employees are more affected by NIHL than the low risk group. While this graph brings visual clarity in showing the difference between the two exposure groups there is still a significant percentage of diseased people among the low exposure group. This makes the statistical test relevant in bringing the assurance value before making a conclusion based just on trends, hence the use of the z-test.

The other pattern that was observed in both exposure groups is that the left ear is more affected by NIHL than the right ear. It would be expected that both ears should be affected almost to the same extent, especially in a mining environment. Therefore this pattern came as a surprise.

There are also more subjects with their right ear diseased than with both ears affected. It must be noted that when each ear was looked at, the subjects with both ears diseased were not sifted out and excluded. Therefore those with both ears simultaneously diseased are automatically part of the individual groups with either the left or right ear diseased.

The fact that each ear on its own is more commonly affected than both ears together is itself not surprising when one considers the possibility that the acquisition of the disease could be chronologically staggered between the two ears, especially early disease. This is the likely reason for both ears being simultaneously less frequently affected than either ear on its own.

The fact that the left ear seems to be consistently more frequently affected than the right ear was not an expected result as there are no apparent factors that were observed to explain this. However this is a feature that has previously been observed by several researchers with varying but inconclusive explanations.

Rudin et al (1998) found that in the general population of men born between 1913 and 1923 hearing acuity in the right ear was generally better than in the left. They went on to suggest that this might be due to a biological difference between the two ears. The pattern of the left side being worse off than the right was also observed by Chung et al (1983).

Others such as Nerbonne and Accardi (1975) have argued that the presence of greater hearing loss on the left is based on environmental (e.g. drivers of left hand trucks in the USA) rather than biological factors. An undeniable fact though is that many other studies have consistently shown that hearing loss seems to occur more on the left ear than on the right one, e.g. Dufresne et al (1988) and Pfeiffer and Maur (1983).

The comparative proportions of NIHL in those subjects where both ears are affected (binaural) are 40 vs. 23. Again this seems to indicate that after five years of exposure to noise the high exposure group, by comparison, shows an obvious negative outcome arising from their exposure. The study subjects with binaural disease are important for making conclusions in this study because most experts, such as Rand Mutual (2001), include the involvement of both ears as a defining aspect of NIHL.

The criteria that were used to define disease for this study (Coles, 2000) have already been discussed above. These criteria may be applied to any one ear but the statistical test was done in those subjects that had both ears affected. The main reason for this was the fact that NIHL is generally regarded as a binaural disease and hence the stipulations by Rand Mutual (2001, monaural hearing impairment) that:

- NIHL affects both ears to more or less an equal degree.
- If, therefore, the hearing loss is monaural, it must be assessed whether the loss is commensurate with noise exposure to one ear more than the other such as gun shots in security workers.

As it is clear that the diamond mining environment is not commensurate with exposure to only one ear, it makes sense therefore to do the statistical testing only in those that have both ears diseased.

A curious outcome of this study was the fact that a significant difference between the exposed group and the control group was observed within a five year period. This was not a foregone conclusion at the beginning as NIHL is known to be a disease of insidious onset. The value of this observation is to show that the criteria that were used in this study may be sensitive enough to detect the very early changes of NIHL. It remains to be seen though, if they would be specific enough to be used reliably on a wider scale. It would therefore be a worthwhile effort to employ this method of 'record review' again and again to test its consistency in producing

reliable results. Even better a prospective cohort study using the same criteria would add more value to such an effort.

An additional trend that was observed was the difference in the occurrence of NIHL between men and women as shown in table 4.1.3b. While this was not part of intended scope of observation the trend was observed nevertheless and literature has collaborated similar findings in other settings.

It was not possible to make such a comparison among the high risk group because there were no female subjects in that group. Because this observation was only made in the low risk group, it suggests community rather than occupationally acquired disease.

