Occupational noise induced hearing loss in South African miners: risk assessment explored at a platinum mine in South Africa

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Declaration

This thesis is submitted in the integrating narrative format, approved by the Faculty of Health Sciences, of published work.

I, Liepollo Ntlhakana, declare that this thesis is my own work. It is being submitted for the degree of Doctor of Philosophy at the University of the Witwatersrand, Johannesburg, South Africa. This work has not been submitted previously for any degree or examination at this, or any other, university.

I have read the sections on referencing and plagiarism in the Wits Plagiarism Policy and I have followed the required conventions in referencing the thoughts and ideas of others. I understand that the University of the Witwatersrand may take disciplinary action against me, including suspension or permanent expulsion if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.

Signature: 

Date: 20 September 2021

Place: Johannesburg, South Africa

Dedication

My PhD is dedicated to the following people:

My uncle (Rangoane Morake Monyane), a former miner (driller), no longer with us on this earth. Your memory lives on Rangoane. My PhD study is based on my perception of your life story. Thank you for fuelling my passion to understand the causes of hearing loss in miners who have worked, and continue to work, in the South African mines.

To my parents for the life lessons:

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Publications arising from this thesis

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Preface

This PhD is a journey that started in the early years of my profession as an audiologist. In 2002, as a locum audiologist, I conducted audiometry screening to monitor hearing for workers in the construction industry. It was the implementation of the hearing conservation programme (HCP) that drew my attention. In 2010, I was reintroduced to HCPs, where I reviewed the audiologist's role in the implementation of HCPs across various occupational settings in South Africa, on behalf of the South African Association of Audiologists (SAAA). At the Sefako Makhatho Health Sciences University (formerly known as MEDUNSA), I was a clinical tutor in occupational audiology. This ignited my passion and desire to develop myself in this niche. In 2014 I completed a Masters' degree in audiology at the University of the Witwatersrand. The title for my dissertation was "*The use of hearing protection devices in hearing conservation programmes: knowledge, attitudes and views of the South African mine workers regarding noise induced hearing loss and the use of hearing protection devices in the gold and non-ferrous mining subsections*". In 2014, I started teaching a short course in audiometry for Occupational Health Nurses (Diploma in Occupational Health Nursing, University of the Witwatersrand), and I continue to facilitate this course. The combined knowledge from my MA in Audiology and lessons from the audiometry short course have allowed me to identify gaps in the South African HCPs and possible reasons why occupational noise induced hearing loss (ONIHL) may be difficult to prevent, despite it being a preventable occupational disease.

I have realised that HCPs risk assessment records kept by various industries were key to unravelling the epidemiology of ONIHL. The South African mining industry has implemented HCPs for years and has submitted annual reports on occupational noise exposure levels, measures employed to reduce noise levels, and ONIHL cases to the Department of Mineral Resources and Energy. I have used this information to investigate the mining industry's risk assessment methods used for the prevention of ONIHL. This thesis aimed to explore risk assessment practices for ONIHL at a large-scale platinum mine in Limpopo province, South Africa, so to propose an early identification predictive model for ONIHL.

Abstract

Background: Occupational noise-induced hearing loss (ONIHL) is one of the most common occupational health diseases affecting miners in South Africa. There are challenges around the high prevalence of ONIHL in South African miners that have been linked with excessive noise exposure levels, and ineffective HCPs, with poor quality records that impede accurate monitoring of miners at risk of developing ONIHL. The main aim of this study is to explore risk assessment practices for ONIHL at a large-scale platinum mine in Limpopo province, South Africa, so to propose an early identification predictive model for ONIHL.

***Objectives*:** The objectives of this research were:

1. To describe the audiometry surveillance system (including record keeping) in a large South African mine over a five-year period (2014-2018)
2. To identify factors that impede the early identification of ONIHL, from mine records captured within an information management system, from 2014-2018
3. To determine if the mine used a proactive data management system (PDMS) to identify miners at risk of ONIHL
4. To establish how the mine manages miners presenting with risk factors associated with ONIHL, within the HCP
5. To propose an early identification predictive model for ONIHL in the mining industry

Methods: This was a respective cohort study. Data were accessed from one platinum mine in Limpopo province, South Africa. The individual miners' audiometry medical surveillance (health and safety) and occupational hygiene records (N=305) for the period 2014 to 2018 were analysed. Thereafter, the mine's two datasets, which contained miners' diagnostic audiometry records (N = 1 938) and a subset of records of miners diagnosed with ONIHL (n = 73) were analysed.

STATA was used for data analysis, but the data were analysed differently for each study objective. For objectives 1 and 2, data were analysed using descriptive statistics. For objective 3, miners' risk factors associated with ONIHL were identified

and described using the functional risk management structure, thereafter, a logistic regression model was used with the baseline percentage loss of hearing (PLH) margins of 0% - 40% (in 5% increments) to estimate the adjusted predictions for miners at risk of developing ONIHL, and the contribution of noise exposure as a risk for ONIHL was estimated using a two-way sample proportion test. For objective 4, ethical principles prescribed by the Health Professions Council of South Africa, the Protection of Personal Information Act, and the National Health Act (Act No.61 of 2003), that guide data access for medical research were applied to the mine's audiometry medical surveillance data to identify ethical challenges related to data access. For objective 5, miners' demographic and occupational exposures (noise and platinum mine dust) were analysed to examine their association to standard threshold shift (STS) and miners' age, sex, PLH, and dust and noise data were used to predict STS, using a linear mixed effects regression model.

Results: The results are detailed in the papers published and submitted for publications. The abstract provides a summary of findings drawn from the papers.
In paper 1, most of the miners were male (89.6%), and more than 50% were younger than 41 years. There was inaccurate and insufficient recording of risk factors for hearing loss in the medical surveillance records. Some miners were exposed to dangerously high noise levels (as high as 104 dBA). Miners as young as 21 years of age were diagnosed with ONIHL.

In Paper 2, we identified and described risk factors associated with ONIHL and calculated risks for ONIHL. A linear regression model estimated miners' risks of ONIHL at baseline. Miners with a 0% baseline PLH had a 20% predicted risk of ONIHL; and a 45% predicted risk if they had a 40% baseline PLH. Seventy-three miners had a confirmed diagnosis of ONIHL.

Paper 3 showed changes in the miners' standard threshold shift (STS) ranging from 8.3 dBHL at baseline (2014/2015) to 10 dBHL in 2016, with no changes thereafter. Less than 10% of the miners were at risk of ONIHL (>26 dBHL; STS). A linear mixed effects regression model estimated that male miners' STS were more associated with ONIHL than their female counterparts. When combined, age, PLH, noise exposure

and years of exposure were associated with STS at < 10%. There was no statistically significant association between PMD and STS in hearing.

In the fourth paper, a lack of clearly defined medical ethics policies around data access for research, and Protection of Personal Information Act (POPIA) regulations and their application on miners' audiometry, occupational hygiene, and medical data restricted data access for the latter. In this paper, different data access practices for different datasets, with stricter restrictions, were applied to miners' medical surveillance records (medical conditions and treatments).

Conclusion: Systems need to be set in place to ensure integrated accessing, analysing, and reporting miner-specific demographic, medical, occupational, and non-occupational exposure information. Annual surveillance records should be complete, accurate and should include any ear-related conditions, such as impacted wax and middle ear infections. The machine learning systems (MLSs) used for HCP risk assessment are partially effective in reducing risk and preventing ONIHL. To improve efficiency, all risk factors associated with ONIHL should be included in the mine's electronic data recording system. The use of percentage loss of hearing (PLH) to track miners' hearing may be sufficient for ONIHL compensation, but it is not adequate for identifying early signs of any type of occupational hearing loss, including ONIHL. Thus, the use of STS will ensure tracking of miners' hearing and the identification of early signs of occupational hearing loss. Age, sex, years of exposure to noise, and noise exposure levels combined effects and strength of association can be used to predict STS for this group of miners. Our findings may be used to measure the efficiency of the mine's HCP, and its efforts in preventing ONIHL among miners.

Keywords: platinum miners, risk assessment, risk factors, occupational exposures, electronic data, hearing conservation programmes, occupational noise induced hearing loss, noise, dust, percentage loss of hearing, standard threshold shifts, medical ethics, health care providers, machine learning systems

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Abbreviations and acronyms

ADBA	Audiometric data base analysis
COIDA	Compensation for Occupational Injuries and Diseases Act No. 130 of 1993
COP	Code of Practice
dB	Decibel
DME	Department of Minerals and Energy
DMRE	Department of Mineral Resources and Energy
DPOAEs	Distortion-product optoacoustic emissions
GDP	Gross domestic product
HCP	Hearing conservation programme
HEGs	Homogenous exposure groups
HPD	Hearing protection device
KPI	Key performance indicator
LMIC	Low-and-middle-income country
MHSC	Mine Health and Safety Council
MHSA	Mine Health and Safety Act No. 29 of 1996
MLS	Machine learning system
MOSH	Mine Occupational Safety and Health
MSHA	Mine Safety and Health Administration
NIHL	Noise induced hearing loss
OEL	Occupational exposure level
OHC	Outer hair cells
OHN	Occupational health nurse
OHSA	Occupational Health and Safety Act No. 85 of 1993
OMP	Occupational medical practitioner
OSHA	Occupational Safety and Health Administration
ONIHL	Occupational noise induced hearing loss
PDMS	Proactive data management system
PLH	Percentage loss of hearing
PTS	Permanent threshold shift
RBME	Risk-based medical examination
SNHL	Sensory neural hearing loss
STS	Standard threshold shift
SANS	South African National Standards
TTS	Temporary threshold shift
WHO	World Health Organization

Definitions of terms

Audiologist: Graduate in audiology registered with the relevant national body (Health Professions Council of South Africa).

Audiometrist: A person qualified in audiometric techniques from an institution registered with the relevant national authority or any of its structures in terms of the relevant national legislation and registered with the relevant national body (South African Nursing Council or the Health Professions Council of South Africa).

Audiometric data base analysis (ADBA): A method that allows for miners' audiometry data analysis from baseline to exit to judge the effectiveness of a hearing conservation program (HCP).

Disabling hearing loss: Refers to hearing loss greater than 40 decibels (dB) in the better hearing ear in adults and a hearing loss greater than 30 dB in the better hearing ear in children. The majority of people with disabling hearing loss live in low- and middle-income countries.[2]

Hearing conservation programme (HCP): A programme designed to prevent hearing loss in the workplace.

Leq8hr: An Equivalent Continuous Sound Pressure Level (Leq), at 3 dBA exchange rate, and is a measurement parameter designed to represent a varying sound source over a given time (eight hours) as a single number.[3]

National mining regulatory body: Department of Mineral Resources and Energy.

NIHL milestone regulation (2016): The regulation stating that no employee's STS should exceed 10 dBHL from the baseline when averaged at 2000, 3000 and 4000 Hz in one or both ears.[1]

Noise-induced hearing loss (NIHL): Permanent hearing loss caused by exposure to loud sounds; characterised by a high frequency hearing loss and tinnitus.

Percentage loss of hearing (PLH): determined by audiometric testing, using hearing levels (HL) at the frequencies of 500 Hz, 1 kHz, 2 kHz, 3 kHz and 4 kHz to calculate hearing disability.

Permanent threshold shift (PTS): A permanent shift in the auditory threshold is a permanent hearing loss caused by prolonged exposure to excessive noise (≥85 dBA).

Risk based medical examination (RBME): A medical examination conducted at regular time intervals (bi-monthly, tri-monthly, annually) to monitor workers to identify health risk factors.

Sensory neural hearing loss (SNHL): Permanent hearing loss caused by damage to the inner ear or the auditory nerve that sends signal from the ear to the brain.

Standard threshold shift (STS): A change in hearing threshold, relative to the baseline audiogram for that employee, of an average of 10 decibels (dB) or more at 2000, 3000, and 4000 hertz (Hz) in one or both ears.

Temporary threshold shift (TTS): A temporary shift in the auditory threshold that can occur suddenly after exposure to excessive noise, causing temporary hearing loss that lasts for 16-48 hours after cessation of the noise.

4 KHz notch: hearing threshold of 4 kHz at least 10 dB greater than that at 2 and 8 kHz; regarded as the signature notch in audiograms of NIHL (Wilson, 2011). This is a characteristic notching of the audiogram referred to as a "noise notch" which is greater at 4 kHz than at the adjacent frequencies (usually 3 kHz and 6 kHz). It is commonly seen in individuals with noise induced hearing loss, the presence of the notch, in and of itself is not diagnostic.

CHAPTER 1: INTRODUCTION

This chapter provides the background to, and contextualises, this PhD thesis. Occupational noise induced hearing loss (ONIHL) in South Africa which affects the South African mining industry, the individual miner, the mines themselves, and the Government, is discussed. Risk assessment practices used by South African mining companies for prevention of ONIHL are described. The problem statement and the rationale for this study are presented, followed by the presentation of the aim and objectives.

1.1 Background

Hearing loss is a loss of hearing sensitivity which may be as a result of outer and/or middle ear pathology, including impacted wax, ear infections, congenital ear malformations, or cochlear pathology, such as systemic conditions (e.g. related to age or degeneration and neurological), inner ear infections, trauma due to excessive noise exposure, and ototoxicity.[1] According the World Health Organization (WHO), more than 30 million people worldwide are exposed to excessive noise levels in the workplace.[2] For example, manufacturing, farming, construction, transportation, music and mining workplaces have been reported to use equipment which emits excessive occupational noise levels associated with hearing loss across the globe.[3] Occupational noise is considered the main risk factor for occupational noise induced hearing loss (ONIHL).

Occupational induced hearing loss is hearing loss caused by over exposure to noise in the workplace. According to the South African Noise Induced Hearing Loss (NIHL) Regulation, excessive occupational noise is known as eight-hour time-weighted average noise intensity level of ≥ 85 dBA[4] and causes a sensorineural type of hearing loss that occurs gradually over time due to high intensities and/or high frequencies of noise. Excessive noise exposure causes permanent damage to the organ of Corti, affecting both ears.[1] The initial damage to the organ of Corti's outer hair cells is identified by high frequency sensorineural hearing loss identified on an audiogram, in the region of 3000 - 6000 Hz.[1] Characteristically, ONIHL on the audiogram shows as a distinct ‘noise notch’ (a dip of the air and bone-conduction) at 4000 Hz, which is not pathological.[5]

Hazardous noise exposure affects the hearing system in various ways, such as a temporary hearing loss, which may affect one or both ears. This is referred to as a temporary threshold shift (TTS), which lasts for 16 to 48 hours after the cessation of a loud sound. However, continuous, and prolonged exposure to excessive noise (≥85 dBA) results in a permanent threshold shift (PTS). This PTS is irreversible and is known as ONIHL.[1,6]

Occupational noise induced hearing loss has a negative impact on the affected individual’s communication ability in his/her daily social interactions with family, friends and co-workers.[2] Hearing health concerns related to social factors include reduced communication skills. For example, difficulty hearing high frequency sounds and understanding speech; difficulty hearing warning signals; and limited participation in other social activities, leading to psychological and social isolation.[2] Additionally, there are socio-economic drivers of hearing loss such as unemployment, limited access to high quality health care, and poor sanitation and housing.[10] Thus, the burden of ONIHL negatively affects workers’ quality of life and socio-economic well-being long after employment has seized.

The WHO classifies noise induced hearing loss (NIHL) caused by occupational noise exposure as a disabling global burden[7] and a significant public health problem that is endemic in many occupational settings.[7,8] Occupational noise induced hearing loss is estimated to be the most prevalent disabling condition in workers, affecting an estimated 18% of the adult population in various occupations, and more workers in low-and-middle income countries (LMICs) than in the global north.[5] A study conducted by Nelson et al.[3] in the early 2000s showed that the global burden of ONIHL ranged from 7% to 21%.[3] A Centres for Disease Control and Prevention (CDC) study, using data from the National Institute for Occupational Safety and Health (NIOSH) from 2003 to 2012, reported that 2.53 disability-adjusted life in years (DALYs) per 1000 workers in the USA were due to noise exposure.[9]

Occupational noise induced hearing loss is also highly ranked among common occupational medical conditions in Africa.[10,11] Accurate occupational noise exposure data from countries in Africa should be used to calculate accurate and up-to-date prevalence rates of ONIHL in the region.

Prevalence of occupational noise induced hearing loss in sub-Saharan Africa

The reported high prevalence rates (23% - 47%) of ONIHL in sub-Saharan Africa[12,13] highlight the need for prevention of this condition, in preference to early identification of cases. Studies in the sub-Saharan region, in industries where noise is a problem, have reported higher excessive noise exposure levels (>100 dBA). These levels are higher than the regulated noise exposure level of 85 dBA (equivalent continuous sound pressure level (Leq8hr),[3] as per South African regulations.[14] Some studies have reported high prevalence rates (> 20%) of ONIHL in the agriculture and mining industries, but there is a paucity of evidence for ONIHL prevalence in the construction industry in this region.[3, 7] However, reported prevalence rates of ONIHL in some industries and countries in the sub-Saharan region should be interpreted with caution as some are based on hearing screening results.[13,15]

Prevalence of ONIHL in the mining industry in South Africa

In South Africa, ONIHL is the third most commonly reported occupational health disease after tuberculosis and silicosis, with a prevalence rate of higher than 30%.[16] Mine workers in all commodities are affected.[16] Occupational noise induced hearing loss is a burden for the individual miner, the employer (i.e. the mine), and the Government.

Even though there are reports of excessive noise levels in the South African mining industry, in 2006, Begley criticised the mining industry for its inaccurate recording/reporting of noise measurements.[17] Recording and reporting of noise measurements are critical to identify risks for ONIHL and have been used to calculate accurate prevalence rates for ONIHL. Although this can be, and is, done through research, it is essential that access to data does not compromise confidentiality.

The burden of ONIHL in South African miners has been estimated from the number of cases reported annually by the mines to the (now) Department of Minerals and Energy (DMRE)[16], ONIHL compensation claims reported by the Rand Mutual Assurance (RMA) company, and a study on prevalence rates in one gold mine (Strauss, 2012).[18] The DMRE reported a fluctuation in the number of NIHL cases from 2016 to 2018 in its annual reports.[16] There are more cases of ONIHL reported in the gold and platinum mines than in other mines (there are more miners employed by these two mining sectors).[19-21] More specifically, an increase in the number of ONIHL cases was reported in the platinum mines, from 347 (N = 966) in 2016 to 535 (N = 1 141) in 2017. In 2018, the number of cases reported increased to 886.[16,22]

Reports compiled by the individual mines tell a different story from that of the DMRE reports, i.e. that there was a decline in the number of ONIHL cases from 2014 to 2018. For example, the AngloGold Ashanti mine reported a decrease from 35 to 30[20], and Anglo-American plc, from 90 to 30.[21] Unfortunately, there was no statistical significance on the cases reported as the annual reports did not provide information about the number of miners employed and, therefore, the rates of ONIHL cannot be determined from these reports. The RMA Company reported an ONIHL compensation claims rate of 7.05% in 2008, and 90% in 2019, for the mining industry.[23] This increase might have been due to the mines' increased capacities and/or abilities to assess and diagnose miners with ONIHL over the 11-year period. Future research should further investigate the associations thereof.

1.2 Occupational noise induced hearing loss in South Africa

1.2.1 Risk factors for ONIHL

Occupational noise induced hearing loss is exacerbated by various risks factors, such as individual susceptibility, occupational exposures, certain medical conditions, and the treatments thereof. Increasing age, being male and black[24,25], occupational exposure to noise with poor use of hearing protection devices (HPDs)[25,26], exposure to chemicals[27], treatments for tuberculosis (TB), human immunodeficiency virus (HIV)[28], and vibration[29] are risk factors associated with ONIHL in South African miners. There is limited research on the associated risk of cancer treatments, exposure to chemical agents (e.g. carbon monoxide, solvents and heavy metals), and exposure to recreational noise in South African miners with ONIHL.

The management of risk factors for ONIHL is possible with efficient risk-based surveillance programmes, which include reduced noise exposure, audiometry monitoring of workers at risk of developing ONIHL, and accurate recording and reporting of data.[25,30] Unfortunately, all risk factors might not be recorded in the mines' medical surveillance reports.[17,31] In some instances, records about medical conditions and treatments thereof are maintained in databases that are separate from those containing the occupational exposure and hearing conservation programmes (HCPs) data.[32] Information about the burden and impact of risk factors associated with ONIHL is largely available from international studies. There is minimal evidence from LMICs, such as South Africa, thus, ONIHL pathogenesis requires further research.

1.2.2 Hearing conservation programmes

The high burden of ONIHL in the South African mining industry has been attributed to ineffective and costly HCPs employed for the past 20 years.[33] The seven pillars of an HCP include measuring noise levels; use of engineering and administrative controls to reduce excessive noise exposure levels; training and education; the use of HPDs; medical surveillance; and audiometry testing.[14] The commonly reported reason for the failure of HCPs in the South African mines, as cited in the literature by Strauss et al. (2014)[24] and Grobler et al. (2020)[25], is continual exposure to excessive noise levels.[24,25] Focus is on occupational noise exposure as the main hazard for ONIHL[24,25,34]; the high cost of engineering controls to reduce noise emitted by equipment[16]; poor compliance with regard to the use of HPDs by miners[26]; miners' limited understanding of education and training content and modes of training, which were reported to restrict efficiency of HCPs [26,35]; and a lack of integrated audiometry medical surveillance data.[17,32] However, there is also a lack of HCPs that adopt complex interventions as an approach for the prevention of ONIHL, and exclusion of audiologists, in the implementation of HCPs.[36,37]

1.2.3 Regulations for the prevention of ONIHL

Reduction of noise at source, noise measurements, routine audiometry, and the use of HPDs have been highlighted as key indicators of ONIHL prevention.[14] However, until 2014, South African legislation focused on compensation for ONIHL rather than prevention. Circular Instruction 171 of the Compensation for Occupational Injuries and Diseases Act No. 130 of 1993[4], which addresses the burden of ONIHL in miners, favours compensation of miners diagnosed with ONIHL above prevention of hearing loss. Instruction 171 states that occupational noise exposure ≥ 85 dBA, measured over an eight-hour working shift (8-hour TWA), leads to compensable ONIHL.[6] There is a need for routine audiometry to be better utilised by mining companies to expedite prevention measures for ONIHL.

The South African Bureau of Standards' South African National Standard (SANS) 10083:2013 refers directly to HCP guidelines for all industries where noise is a problem.[14] The Mine Health and Safety Act (Act No. 29 of 1996) (MHSA) provides for the enforcement of health and safety measures, and has been instrumental in guiding the mining industry towards ONIHL prevention through the implementation of the ONIHL regulations.[19, 38] In 2014, Regulation 839 was introduced into the MHSA to promote the use of the standard threshold shift (STS) for tracking miners' hearing deterioration – a step towards addressing prevention of ONIHL. This is based on an International Organization for Standardization (ISO) standard (ISO1999:2013), which states that a decline of 8 dB in the STS indicates early onset of ONIHL.

1.2.4 Milestones for noise exposure reduction and ONIHL prevention

The HCP and prevention of ONIHL milestones (measurable steps) were developed to reduce the burden of ONIHL.[38] In 2004, the Mine Health and Safety Council (MHSC) set milestones for the mining industry, stating that, after December 2008, the mines, through their HCPs, should ensure that there was no deterioration in hearing greater than 10% amongst occupationally exposed miners; and that, by December 2013, total noise emitted by all equipment used should not exceed 110 dBA.[39,40] To address the 2008 milestone for noise reduction, the mines implemented the purchase and maintenance of quiet mining equipment to show their initiatives for prevention of ONIHL. However, the 2008 milestones were not achieved [45] and were therefore revised in 2014 by the MHSC.[38] The revised milestones stated that, by December 2016, no employee's STS should exceed 10 dBHL from baseline in one or both ears.[42] Nevertheless, even with these milestones in place, the burden of ONIHL on South African miners continues. The failure to meet the milestones might be due to inefficient risk assessment methods and procedures in the mines.[33] Thus, proactive data reporting systems, inclusive of all risks associated with ONIHL, should be further investigated to ensure that HCPs are effective, and that the ONIHL milestones set by the South African mining industry are met.

1.3 Risk assessment practices followed by the South African mines for prevention of ONIHL

Risk assessment practices can only be efficient if data are recorded accurately.[29] Currently, there is no standardised format for recording data in the mining industry, which would allow for accurate assessment of the effectiveness of mines' HCPs.[17,29] Auditing of HCPs by the DMRE may be accomplished with the use of the mines' risk assessment electronic repositories, where individual mines' internal risk assessments require accurate reporting of occupational activities associated with health risks.[29]

One of the most commonly used risk assessment tools in HCPs is the audiometry database analysis method (ADBA), recommended by Franz and Phillips in the late 1980s.[29] It is used by most large-scale mines to identify miners' occupations, workplaces, and activities where there are many employees with hearing loss. The ADBA method was initially intended to show that audiometry databases can be used to measure mines' HCP effectiveness. However, it was found to be ineffective in tracking all hearing health conditions.[43]

Record keeping practices, electronic systems, and end-users' skills in data recording play critical roles in predicting ONIHL and the success of an HCP. Accurate HCP data analysis requires complete and valid data, including relevant risk factors, so that the mines can predict and prevent ONIHL.[17,25] Data must also be consistently recorded for each miner.[44] However, the mines' HCP risk assessment practices and procedures are not optimal for the recording, reporting and access of data to ensure accurate prediction of ONIHL.[10,17]

1.3.1 Challenges related to the South African mines' hearing conservation programme data

Accurate HCP records, used to track hearing and predict early onset of hearing deterioration, are essential for the prevention of ONIHL. Miners' HCP records, which include exposure to occupational hazards (including noise and chemicals) and monitoring of miners at risk for related health effects, which are kept by the mines' hearing conservation practitioners, have been labelled by some researchers as flawed[17], lacking rigor and not preventing ONIHL.[36] In addition, the mines' implementations of the HCP pillars for the reduction of occupational noise levels, lack of data on the use of HPDs by miners, and incomplete audiometry records are challenges which hinder the South African mines' HCPs efficiency.[14,25,38]

1.3.2 Challenges related to data access in South African mines

There are challenges for researchers in accessing miners' medical surveillance data required for research on the prevention of ONIHL. The mines collect copious amounts of data but do not necessarily have the resources to analyse the data beyond their administrative requirements. In addition, the use of heterogeneous electronic health systems by the mining companies, and a lack of standardised formats to record medical data, also restrict access to data. More sophisticated statistical analysis requires skills and expertise of occupational health researchers. One solution is for skilled occupational health researchers, who are trained in data analysis, to do this. The regulations applied by the mines to protect miners' personal information and ensure confidentiality of medical records include the Protection of Personal Information (PoPI) Act of 2013[45], National Health Act (Act No.61 of 2003)[46] and Ethical Rules of the HPCSA.[47] However, confidentiality policies and legislation, and the misinterpretations thereof, can present obstacles to data access and thus prevent the publication of important findings from the analysis of the data.

1.3.3 Information related to risk factors for occupational noise induced hearing loss

Hearing conservation programme data should be recorded, accessed, and analysed appropriately to ensure accurate estimates of risks for ONIHL. Estimating a miner's risk for ONIHL is restricted by a lack of 'non-occupational' information, such as exposure to loud music, use (or non-use) of HPDs and pre- or co-existing chronic medical conditions and treatments that affect the auditory and balance systems. These data are not recorded in the miners' HCP records.[25,27,28] Some studies have reported a lack of integrated HCP data as a hindrance to accurate estimation of ONIHL for the South African miners.[25,48]

1.4 Study rationale

Worldwide, ONIHL is a public health problem caused by exposure to excessive noise in the workplace. South Africa is no exception, especially with regard to the mining industry.[11,20] There is paucity of both epidemiological studies on ONIHL and accurately recorded HCP data to measure the burden of disease of ONIHL in the South African mining industry.

In South Africa, NIHL regulations, HCP guidelines, and DMRE milestones guide the mines with regard to recording hearing health and audiometry data and monitoring progress of the prevention of ONIHL in the mining industry. Nevertheless, there is still a high burden of ONIHL in the mining industry, which warrants further investigation. Accurate estimates of the incidence and prevalence rates of ONIHL are also lacking. Prevention of ONIHL is important to reduce the burden of disease and to improve miners' quality of life.[20,53] High quality HCP data will allow accurate risk assessment and management of miners at risk of developing ONIHL.

The research described in this thesis was conceptualised with the hope that the findings would illustrate the importance of accurate record keeping for tracking miners' audiometry medical surveillance data for the prediction and prevention of ONIHL.

1.5 Study aim and objectives

The aim of this research was to explore risk assessment practices, which incorporate data management, at a large-scale platinum mine in Limpopo province, South Africa, with the intention of proposing a predictive model for the early identification of ONIHL.

Objectives

1. To describe the audiometry surveillance system (including record keeping) in a large South African mine over a five-year period (2014-2018).
2. To identify factors that impede the early identification of ONIHL, from mine records captured within an information management system, from 2014-2018.
3. To determine if the mine used a proactive data management system (PDMS) to identify miners at risk of ONIHL.
4. To establish how the mine manages miners presenting with risk factors associated with ONIHL, within the HCP.
5. To propose an early identification predictive model for ONIHL in the mining industry.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

In this chapter, I describe and discuss findings from international and local studies and highlight the knowledge gaps under the topics covered in my research, namely, the prevalence of occupational noise induced hearing loss (ONIHL) in the mining industry, risk assessment approaches used for early identification of risks associated with ONIHL, and the prediction and prevention of ONIHL. The conclusion highlights gaps in the literature that restrict the prevention of occupational hearing loss in the mining industry.

2.2 Burden of occupational noise induced hearing loss

The World Health Organization (WHO) identifies NIHL as one of the most common and costly disabling occupation-related impairments, with a global estimated annual cost of 750 billion US dollars.[11] There is thus an urgent need for hearing health care and hearing conservation programmes (HCPs) to be implemented to prevent ONIHL.

2.2.1 Global prevalence of occupational noise induced hearing loss

The prevalence of ONIHL is high (7% to 21%), worldwide.[3] However, there are differences in the prevalence rates of ONIHL between high income countries (HICs) and low-and-middle income (LAMICs) countries.[3] The highest prevalence rates (> 30%) of ONIHL are reported by LAMICs, mainly in the mining industry.[11,18] The high prevalence rates reported by previous studies, as described by Nelson et al. (2005)[3], highlight the global burden of ONIHL in different countries and occupational settings. However, there are no recent estimates of the global prevalence rate of ONIHL.

Worldwide, 16% of the disabling hearing impairment in adults is due to exposure to occupational noise, which currently affects about four million workers.[2] The occupations most affected by ONIHL are those related to mining, construction and manufacturing workplaces.[9, 50] In the USA, the prevalence rate of ONIHL in the mining industry, from 2006 to 2010, was estimated to be 24%.[51] In Australia, a prevalence rate of ONIHL of 7% was reported for the 2008/9 period.[52] Both the USA and Australia are HICs but their ONIHL prevalence rates differ, with the USA reporting a higher prevalence rate than Australia. The USA ONIHL prevalence figures are calculated from occupational noise level data from the United States and the National Institute for Occupational Safety and Health (NIOSH) and National Occupational Health Survey of Mining data which was collected historically from three different sources in the early 2000s.[3] The global prevalence of ONIHL may be difficult to estimate due to the use of different data sources from various countries and workplaces. Consequently, there is a dearth of recent ONIHL prevalence.[3,53]

Analyses of compensation claims for ONIHL have been used to highlight the financial burden on different countries. In the United States, ONIHL compensation costs, amounting to 1.2 billion US dollars, was paid out, mainly to military veterans, from 1979 to 2014.[54] In Australia, the mining industry reported that 19% of their compensation claims were paid out to workers diagnosed with ONIHL during the 2008/9 period.[52] ONHIL compensation costs were based on historical data.

2.2.2 Prevalence of occupational noise induced hearing loss in Africa

The prevalence rates of ONIHL in the mining industry in Africa are available historically, from 2004 up until 2015.[3,50] In 2005, the estimated prevalence of ONIHL in African countries was reportedly higher than 21%.[3] For example, Amedofu reported a prevalence rate of 23% among gold miners in Ghana in 2002,[12] and Masaka reported that the prevalence rate of ONIHL in nickel miners in Zimbabwe in 2009 was 27.4%.[15] Following a study on Tanzanian open-pit and under-ground miners, conducted in 2015, Musiba reported that the prevalence rate of ONIHL was 47%, and that miners as young as 20 years were affected.[13] However, not enough studies have reported year-on-year prevalence rates of ONIHL to allow for comparisons of trends of the disease. Thus, there is a need for regular and frequent analysis of up-to-date audiometry data for accurate and current estimates of prevalence rates of ONIHL in the mining industry in Africa.

There may be a financial burden on some African countries that have reported ONIHL prevalence rates. These African countries are defined as low and middle-income countries (LMICs) based on their gross domestic product (GDP) to which mining contributes significantly.[23] However, there is paucity of information about the burden of ONIHL on African countries' GDPs.[3] This can be rectified, to some extent, by reporting on compensation payouts for ONIHL to miners in sub-Saharan Africa.

2.2.3 Prevalence of occupational noise induced hearing loss in South African mines

Occupational noise induced hearing loss is common in South African mines across different commodities, but there are very few studies on prevalence rates. In only one large study was gold miners' data analysed (Strauss et al., 2012), resulting in an estimated prevalence of ONIHL of 17%.[18]

Some South African mines favour using the number of cases to demonstrate the burden of ONIHL and as a measure of their prevention efforts for ONIHL, rather than reporting prevalence rates. In the Department of Mineral Resources and Energy's (DMRE) 2016/2017 annual report, the numbers of ONIHL cases were highest for the platinum (N=535) and gold (N=390) mines, respectively.[16] Individual mines reported a decrease in their ONIHL cases from 2016 to 2017.[20,21] For example, AngloGold Ashanti reported a decrease in cases from 35 to 30[20], and Anglo-American plc, from 90 to 30.[21] Despite these reductions in numbers, it is evident that the mines are struggling to prevent ONIHL.[32]

The Rand Mutual Assurance company (RMA) administers claims for occupational injuries and some occupational diseases (including ONIHL) for the South African mining industry, in terms of the Compensation for Occupational Injuries and Diseases (COID) Act.[23] For the period 2016/2017, 90% of the claims processed by RMA were for ONIHL.[23] The compensation claims rate reported by the RMA is based on the number of successful ONIHL claims, viz. 1 226 in 2016, 1 462 in 2017, and 1 165 in 2018. In 2019, the RMA reported 433 successful ONIHL-related claims, which indicated a decrease in successful claims from 2016 to 2019.[23] The decrease in the number of successful ONIHL compensation claims may be due to various factors, such as the possibility of fewer ONIHL claims submitted to the RMA by individual mines (i.e. the under reporting of ONIHL cases); and the rate at which claims were processed per annum. These factors need to be investigated.

2.3 Risk assessment of occupational noise induced hearing loss

The implementation of HCPs as risk assessment tools for prevention of ONIHL should incorporate individual miners' medical surveillance history from baseline (initial entry) and during employment history. Specific to hearing health care, miners' audiometry medical surveillance data should be able to identify risk factors associated with ONIHL. Previous studies have highlighted the importance of risk characterisation and management (assessment and intervention strategies) of risks associated with ONIHL.

2.3.1 Risk factors associated with occupational noise induced hearing loss

Worldwide, ONIHL is associated with multiple risk factors, such as personal factors (e.g. genetic factors, age, gender, race/ethnicity, smoking, medications, contextual diseases, etc.)[24,25,28,50,55-58], physical factors (e.g. lighting, vibration, heat, cold), chemical agents (e.g. carbon monoxide, solvents, heavy metals)[27,59], and occupational factors (e.g. excessive noise exposure, non-use of HPDs, workload, shift).[9,25,60] Previous studies in the USA reported that male adults have a long history of working in industries where noise is a problem, thus males were more affected than their female counterparts.[3,9] More cases of ONIHL in male workers were attributed to differences in anatomical and physiological structures between males and females.[50,55] Although most of the previous studies have only identified risk factors associated with ONIHL, Golmohammadi and Darvishi (2019)[61], in their systematic review on the combined effects of occupational exposure to noise and other risk factors associated with ONIHL provided a risk ranking of stronger risk factors for ONIHL.[61] In addition, previous studies have reported on the health effect (ONIHL) of occupational exposure to noise and other risk factors, but have not shown a model outcome on the interactions between multiple risk factors, and impact thereof, specifically for ONIHL.

Despite the multiple risk factors associated with ONIHL being reported, the focus, in various occupational industries, globally, has been on excessive noise exposure levels (≥ 85 dBA; Leq8hr) and monitoring the hearing of workers exposed to occupational noise. These two factors are used as measures of the effectiveness of a company's hearing conservation programme (HCP).[16,18,29] Consequently, there seems to be a limited understanding and quantification of risk factors associated with ONIHL, which hinders the effectiveness of HCPs.

2.3.2 Management of risk factors associated with occupational noise induced hearing loss

Risk management strategies (assessment and intervention) are designed to identity workers at risk for occupational exposures, to prevent the associated occupational health effects.[29] In HCPs, hearing conservation practitioners also use risk assessment methods and interventions, inclusive of the HCPs pillars of noise measurements, employing engineering and administrative controls to reduce excessive noise exposure levels, training and education, the use of HPDs, medical surveillance, and audiometry testing[14,62] for the prevention of ONIHL. Nevertheless, there is limited research on the specific risk assessment methods used by hearing conservation practitioners, globally, as well as in the South African mines. Some researchers, however, have provided recommendations for risk assessment methods to prevent ONIHL.[48,63] In a study conducted by Moroe et al. (2020), the authors implemented a feedback-based noise management matrix using data from a South African platinum mine to show efficient monitoring and management of HCPs and measures for predicting ONIHL.[48] While their findings provided the basis for predicting ONIHL, there was no specific dose assessment data used.[48] Thus, there is paucity of epidemiological and risk characterisation studies which provide estimation of the incidence and severity of ONIHL on miners.

2.4 Hearing conservation programmes

Hearing conservation programmes have been identified as solutions to the high burden of ONIHL in industries where workers are exposed to excessive noise,[64] since 1983 when the hearing protection, audiometric testing, and training were introduced.[65] Although the HCP pillars are similar globally, there is no standard for their implementation due to differences in industries and countries' HCP guidelines.[3,65] Hearing conservation programmes are used to mitigate the impact of occupational noise and have been able to reduce the prevalence of ONIHL, but there is room for improvement (in identifying, assessing and controlling threats) to eventually prevent

ONIHL globally.[2] The implementation of inclusive HCP methods guides HCP policy reviews, improves effectiveness of HCP, and prevents ONIHL.[48]

Some studies in South Africa have supported the utilisation of mine-specific HCPs and risk assessment methods to prevent ONIHL because of the different commodities that are mined and the related differences in activities and exposures.[37,66] Franz and Phillips (2001)[33] proposed a functional risk management system, which shows interactions between the HCP elements and the flow process, to ensure control of excessive noise exposure and prevention of ONIHL.[29] Moroe and Khoza-Shangase (2020) proposed that, due to the complexity of HCPs, risk assessment should be based on a realist approach.[36] Moroe et al. (2020), also used a feedback noise measurement matrix in their study, which highlighted the importance of accurate measurement of noise exposure levels and the roles played by occupational medical practitioners (OMPs) and miners in ensuring the success of HCPs in South African mines.[48] Individual mines should thus approach ONIHL risk assessment differently, methodically, guided by mine-specific occupational exposures and miner-specific risk factors.

Begley (2006)[17] suggested that tracking of miners' hearing and early identification of risk for ONIHL, within HCPs, could guide effective implementation of administrative controls and potentially prevent ONIHL. However, this was not achieved, as some miners' audiometry records were incomplete.[17] More recently, Grobler et al. (2020) published the findings of a study in which they used the averaged high frequencies (2, 3, and 4 KHz) as a method to predict hearing deterioration rates for gold miners exposed to noise, over a period of four years.[25] They predicted hearing deterioration rates of 3.5 dB and 2.9 dB, respectively, for the two groups. However, they did not comment on the quality of the miners' hearing thresholds used to predict miners' hearing deterioration rate.[25] Previous studies showed that tracking of miners' hearing has the potential to show early onset of hearing loss, and may therefore be an efficient measure taken to mitigate ONIHL.[18,25,66] Thus, there is a need to standardise tracking of miners' hearing, to record miners' hearing deterioration over a period of time, and to ensure that miners' hearing thresholds used are of good quality.[17]

To improve the quality of miners hearing thresholds, which may be used to predict ONIHL and to fill in the gaps of some of the hearing thresholds, machine learning analysis, as suggested by Aliabadi et al. in 2015 and by Pitathawatchai et al. in 2021,[67,68] may be considered by researchers in the South African mining industry. In addition, audiometry tests such as the distortion-product otoacoustic emissions (DPOAE) test - one of the recent advances in audiometry in the South African mining industry - has been reported to be sensitive for the early identification of ONIHL.[66] There are various methods used to track South African miners' hearing deterioration, which need to be synthesised, but require empirical evidence to show early identification and accurate prediction of ONIHL.

In South Africa, mines have recorded STSs annually to show hearing threshold changes, and the consequent hearing deterioration as a function of various risk factors associated with ONIHL, including occupational, non-occupational and medical, but no results have been published.[42] The 2014 NIHL Milestones mandated by the DMRE[37], from December 2014 to December 2016, hopes to improve the mines' HCP efficiency and tracking of miners hearing.[42] The hearing thresholds tracking method used by the South African mines, as recommended by the current NIHL Milestones, is in line with the hearing loss classification recommended by the WHO as stated in their 2021 World Hearing Day report.[2] The estimated effect of the combined risk factors (noise, chemicals, recreational noise, age, sex, race, and ototoxic medications) on the auditory system may be significant, but this is unknown, as some studies have only reported on one (noise)[9,69] or two (noise and age[25,26]; noise and elevated blood pressure[56]; noise and ototoxic medication[32]) factors associated with ONIHL. Thus, to estimate the combined effect of risk factors on miners' hearing and risks for ONIHL, more studies need to be conducted by the South African mines. There is a need for the mines to publish miners' STSs results to show the mines' journeys towards ONIHL prevention.

2.4.1 Record keeping in prevention of occupational noise induced hearing loss

The rationale for accurate maintenance of workers' HCP databases is informed by the need for early identification of workers at risk of developing ONIHL, identification of risk factors associated with ONIHL, efficient audiometry surveillance, which is critical for medical decisions, and intervention strategies to reduce the burden of, and/or prevent, ONIHL.[14,42,62] In a study conducted in the United States, noise exposure associated with ONIHL was found to be the most frequent self-reported complaint by workers.[64] Thus, there was a focus on noise exposure as the main hazard to be monitored and recorded in HCPs.[64] In the United States, some studies on HCPs and ONIHL have recommended that data on noise exposure levels and chemical agents, such as carbon monoxide, toluene, trichloroethylene, trichlorophenol, xylene, and formaldehyde should be detailed in the workers' HCP records.[59,69] In addition, Tikka et al. (2020) conducted a systematic review of interventions to prevent ONIHL, and recommended that noise exposure levels, duration of noise exposure (hours/shift), and years of exposure (> 10years), should be included in the workers' HCP records.[53] In this way, comprehensive data on occupational exposures, noise and chemicals can inform hearing conservation efforts.

Globally, individual workers' personal characteristics, such as age, sex, cigarette smoking, use of ototoxic medication, and type 2 diabetes and hypertension, increase the risk of ONIHL, and should be included in the workers' HCP records.[70,71] In addition, the Occupational Safety and Health Act (Act 29 of 1996) mandates that "prior to receiving audiometric testing, personnel covered by PER 04-00-003 will complete an audiometric history form in order to document pertinent medical history, noise exposure, and use of hearing protection" to ensure accurate records for the prevention of ONIHL.[59,62] Yet, HCP records have been inconsistently maintained, reducing opportunities to use comprehensive records, specifically to prevent ONIHL.