The pattern of males being more affected by NIHL than females, has previously been observed and reported by others such as Robinson and Sutton (1979). It was again acknowledged by Phaneuf and Hetu (1990) when they discussed the epidemiological aspects of hearing loss among industrial workers. The main reason for this that has been advanced by these and other researchers has been the debatable issue of women being generally associated with quieter hobbies than men. Nevertheless the fact that women seem generally to be less affected by noise in population studies is well established from studies such as the two mentioned here.

5.3 Notching

Notching is a feature that goes hand in hand with NIHL. The scientific basis of the notch is that NIHL first affects the higher frequencies range of 3 KHz to 6 KHz. Only later and in more advanced forms does the loss of hearing spread to other (lower) frequencies. The dip or notch that appears on the audiogram is in fact just a manifestation of the downward shift in hearing ability that has already occurred in these higher frequencies.

The audiometric notch is therefore a typical feature of noise in NIHL and if present can be identified in the graphic presentation of pure-tone threshold pattern (see appendix 3). There is no universal agreement on the exact features of the audiometric notch. According to McBride (2001) “The main problem seems to be that there is no standard definition of an audiometric notch, so people tend to develop their own criteria”.

As a result some researchers, e.g. Mostafapour et.al. (1998) use consensus of three competent observers as a criteria for determining the presence or absence of the notch. These researchers measure the depth of the notch from the low frequency side of the graph. They also measure the exact frequency at the bottom of the notch to determine the extent expression of the notch.

There is general consensus that the notch occurs typically at the 4 KHz frequency. Scholars such as Seidman (1999), while agreeing that it occurs typically at 4KHz, have said however that it occurs anywhere in the higher frequencies (3KHz – 6KHz). Others such as McBride and Williams (2001) contend that at 6 KHz the notch is variable and of limited importance. Their view is that it is only significant when it appears at 4 KHz.

In his review article Touma (1992) states that “the 4KHz notch is an important diagnostic sign of early NIHL”. Others such as Mc Bride and Williams (2001) state that “the notch at 4KHz is a well established clinical sign and may be valuable in confirming the diagnosis, the 6KHz notch is variable and of limited importance”.

In their article written for the purpose of clarifying diagnostic standards for the British legal setup Coles et. al. (2000) contend that such a notch is not pathognomonic of NIHL. They go on to state that likewise the absence of such a notch does not preclude the presence of some NIHL.

5.4 Ageing & down-sloping

The effect of the natural aging process, on the hearing ability, is generally regarded as that of causing a gradual deterioration. This is called presbycusis. Mills et al (1998) define presbycusis as the hearing loss associated with increased chronological age. The Framingham Heart Study, which is an ongoing cohort study, was used by Moscicki et al (1984) to determine the effects of age on the hearing ability. They found that hearing loss (HL greater than 25 dB on the average at 0.5 KHz, 1 KHz and 2 KHz) was 0.2% at birth and 30% between the ages 57 and 89 and thus confirmed the generally accepted phenomenon of gradual loss of hearing with advancing age.

Graph 4.1.5a shows that, in percentage terms, there are more subjects with down-sloping among the high risk group than the low risk group. Coles et. al have described down-sloping as being associated with aging on one hand and being accentuated by NIHL on the other hand. This means that while down-sloping typically occurs in older/ageing people it is in fact a sign of NIHL when it does occur in these older people. Accordingly the trend in graph 4.1.5a is not surprising. Appendix 2 demonstrates a graphical presentation of down-sloping.

An ISO standard (ISO-1999), by way of a formula, has been developed to factor in the age related component of hearing loss in older person when measuring NIHL i.e. bringing together the additive effects of the age component and the noise component. Mills et al (1998) have also cautioned on the limitations of applying ISO-1999 to individuals by writing “...because the formula works by applying results of epidemiologic data which have been averaged across thousands of persons to individuals”. This serves to highlight the fact that people are subject to individual variations that are imposed by such factors as ototoxic drugs, genetic predisposition, cardiovascular disease etc.