To ensure the maintenance of accurate HCP records, the South African mines follow the regulations and guidelines mandated by the MHSC and the DMRE[72], medical ethics regulations[73], and the POPI Act of 2013.[42] The mines submit annual HCP reports to the DMRE, which cover information such as noise exposure levels, engineering controls (e.g. buying 'quiet' equipment), the use of HPDs, and the number of miners diagnosed with ONIHL.[36] Other risk factors, such as the miners' previous diagnosis of other types of hearing loss, medical conditions, the use of ototoxic medication, and exposure to occupational chemicals, are recorded separately from the HCP records submitted to the DMRE, which hinders accurate record keeping of HCP data for the prevention of ONIHL.[17,22]

So far, the risk assessment methods used by South African mines have not provided accurate information for appropriate mitigation strategies that may successfully prevent ONIHL. The audiometry database analysis (ADBA) technique recommended by Franz and Phillips in the late 1980s[29], which uses miners' audiometry surveillance data to monitor miners' hearing, was found to be inefficient in the early tracking and identification of miners at risk of developing ONIHL.[17,24,25,55] The use of this technique showed that, although the mines kept HCP data that allowed for the prediction and prevention of ONIHL,[64] the data were inconsistent, rendering their HCPs inefficient and thwarting their efforts to prevent ONIHL. Nevertheless, previous authors reported only on selective data relevant for their studies and not comprehensive HCP data kept by the mines and the risk assessment method used to prevent ONIHL.

2.5 Summary of the literature reviewed

From the literature reviewed, it is evident that the South African mines' HCPs need to include mine-specific activities and recording of occupational exposures that might increase miners' risks of ONIHL.[16,34] Some researchers have suggested that the mines' HCPs should be re-evaluated, and have proposed that other implementation approaches, such as realist and feedback-based noise monitoring models[36,63], be considered to improve individual mines' HCP outcomes, and in the prevention of ONIHL.[64,75]

Machine learning systems used by the mines for HCP risk assessment are used to monitor miners and predict risk for ONIHL. Machine learning is a data analysis method that automates data and uses computer systems with artificial intelligence (AI) functionalities, for example, Excel Spreadsheets, to predict outcomes.[44,68,75] However, some research findings on ONIHL cases are cause for concern with regard to the interactions between multiple risk factors associated with ONIHL, which are not completely recorded. For example, information about ototoxic medications for tuberculosis and HIV, occupational chemical exposures, and exposure to recreational noise are not included in HCP records.[18,25,27,28,56] Thus, there is a need for the mines' machine learning systems (MLSs) to comprehensively include accurate HCP data in order to track miners' hearing function and prevent ONIHL.

There are difficulties in measuring the effectiveness of HCPs due to regulations and guidelines mandated by the Mine Health and Safety Council and the DMRE[72], medical ethics regulations[73], and the POPI Act.[42] The merging of HCP data sources (or lack thereof)[74], and the MLSs employed by the mines' lack of comprehensive HCP data, appear to have benefits and limitations that need to be further explored.[36,37]

Table 2.1 summarises gaps in the literature on the mines' HCPs, and prediction and prevention of ONIHL.

Table 2.1. Summary of literature reviewed

Topic	What is known	Knowledge gaps
Prevalence of ONIHL	Worldwide, estimated prevalence of ONIHL due to noise exposure ranges from 7% to 21%. African countries have higher prevalence rates (>20%) of ONIHL.	Prevalence rates of ONIHL are based on data collected more than 15 years ago. Updated estimates of prevalence rates are not available in the literature. The prevalence rate of ONIHL in African countries is based on fewer than 10 studies.
Risk factors associated with ONIHL	Noise exposure is considered the main risk factor for ONIHL. Age and sex, and exposure to recreational noise and chemicals, ototoxic treatment for TB and HIV are associated with ONIHL.	More studies are needed: • To assess the effects of all the associated risk factors on the miners' hearing function and auditory system, including synergistic effects. • To predict risk for ONIHL and develop predictive models for ONIHL. • To estimate the incidence of ONIHL.
HCP record keeping	Globally, HCPs are implemented to prevent ONIHL. There are South African regulations and guidelines for the reporting of miners exposed to excessive noise levels, and cases of ONIHL.	There is a need for epidemiological studies on the prediction and prevention of ONIHL in the South African mines.
Prediction of ONIHL	Miners' hearing deterioration can be assessed by tracking changes in high frequency thresholds over time. Cases of conductive hearing loss (CHL) have been reported in some miners. Prediction of hearing loss is based on exposure to excessive occupational noise.	There is a need to explore audiological monitoring of miners who are on treatment for TB, HIV, and cancer, to track their hearing deterioration. There is a need to assess the association of other occupational exposures, such as dust and chemicals with CHL and occupational hearing loss.

2.6 Conceptual framework of the research

In conducting this research, a systems thinking approach was applied when reviewing the mine's audiometry and occupational hygiene data to assess the HCP risk assessment practices. In the conceptual framework illustrated in Figure 2.1, the mine's HCP risk assessment practices are grouped as follows: processes; the actors (e.g. mine managers, occupational medical officers, and occupational hygienist, referred to as hearing conservation practitioners) and activities employed by the hearing conservation practitioners in the risk assessment for, and prevention of, ONIHL.[75] According to the WHO, systems thinking is an approach applied to strengthen health systems.[75] As shown in Figure 2.1, three major processes illustrate the conceptual framework used in this PhD, viz. health system building blocks, MLSs and HCP outcome measures. Each comprises a number of activities. Within the health system building blocks process, the following activities were adopted from the WHO health system strengthening conceptual framework, viz. leadership and governance; finance; service delivery; health workforce; information system and medical technologies.[75] The MLSs process included the MLSs used by the mine to record and analyse personal and medical records for all the miners (e.g. MS Excel, African Management System (AMS), QMed). Finally, the HCP outcome measures include activities for individual hearing conservation practitioners and data recorded for each individual miner. The arrow at the bottom of the conceptual framework used in this study and adopted from the WHO's health systems strengthening framework, shows an integrated HCP and reporting of miners' audiometry medical records for the prevention of ONIHL and occupational hearing loss. In addition, in Figure 2.1, a systems thinking approach is used to describe the risk assessment practices applied by the mine's hearing conservation practitioners to assess the risk of, and prevent, ONIHL.

In describing the risk assessment practices used by the mine's hearing conservation practitioners, the health system strengthening conceptual framework used in the PhD outlines the health system building blocks for decision-makers, thereby highlighting activities within the mine's HCP. To ensure an efficient HCP, key performance indicators (KPIs) for decision-makers should be aligned with activities outlined within the health system building blocks process, as well as the mine's HCP outcomes. The decision-makers' (mine managers and occupational medical officers) described activities and KPIs may include competencies in ensuring that relevant policies around electronic health systems (EHSs) are accessible, purchasing of comprehensive mine-specific EHSs is done, ensuring rigorous privacy controls protecting EHSs, employing qualified professionals to implement successful surveillance programmes, and ensuring the financial viability of such programmes.[76,77] Therefore, the conceptual framework shows synergies between the process and activities, as well as limitations which impede HCP outcomes.[18,19,75]

In Figure 2.1, the use of MLSs is one of the three main processes in the study's conceptual framework. The ability of the hearing conservation practitioners to use MLSs, and to record and maintain accurate HCP data is key to the success of an effective HCP. The clarification of the role of each hearing conservation practitioner, and the description of the MLS used by individual hearing conservation practitioner in the health systems strengthening framework is crucial. Thus, KPIs should be designed and aligned with skills such as accurate data recording and reporting of occupational exposures and the associated health effects. Competency in using MLSs purchased by the mine could be based on the accuracy of records kept by each individual hearing conservation practitioner. Machine learning systems' end-users' (hearing conservation practitioners) abilities to record occupational exposures, their hazardous effects, and hearing health risks aid in strengthening a health system toward ONIHL prevention, and may be reported as HCP outcomes for the hearing conservation practitioners. Miners' consent to participate in HCPs, and their understanding of their hearing health, indicate that they are empowered to maintain hearing health care which may be an essential measure of a successful HCP pillar of education and training.[75,77]

In Figure 2.1, the last core process in conceptual framework is the HCP outcome measures. The HCP outcome measures are aligned with decision-makers' competencies, drawn from the health system building blocks and the hearing conservation practitioners' competencies, measured from the quality of records in the mine's MLSs. To ensure efficient audiometry medical surveillance, each individual miner's records should consistently include information stated in Figure 2.1 for each miner. The mine's integrated electronic health system (QMed) should ensure integrated recording, analyses and reporting of each miner's health and safety data as illustrated by the arrow at the bottom of the conceptual framework.

Therefore, the health systems strengthening conceptual framework employed in this PhD study, adopted from the WHO's health systems strengthening framework[77], explores risk assessment practices, which incorporate the three processes (health system building blocks, MLSs, and HCP outcome measures), thereby highlighting the benefits of an integrated data management for the mine's audiometry medical surveillance records. In 2001, Franz and Phillips[29] recommended the integration of basic KPIs in mines' HCP review summaries. The health systems strengthening conceptual framework moves beyond the recommendations made by Franz and Phillips,[29] and indicates the specific KPIs in the mine's HCP review summary.

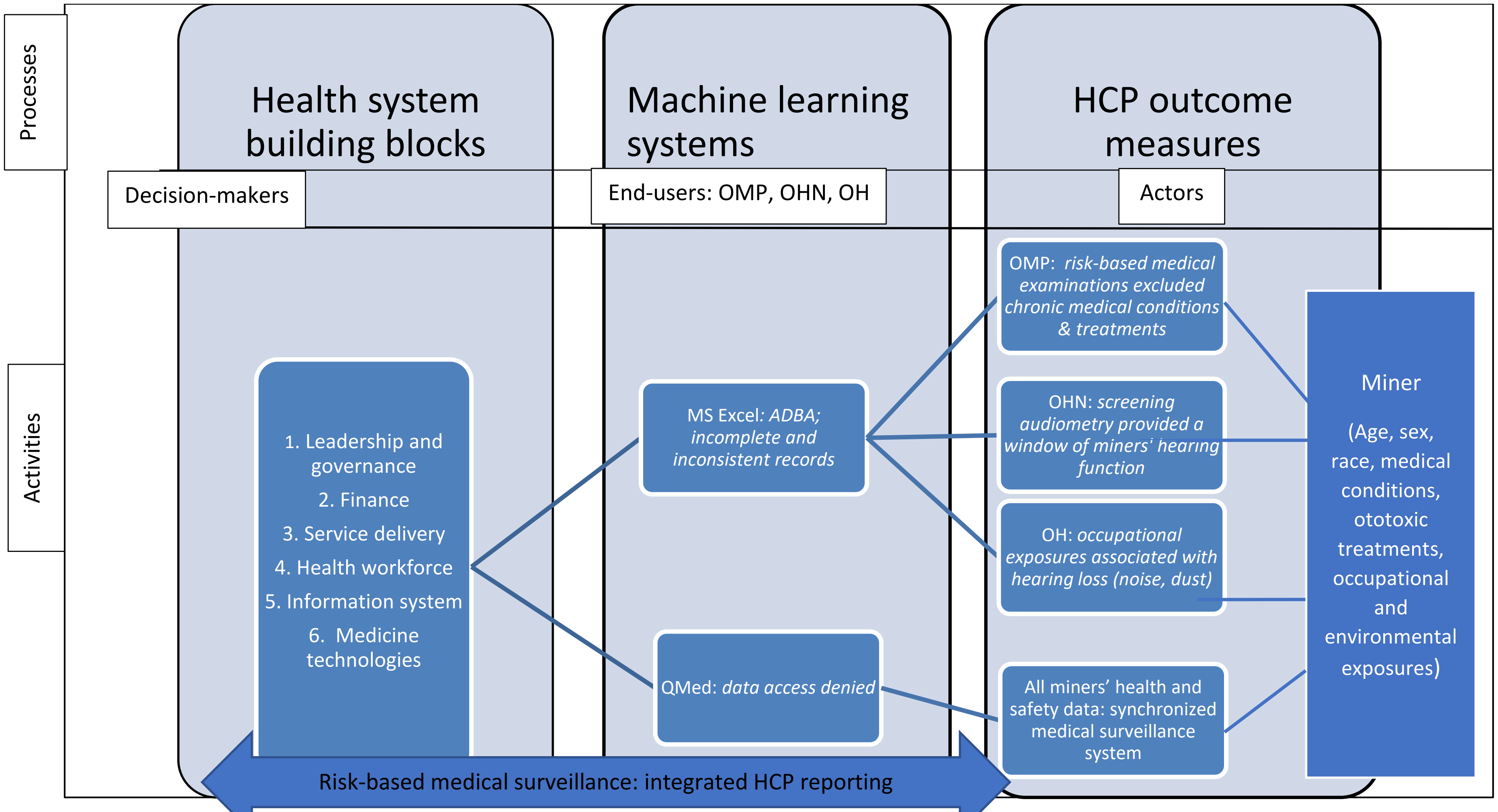

Figure 2.1. Conceptual framework adopted from the World Health Organization's health systems strengthening framework for an integrated HCP and prevention of occupational hearing loss (WHO, 2009)[77]

CHAPTER 3: METHODOLOGY

3.1 Introduction

This chapter provides a layout of the methodology for this PhD. Audiometry medical surveillance electronic records accessed from the mine's MLSs (MS Excel spreadsheets) were analysed to explore their role in risk assessment practices, and prevention of ONIHL. The secondary data review processes are described in this chapter to provide a detailed application of the risk assessment steps implemented and the HCP outcomes obtained for prediction and prevention of ONIHL. Audiometry screening and occupational hygiene records were analysed to examine hearing deterioration using miners' STS, and the associated exposure to noise and PMD, for miners employed at one of South Africa's largest platinum mines over a period of five years. This chapter concludes with the ethical considerations of the study.

3.2 Study design

This was primarily a retrospective cohort study. Miners' hearing deterioration was tracked longitudinally over five years and risk factors associated with ONIHL were identified. However, to address specific objectives of the study, other study designs were used, for example, a cross-sectional design was used for objective 1; secondary data analysis was used for objectives 2, 3 and 5 to describe ONIHL risks from the miners' records and estimated STS deterioration from 2014 to 2018; and a case study design was used to address objective 4. Secondary data from a large platinum mine were analysed to meet the objectives listed in section 1.5. The mine's audiometry medical surveillance records were accessed from the machine MLSs to describe risks for ONIHL, and risk assessment practices used for the prediction and prevention of ONIHL. Furthermore, the seven pillars of HCPs were identified from the data analysed to describe risk assessment practices used to monitor miners' hearing deterioration, and predict risk of, and prevent, ONIHL.

A quantitative approach was used in this study as the HCP electronic records were accessed from the mine's MLSs. Secondary data were accessed from the mine's MLSs and analysed to address the objectives of the research.

3.3 Study site

The data were accessed from one of the Anglo-American platinum mines in Limpopo province, South Africa. The region in which the mine is situated (Figure 3.1), produces more than 75% of the world's platinum and the mine is one of the largest in the region.[16]

The choice of the mine was based on the large number of employees at risk of developing ONIHL from exposure to excessive noise levels, the readily available miners' audiometry medical surveillance records, and the support offered by the mine's hearing conservation practitioners. The mine kept their data in MLSs so to identify risk factors associated with ONIHL, and to track miners' hearing over a period of time. This allowed easy access to data for analysis.

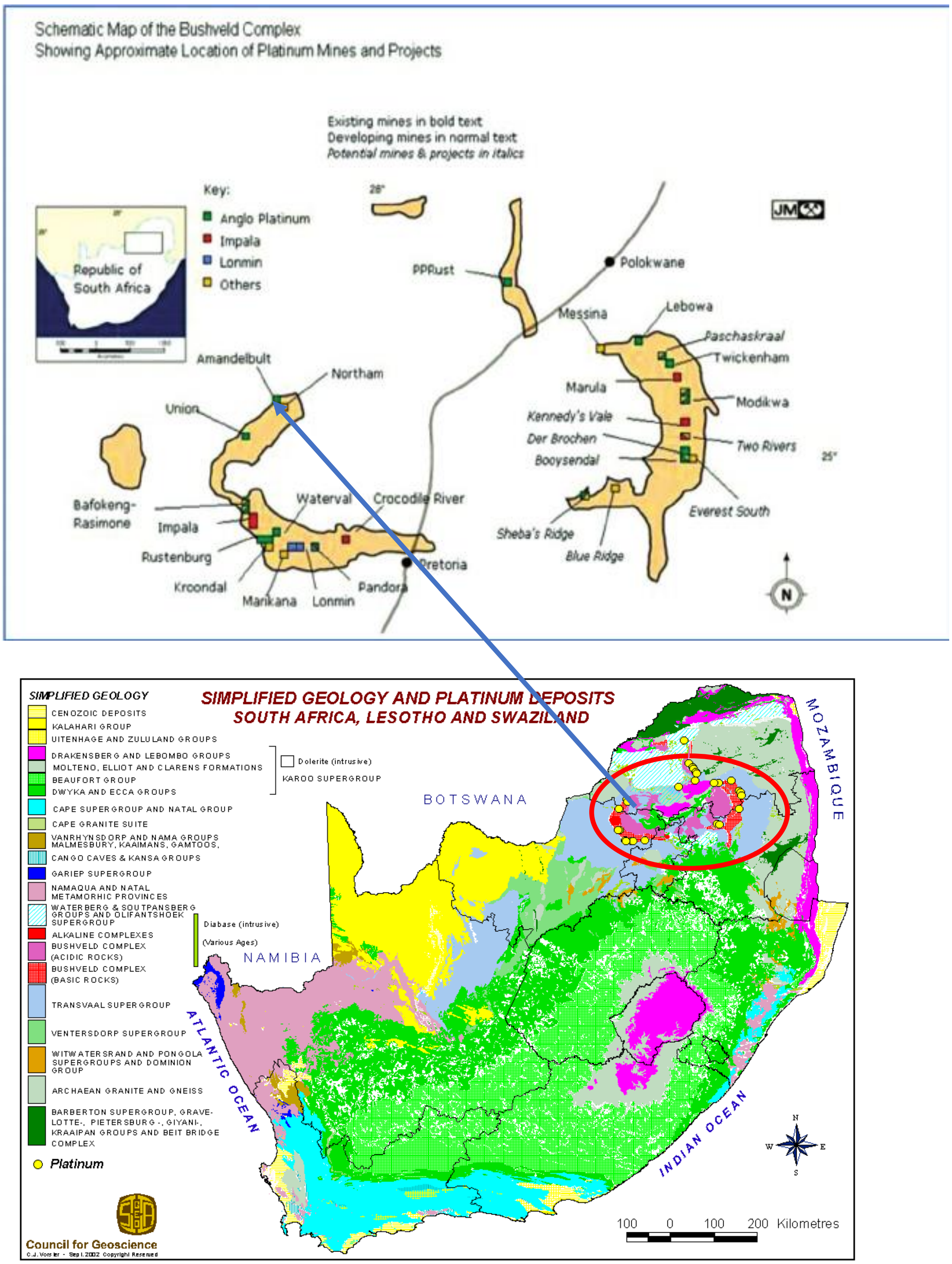

Figure 3.1. Map of South Africa showing the study site and platinum geology (source: https://www.geoscience.org.za/images/Maps/platinum.gif)[78]

3.4 Study population

The study population included all miners whose data were captured in the mine's HCPs electronic databases (Excel spreadsheets) from 2014 to 2018. A miner was defined as any employee whose records were captured in the mine's MLSs, who worked underground and/or on surface, was exposed to noise suspected to be above the occupational exposure level (OEL) of 85 dBA[4,14], and whose hearing was monitored by the hearing conservation practitioners. The study period was from 2014 to 2018. The population comprised ±15 000 individual miners' records captured in the mine's MLSs.

3.5 Data sources

All data were accessed from the mine's hearing conservation practitioners' MS Excel spreadsheets. The three data sources were:

Hearing screening dataset (dataset 1): Hearing screening is conducted annually on each individual miner, by a qualified audiometrist who was also an occupational health nurse (OHN), to assess risk for hearing loss. Data from the screening examinations were stored as MS Excel spreadsheets in a hearing screening dataset. At the time of the study, this dataset contained the bilateral audiogram records of 24 321 individual miners, including the results of tested frequencies of 0.5, 1, 2, 3, 4, 6 and 8 kHz, which were used to calculate PLH scores and bilateral standard threshold shift (STS).

Audiometry medical surveillance dataset (dataset 2): Data from the hearing screening audiograms of miners considered to be at risk for ONIHL, with a percentage loss of hearing (PLH) > 2.5% from baseline, and some miners who presented with ear-related conditions (considered to indicate risk for ONIHL) were stored in this database. The dataset comprised records from 1 938 miners who were referred by the audiometrist to the OMP, of which 470 were referred by the OMP to the audiologist for diagnostic audiology examinations. The dataset included 76 records of miners who had been compensated for ONIHL.

Figures 3.2 A and B show the outside and inside of the booths used by audiometrists to conduct automated hearing screening for miners.

Figure 3.2 A. The outside of an audiometry hearing screening booths

(Photo credit: Liepollo Ntlhakana)

Figure 3.2 B. Inside an audiometry hearing screening booth

(Photo credit: Liepollo Ntlhakana)

Occupational hygiene dataset (dataset 3): Occupational hygienists record exposure data for occupational hazards that are known to cause illness or have adverse health effects (including noise).[25] These data are stored in a separate occupational hygiene database. This database contained records of 15 769 individual miners and included data on occupations (job titles), noise exposure levels (dBA), and platinum mine dust (PMD) exposure levels (mg/m³). The occupational hygienist recorded occupational exposures and risk-rankings in Figure 3.3 in the MS Excel spreadsheets.

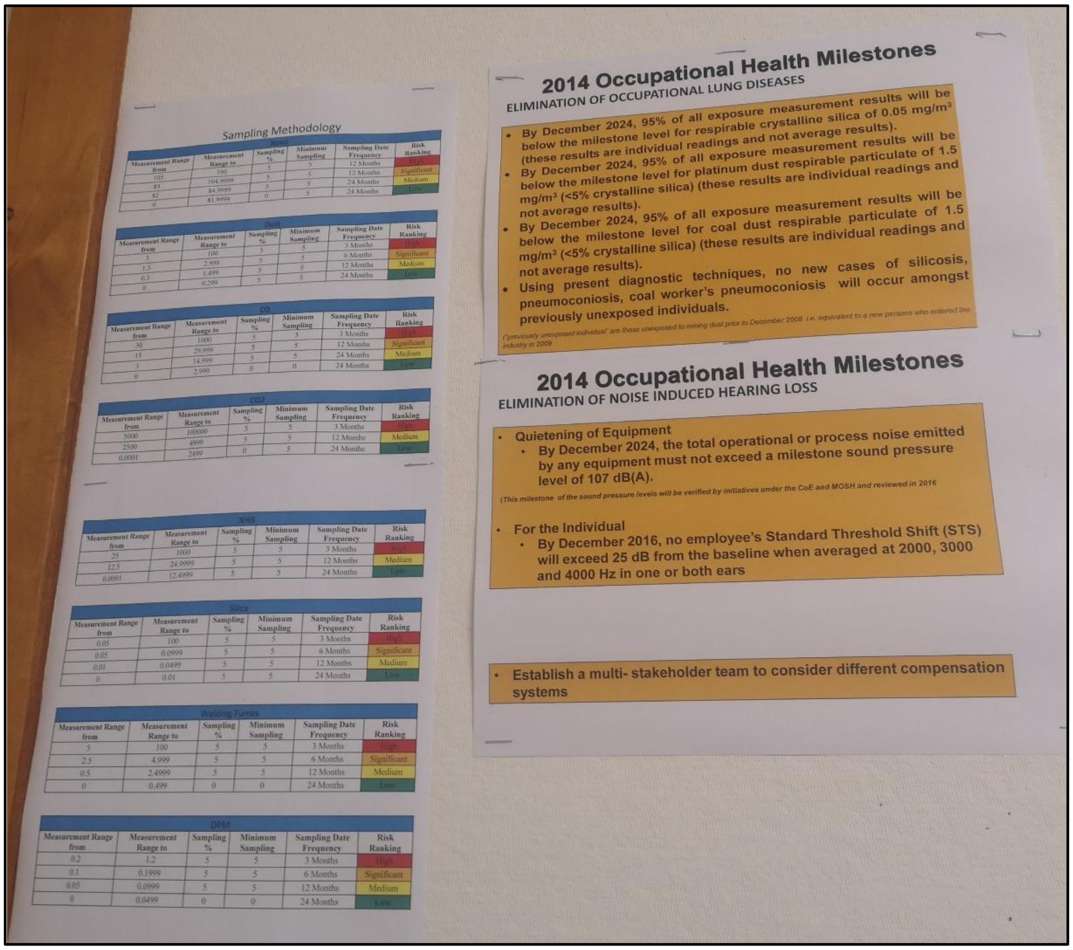

Figure 3.3. Risk-rankings for occupational exposures

(Photo credit: Liepollo Ntlhakana)

3.6 Data Collection

Data used for the study was already collected by the mine's hearing conservation practitioners (as described in section 3.5) and stored in electronic records in the mine's MLSs. The data were further organised, using the self-developed data collection sheet (Appendix 8) as the inclusion criteria for the miners' records included in the PhD study. These were organised into MS Excel spreadsheets, and then imported into STATA version 15.1. All data included the employee number, age and sex of each miner. These three variables were used to merge the datasets, using STATA version 15.1. Table 3.1 illustrates the datasets accessed and managed during data collection process for the study.

Table 3.1. Summary of data accessed from 2014 - 2018

Inclusion criteria / Datasets	**Longitudinal secondary data analysis**		
	Dataset 2		Merged datasets 1 & 3
Data sources / Accessed	Audiometry (OMP)	Referred for diagnostic audiometry (OMP)	Annual hearing screening (OHN) and occupational hygiene records (Occupational Hygienist)
Percentage loss of hearing (PLH)	≥ 10%	≥ 2.5%	≤ 50%
Sample size (N)	470 Sub-set (n=76)	1 938 Sub-set (n=73)	12 629
Variables	Age; sex; occupation; noise exposure level; baseline, periodic and diagnostic PLH; STS; ear-related conditions; ONIHL diagnosis		

3.7 Data analysis

Electronic secondary data were analysed using STATA version 15.1. The three datasets accessed from the mine's MLSs were merged, using the individual mine' worker's number, date of birth and sex. Data were analysed differently for each study objective. For objectives 1 and 2, data were analysed using descriptive statistics. For objective 3 (to determine if the mine used a PDMS to identify miners at risk of ONIHL), risk factors associated with ONIHL were identified using the functional risk management structure. Thereafter, a logistic regression model was used for the baseline PLH margins of 0% - 40% (in 5% increments) to estimate the adjusted predictions for miners at risk of developing ONIHL. The contribution of noise exposure as a risk for ONIHL was estimated using a two-way sample proportion test. For objective 4, ethical principles prescribed by the Health Professions Council of South Africa, the POPI Act[45] and the National Health Act[72] that guide data access for medical research were applied to the mine's audiometry medical surveillance data to identify ethical challenges related to data access. For objective 5, miners' demographic and occupational exposures (noise and platinum mine dust) were analysed to examine their association with STS. Age, sex, PLH, and dust and noise data were used to predict STS, using a linear mixed effects regression model.

Table 3.2 provides an overview of the objectives, data analysis, and the research outcomes (study results) which are further summarised in Chapter 4.

Table 3.2. Overview of objectives, analyses, and PhD outcomes

Objective	Data analysis	PhD outcome
To describe the audiometry surveillance system (including record keeping) in a large South African mine over a five-year period (2014-2018)	Descriptive statistical analysis – frequency tables, bar graphs to analyse miners' audiometry medical surveillance records.	**Paper 1:** Occupational noise-induced hearing loss in platinum miners: what do the data tell us?
To identify factors that impede the early identification of ONIHL from mine records captured within an information management system from 2014-2018		
To determine if the mine used a proactive data management system (PDMS) to identify miners at risk of ONIHL	Descriptive statistical analysis – frequency tables and the functional risk management framework were used to identity risk factors associated with ONIHL. A logistic regression model was used for the baseline PLH margins of 0% – 40% (in 5% increments) to estimate the adjusted predictions for miners at risk of developing ONIHL. Two-way sample proportions test (z-test) was used to estimate the contribution of noise exposure as a risk factor for ONIHL.	**Paper 2:** Estimating miners at risk for occupational noise-induced hearing loss: A review of data from a South African platinum mine
To establish how the mine manages miners presenting with risk factors associated with ONIHL within the HCP	Case study. Self-developed checklists used to review the mine's electronic audiometry medical and occupational hygiene records. Document analysis was used to describe data access practices for ONIHL prediction and prevention.	**Paper 4:** Using machine learning systems to predict occupational hearing loss for platinum miners in South Africa: A case study of ethical challenges to research in the mining industry
To propose an early identification predictive tool for ONIHL	Mixed effects linear regression model.	**Paper 3:** Predicting standard threshold shifts for occupational hearing loss among miners at a large-scale platinum mine in South Africa

3.8 Ethical considerations

The study adhered to ethical considerations. Permission to use the miners' electronic data was granted by the participating mine. Ethics clearance was obtained from the University of the Witwatersrand's Human Research Ethics Committee (Medical); Clearance certificate no. M180273 (Appendix 1).

- *Confidentiality*: Data accessed from the participating mine's MLSs was stored securely; access to the data was restricted to the researcher and supervisors. All identifiable participants' personal information was excluded from the datasets provided by the mine. Strict confidentiality was adhered to when analysing and/or handling data.
- *Anonymity*: data were coded and encrypted to ensure confidentiality and secure the records.
- *Data preservation strategy and standards*: Data collected from the participating mines were stored securely for the duration of the study as prescribed by the university research guidelines and the mines' guidelines, according to the POPIA, 2013.

CHAPTER 4: RESULTS

4.1 Introduction

This chapter provides an overview of the results of the research. Four scientific papers were drafted and submitted in fulfilment of the PhD study. The published and submitted papers can be found in appendices 2 to 5.

4.2 Summary of papers

4.2.1 Paper 1: Record keeping in a hearing conservation programme of a South African platinum mine: what are we missing? (Appendix 2)

This paper addresses the first two objectives of the PhD, viz. to describe the electronic records of a South African platinum mine's audiometry medical surveillance system, and to identify risks that impede early identification of ONIHL.

All miners were male; their mean age was 47.7 ± 8.5 years (range 21 - 63 years) and their mean years of experience was 10 ± 8 years (range 1 - 18 years).

The ear-related conditions of the miners examined by the OMP, the occupations and related noise levels, and the characteristics of miners with and without ONIHL, were described. Of the 305 individual miners' records reviewed from 2014 to 2017, 76 miners were diagnosed with ONIHL. Some of the miners were diagnosed with other ear-related conditions (n=29), and 94.8% were exposed to excessive noise levels at work. Some miners' audiometry medical surveillance records were incomplete, i.e. missing information on hearing thresholds (23.6%). The conclusion was that incomplete and insufficient audiometry medical surveillance data restrict the mine's efficient implementation of hearing conservation programme (HCP) elements aimed at mitigating ONIHL.

4.2.2 Paper 2: Estimating miners at risk for occupational noise-induced hearing loss: A review of data from a South African platinum mine (Appendix 3)

Paper 2 addresses the second objective of the PhD, viz. to determine if the mine used a PDMS to identify miners at risk of ONIHL. This paper was based on secondary data analyses to assess factors that hearing conservation practitioners deemed useful for identifying 'at risk' miners; and to establish factors that would pave the way for the integration of the 2014 HCP milestones into the mine's current proactive data management system (PDMS). In this paper, two datasets were reviewed: one of diagnostic audiometry records (N = 1938), and a second of miners diagnosed with ONIHL (n = 73) from 2014 to 2018.

The findings revealed that only 34% (n = 669) of the miners had valid baseline audiometry records. Miners with a 0% baseline PLH had a 20% predicted risk of ONIHL, and a 45% predicted risk if they had a 40% baseline PLH; 80% (n = 59) of the miners diagnosed with ONIHL were exposed to noise levels ranging between 85 dBA to 104 dBA. It was concluded that there were gaps in the mine's PDMS – indicating that the mitigation of risks for ONIHL requires further attention, and that the quality of the mine's audiometry medical surveillance records should be improved to ensure that the HCP is effective.

4.2.3 Paper 3: Predicting standard threshold shifts for occupational hearing loss among miners at a large-scale platinum mine in South Africa (Appendix 4)

This paper addresses objective 5 of the PhD, viz. to propose an early identification predictive tool for ONIHL. The association of STS with exposure to noise and platinum mine dust (PMD) were examined, and a mixed effects linear regression model was used to estimate the association of STS with occupational hearing loss among miners at the platinum mine, using demographic data and five years of audiometry, noise, and dust data. The dataset used for the analysis contained 17 304 individual miners' records, of which total of 4 675 were excluded for various reasons (duplication, missing variables, etc.). Thus, there were 12 692 miners' records analysed for the period 2014 to 2018, to predict miners' STS, using age, sex, noise and PMD levels, and percentage loss of hearing (PLH) variables. Miners were categorised by sex, age, noise exposure levels, PMD levels, PLH and STS scores as illustrated in Table 1 in the paper submitted.

There were more male miners (89.6%) than females (10.4%) and more than 50% of the miners were younger than 41 years. The findings from the linear mixed effects model estimated exposure associated with sex (being male) at 27% and 21% for the left and right ear, respectively. The estimated effect of age, PLH, noise exposure and years of exposure was < 10% for each variable. There was no statistically significant association between PMD and STS in hearing. The conclusion was that the combined effects of age, sex, years of exposure to noise, and noise exposure levels, and their strengths of associations, may be used to predict STS for this group of miners.

4.2.4 Paper 4: Using big data to predict occupational hearing loss for platinum miners in South Africa: A case study of data sharing practices and ethical challenges in the mining industry (Appendix 5)

Paper 4 addresses objective 4 of the PhD, viz. to establish how the mine manages miners presenting with risk factors associated with ONIHL from the mines' HCP records captured in MLSs. Therefore, paper 4 describes audiometry medical surveillance data and ethical challenges in accessing data from MLSs used for the prediction and prevention of occupational hearing loss in miners at a South African platinum mine. The findings from this paper showed that some audiometry screening and occupational exposure records were incomplete and/or inaccurately captured; access to miners' medical conditions and treatment records was denied; and ethical challenges found were around a lack of clarity regarding permission rights for researchers and a lack of standardised recording of audiometry surveillance data. Furthermore, there was no criteria governing divulgence of miners' confidential personal and medical records for research. In conclusion, efficient MLSs, and the application of medical ethics for the prediction and prevention of occupational hearing loss, depend on accurate and consistent HCP data input and clear company regulations related to data access for medical research.

4.3 Conclusion

The mine's risk assessment practices partially enable audiometry medical surveillance to identify risks associated with, and miners at risk of, developing ONIHL. However, factors such as poor quality of audiometry medical surveillance records, siloed reporting of occupational exposures and health risks, specifically associated with ONIHL, and the use of different data sources by hearing conservation practitioners affect the mine's MLSs efficiency to monitor miners at risk for ONIHL. Furthermore, the mine's company policies and regulations around data handling and access for medical research should be clarified in order to encourage collaborations with research institutions, allow for independent objective review of data, and allow for objective contextually relevant evidence-based practice.

CHAPTER 5: DISCUSSION

5.1 Introduction

Occupational noise induced hearing loss is an avoidable disease that requires adequate preventive measures to be implemented by the mines. Yet, according to the WHO[79] and the South African MHSC[16], ONIHL prevalence rates provide evidence to the contrary. Evidently, HCPs, introduced specifically by the South African mines in 1988, their mitigating strategies have not been successful at preventing ONIHL in miners, possibly due to the heavily industrialised nature of South Africa mines.[29]

The design of HCPs constitutes seven pillars, viz. noise measurements, engineering controls, administrative controls, education and training, HPDs, medical surveillance and audiometry.[14,29] Five of the seven pillars (noise measurements, engineering controls, medical surveillance and audiometry, HPDs and risk-based medical surveillance) were investigated by occupational health researchers. Although research has focused on noise measurements, audiometry measures and the use HPDs, these controls have not successfully mitigated risk for ONIHL.[19,22,24,25,31,35] This is exacerbated by the way in which the mines record data – as reported by Begley in 2006.[17] Begley reported that the South African mines' inability to collect data uniformly and systematically negatively impact miners' HCP electronic records,[17] which may have resulted in challenges such as poor quality data. This, in turn, impeded data analysis[17] and restricted data access for research purposes.[83] These challenges impede the prediction and delay efforts towards the prevention of occupational hearing loss. Although Begley's report is more than 15 years old, and mines have begun to invest in improved data management systems, there is no recent research that interrogates the mines' audiometry medical surveillance records.

The aim of this PhD research was to explore risk assessment practices, which incorporate data management, at a large-scale platinum mine in Limpopo province, South Africa, with the aim of proposing a predictive tool for the early identification of ONIHL. The specific objectives were accomplished by analysing the miners' electronic audiometry medical surveillance data. The research findings facilitated the understanding of the miners' hearing function; risk factors associated with ONIHL;

implementation of the mine's audiometry medical surveillance programmes; hearing monitoring procedures and interventions for miners diagnosed with ONIHL; and data management within the integrated HCP health system that is used to predict and prevent ONIHL. The findings highlight the importance of maintaining good quality records that can be analysed to predict miners' hearing deterioration, and to facilitate the early identification of risk factors for occupational hearing loss, with the intention of preventing deterioration in hearing function.

In this chapter, I discuss the key findings from the research as presented according to the listed objectives, which are mirrored in the papers presented in Chapter 4 (published, or submitted for publication), as illustrated in Table 3.2. In addition, I propose recommendations for the systematic and integrated management and prevention of ONIHL for the study mine, which could be applied to other mines. I conclude the chapter by highlighting the scholarly contribution and policy impacts of the research that I conducted.

5.2 Key Findings

The research findings are grouped and discussed in accordance with the main processes of the health system strengthening conceptual framework (Figure 2.1). The three main processes are health system building blocks, MLSs, and HCP outcome measures. Figure 5.1 is used to illustrate the mine's integrated HCP outcomes grouped into the prevalence of ONIHL in miners, risk factors associated with ONIHL and the MLSs used to record miners' audiometry medical surveillance records and predict early signs of ONIHL.

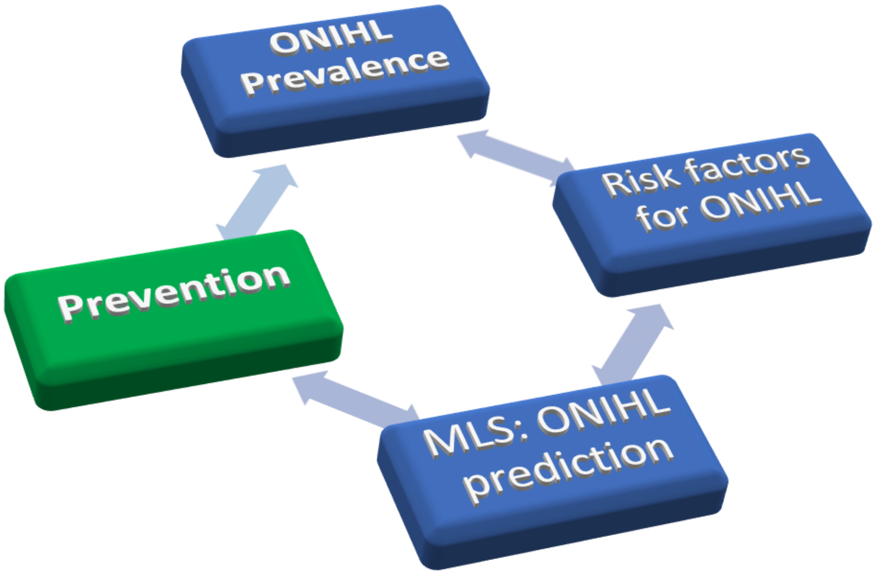

Figure 5.1. A summary of the mine's integrated HCP outcomes for ONIHL prevention

5.2.1 Prevalence of occupational noise induced hearing loss

Trends in the prevalence of ONIHL in the miners were calculated from 2014 to 2018. The objectives of the study included estimating the prevalence of ONIHL at the mine. In analysing the mine's audiometry medical surveillance records, and identifying factors that impede early identification of ONIHL from the mine's records, miners' hearing function was described, and risk factors associated with ONIHL were identified to show impeding factors which negatively impact the early identification of ONIHL. The mining company used the number of miners diagnosed with ONIHL to calculate and report the prevalence of ONIHL, as well as to show progress made by the mining company to reduce the prevalence of ONIHL. Analysis of the audiometry hearing screening data showed that 10% (n=1 274) of the miners had a PLH > 5% and STS ≥ 26 dBHL, and that 76 were diagnosed with ONIHL from 2014 to 2018. Although the PLH and STS scores defined 10% of the miners to be at risk of ONIHL, fewer than 10% had a confirmed diagnosis of ONIHL.

In the 2016/2017 DMRE annual report, the platinum mining industry reported 47% (535 platinum miners out of a total of 1 141 ONIHL cases reported in 2017) cases of ONIHL. There was a 10% increase in cases of platinum miners diagnosed with ONIHL in 2017, with 537 reported cases (out of a total of 1 141), compared to the 347 cases out of a total of 966 in 2016.[16] There are discrepancies between ONIHL cases reported by the DMRE and individual mines. Nevertheless, it is evident that the mines are struggling to prevent ONIHL.[16] Of concern is that, even though there has been a decrease in the number of cases of ONIHL reported by individual mines, there is still a lack of understanding about, and recording of, the risk factors associated with ONIHL, as well as the actual prevalence rates of ONIHL on individual miners in South African mines.[84,85] Thus, the mining industry requires prevalence studies to account for the disabling hearing loss in the workplace.

5.2.2 Risk factors associated with occupational noise induced hearing loss

Recording audiometry, medical and occupational hygiene surveillance data in multiple databases can result in ineffective HCP interventions. The miners' records in the research study were kept in three different databases by the OHN, OMP and occupational hygienist. There was an additional database that contained information about a number of risk factors associated with ONIHL, such as ear-related conditions (impacted wax, ear infections, ear surgeries), TB and HIV treatments, types of HPDs provided to miners, and occupational exposures such as noise and chemicals. However, this database was not made available during the research study, which hindered accurate estimation of the associated risks of ONIHL on individual miners. The consequences of excluding data, in this case study included lack of proper surveillance and an inability to institute early preventive interventions. There is a need for integration of miners' electronic records to ensure accurate and valid identification of miners at risk for ONIHL.[86]

Risk factors associated with ONIHL include modifiable and non-modifiable factors. Modifiable risk factors include exposures (to occupational noise, recreational noise, dust, and chemicals); and lifestyle factors (smoking, and other behaviours that are associated with hypertension). Modifiable risk factors are preventable.[87] However, non-modifiable risk factors cannot be changed. These include age, genetic susceptibility, race and sex. Inclusive HCPs should consider both modifiable and non-modifiable risk factors when addressing the prevention of ONIHL.

Occupational noise exposure is the main modifiable risk factor associated with ONIHL, and has a direct impact on miners' quality of life. Miners exposed to excessive occupational noise have reported difficulty in hearing, which can affect their ability to communicate with peers and family, and prevent them from hearing warning signals at work.[26] Miners in our study were exposed to noise levels as high as 104 dBA, in addition to platinum mine dust (PMD), silica dust, carbon monoxide, and nitrogen sulphide, which were reported to be below detectable levels.[88-90] Although, these other occupational exposures have been reported to have limited health risks, there are some reports about associated allergic reactions associated with occupational hearing loss.[88-90]

The main concern is the effect of excessive noise levels on ONIHL, which has been reported in previous studies. Interventions to reduce noise exposure include the use of HPDs and the purchase of quieter equipment to reduce noise emission. However, intervention efforts have not had a significant effect on reducing the prevalence of ONIHL.[84,85] While noise exposure is addressed in mine hearing loss interventions, (more recently, through the purchase of quieter equipment)[16], there is limited literature from the South African mines. Other modifiable risk factors such as the use of HPDs[26], and exposure to PMD, silica dust, carbon monoxide, and nitrogen sulphide are not considered in HCPs intervention strategies.