In their review article Boettcher et al (1987) argue that there is a synergistic effect between ototoxic drugs, e.g. Aminoglycosides, and noise. In another review article Touma (1991) concludes that cardiovascular diseases such as hypertension and arteriosclerotic disease do not cause NIHL by themselves, but they do increase the susceptibility of the cochlear to noise. This can increase the risk of NIHL and thus affect individual response to noise. These individual factors that can influence individual response were not followed up in this study because it is reasonable to assume that they are equally at play in both exposure groups, and are not likely to introduce any significant confounding.

Again, in the context this study the debate on the effects of ageing, as observed and discussed earlier, is not likely to distort the outcome of the comparison between the exposed and non exposed groups. This is because of the fact that the two groups in this study are of comparable age distributions. This means, therefore, that factors such as individual variation/sensitivity and age effects are almost equally at play in both exposure groups, leaving noise exposure as the main significant difference in the risk factors for 'hearing loss' between the two groups. The consequence of this is attribution of the NIHL that has been observed in the high exposure group to noise exposure.

5.5 Temporary Threshold Shift (TTS)

TTS was described by Cummings et al (1998) as a form of physiological fatigue that commonly occurs in the inner ear when it is exposed to hazardous noise levels. It has been described as a form of NIHL that recovers spontaneously within 16 hours after the termination of exposure. The relevance of this phenomenon is further highlighted by Rand Mutual Assurance's Arthur Begley when he states that it is critical to distinguish between TTS and NIHL when assessing compensation claims. The confounding nature of TTS is also thus highlighted.

An essential aspect of the study design in this project was that one group was exposed to significant noise levels while the control group is not. The exposure group would therefore be expected to be affected by TTS and the control group would not. As this is a retrospective record review this presents a confounder that was not controlled for. This means that it is possible that some or all of the subjects that acquired the disease were actually demonstrating TTS rather than permanent disease. This possibility weakens the conclusions that can be derived from the trends discussed earlier.

This study must therefore be seen as a preliminary one that cannot arrive at a solid conclusion. A future follow up study that may be conducted to validate these results will provide more assurance if it can control for this confounder. A prospective cohort study, in which the number of hours since the last exposure is controlled, would fulfill that need.

6. RECOMMENDATIONS AND CONCLUSIONS

6.1 Recommendations

The observations that were discussed in the results section lead to the following questions:

1. Is monaural hearing threshold shift a precursor to binaural shift?
2. Is left ear hearing loss a more reliable form of monaural hearing loss and thus a more sensitive possible precursor?

3. Can these results be generalized to other similar industrial setups i.e. the diamond mining industry or even the mining industry in general.
4. Are the existing controls and current Hearing Conservation Programs that are employed by the mine serving their stated purpose of preventing NIHL from occurring?

The first two questions pose an interesting debate that may be pursued and enriched through further research. Just based on the work done in this project there is no way of telling what the answers are. These results have however created a basis for motivation of further research on these issues. A good starting point would be to extend this study design to include other diamond mines. This should be made easier by the fact that all the big South African diamond mines belong to the same mining house. Therefore they share the same technologies, standards and procedures as the mine that was used for this project. Extending this study would essentially entail looking at a wider database, which can be sourced from those other mines.

A wider study would also answer the third question on whether these results can be generalized because one must be cautious of making that conclusion on the basis of this study. This is because some of the diamond mines are using the open pit method of mining whereas this study has only looked at an underground mine. There is also the undetermined issue of housekeeping in those other mines which must be proven to match that of this mine for any generalization to make sense i.e. if they have better housekeeping it would be expected that their incidence of NIHL would be less than that observed in this study.

The answer to the fourth question above is a 'no'. The study shows that the current controls, in the form of Hearing Conservation Program (HCP), are probably effective in significantly reducing NIHL but not in preventing it altogether from occurring. The HCP best practice can only be implemented successfully if the teams are committed and motivated, which is mainly achieved through a well orchestrated education and re-induction program. This is regardless of any other technical inputs and resources that may have been ploughed into the program.