Younger male miners were at risk for ONIHL within the first 10 years of working in the mines. This might be associated with non-modifiable risk factors such as genetic factors and sex; and modifiable risk factors, such as history impacted wax in the ear, otitis media, exposure to recreational noise and other factors.[96,97,100] Therefore, to allow for early intervention and prevention of ONIHL, the hearing function of younger miners who have been identified with non-modifiable risk factors should be comprehensively and regularly monitored from the time that they enter the mining industry.[80,81,101]

5.2.3 Machine learning systems used for risk assessment of miners with occupational noise induced hearing loss

Machine learning systems used in HCPs by the South African mines record and analyse miners' audiometry medical surveillance records and provide a basis for the prediction of ONIHL. Therefore, MLSs used by the mines should improve HCP risk assessment; and data accessed in the MLSs should be of good quality and be easily accessible for research purposes, in order to identify early signs of ONIHL.

Risk assessment methods for miners with occupational noise induced hearing loss

The risk assessment practices used by the mine's hearing conservation practitioners indicated a skewed audiometry surveillance of (and analysis of) risk factors associated with ONIHL. On exploration of the mine's PDMS used to manage miners at risk of ONIHL, it became evident that the mine's hearing conservation practitioners used different databases, which were activity specific. For example, the occupational hygienist's database contained only occupational exposures and exposure level data. The ADBA technique that was used by the mine lacked complete audiometry records. For example, some miners' audiometry screening records were incomplete; and for some miners diagnosed with conductive hearing loss there were no follow-up audiometry records. Furthermore, data regarding diagnosis and treatment for those with diabetes and hypertension and those on TB and HIV treatments, was missing from the records, rendering them incomplete. This made the records, effectively incomplete. Consequently, risk management methods did not effectively identify miners at risk of developing ONIHL. Therefore, it is recommended that non-modifiable risk factors for ONIHL be included in audiometric monitoring as a prevention strategy for ONIHL.[63]

Record keeping and methods to prevent occupational noise induced hearing loss

Accurately and confidentially kept audiometry medical surveillance records of individual miners is key to ensuring consistent tracking of miners' hearing and to measure the efficiency of the mine's HCP in preventing ONIHL, as well as ensures protection of those records.[17] In tracking miners' hearing, the mining company used

STS ≥ 26 dBHL to classify a miner as being at risk of having ONIHL.[46] This 'risk definition' is mandated by the MHSC (Regulation 839) for South African mines. It is more sensitive than the 35 dBHL hearing loss classification, which is recommended by the WHO[2] to be used for early identification of ONIHL. The South African mines additionally use the PLH scores to track miners' hearing function, and the PLH scores (Instruction 171) are used for ONIHL compensation.[38,46]

Although both PLH and STS are used to track miners' hearing, they are calculated using different methods and, consequently, their HCP outcomes differ. Findings in this thesis showed an average 1.7 dBHL STS and a minimal PLH shift (1.2%) for the miners, from 2014 to 2016. The PLH scores provided information about the miners' low frequency hearing, which is important for speech and communication abilities.[82] The STS provides important information about hearing in the high frequency zones, which indicates early onset of ONIHL. Occupational noise-induced hearing loss initially affects the high frequencies, which is why the use of STS is recommended by the DMRE (Regulation 839) as being essential for ONIHL prevention.[38] However, the STS used by the South African mining industry is limited to the 2, 3, and 4 kHz high frequencies and is not the extended to the high frequency range of 3, 4, and 6 kHz. These additional frequencies are used by the National Institute of Occupational Health and Safety (NIOSH) to identify hearing loss prevention. Due to excessive noise exposure levels emitted by some mining equipment, the industry should consider including the extended high frequencies in audiometry surveillance. There is also a need for the South African mines to define their HCP outcomes, as set out for PLH and STS, in tracking miners' hearing function.

Data access for prediction and prevention of occupational noise induced hearing loss

Gaining access to miners' audiometry and occupational hygiene records is more complicated than gaining access to the medical records. During data collection, it became evident that the mine's hearing conservation practitioners used different data access practices for medical surveillance data and HCP data. Miners' medical conditions (HIV and TB) and treatments thereof were not available for review. The hearing conservation practitioners cited medical ethics and POPIA restrictions as reasons for denying access to the records. Treatments for TB and HIV are associated with NIHL, but lack of access to these data case impedes our understanding of ototoxic monitoring practices used to predict early signs of, and prevent ONIHL.[28] The additional consequence of data restrictions to miners' medical conditions and treatments is that it hinders research efforts to assess HCP outcomes for ONIHL and will negatively affect decision-making processes regarding the implementation of effective and more productive noise exposure intervention strategies for the prevention of ONIHL.[83]

The research described in this thesis was one of the first attempts to review the HCP electronic records to explore the mine's systematic approach to risk assessment. Concurrently, the issues of medical ethics and protection of personal information for the management of miners at risk for ONIHL was explored. More studies related to medical ethics are necessary, incorporating the review of the mines' HCP electronic records, to comprehensively understand the surveillance programmes implemented by the mines, the types of records used to monitor miners' hearing and prevent ONIHL, and related ethical practices.

Prediction of occupational noise induced hearing loss

Accurate prediction of ONIHL requires complete and valid audiometry data to systematically track miners' hearing during their employment. This study was one of the first to use miners' audiometry records to examine the association of STS with occupational hearing loss, and estimate the risk of ONIHL among miners. The combined effects of age, sex, years of exposure to noise, and noise exposure levels can be used to predict STS for the group of miners in our study. In addition, changes were observed in the miners' hearing levels, ranging from 8.3 at baseline (2014/2015) to 10 dBHL in 2016, showing a 1.7 dBHL average hearing deterioration over two years.

The noise exposure records for miners showed a maximum level of 105 dBA. More than 70% of the miners in the cohort were exposed to > 85 dBA over the five-year period. Grobler et al. (2020), used the averaged high frequencies (2,3,4 kHz) and predicted hearing deterioration rates of 3.5 dB and 2.9 dB for gold miners exposed to noise and those not exposed to noise, respectively, over a period of four years.[25]

Findings from this research highlight the need for the South African mines to further investigate their noise reduction strategies.

The combined estimated effect and the risk-ranking of risk factors, such as recreational noise exposure; previous occupational noise exposure; history of conductive hearing loss; and the use of ototoxic medication for TB and HIV, on the miners' auditory system is known.[25,28,57,81] In a systematic review, Golmohammadi and Darvishi (2019)[62] combined the effects of occupational exposure to noise and other risk factors associated with ONIHL, and provided a risk ranking of factors (personal factors, occupational factors, physical agents, and chemical agents) associated with ONIHL, from the highest risk category (personal factors) to the lowest risk category (occupational factors).[62] High noise exposure levels, which continue to be reported by the South African mining industry; increase the miners' risks of ONIHL and should be monitored in conjunction with non-modifiable risk factors to ensure accurate prediction and early signs of ONIHL.[25,34]

5.3 Integrated research findings

To reduce the burden of ONIHL, which affects most South African miners, a complex interplay of intrinsic and extrinsic factors related to the individual miner, the employer, hearing conservation practitioners, and policymakers, influence the implementation of a successful and efficient HCP. Occupational hearing loss may be avoidable for miners should noise controls (engineering administrative and use of HPDs) be adequately implemented by the mines' hearing conservation practitioners. The use of a health systems strengthening conceptual framework, and a systems thinking approach, to explore the mine's HCP and ONIHL in this study, allowed for an integrated view of the mine's HCP.

Consequently, a standardised format for recording audiometry medical surveillance data to allow for accurate assessment of the effectiveness of mines' HCPs was proposed. This promotes best practice principles.[80] The emerging areas of interest, drawn from the health systems strengthening framework, were guided by the WHO health system[76], and provided an integration of the research objectives. These included medical surveillance service delivery processes, management of miners at risk for ONIHL, maintenance of medical surveillance records, data access technologies and challenges, hearing health policies, and human resource issues. Table 5.1 summarises the emerging areas of interest drawn from the findings.

Table 5.1. Summary of the emerging areas of interest

Emerging areas of interest	Summarised findings
Audiometry medical surveillance service delivery processes	All miners are mandated to attend annual audiometry medical surveillance. Audiometry medical surveillance records contain PLH and STS scores to track miners' hearing.
The main risk factor that triggers audiometry medical surveillance	Driven by noise exposure levels. Other modifiable and non-modifiable risk factors associated with ONIHL were under-reported.
Management of miners at risk for ONIHL	The mine's MLSs did not comprehensively integrate risk factors associated with ONIHL, lacked advance data analysis for prediction of ONIHL, HCP outcomes could not be measured due to incomplete audiometry medical surveillance records for individual miners.
MLS technologies and data access challenges: POPI Act vs Ethical Codes of best practice	Restricted to MS Excel which hinders the application of advanced data analysis required to develop predictive models. Marked by inconsistencies in the miners' records. POPI Act and Ethical codes' contradictions and restrictions regarding sharing of miners' medical information.
Discrepancies between regulations and practice: hearing health policy	A bottom-up approach from individual miners to hearing conservation practitioners to the mine managers, requires role clarification aligned with the mine's HCP outcomes, to ensure an efficient HCP.

5.4 Strengths and limitations

The research had both strengths and limitations, many of which were related to the analysis of (secondary) administrative data. While the data were relatively easy to access, there were restrictions based on confidentiality. Access to secondary data saved resources (time and money), and the datasets contained most of the required variables. Statistical methods used to analyse the data varied, and were a strength of the study. The research was strongly supported by the hearing conservation practitioners who were instrumental in collecting the data. However, yet not unexpectedly, some of the records were incomplete, and some of the data were of poor quality. This is not uncommon when data are collected for non-research purposes, as data collection is often less rigorous where there are fewer validity checks.[102]

The restriction of access to the miners' medical surveillance records – which included chronic medical conditions and treatment – was a limitation that affected the ability to develop a comprehensive predictive model. Thus, not all risk factors associated with hearing loss were included in the model. All limitations were communicated to the mine's hearing conservation team and occupational health and safety managers at a series of meetings held at the mine.

The different data sources and different capturing formats used by the mine's hearing conservation practitioners presented difficulties. To address these problems, rigorous data cleaning was conducted prior to analysis: the first in MS Excel, and second in STATA version 15.1. In STATA, simple and complex data analysis were performed.

The study relied on the available secondary data, which was accessed from 2014 to 2018, and the data used contained once-off measurements of the exposures and hearing health effects. Thus, the analysis and findings could not be used to derive causal relationships between exposures and the outcome.

The mixed effects linear regression model used in the study was not tested to develop the predictive model which may be important to highlight future hearing deterioration for this group of miners. However, findings of the linear regression model highlighted the strength in association for the risk factors. In addition, the data used in the mixed effects linear regression model, and the results obtained from the model, may be used to propose the predictive model for early identification of ONIHL.

5.5 Recommendations

The recommendations are based on the global summary of findings of this PhD research and may be used by the mine to improve their HCP effectiveness and prevent ONIHL.

The specific recommendations to be considered by the mine are as follows:

- Using combined medical surveillance records will allow the mine's hearing conservation practitioners to holistically address each individual miner's hearing health risks and apply individualised interventions, as well as to engage in nuanced discussions regarding the miners' ear and hearing health and their services thereof.
- A clearly outlined risk assessment criteria for medical surveillance and monitoring of miners at risk of occupational hearing loss should be mine-and-miner-specific in order prevent any type of hearing loss, thereby incorporating occupational exposures and hearing health risks. The criteria for risk assessment should also be expanded into the audiometry short course curriculum, so to improve audiometry skills for OHNs, OMPs and audiologists.
- There were specific challenges that were outlined in paper 3 regarding using secondary electronic records (for example, some miners' employee numbers were missing; incomplete dates of birth were recorded; there were duplicate records; PLH scores were >50%; and access to medical condition records were restricted). These points may be used to guide future research during data management to improve the quality of HCP records.
- Streamline of technologies used by the mines for data recording and reporting HCP to the mines' cloud system would improve the quality of records kept, and surveillance outcomes set out by the mine would prevent ONIHL.

- The POPI Act and Medical Ethics Codes should be reviewed and integrated into the mines' MLSs to support the end-users, secure miners' records, to ensure easy access during reporting, for medical research purposes, as well as to influence health policy.
- Allow for a bottom-up approach for HCP risk assessment and management (hearing conservation practitioners) to drive medical surveillance service delivery processes to strengthen the mines' hearing health systems.
- Human resource support, such as regular reviews by mine managers of monitoring of the ratio of hearing conservation practitioners to miners, so to reduce staff burnout effects, which, in-turn affect HCP data quality.
- Interdisciplinary collaborations amongst hearing conservation practitioners should be encouraged to reduce the burden of ONIHL on miners, such as the introduction of education and training to improve miners' understanding of hearing health care, the importance of an understanding of integrated audiometry medical surveillance on their hearing health.

5.5.1 Recommendations for future research

This study was a review and an analysis of the mine's secondary audiometry, medical and occupational hygiene data, which was used to explore the risk assessment for ONIHL, with the hope of proposing a predictive model for early identification of ONIHL. Numerous possibilities for future research are listed as follows:

- This study used siloed audiometry medical surveillance which created a skewed analysis of the mine's HCP. This, in turn, provided incomplete HCP outcomes. A follow-up study may consider including datasets previously excluded from this study – such as medical conditions and treatments – so to provide a holistic view of the mine's HCP and replicate similar analysis in order to generalize findings for the South African mining industry;
- ADBA data analysis and risk characterization used in this study may be further explored. Additionally, classifications of workers into HEGs may be considered by other industries where noise is a problem, in order to determine ONIHL trends in those groups;

- In order to predict ONIHL, research that explores data analysis, and which integrates managing secondary data with missing hearing thresholds for the miners, may be conducted;
- While this research explored and identified inefficiencies in the mine's HCP linked to human resource capabilities, future research may explore capacity strengthening for hearing conservation practitioners;
- Future research should explore the additional effects of reverberation and direct noise exposure, combined with the use of HPDs, and other administrative and engineering noise control measures, along with education, training, as enforced by safety rules and policies;
- Comparisons of data accessed from MS Excel, and data stored in the cloud for consistencies in reporting occupational exposures and health risks, may be conducted by researchers in order to continuously improve research for HCP in the South African mines;
- The inclusion of the miners' records of those diagnosed with TB and HIV may be incorporated in the statistical model used in this research study in order to enhance prediction of ONIHL for miners;
- An exploration of the quality of life for miners diagnosed with TB, HIV and occupational hearing loss; and
- The impact of education and training on the mine's data management system, in order to improve the mine's data quality for medical research.

5.6 Scholarly contribution of the PhD study

Summary of literature reviewed on the mines' HCPs, and the scholarly contribution of the PhD study explored towards the prediction and prevention of ONIHL.

Table 5.2 summarizes gaps in the literature, and the contribution of the PhD in addressing some of these gaps.

Table 5.2. Summary of literature review

Study objective	What is known	Knowledge gaps	PhD scholarly contribution
Prevalence of ONIHL	Worldwide estimated prevalence of ONIHL due to noise exposure ranges from 7% to 21%. African countries have higher prevalence rates (>20%) of ONIHL.	There is a dearth of recent studies on prevalence rates of ONIHL.	Used recent miners' records to show risk assessment practices used to identify cases of miners diagnosed with ONIHL, and those compensated for ONIHL. The study established a baseline for a cohort study.
Risk factors associated with ONIHL	Noise exposure is considered the main risk factor for ONIHL. Age and sex, exposure to recreational noise and chemicals, and ototoxic treatment for TB and HIV are associated with ONIHL.	More studies are needed to investigate the combined effect of all the associated risk factors on the miners' hearing function and auditory system.	Provided a description of the miners' risk assessment approach, risk factors specific to the mine and efficiency of the mine's audiometry surveillance. 1st study to estimate miners' risk for ONIHL using baseline PLH scores.
HCP record keeping	Globally, HCPs are implemented to prevent ONIHL. Regulations and guidelines exist in South Africa for the reporting of the number of miners exposed to excessive noise levels and cases of ONIHL.	Dearth of studies on the following HCP pillars: risk-based medical surveillance and administrative controls used by the South African mine. There is a need to explore epidemiological studies for the prevention of ONIHL in the South African mines.	Measured the efficiency of the mine's HCP towards ONIHL prevention. Highlighted the importance of combining audiometry and medical surveillance as tools for audiological monitoring.
Prediction of ONIHL	Tracking of miners' hearing thresholds using high frequency thresholds for all miners to show a deterioration over time. Cases of conductive hearing loss (CHL) reported with some of the miners. Prediction of hearing loss was based on exposure to excessive occupational noise.	Literature gaps on: Audiological monitoring of miners on treatment for TB, HIV and cancer; Other occupational exposures such as dust and chemicals associated with CHL; Studies that show a combined effect of risk factors on the miners' auditory systems and hearing functions.	This is the first study to: Use miners' STS to examine the association of occupational hearing loss with exposure to noise and platinum mine dust; Included platinum mine dust (PMD) as an additional occupational exposure, to predict hearing deterioration.

5.6.1 New knowledge

New knowledge has been drawn from the key findings and has been organised in accordance with the study objectives and papers published and submitted.

To describe the audiometry surveillance system (including record keeping) and to identify factors that impede the early identification of ONIHL from the mine's records over a five-year period (2014-2018). Paper 1: Occupational noise induced hearing loss in platinum miners. What do the data tell us?

In paper 1, this research study provides risk assessment and management criteria used by hearing conservation practitioners to identify miners at risk of developing ONIHL. This paper further highlighted factors that impede prevention of ONIHL. The findings indicate that other occupational exposures associated with ONIHL, such as PMD, silica dust, carbon-monoxide, nitrogen sulphide, medical conditions and treatments thereof were excluded from the mine's HCP. Thus, the mine's risk assessment for ONIHL provided a limited view of the miners' occupational exposures associated with the ONIHL risk, hence an inability to institute early intervention that is preventive, rather than compensatory, in nature.

The findings indicated that the prevalence of ONIHL, based on the number of ONIHL confirmed cases, was less than 10%.

To determine if the mine used a proactive data management system (PDMS) to identify miners at risk of ONIHL. Paper 2: Estimating miners at risk for occupational noise-induced hearing loss: A review of data from a South African platinum mine.

This study is one of the first to explore the ADBA method using miners' audiometry medical records in order to determine whether the mine used a PDMS. The ADBA method was recommended by Franz and Phillips in the early 2000s, specifically for the South African mining industry to monitor miners at risk of developing ONIHL. In addition, the ADBA method was used to determine the relevance and accuracy of the records in predicting early signs of ONIHL. The data collection and analysis method used in this study may be explored by other mining commodities to determine generalisability of our results.

In this paper, records for miners diagnosed with ONIHL were analysed, in order to predict risk for ONIHL at baseline. The logistic regression results indicated that miners with a 0% baseline PLH had a 20% predicted risk of ONIHL. It is concerning that only 34% of the 1 938 records of miners referred to the audiologist for diagnostic audiometry had valid baseline PLH scores.

To propose an early identification predictive tool for ONIHL. Paper 3: Predicting standard threshold shifts for occupational hearing loss among miners at a large-scale platinum mine in South Africa.

Paper 3 showed that PLH and STS (new milestone) scores (calculated from the miners' pure tone air conduction thresholds) were from similar high frequencies (234kHz) and were used concurrently. However, PLH scores are heavily weighted on the low frequencies. This study was one of the first to use miners' audiometry records to predict STS and explore risks for ONIHL. The findings show that the combined effects of age, sex, years of exposure to noise, and noise exposure levels can be used to predict STS for the group of miners in this study. The STS calculated from 2014 to December 2016 (1.7 dBHL from baseline) may be used by the mine show their outcome for the Regulation 839 (NIHL Milestone).

In paper 3, the data analysis method used was a linear mixed effects model. This method aims to estimate the associated effects of various exposure factors on the bilateral STS, and to examine miners' hearing deterioration using STS, when the miners' age and sex were controlled. Goodness of fit validated the final mixed effects linear regression model using likelihood ratio test. This is one of the first studies to complete this type of modelling for a platinum mine in South Africa.

To establish how the mine manages miners presenting with risk factors associated with ONIHL within the HCP. Paper 4: Using big data to predict occupational hearing loss for platinum miners in South Africa: A case study of data sharing practices and ethical challenges in the mining industry.

Paper 4 highlights data access restrictions brought by medical ethics and the POPI Act, which hinders research for the prediction and prevention of ONIHL. This study is one of the first to review the mine's HCP electronic records (so to explore the mine's systematic approach to risk assessment), and of the first to explore medical ethics and protection of personal information for the management of miners at risk for ONIHL.

Additionally, the current climate of instability in the mining industry was also considered as a possible challenge in terms of data access for hearing conservation practitioners (for example, the miners' medical records).

5.7 The policy impact of the PhD study

A series of studies drawn from this research contributed to the ongoing debates around the burden of ONIHL on individual miners and the mines, and the measures required to prevent the persistence of ONIHL in South African miners. In order to improve the effectiveness of the mines' HCP surveillance system, data should be managed in MLSs, which allow for decentralisation of the mines' records. This has the potential to strengthen the mine's hearing health systems and service delivery, and therefore prevent ONIHL. While reinforcing previous studies' reports on the risk factors associated with ONIHL in South African miners, and the fact that reduced noise exposure levels will reduce the burden and the number of cases of ONIHL, this PhD highlights the negative impact of PMD exposure (a possible risk factor for ONIHL) and supports its inclusion as an occupational exposure in the HCP pillars.

In order to address the needs of the end-users (hearing conservation practitioners and miners), to improve efficiency in reporting, as well as to allow for easy uptake of tools used to improve efficiency of the mine's HCP, a bottom-up approach for risk assessment and management should be encouraged (as opposed to the current approach).

This research has contributed to new knowledge for the implementation of Regulation 839 (NIHL Milestone). The evidence-based findings from this study support the ONIHL preventive nature of Regulation 839, provided that the mines accurately and consistently record good quality HCP data for individual miners. The methods used in this PhD to predict miners' STS over time show evidence-based practices for pure-tone audiometry and medical surveillance, and recommend a framework to guide the mines' accurate recording and reporting of HCP data for prediction and prevention of ONIHL.

While effective HCPs have not been reported due to challenges such as excessive noise exposure levels, reports on the lack of compliance regarding the use of hearing protection devices by the miners, and the siloed implementation of HCP. The mine's HCP records provide evidence that the risk assessment and management of ONIHL may be achieved if accurate and valid miners' records are kept by the mines, and that regular policy reviews that guide the HCP implementation are conducted. The application of the POPI Act with regard to the mine's MLSs and their integration into the NIHL regulations and HCP guidelines, should be reviewed by the South African mining industry.

CHAPTER 6: CONCLUSION

This chapter presents the overview of the research, a summary of the methodology, a summary of findings, and the conclusion.

6.1 Overview of the study

The burden of ONIHL in the South African mining industry has a negative impact on individual miners, the mines, and the Government, despite the implementation of HPCs, which are intended to prevent ONIHL. The South African mining industry has been criticised for implementing ineffective HCPs, which are pro-compensatory, rather than preventive of ONIHL. Thus, the aim of this study was to explore risk assessment practices, which incorporate data management, at a large-scale mine in South Africa, with a view of proposing a predictive model for the early identification of ONIHL. The findings from the research addressed gaps in the mine's HCP risk assessment practices and have been discussed in chapter 4 in the papers published in, and submitted to, peer-reviewed journals.

6.2 Summary of the methodology

This was a retrospective analysis of secondary data, using a quantitative approach. Data collected from 2014 to 2018, and kept in MLSs (MS Excel spreadsheets) by the mine's hearing conservation practitioners, were analysed. Secondary audiometry medical records and occupational hygiene records were collected from the mine's three data sources, viz. a hearing screening dataset (N = 24 321), an audiometry medical surveillance dataset (N = 1 938), and an occupational hygiene dataset (N = 15 679). Thereafter, the hearing screening and occupational hygiene datasets were merged, and duplicate records were removed to ensure longitudinal tracking and analysis of individual records (N = 12 629) from 2014 to 2018. The quantitative data were analysed using descriptive statistics and logistic regression analysis. The participating mine granted permission for the research study, and ethics approval to conduct the study was obtained from the University of the Witwatersrand's Human Research Ethics Committee (Medical) (Appendix 1).

6.3 Summary of results

This is the first study to analyse individual miners' records that included audiometry medical surveillance and occupational exposures, to explore the mine's risk assessment practices and records kept for the prevention of ONIHL. The mine's risk assessment methods partially identified miners at risk of ONIHL and risk factors for ONIHL which were identified may be used to predict miners' STS over a period of time. The summarised results are drawn from the key findings, viz. the prevalence of ONIHL, risk assessment practices used for the prevention of ONIHL, and prediction of ONIHL.

Prevalence of ONIHL

The mine's MLSs used to record audiometry medical surveillance data for the miners showed a reduction in the number of ONIHL cases from 2014 to 2018. These records were therefore partially effective in identifying miners already diagnosed with ONIHL. However, the multiple risk factors associated with ONIHL were not comprehensively managed to prevent ONIHL in the miners; hence the persistent prevalence of ONIHL reported by the mine.

Risk assessment and prevention of ONIHL

In 2006, Begley criticised the mining industry for its inaccurate recording/reporting of noise measurements and audiometry screening thresholds.[21] In this study, it was demonstrated that the use of efficient MLSs as HCP risk assessment tools can ensure the consistent collection of good quality data. The data collection sheet used in this study can be used as a template to design the HCP repositories (mines and national) and may guide medical decisions and service delivery towards the prevention of ONIHL. In addition, user-friendly MLSs with clearly outlined specific HCP outcomes and measurable outcomes for each hearing conservation practitioner and individual miners, may improve the mine's HCP efficiency and prevent ONIHL.

Prediction of ONIHL

This study, conducted at a South African mine, provides new knowledge on the use of miners' audiometry and occupational exposure data to predict changes in hearing function over a period of time, and to propose a prediction model for the early identification of ONIHL in miners.

The use of the systems thinking as a health systems' strengthening framework is proposed for a comprehensive risk assessment, to reduce the burden of ONIHL on the individual miners, the mines, and the national mining industry. The comprehensive risk assessment technique and MLSs used for recording and reporting occupational hazards and health risks are likely to guide inter-professional collaborations between hearing conservation practitioners, decision-makers, and research institutions. In addition, incomplete hearing thresholds obtained from the audiometry medical surveillance data may be predicted. However, the quality of the data recorded should be improved to ensure accurate prediction and prevention of ONIHL.

6.4 Conclusion

In conclusion, electronic audiometry medical surveillance records should be of good quality, be consistently kept, be able to identify occupational and person-specific risks and associated health risks, show specific HCP KPIs and the improved performance thereof, and guide hearing health care services intended for the prevention of ONIHL. Findings and conclusions from this study may add to knowledge on HCPs and ONIHL prevention, and may be investigated further by other mining commodities and other industries where noise is a problem, to assist the country, as a whole, to work towards prevention of ONIHL in South Africa. However, the findings may not be generalised to other mines because the study only used one mine's electronic audiometry medical and occupational hygiene data.

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APPENDICES

Appendix 1: Ethics Clearance Certificate

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

R14/49 Ms Liepollo Ntlhakana

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M180273

NAME: (Principal Investigator)	Ms Liepollo Ntlhakana
DEPARTMENT:	School of Public Health
PROJECT TITLE:	Noise induced hearing loss (NIHL) in mine workers in South Africa: Risk assessment explored
DATE CONSIDERED:	23/02/2018
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Prof Gill Nelson and Prof Katijah Khoza-Shangase
APPROVED BY:	CB Penny Professor CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	11/04/2018

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

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the Third Floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in **February** and will therefore be due in the month of **February** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature   Date 16-04-2018

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix 2: Record keeping in a hearing conservation programme of a South African platinum mine: what are we missing?

Occupational noise-induced hearing loss in platinum miners: what do the data tell us?

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Society membership: G Nelson is a Life Member of MMPA

Keywords: miners, occupational noise-induced hearing loss, compensation, electronic data systems

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ABSTRACT

Background: Occupational noise-induced hearing loss (ONIHL) is one of the most common occupational health diseases affecting miners in South Africa. Accurate and appropriate medical data are essential for making valid diagnoses.

Objectives: The purpose of this study was to describe the electronic records of a South African platinum mine's audiometry medical surveillance system and their role in early diagnosis of ONIHL. Ear-related conditions of affected miners, occupations, and noise levels were concurrently reviewed, and the characteristics of miners with and without ONIHL were described.

Methods: This was an analysis of secondary data from the electronic audiometry and employee occupational records of 305 platinum mine workers for the period 2014 to 2017. Data were analysed using descriptive statistics.

Results: Although the audiometry records contained appropriate and relevant data, including annual hearing screening percentage loss of hearing (PLH) shifts, there was evidence of inaccurate and insufficient recording of risk factors for hearing loss in the medical surveillance records. The records indicated that the miners in some occupations were exposed to dangerously high noise levels, exceeding 85 dB(A). Miners as young as 21 years of age were diagnosed with ONIHL.

Conclusion: The insufficient and inaccurate data captured in the miners' records has important implications for the mine's efficient implementation of hearing conservation programme (HCP) elements aimed at mitigating ONIHL. The hazardous noise levels recorded call for increased attempts to meet noise level regulations, while the presence of conditions such as pseudohypacusis highlights the need for exploration of more reliable assessment measures.

INTRODUCTION

Noise-induced hearing loss (NIHL) is defined as a sensorineural type of hearing loss that occurs gradually over time due to overexposure to noise that causes permanent damage to the organ of Corti, affecting both ears.[1] A person with NIHL will have an audiogram that indicates sensorineural hearing loss in the high frequency region of 3 000 to 6 000 Hz. Noise sources that cause occupational NIHL (ONIHL) are continuous or intermittent. Exposed individuals experience a rapid increase in hearing loss during the first 10 to 15 years of exposure, and a gradually progressive hearing loss thereafter.[1] Continuous, excessive noise exposure is defined as a noise level ≥ 85 dB(A), averaged over an 8-hour period.[1] This causes an initial temporary threshold shift (TTS) that lasts for 16–48 hours, and is a risk factor for a permanent threshold shift (PTS). The relationship between TTS and PTS is dependent on the extent of damage to the outer hair cells (OHCs). This damage is irreversible but preventable.[1]

In South Africa, employees in the mining and construction industries are exposed to very high noise levels.[2] Occupational NIHL (ONIHL) is highly prevalent among South African miners[3,4] but can be prevented if adequate noise-control measures are practised.[5] The Compensation for Occupational Injuries and Diseases Act, 1993 (Act No. 130 of 1993) (COIDA) gazetted Circular Instruction 171,[6] stipulates that an employee exposed to occupational noise at or above the 85 dB(A) noise rating limit (8-hours) time weighted average (TWA), and who has been diagnosed with ONIHL, should be compensated.[6] However, the South African National Standard (SANS 10083:2013) rather promotes the prevention of ONIHL, and stipulate that prevention measures must be instituted by companies for hearing conservation purposes.[7] Diseases in the mining industry, including pulmonary tuberculosis and human immunodeficiency virus (HIV), have been well documented.[5,8,9] However, there is little information available on the synergistic effects of these diseases, and their treatments with noise exposure, on the auditory system, or their potential as determinants for ONIHL risks. Such evidence is important as it can assist in developing disease control policies for the mines and health service planning.[9]

High prevalence rates of ONIHL have been reported. A 2017 report by the (now) Department of Mineral Resources and Energy showed an increase from 966 in 2016 to 1 141 cases in 2017 for their member mines.[10] Although these increases were in both the gold and platinum sectors, there was a 54% increase in the number of ONIHL cases reported by the platinum mines, from 2016 to 2017.[10] A total of 2 107 cases of ONIHL was reported by all mines that submitted audit reports in 2016/2017.[10] However, more recent reports by the individual mines reflect a different picture, i.e. that there is a decline in ONIHL cases reported from 2014 to 2018. For these years, AngloGold Ashanti mine reported a decrease in ONIHL cases from 35 to 30,[11] and Anglo American plc, from 90 to 30.[12] It has been suggested that, in general, reported rates of ONIHL are neither reliable nor valid due to partial reporting within the mine's hearing conservation programme (HCP), inaccurate or inadequate recording of noise levels, and inefficient capturing of audiometric data.[3,4,13-15]

In the study reported in this paper, we explored the use of an electronic information management system used by the mine to report on the miners' audiometry records, including noise exposure levels, the use of hearing protection devices (HPDs), medical surveillance, and audiometric test results.[16,17] The mine uses Microsoft Excel to record data for miners at risk of developing ONIHL, those who are diagnosed with ONIHL, and the processing of ONIHL compensation claims.[18] An attempt by Begley to create an audiometry database for the South African mining industry was trialled in 2005,[18] to pave the way for a national audiometry repository and to track ONIHL claims. Unfortunately, this was unsuccessful.[18] Reasons for failure included that baseline audiometry data were duplicated, noise exposure levels were not provided by the mines, and screening audiometry data provided by the mines were erroneous.[18]

The aim of the study was to describe the electronic records of a South African platinum mine's audiometry medical surveillance system, and its role in the early diagnosis of ONIHL. In addition, ear-related conditions of the miners examined by the occupational medical practitioner (OMP), and the occupations and related noise levels, were investigated, and the characteristics of miners with and without ONIHL were described.

METHODS

This cross-sectional study was an analysis of secondary data containing the miners' medical surveillance and audiometry records (N = 305) accessed from the OMPs' electronic records from a platinum mine in Limpopo province, South Africa, from 2014 to 2017. According to the SANS 10083:2013, medical surveillance records for employees at risk of developing ONIHL must be reviewed by the OMP for hearing loss prevention and reporting of ONIHL compensation claims. Therefore, in order to describe the mine's medical surveillance electronic record-keeping, and its role in the early diagnosis of ONIHL, we obtained the OMP's electronic records from the mine. The OMP recorded miners' audiometry examination data in three different datasets (Figure 1). The first comprised data from screening audiometry examinations conducted by the occupational health nurse OHN (N = 480). The second dataset comprised diagnostic audiometry data for those who were referred by the OHN to the OMP because their percentage loss of hearing (PLH) scores were > 2.5%; the OMP's examination included ear-related conditions. All miners with ear conditions and/or PLH > 2.5% were then referred to the audiologist for diagnostic audiology examinations (N = 470). The third dataset contained both screening and diagnostic audiometry data for only those miners who had been compensated for ONIHL (N = 76).

Variables included in the analysis were age at examination, occupation, duration of employment (calculated from year of first medical examination date to 2017), reason for referral to the OMP, date of OMP referral to the audiologist, baseline PLH score, noise exposure levels (area noise measurements in sound pressure in dBA(LAeq,8h), and age at ONIHL diagnosis.

The three datasets that were provided by the mine in Microsoft Excel format were merged, and then imported into and analysed using Stata 15.1. Continuous data were presented as means and standard deviations and categorical data were described as frequencies and percentages.

Ethical clearance was obtained from the University of the Witwatersrand's Human Research Ethics Committee (clearance certificate no. M180273).

RESULTS

Demographic characteristics

The 480 audiometry records reviewed contained data for 305 male underground miners (some miners had

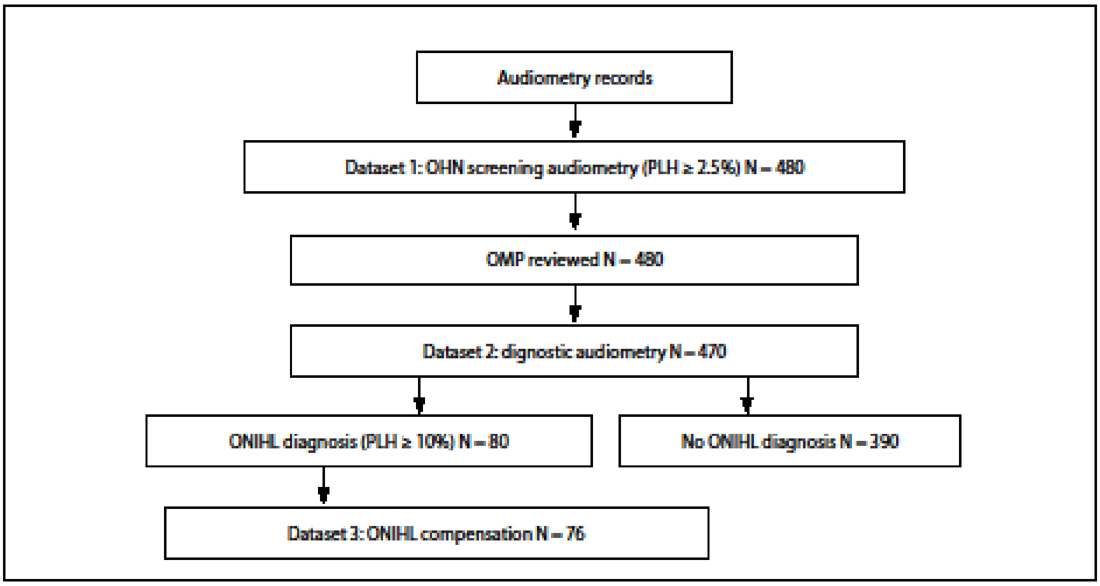

Figure 1. Audiometry datasets reviewed

duplicate audiometry records). The mean age of the miners was 47.7 ± 8.5 years (range 21 to 63 years), and the mean years of work experience was 10 ± 8 years (range one to 18 years). Eighty miners were diagnosed with ONIHL, of whom 76 were compensated (Figure 1).

Electronic records of the mine's medical surveillance programme

All miners had undergone annual screening examinations by the OHN, and miners at risk for ONIHL were referred to the OMP. The miners' annual hearing screening results were not consistently and regularly recorded, year-on-year, from 2014 to 2017. Of the 76 miners diagnosed with ONIHL, most 69 (98.8%) had only one annual screening audiometry record for the period 2014 to 2017 (Table 1).

The PLH scores recorded in the screening and diagnostic audiometry datasets (datasets 1 and 2, respectively) were inconsistent (Figure 2). For example, in 2016, 114 of 170 miners (67.1%) in the screening audiology dataset were recorded as having a PLH of ≤ 10%, but 146 of 163 of these miners (89.6%) had PLH scores of ≤ 10% recorded on the diagnostic audiometry dataset. In 2017, 72 miners were recorded as having a PLH ≥ 10% in the screening audiometry dataset, but only 17 of the 72 (23.6%) had a PLH of ≥ 10% recorded in the diagnostic audiometry dataset.

Although miners were referred to the OMP for examination, records in the diagnostic audiology dataset did not include any ear-related conditions or details regarding common ear-related signs and symptoms such as tinnitus, vertigo, otalgia and impacted cerumen. Ear-related conditions were recorded in the OMP medical surveillance notes, but only for the 76 miners who were compensated for ONIHL, although no information was recorded for 2014 (Table 2). In addition, chronic medical conditions, such as tuberculosis (TB) and HIV, and their respective treatment regimens, which are known to be associated with hearing loss, were not recorded in any of the datasets.

Table 1. Number of miners' screening audiometry records (N = 76)

Screening audiometry records (n)	Miners	
	n	%
1	69	90.8
2	6	7.9
3	1	1.3

Other information that was recorded only for the miners who received compensation for ONIHL (N = 76) was the baseline PLH score.

Mine workers' occupations and noise exposure levels

According to the medical surveillance data (notes made by the OMP in the diagnostic audiometry dataset), all miners were provided with HPDs. Eighty of the 305 (Figure 2) miners were diagnosed with ONIHL by the audiologist (PLH > 10 in the diagnostic audiometry database) and 76 (26.2%) were compensated.

Noise exposure levels (Table 3) were recorded as 8-hour time-weighted average (TWA) (LAeq,8h) area noise measurements. Sixty-five of the 76 compensated miners (85.5%) worked in occupations that exceeded the legislated (≥ 85 dBA) noise exposure. For these 65 miners, the recorded noise exposure levels in the work areas ranged from 87 to 103 dB(A). The only occupations for which noise levels were below 85 dBA were winch transport operator assistant and supervisor, underground fitter, underground mine overseer, shaft bell operator, pump team supervisor, and shaft timber worker.

Characteristics of miners with and without ONIHL

The baseline PLH scores, age at ONIHL diagnosis, duration of employment and noise exposure levels were reviewed for all miners, i.e. both those who were diagnosed with ONIHL (n = 76), and those who were not (n = 229). Only the miners with ONIHL had baseline PLH scores and age at ONIHL diagnosis recorded (Table 4).

Eighteen (23.3%) of the miners diagnosed with ONIHL were younger than 41 years. Among those with ONIHL, similar proportions of miners had worked for 0–5 and 6–10 years. More than half of the miners diagnosed with ONIHL had baseline PLH scores of 0 to 5 (n = 43; 56.6%). Many miners who had worked for more than 10 years (n = 108; 47.6%) did not have ONIHL. In both groups, most of the miners (around 95%) had high recorded noise exposure levels (≥ 85 dBA).

DISCUSSION

Annual hearing screening examinations

We reviewed miners' electronic records to describe the platinum mine's hearing conservation programme, and its role in early diagnosis of ONIHL. All miners had undergone annual screening examinations by the OHN and/or the OMP. However, annual hearing screening, by the OHN, was not conducted systematically.[19,20] Individual miners'

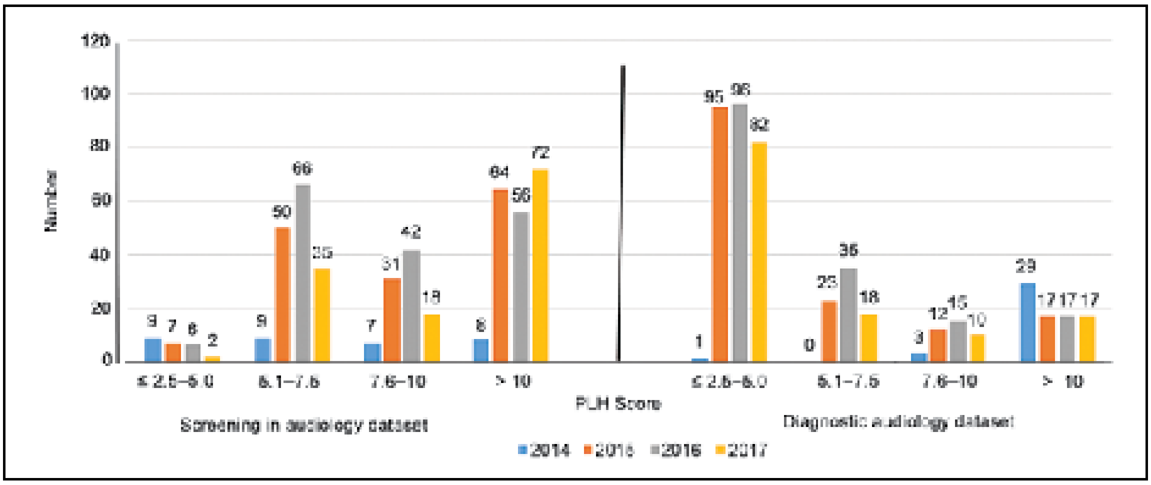

Figure 2. PLH scores in the screening and diagnostic audiometry datasets, 2014 to 2017

audiometry screening records were not available for every year of the study period, which prevented consistent tracking of the miners' hearing function. Incomplete individual screening audiometry data could prevent early identification of hearing loss, which is important for hearing conservation purposes.