Another key aspect of the HCP is a regular review that is based on outcomes. These outcomes are in the form of audiograms for individual employees as determined by an appropriate medical surveillance program. SIMRACC (2001, p210) summarize the 'best practice' format for a HCP review requirements as follows:

Table 6.1a: Summary of HCP review requirements

Programme element	Evaluation parameters/indicators	Review period	Basis of KPIs
Risk assessment & OH monitoring	Emission and exposure levels; Number/percentage of workers affected	Quarterly/6-monthly	Variance with previous findings and with agreed targets
Education, motivation and training (EMT)	Level of knowledge and skills measured by pre- and post-EMT tests	Quarterly/6-monthly	Collective variance between pre- and post-EMT results;
	Employee attitudes and behaviour determined by workplace interviews/ questionnaires/ observations;		Shifts in employee attitude or behaviour;
	HPD compliance level; Audiometric trends		Variance with previous findings and with agreed targets
Noise control engineering (NCE)	Noise emission and exposure levels; Audiometric trends	Quarterly to annually	Variance with previous findings and with agreed targets
Noise control engineering (NCE)	Noise emission and exposure levels; Audiometric trends	Quarterly to annually	Variance with previous findings and with agreed targets
Administrative control measures	Individual exposure levels	Quarterly/6-monthly	Variance with previous findings and with agreed targets
	Individual audiometry results;	Annually	
	Audiometric trends	Annually	
Personal protection	HPD compliance level	Quarterly	Variance with previous findings and with agreed targets
	Audiometric trends	Annually	
Medical surveillance/audiometry	Average values, distributions or prevalence of critical variance in: Audiometric category, particularly with regard to 3,4 and 6 kHz; Threshold shifts at 3,4 and 6 kHz; Threshold shift at 4 kHz only; Percentage loss of hearing	Annually or 6-monthly, as appropriate	Variance with previous findings and with agreed targets

Reproduced from SIMRACC (2001, p 210)

6.2 Conclusions

There were two main findings in this study:

- There was indeed more incidence of NIHL among exposed subjects, since the purpose of the study was to establish if more hearing loss has occurred in exposed subjects during the observation period.
- The incidence of NIHL was higher amongst the older subjects in both exposure groups.

As discussed earlier, this means that the current controls employed by the mine are not enough to arrest the development of NIHL among employees. This must be seen against the background of the MOHAC mining industry milestones that were discussed earlier (see section 1.4 above). One of these milestones is that “after December 2008 the Hearing Conservation Programs must ensure that there is no deterioration in hearing of greater than 10% amongst occupationally exposed individuals”. The best strategy to achieve this is firstly to have an effective early detection mechanism, one that is more sensitive than what is currently used in the industry. This is over and above the need to further refine current noise control measures.

Since there is no current minimum standard that is widely accepted at present, it can be expected that some serious efforts will soon be made by industry to set these standards, especially to get ready for the MOHAC milestones which are based on a zero tolerance principle. This will entail the setting of strict criteria for early detection such as those used in this study.

The main challenge of that new standard will be to find a balance between over sensitivity and lax standards. One task is to ensure that the standard is not too sensitive as this will create too many false positives. This could become a nuisance in that it would stretch the scarce resources of an ailing industry through unnecessary workplace redeployments and the need for repeat confirmatory screening audiograms. On the other hand the milestones set very stringent public targets for the industry. Therefore such new criteria will then have to be modified, if necessary, to make them feasible for local conditions; especially with regard to availability of resources.

The second finding, as stated above, relates to presbycusis. Even though this study has confirmed the additive relation between aging and NIHL it must be remembered that presbycusis is a natural phenomenon. The fact that NIHL occurred more in the older population does not distinguish whether this is a synergistic effect or just an additive sum of two factors acting in the same direction. As this study did not set out to establish this, it will not be pursued further in this discussion. This is however an issue that could be analyzed in another study with the relevant set of objective as there are benefits in establishing the exact nature of the interplay between noise damage and age. An example of the practical relevance of such knowledge would be the decisions (if not policies), relating to the placement of older workers in high noise areas, that could emanate from that knowledge.