Referral of miners for audiometry

Miners with recorded PLHs ≥ 2.5% were referred to the OMP for management and to the audiologist for ONIHL diagnosis, as an early intervention for the prevention and diagnosis of hearing loss. However, reasons related to hearing loss and follow-up interventions were not included in the miners' electronic audiometry records. It is possible that this information is provided in written records but was not available in the electronic files provided. Although referring miners with a 2.5% PLH to the OMP is the correct procedure to follow,[21,22] excluding factors such as medical conditions and occupational exposures associated with hearing loss in the miners' screening audiometry records for any reason, may contravene the Compensation for Occupational Injuries and Diseases Act (Act No. 130 of 1993) (COIDA) gazetted Circular Instruction 171, Section[8,6] and delay the diagnosis of hearing loss.

Missing information

Although baseline PLH scores can be used to predict a miner's pre-existing risk for hearing loss not related to occupational noise exposure, only miners with ONIHL had baseline PLH data recorded in the audiometry database. The procedure is a requirement for ONIHL compensation (Instruction 171),[6] and also allows for tracking of a miner's hearing function. However, exclusion of baseline PLH scores for other miners not diagnosed with ONIHL from the audiometry records prevents the calculation of the miner's PLH shift from baseline and the tracking of the miner's hearing function. Therefore, all miners, regardless of whether or not they have been diagnosed with ONIHL, should have their baseline PLH noted in all electronic audiometry records.

Ear-related conditions and interventions

Some of the 76 miners with compensated ONIHL presented with auditory pathologies that were identified during hearing screening, and subsequently diagnosed by the OMP. Although all miners with ear-related conditions identified during hearing screening were, in theory, referred to the OMP and the audiologist for further intervention and diagnostic audiometry, respectively, the data regarding ear-related conditions were only recorded in the dataset of the 76 miners who were compensated for ONIHL. They were not recorded for those miners who had not been diagnosed/compensated for ONIHL. Inadequate recording of ear-related conditions prevents early identification of hearing loss initiatives, which are recommended by Franz and Phillips (2001).[23] Therefore, all ear-related conditions identified during hearing screening and related interventions should be noted in the individual miners' audiometry screening records, as evidence for risk-based medical surveillance implementation.

Signs and symptoms associated with hearing loss

Common ear-related signs and symptoms associated with hearing loss, such as tinnitus, vertigo, otalgia and impacted cerumen[15,24] were not recorded in the electronic diagnostic audiometry database by the mine's OMP. This limits efforts to prevent other types of hearing loss (other than ONIHL), e.g. conductive hearing loss. In addition, there was no information in the miners' audiometry records about chronic conditions that are known to adversely affect hearing function, including TB and HIV, and treatment for these diseases. Synergies between these diseases and hearing loss, as well as between treatments for the diseases and hearing loss, have been observed in clinical settings, and some researchers have reported hearing preservation as a benefit derived from hearing monitoring programmes for miners on TB and HIV treatment.[25,26]

Use of hearing protection devices

The use of hearing protection devices (HPDs) is important but is a last resort to prevent ONIHL when engineering controls and other efforts to reduce personal noise exposure have failed.[27,28] Although the mine reportedly provided all the miners with HPDs, it is unlikely that there was 100% compliance of HPD use. Several studies have shown that miners prefer to not use HPDs for various reasons, e.g. discomfort, incorrect fit, interference with hearing abilities, etc.[15,24] No information about the use of HPDs was recorded in the databases. If this information is not in the miners' audiometry records, it is difficult to design individualised interventions, such as awareness training, HPD fit, etc.[28]

Poor record-keeping

Otitis media and dull tympanic membrane, and hearing loss not ascribed to ONIHL, were reported as ear-related conditions in the group of 76 compensated miners. Previous studies[15,24] have reported similar findings in gold and platinum miners in South Africa. There were fewer ear-related conditions recorded for the 76 miners with ONIHL than expected. Previous studies have cited poor record-keeping with regard to ear-related conditions in the mines' medical surveillance records as one of the reasons for not being able to review ear-related conditions and/or interventions.[18,24] This poor record-keeping with regard to the miners' ear-related conditions and intervention strategies inhibits efforts to diagnose hearing loss early, and to prevent it.

Table 2. Number of miners and types of ear-related conditions recorded by the OMP

Condition	Year of screening test				
	2014 n	2015 n	2016 n	2017 n	Total N
Rapid deterioration of hearing*	No medical comments recorded	0	1	1	2
Dull tympanic membrane and possible otitis media		1	2	3	6
Hearing loss not ascribed to ONIHL		2	1	4	7
History of surgery: middle ear surgery		2	0	0	2
Pseudohypacusis**		6	3	3	12
Total	0	11	7	11	29

* unexplained sudden hearing loss
** a condition in which hearing loss is exhibited in the absence of any organic disease, usually due to malingering

Misdiagnosis, using audiometry protocol

The diagnosis of pseudohypacusis (malingering) in some of the miners, also reported by De Koker in South African gold miners in 2004,[17] might be due to the potential for financial compensation for ONIHL.[17,29,30] De Koker recommended the inclusion of auditory steady-state response (ASSR) in the diagnostic audiometry protocol, while the Health and Safety Executive (HSE)[30] has recommended distortion-production oto-acoustic emissions (DPOAE) as a sensitive test for the early detection of outer hair cell damage.[30]

Inaccurate and misleading noise exposure data

Excessive area noise exposure levels have been identified as the leading cause of ONIHL in the mines.[2] It was therefore not surprising that most miners diagnosed with ONIHL had recorded noise measurements ≥ 85 dB(A). However, noise measurements in the mines are recorded as 8-hour time-weighted average (TWA) (LAeq,8h) area noise measurements. This is misleading as high noise levels are effectively hidden.[31] Although the highest recorded noise level in the database of the 76 platinum miners with ONIHL was 103 dB(A), this might obscure (average out) excessively high exposures. The ONIHL risk is increased for miners exposed to excessive noise levels, but the risk might not be accurately identified if only average noise measurements are recorded.[32] In addition, Edwards et al. (2011) recommended using a dosimeter for more accurate noise measurements in order to include measures of noise for all work-related activities in a full work shift, closer to the miner's ear (personal measurements rather than area measurements).[33]

No data about exposure to non-occupational noise are recorded in the database

While studies have reported that older age (presbycusis) is associated with ONIHL in the mining industry,[13,34] miners as young as 21 years were diagnosed with ONIHL and accordingly compensated. Strauss et al. (2014) also reported that gold miners younger than 31 years were at risk of NIHL.[34] This might be explained by a pre-existing hearing loss due to exposure to non-occupational noise, such as loud music. In a study on the use of personal listening devices (PLD) by young adults (14–31 years old), it was concluded that hearing loss was a result of exposure to loud music.[35] Strauss et al. (2012) demonstrated that the high prevalence of NIHL in South African gold miners was related to the miner's age.[3] Our findings and those of Strauss et al. (2014) suggest that young miners could have joined the mines with pre-existing non-occupational noise-related hearing loss. Therefore, investigations into the miners' hobbies (related to noise exposure), and duration thereof, may assist researchers in understanding the early onset of ONIHL in younger miners.

Limitations

These findings may not be generalisable to the HCPs of all the South African mines. The electronic records that were reviewed were from one platinum mine in Limpopo province. The sizes of the two groups (those with ONIHL and without ONIHL) were relatively small. The fact that the miners' medical surveillance audiometry records were recorded in different databases made it difficult to analyse the data as some records were duplicated and some had missing data, which effectively reduced the sample size. Not all the miners had baseline records that could be used as valid reference points; some miners had PLH scores higher than 10% (indicating pre-existing hearing loss) with no previous evidence of a hearing loss diagnosis.

Table 3. Occupations and noise exposure levels for mine workers diagnosed with ONIHL (N = 76)

Occupation	Mean noise level (dBA)*	n	%
Scraper winch operator	103.8	4	5.3
Pipes, tracks and ventilation (PTV) worker	95.6	3	3.9
Developing machine operator	94.8	7	9.2
Lightweight machine operator	94.5	22	28.9
Cheesa**	92.4	10	13.2
Mining team supervisor	91.3	6	7.8
Shift supervisor mining	91.3	3	3.9
Stope timber miner	89.5	6	7.8
Processor	87.9	1	1.3
Haulage construction aid	87.0	2	2.6
Haulage construction supervisor	87.0	1	1.3
Winch transport operator assistant	84.5	2	2.6
Winch transport operator supervisor	84.5	1	1.3
Underground fitter	84.2	2	2.6
Underground mine overseer	84.1	1	1.3
Incline shaft bell operator	82.9	3	3.9
Pump team supervisor	82.9	1	1.3
Shaft timber worker	82.9	1	1.3

*8-hour time-weighted average (TWA)
**responsible for placing explosives

Misdiagnosis, using audiometry protocol

The diagnosis of pseudohypacusis (malingering) in some of the miners, also reported by De Koker in South African gold miners in 2004,[17] might be due to the potential for financial compensation for ONIHL.[17,29,30] De Koker recommended the inclusion of auditory steady-state response (ASSR) in the diagnostic audiometry protocol, while the Health and Safety Executive (HSE)[30] has recommended distortion-production oto-acoustic emissions (DPOAE) as a sensitive test for the early detection of outer hair cell damage.[30]

Inaccurate and misleading noise exposure data

Excessive area noise exposure levels have been identified as the leading cause of ONIHL in the mines.[2] It was therefore not surprising that most miners diagnosed with ONIHL had recorded noise measurements ≥ 85 dB(A). However, noise measurements in the mines are recorded as 8-hour time-weighted average (TWA) (LAeq,8h) area noise measurements. This is misleading as high noise levels are effectively hidden.[31] Although the highest recorded noise level in the database of the 76 platinum miners with ONIHL was 103 dB(A), this might obscure (average out) excessively high exposures. The ONIHL risk is increased for miners exposed to excessive noise levels, but the risk might not be accurately identified if only average noise measurements are recorded.[32] In addition, Edwards et al. (2011) recommended using a dosimeter for more accurate noise measurements in order to include measures of noise for all work-related activities in a full work shift, closer to the miner's ear (personal measurements rather than area measurements).[33]

No data about exposure to non-occupational noise are recorded in the database

While studies have reported that older age (presbycusis) is associated with ONIHL in the mining industry,[13,34] miners as young as 21 years were diagnosed with ONIHL and accordingly compensated. Strauss et al. (2014) also reported that gold miners younger than 31 years were at risk of NIHL.[34] This might be explained by a pre-existing hearing loss due to exposure to non-occupational noise, such as loud music. In a study on the use of personal listening devices (PLD) by young adults (14–31 years old), it was concluded that hearing loss was a result of exposure to loud music.[35] Strauss et al. (2012) demonstrated that the high prevalence of NIHL in South African gold miners was related to the miner's age.[3] Our findings and those of Strauss et al. (2014) suggest that young miners could have joined the mines with pre-existing non-occupational noise-related hearing loss. Therefore, investigations into the miners' hobbies (related to noise exposure), and duration thereof, may assist researchers in understanding the early onset of ONIHL in younger miners.

Limitations

These findings may not be generalisable to the HCPs of all the South African mines. The electronic records that were reviewed were from one platinum mine in Limpopo province. The sizes of the two groups (those with ONIHL and without ONIHL) were relatively small. The fact that the miners' medical surveillance audiometry records were recorded in different databases made it difficult to analyse the data as some records were duplicated and some had missing data, which effectively reduced the sample size. Not all the miners had baseline records that could be used as valid reference points; some miners had PLH scores higher than 10% (indicating pre-existing hearing loss) with no previous evidence of a hearing loss diagnosis.

Table 3. Occupations and noise exposure levels for mine workers diagnosed with ONIHL (N = 76)

Occupation	Mean noise level (dBA)*	n	%
Scraper winch operator	103.8	4	5.3
Pipes, tracks and ventilation (PTV) worker	95.6	3	3.9
Developing machine operator	94.8	7	9.2
Lightweight machine operator	94.5	22	28.9
Cheesa**	92.4	10	13.2
Mining team supervisor	91.3	6	7.8
Shift supervisor mining	91.3	3	3.9
Stope timber miner	89.5	6	7.8
Processor	87.9	1	1.3
Haulage construction aid	87.0	2	2.6
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*8-hour time-weighted average (TWA)
**responsible for placing explosives

Recommendations

Sufficient and accurate miners' audiometry records should be recorded annually and kept in a single database. The mine can enhance or adopt several strategies to improve electronic recording of miners' audiology data at the mine, which would assist in monitoring and preventing ONIHL. Every miner should be screened annually, and checks should be put in place to ensure that the findings are captured and accurately recorded in the electronic database. If any miner has a PLH of 2.5 or more, the OMP should investigate reasons for this, in addition to exposure to high noise levels, and record relevant notes in the miner's audiometry record.

Baseline PLH scores should be included in the electronic audiometry records for all the miners so that PLH shifts can be identified and acted upon, using appropriate interventions. All ear-related conditions and any other relevant medical information, such as TB and HIV treatment and co-exposures that are associated with hearing loss (e.g. chemicals and dust), should also be included in the electronic database.

Detailed information about the provision and usage of HPDs and any other interventions to prevent hearing loss should also be recorded in order to implement miner-specific HPD interventions. Audiologists should routinely use DPOAE and ASSR in diagnostic audiometry in order to rule out pseudohypacusis. It is imperative that the mines rethink their policies/guidelines for reporting noise levels which are currently reported as averaged measurements. Last, information about non-occupational exposure to noise should be collected and recorded for every miner. Complete, accurate and integrated recording of the miners' audiometry records will provide a holistic view of the miners' hearing function, which is critical for the mines' HCPs.

CONCLUSION

The findings from our study indicate the need for a single, comprehensive electronic audiometry database for the mines. The databases should include all relevant medical and occupational and non-occupational exposure information. The data should be captured regularly and checked to ensure that annual records are available for all miners. In addition to eliminating excessive noise exposure levels, early diagnosis and prevention of associated risks, such as ear-related conditions, could potentially improve the mine's medical surveillance and audiometry, and reduce hearing loss. Hearing conservation practitioners should continue to focus on early detection in order to prevent hearing loss, in addition to prevention of exposure.

LESSONS LEARNED

- Recording the miners' audiometry and medical surveillance data in multiple databases can result in inconsistencies and hamper HCP efforts to diagnose hearing loss early.
- The monitoring of PLH shifts should be used for early diagnosis and prevention of hearing loss.
- Accurate and comprehensive electronic recording of audiometry information will enable efficient evaluation of HCPs.

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Table 4. Characteristics of miners with and without ONIHL

Characteristic	ONIHL Yes n = 76		ONIHL No n = 229	
	n	%	n	%
Age at ONIHL diagnosis (years)				
20–40	18	23.7	no data	
41–50	22	28.9		
51–65	36	47.4		
> 65	0	0		
Duration of employment (years)				
0–5	29	38.2	16	7.0
6–10	23	30.3	105	45.8
11–15	6	7.9	103	44.9
> 15	18	23.7	5	2.2
Baseline PLH score				
0–2.5	23	30.5		
2.6– 5.0	20	26.3		
5.1–7.5	7	9.2	no data	
7.6–10	9	11.8		
>10	17	22.4		
Noise exposure level (dBA)				
83.1–84.9	4	5.3	12	5.2
≥ 85	72	94.7	217	94.8

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DECLARATION

The authors declare that this is their own work; all the sources used in this paper have been duly acknowledged and there are no conflicts of interest.

AUTHOR CONTRIBUTIONS

Conception and design of the study: LN, KK-S, GN
Data acquisition: LN
Data analysis: LN
Interpretation of the data: LN, KK-S, GN
Drafting of the paper: LN
Critical revision of the paper: LN, KK-S, GN

Appendix 3: Estimating miners at risk for occupational noise-induced hearing loss: a review of data from a South African platinum mine

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AOSIS

Estimating miners at risk for occupational noise-induced hearing loss: A review of data from a South African platinum mine

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Background: Occupational noise-induced hearing loss (ONIHL) is a complex, but preventable, health problem for South African miners. Meticulously collected data should be made use of to design interventions to address this health issue.

Objectives: A single mine's electronic data were reviewed in a secondary data review to determine, from the records, factors that hearing conservation practitioners deemed useful for identifying 'at risk' miners and to establish factors that would pave the way for the integration of the 2014 hearing conservation programme (HCP) milestones into the mine's current proactive data management system (PDMS). The objectives of this article were to establish how miners with published risk factors associated with ONIHL were managed by the mine's hearing conservation practitioners as part of the HCP; to determine if the mine's hearing conservation practitioners could estimate miners' risk of ONIHL using baseline percentage loss of hearing (PLH) as a hearing conservation measure; and to estimate the contribution of noise exposure to ONIHL risk.

Method: In a secondary data review design, records in a platinum mine's two electronic data sets were reviewed: the first contained diagnostic audiometry records (N = 1938) and the second comprised a subset of miners diagnosed with ONIHL (n = 73). Data were available for the period 2014–2017 and included demographic, occupational, audiometry and ONIHL diagnosis data. Miners' risk factors associated with ONIHL were identified using the functional risk management structure. A logistic regression model was used for the baseline PLH margins of 0% – 40% (in 5% increments) to estimate the adjusted predictions for miners at risk of developing ONIHL. The contribution of noise exposure as a risk for ONIHL was estimated using a two-way sample proportion test.

Results: The mean age of the miners (all male candidates) was 47 ± 8.5 years; more than 80% had worked for longer than 10 years. Valid baseline audiometry records were available for only 34% (n = 669) of the miners. Miners with a 0% baseline PLH had a 20% predicted risk of ONIHL, and a 45% predicted risk if they had a 40% baseline PLH – these employees were referred. The noise exposure risk rankings revealed that 64.9% (n = 1250) of the miners were exposed to 91 dBA – 105 dBA noise exposure levels and that 59 (80.8%) diagnosed with ONIHL were exposed to noise levels of up to 104 dBA.

Conclusion: These findings indicate significant gaps in the mine's PDMS, requiring attention. Nonetheless, the mine's current data capturing may be used to identify miners at risk of developing ONIHL. The PLH referral cut-off point (≥2.5%) used by the mine's hearing conservation practitioners, when used in conjunction with baseline PLH shifts, was the major factor in early identification of ONIHL in miners exposed to ≥85 dBA noise. An inclusive integrative data management programme that includes the medical surveillance data set of the miners' noise exposure levels, occupations, ages and medical treatments for tuberculosis and human immunodeficiency syndrome is recommended, as these are important risk indicators for developing ONIHL, particularly within the South African context.

Keywords: Occupational exposures; Risk factors; Electronic data; Hearing conservation programme; Hearing loss; Miners.

Introduction

The World Health Organization (WHO) reported a 16% prevalence of occupational noise-induced hearing loss (ONIHL) in 2010 (WHO, 2010). In South Africa, ONIHL is the third most commonly reported occupational disease affecting miners (Balfour-Kaipa, 2014). Individuals with ONIHL

Note: Special Collection: Occupational Hearing Loss in Africa.

are susceptible to sleep disturbances, psychological stress associated with the frustration of losing hearing function, fatigue and cardiovascular problems (Malatji & Stewart, 2013). Workers' susceptibility to ONIHL is exacerbated by ageing, sex (Khoza-Shangase, 2019; Strauss, Swanepoel, Becker, Eloff, & Hall, 2012), a history of otalgia and middle ear infections (Edwards, 2008), previous diagnosis of sensory neural hearing loss, cigarette smoking, hypertension and type 2 diabetes (Hong, Lee, Park, & Kim, 2014). The risk of developing ONIHL is increased for workers currently on treatment for tuberculosis (TB), human immunodeficiency syndrome (HIV) and/or cancer (Khoza-Shangase, 2019). The increased risk of ONIHL is because of the synergistic effect of high noise levels and the other ototoxic factors mentioned above (Campo, Morata, & Hong, 2013; Hong et al., 2014; Khoza-Shangase, 2019). The symptoms of ONIHL include a sense of fullness in both ears, tinnitus, balance problems, difficulty following conversations and hearing warning signals, and progressive hearing loss in one or both ears (Feuerstein & Chasin, 2009).

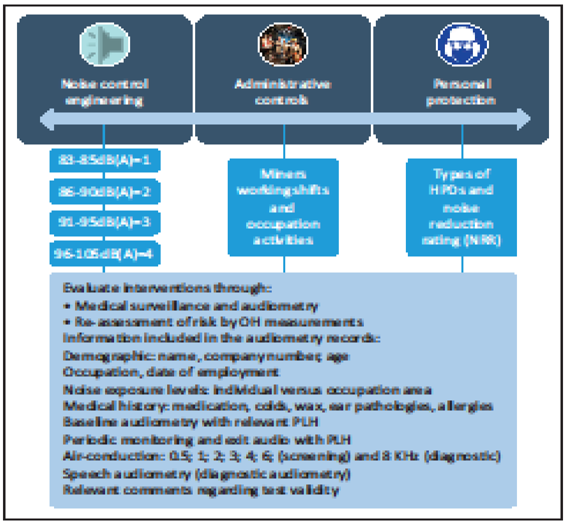
In the diagnosis and management of ONIHL, it is important to include tracking and monitoring all the aforementioned risk factors to ensure efficient implementation of any hearing conservation programme (HCP). Occupational diseases in the mining industry, including pulmonary tuberculosis and silicosis, for example, have been well documented (Hermanus, 2007; WHO, 2010); however, little evidence exists on how these diseases are treated within HCPs, although synergistic effects of these diseases and their treatments with noise exposure on the auditory system have been raised (Khoza-Shangase, 2019). The authors of this article concur with Hermanus (2007) in arguing that such evidence is important, as it can assist in developing disease control policies for the mines and health service planning, including HCP planning, implementation and monitoring.

The aforementioned comorbid health conditions have not been considered in HCPs (Nelson, Nelson, Concha-Barrientos, & Fingerhut, 2005). In countries like South Africa, where the prevalence of ONIHL is high, it can be argued that the failure to meet ONIHL elimination targets is influenced by the lack of contextual responsiveness to the burden of disease. Consequently, HCPs have been deemed ineffective in preventing ONIHL in South Africa (Edwards & Kritzinger, 2012; Moroe et al., 2018; Ntlhakana, Kanji, & Khoza-Shangase, 2015), in spite of being introduced in South African large-scale mines as early as 1988 (Franz & Phillips, 2001).

A number of studies on HCPs in South African mines have reported factors associated with the failure of HCPs to prevent ONIHL. These include excessive noise levels emitted by equipment (higher than the legislated level of 85 dBA), unsatisfactory uptake on the use of hearing protection devices (HPDs) by miners (Hansia & Dickinson, 2010; Ntlhakana et al., 2015) and evidence of high prevalence rates of ONIHL because of a combination of occupational and non-occupational factors (e.g. age, race and sex) (Strauss, Swanepoel, Becker, Eloff, & Hall, 2014). Weaknesses in HCPs, including poor risk management techniques and flawed audiometric database analysis (ADBA) (Franz & Phillips, 2001), have been proposed as some of the priorities requiring attention by the mining authorities and the audiology community in South Africa (Moroe & Khoza-Shangase, 2018).

The ADBA procedures were developed by the American National Standards Institute Working Group (ANSI S12/WGS12) (ANSI, 1991), with the goal of assessing the effectiveness of HCPs. The ADBA procedures can be utilised to ensure the success of HCPs by identifying potential problem areas and challenges in the HCP prior to employees developing significant hearing loss (Adera, Gullickson, Helfer, Wang, & Gardner, 1995), hence highlighting the need for careful longitudinal tracking and monitoring of employees' hearing function in relation to their noise exposure levels and other key risk factors. Such methods require comprehensive and consistent data collection to allow for an accurate and systematic assessment of the effectiveness of HCPs, which is a complex challenge with any well-meaning, data-reliant management system. The fact that there is more than one ADBA method that can be used introduces another challenge when it comes to comparative analysis of findings within and between organisations. The use of the ADBA for evaluating the effectiveness of HCPs, for example, was found lacking in Adera et al.'s (1995) paper, where ratings of HCPs were found to be inconsistent from year to year, and from procedure to procedure used. Use of such a procedure therefore is bound to present significant challenges, if all important and often contextually relevant factors (including the burden of disease specific to the region) do not form part of the data capturing and analysis processes. As illustrated in Figure 1, the technique includes recording the miners' audiometry data from baseline to exit.

This technique requires the use of a data management system to 'identify occupations, workplaces and activities where hearing loss is progressing most, particularly in the case of a large workforce.....' (Franz & Phillips, 2001, p. 209). Within the South African context, evidence suggests that although the ADBA is used, its effectiveness is questionable (Begley, 2006), possibly because of the factors listed above. Begley (2006) described how South African large-scale mines designed various versions of the ADBA, and how this inhibited the successful tracking of miners' audiological status and the monitoring of those diagnosed with ONIHL. An HCP has seven pillars that include noise control engineering, noise measurement, administrative noise control measures, education–training–motivation, HPD usage, risk-based medical surveillance and audiometry. The technique described by Franz and Phillips focusses on three pillars, namely: (1) noise control engineering, (2) administrative noise control measures and (3) use of personal protection, as a proactive risk management tool for early identification and prevention of ONIHL; the said technique was reportedly adopted by the mine where the current study's data were located. This technique is rather outdated, and there are more recent and more comprehensive HCP structures that cover all pillars of HCPs, such as complex



Source: Adapted from Franz, R.M., & Phillips, J.I. (2001). Noise and vibration. In E.R. Guild, J. Johnson, & M. Ross (Eds.), *Handbook of occupational health practice in the South African mining industry* (pp. 195–232). Johannesburg: The Safety in Mines Research Advisory Committee (SAMRAC).

HPDs, hearing protection devices; PLH, percentage loss of hearing; NRR, noise reduction rating; OH, occupational hearing.

FIGURE 1: Functional structure of a risk management system for occupational noise.

interventions (Moroe, 2018); nonetheless, this was the technique that was followed for the secondary data analysed in the current study. This method reportedly allowed the mine to send ONIHL cases to their insurance company according to Instruction 171.

We analysed data from the mine's medical surveillance and audiometry records to describe the mine's ONIHL prevention efforts (Figure 1).

A proactive data management system (PDMS), as a single point of contact for organisations, has been used for many years to understand complex organisational trends. The PDMS follows best practice principles, allows for efficient monitoring of key factors identified by the company and provides intervention measures where required (Jantti & Cater-Steel, 2017). In South Africa, large-scale mines have attempted to use the ADBA technique that draws data from the mine's medical surveillance and audiometry records, as a PDMS for the management of miners exposed to hazardous noise emitted by their equipment, to build the miners' audiometry database and to prevent ONIHL. However, the ADBA's failure is demonstrated by high noise levels and the continued reporting of miners with ONIHL (Balfour-Kaipa, 2014; Chamber of Mines, 2016). Thus, South African mines have not been successful at designing PDMSs to prevent ONIHL.

Previously reported high incidences of ONIHL in the South African mining industry indicate the miners' hearing loss as a function of percentage loss of hearing (PLH) at 10% or greater since 2001 when the *Compensation for Occupational Injuries and Diseases Act, 1993 (Act No. 130 of 1993)* (COIDA) gazetted Circular Instruction 171 was instituted (Department of Labour, 2001). However, the fact that PLH calculations included only 500 hertz (Hz), 1000 Hz, 2000 Hz, 3000 Hz and 4000 Hz meant that higher frequencies known to be affected early by excessive noise exposure (as in ONIHL) were excluded. Hence, studies that reported on miners' hearing function associated with ONIHL included low and high frequencies (500 Hz – 8000 Hz) (Khoza-Shangase, 2019; Moepeng, Soer, & Vinck, 2017; Strauss et al., 2012) in order to provide the miners a broader hearing function spectrum. However, for ONIHL compensation claim processing, which is still practised by the Compensation Commissioner, the miners' audiometry records had to reflect the PLH score, indicating the miners' hearing loss in spite of the noted weaknesses of using such scores.

This led to the review of HCP milestones by the Minerals Council South Africa, focussing on the mining equipment noise emissions and the tracking of the miners' hearing thresholds (high-frequency standard thresholds) (Inspectorate, 2017). The new milestones set out in 2014 by the mining industry stakeholders stated that no individual miner's standard hearing threshold shift (STS) should exceed 25 dB from baseline, in both ears, and that the total operational or process noise emitted by any equipment must not exceed 107 dBA, by the year 2024 (Mine Health and Safety Council – MHSC, 2015). The use of the STS as a sensitive measure for early detection of hearing loss was deemed a proactive practice of managing miners at risk for ONIHL. This initiative prompted the mines to integrate the miners' newly recorded standard thresholds and threshold shifts (2014–2016) into their current reporting systems in order to improve their efficiency in identifying miners 'at risk' of developing ONIHL and to be in line with WHO targets for ONIHL (WHO, 2010). We reviewed the data recorded by the mine in order to determine, from the records, factors that hearing conservation practitioners deemed useful for identifying 'at risk' miners and to establish factors that would pave the way for the integration of the 2014 HCP milestones into the current PDMS of the mine.

The objectives of this article were to establish how miners with published risk factors associated with ONIHL were managed by the mine's hearing conservation practitioners as part of the HCP; to determine if the mine's hearing conservation practitioners could estimate miners' risk of ONIHL using baseline PLH as a hearing conservation measure; and to estimate the contribution of noise exposure to ONIHL risk.

Methods

Research design

This was a secondary data review of miners' electronic records from a platinum mine in Limpopo province, South Africa. Secondary data are called as such for various reasons, including the fact that the data were obtained by somebody else; the data had already undergone one layer of analysis prior to the secondary analysis; and that the data were collected for a focus or objective different to the one these are currently used for (Sorensen, Sabroe, & Olsen, 1996). This is an identified limitation of the current design; however, the limitation was in itself a key aspect of the study's objective of assessing how the mine utilises its data management system as it is for its HCP.

Study population

We reviewed all miners' electronic medical surveillance and audiometry records at the research site. This comprised records including miners' age, sex, years of experience, occupations, noise exposure levels, medical surveillance and audiometric test results.

Data collection and data management

The records reviewed in this secondary data review were stored in two databases, and comprised data from 2014 to 2017. The main database contained 1963 medical surveillance and diagnostic audiometry records of miners, all of which had a baseline PLH shift of ≥2.5% (value set by the mine to refer miners for diagnostic audiometry), and had been referred to an occupational medical practitioner for further intervention, and to an audiologist for diagnostic audiometry. The second data set was a subset of records of 73 miners who had calculated PLH shifts of ≥10% from baseline. Following the diagnostic audiometry assessment, a diagnosis of ONIHL was confirmed by the audiologist, and some miners had been presented to the Rand Mutual Assurance company for ONIHL compensation. These two sets of data were handled separately.

All data underwent data cleaning processes that included the removal of duplicate records (n = 25), after which 1938 unique records remained in the main database. The audiometric records contained demographic, occupational and audiometry data (screening and diagnostic), and ONIHL diagnosis information. Careful scrutiny and recording of the process followed for miners in both data sets in relation to risk factors was performed for analysis.

It should be noted that because this is a secondary data review, PLH values were what was recorded and therefore reviewed, but it is acknowledged that the South African mines had started moving towards the new HCP milestones (2014) of using STS.

Data analysis

Extracted data were captured into Microsoft Excel, after which they were imported into and analysed using Stata (version 15.1). The variables, such as age, baseline PLH, diagnostic audiometry PLH, years of noise exposure, noise exposure levels and recorded risk factors, were analysed using descriptive statistical analysis, logistic regression analysis, and a two-way sample proportions test (z-test).

To establish how the mine's hearing conservation practitioners managed miners presenting with risk factors associated with ONIHL, risk factors stated in the functional risk management structure (Figure 1) (Franz & Phillips, 2001) were used.

To determine if the mine's hearing conservation practitioners could estimate miners' risk of ONIHL at baseline, PLH margins from 0% to 40% (5% increments) were used to estimate and interpret adjusted predictions, using logistic regression analysis. Finally, the contribution of noise exposure to the risk for ONIHL was estimated using a two-way sample proportion test (z-test), with the significance level set at 95%.

Ethical considerations

Ethical clearance to conduct the study was obtained from the University of the Witwatersrand's Human Ethics Committee (M180273) on 11 April 2018, and permission to access the records was obtained from the management team of the mining company. The study adhered to the Declaration of Helsinki 1975, as revised in 2008, as far as ethical considerations were concerned.

Results

To establish how miners with risk factors associated with occupational noise-induced hearing loss were managed within a hearing conservation programme

The workforce comprised only male mine workers. Tables 1 and 2 illustrate the miners' ages and years of working in the mine, with a mean age of 47 (± 8.5) years (44–55 years) and a working experience of 10 (± 3.5) years (8–13 years). No records of all risk factors, particularly medical conditions important for hearing monitoring such as TB and HIV (ototoxicity), were recorded in the audiology records. Audiology data captured in the mine's ADBA system only included pure-tone audiometry.

The data seem to indicate that hearing conservation factors included in the mine's PDMS to manage noise exposure and

TABLE 1: Demographic characteristics of the miners in the main subset (N = 1938).

Characteristic	N	%
Age (years)†		
20–30	40	2.1
31–40	273	14.1
41–50	594	30.6
51–60	1023	52.8
≥ 61	8	0.4
Working experience (years)‡		
1–5	162	0.8
6–10	1010	52.3
11–15	636	32.9
≥ 16	22	0.1

†, n = 1938; ‡, n = 1930 (eight records with missing data).

TABLE 2: Demographic characteristics of the miners (N = 73).

Characteristic	N	%
Age (years)†		
20–30	0	0
31–40	11	15.1
41–50	38	52.1
51–60	24	33
≥ 61	0	0
Working experience (years)‡		
1–5	5	6.8
6–10	29	39.7
11–15	32	43.8
≥ 16	7	9.6

†, n = 73; ‡, n = 73.

miners at risk for ONIHL were PLH scores for screening and diagnostic audiometry, with categorised referral points for the miners, as ≤2.5%, 5%, 7% and ≥10%, to monitor those miners at risk for ONIHL and for compensation purposes.

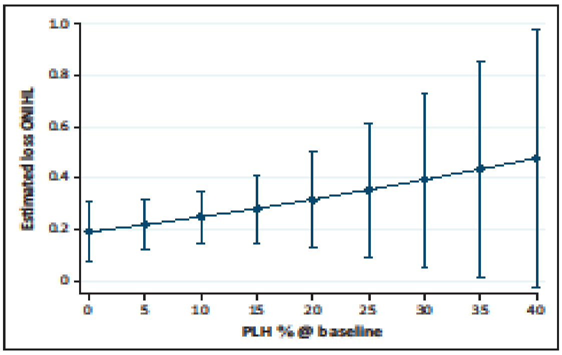
Risk rankings for noise exposure levels were not available, from lowest to highest (1–4), for all the miners. Furthermore, only 34% of the miners (n = 669) had baseline audiometry records; periodic audiometry records were available for review but there were no monitoring audiometry records; and the diagnostic audiometry records included only pure-tone air-conduction results with no speech audiometry data.

To determine if the mine's hearing conservation practitioners could estimate miners' risk of occupational noise-induced hearing loss at baseline

The miners' estimated risk for ONIHL was based on the baseline PLH shift of 2.5% used by the mine. Baseline PLH is core to tracking miner's hearing deterioration and is required for the calculation of the PLH shift for compensation; to determine a PLH shift of >10%. Figure 2 illustrates baseline PLH margins that were generated through logistics regression, from 0% to 40%, used to distinguish (in increments of 5%) between miners at high and low risk of ONIHL. At 0% PLH at baseline, the risk of ONIHL was predicted to be 20%. A 20% PLH at baseline corresponded to a risk level for ONIHL of about 30%; and a risk of ONIHL was predicted to be around 45% when a miner had a baseline PLH of 40%. The baseline PLH shift of 2.5% used by the mine's hearing conservation practitioners is a proactive measure used for the miners' hearing preservation. Baseline PLH scores and PLH scores at ONIHL diagnosis included in the model for the second data subset (N = 73) were used to estimate the predicted risk for ONIHL.

To estimate the contribution of noise exposure to occupational noise-induced hearing loss risk as a proactive measure

The miners' noise exposure levels were recorded as continuous data and were aligned with their occupations. Table 3 shows the mine's noise exposure risk rating categories that we formulated to classify miners at risk of ONIHL.



ONIHL, occupational noise-induced hearing loss; PLH, percentage loss of hearing.

FIGURE 2: Baseline percentage loss of hearing adjusted predictions with 95% confidence intervals for occupational noise-induced hearing loss.

TABLE 3: Noise exposure risk rating categories of exposed miners (N = 1963).

Noise exposure level (dBA)	Noise exposure risk rating category	N	%
≤ 82	0 (low)	81	4.2
83–85	1 (medium)	279	14.4
86–90	2 (significant)	328	16.9
91–95	3	941	48.6
96–105	4	309	15.9
> 105	5 (high)	0	0

More than 80% of the miners (n = 1578) were exposed to noise exposure levels that were higher than the legislated occupational exposure limit (OEL) of 85 dBA, with 64% of the miners falling into the two highest risk rating categories.

Fifty-nine (80.8%) of the 73 miners diagnosed with ONIHL were exposed to noise levels of 85 dBA – 104 dBA; 14 (19.2%) were exposed to noise levels of <85 dBA. Although both groups (those exposed to <85 dBA and those exposed to ≥85 dBA) were exposed to high noise levels, the results indicated that the risk for ONIHL increased with the noise exposure category. The z-test showed a mean difference of 62% in noise exposure levels (p = 0.001) between miners exposed to ≥85 dBA and those exposed to <85 dBA.

Discussion

Our study was guided by Franz and Phillips' (2001) risk management tool, which was introduced in the early 2000s. Analysis of the miners' records revealed that the mine was using a siloed approach for risk assessment of noise hazards and identification of miners at risk of ONIHL. The miners' baseline PLH scores could estimate miners' risk for ONIHL, although the 2.5% PLH used by the mine's hearing conservation practitioners to refer miners for further intervention delayed the process of identifying miners at risk of ONIH and that the OEL for noise, of ≥85 dBA, is not low enough to prevent ONIHL.

With regard to establishing how the mine's hearing conservation practitioners proactively managed miners presenting with risk factors associated with ONIHL findings showed that miners older than 40 years and those who had worked in mining for longer than 6 years were at higher risk of developing ONIHL. The fact that they were referred for diagnostic audiometry with a screening audiometry PLH score of ≥2.5% meant they were suspected of being at risk of developing ONIHL. In other studies, conducted in South African mines (Khoza-Shangase, 2019; Strauss et al., 2012), age was identified as a risk factor for ONIHL, and our findings support this. Miners' increasing age is already considered by the mines' hearing conservation practitioners as a risk factor for ONIHL; increasing work duration could be similarly considered as a risk factor.

The ADBA technique used by the mines requires more sensitive measures to identify miners at risk of ONIHL. The South African mines consider annual and diagnostic audiometry procedures as sensitive measures for identification of hearing loss; hence, both audiometry procedures were conducted on miners working in areas identified as high risk for ONIHL. Although Franz and Phillips (2001) recommended the use of the ADBA technique, based on the findings from Royster and Royster's (1986) study, the large-scale mines designed mine-specific ADBA techniques, guided by the Noise Induced Hearing Loss Regulation 171 (2001) and the SANS 10083:2013. According to both the regulation and SANS 10083:2013, two diagnostic audiogram results should be used to confirm the ONIHL diagnosis. Our review of the mine's electronic records revealed that none of the miners had two diagnostic audiometry records, deeming these results incomplete and inconclusive for the diagnosis of ONIHL (Franz & Phillips, 2001). Although duplicate diagnostic audiometry records were not in the mine's reviewed records, they could have been available and kept with other miners' records. This undermined the ADBA effort to provide a full picture of the miners' ONIHL diagnostic results.

In a review of gold miners' hearing results, researchers argued for the importance of adding an objective diagnostic tool – the distortion-product otoacoustic emissions (DPOAEs) tool – for early detection of ONIHL (Moepeng et al., 2017). In addition, evidence from research on DPOAEs has provided insight into other causes that lead to occupational hearing loss, such as age, ototoxic drugs, chemical exposure, tuberculosis and HIV (Campo et al., 2013; Khoza-Shangase, 2019; Strauss et al., 2014). However, at the time of data collection for our study, the miners' diagnostic audiometry data did not include information about TB and HIV treatment, as well as types of chemicals to which the miners were exposed at work. The 2014 HCP milestones recommended inclusion of the STS as a measure of the miners' hearing function, with the aim of improving hearing loss identification for these populations, for which the mining industry needs to be commended.

The contextual implications for TB and HIV as contributory factors towards miners' hearing loss cannot be ignored. Our review of the records showed that these data were not included in the miners' hearing conservation data, in spite of several studies in the South African mining industry indicating that TB and HIV are associated with hearing loss (Hermanus, 2007; Khoza-Shangase, 2019). Previous research has argued for the inclusion of these conditions in the medical surveillance records of miners (Franz & Phillips, 2001; Khoza-Shangase, 2019; MHSC, 2015), as well as the audiometry records, for audiological monitoring. This should be performed as a proactive way of managing all risks associated with hearing loss.

In a recent record review of hearing function among gold miners, Khoza-Shangase (2019) found that miners with a history of TB treatment presented with worse high-frequency hearing loss than those without a history of TB treatment. The study also highlighted confounding factors that affect the auditory system in this population, namely, the use of ototoxic medications, age and noise exposure. Khoza-Shangase (2019) raised the importance of audiological monitoring for these miners to be integrated into the mines' TB and HIV medical surveillance programmes in order to monitor hearing loss holistically. This recommendation was also made by Franz and Phillips (2001).

Our findings indicated that baseline audiometry referral scores used by the mines' hearing conservation practitioners delay the early identification process and intervention of miners at risk of ONIHL. Even at 0% baseline PLH, the miners were at a 20% risk of developing ONIHL. In addition, the PLH scores provide low-frequency thresholds at baseline for the miners. The 2.5% PLH referral used by the mine was seen as proactive when compared to the legislated referral of 3.2% (SANS, 2013), and the method also provides hearing threshold information that could be used in conjunction with the STS to identify miners' risk of developing ONIHL at baseline.

There is a dearth of literature on the use of baseline PLH as part of HCPs in South African industries where noise is a problem. The only other study that reviewed baseline PLH scores was conducted by Bronkorst and Schutte (2013) who reviewed audiometry records of workers in various occupational settings in the Western Cape province to highlight the importance of using the employees' more sensitive baseline (B-baseline) audiometry results for hearing conservation purposes. The method recommended by Bronkorst and Schutte (2013) showed the value of baseline PLH and the potential use thereof without the need to recreate new baselines for the South African miners.

The miners who were exposed to excessive noise levels (≥85 dBA) had a greater chance of being diagnosed with ONIHL. Of the 73 miners diagnosed with ONIHL, 14 (19.1%) were exposed to noise levels <85 dBA. This implies that the OEL of ≥85 dBA used by the mines did not protect miners from developing ONIHL, or that there could be other risk factors that led to the miners' ONIHL diagnosis. Our findings and those of Edwards et al. (2011) are in agreement as far as noise exposure levels in South African mines are concerned. However, we questioned the association of other risk factors with ONIHL, specific to miners exposed to <85 dBA noise levels. Thus, a recommendation is made for the hearing conservation practitioners in the mining industry to review the legislated OEL (≥85 dBA), and to consider comorbid factors associated with occupational hearing loss, in order to prevent ONIHL.

The fact that the participating mine did not record noise exposure risk rankings is problematic, and it limits efforts for the prevention of ONIHL. It is important for the mines to provide accurate noise exposure rankings in the miners' audiometry records, specific to tasks and occupations, in order to correctly identify miners at risk of ONIHL. In addition, the noise measurement technologies and recording techniques used by the mines' occupational health practitioners should be effective towards the prevention of ONIHL. Although the duration of exposure was not recorded in the current study, we acknowledge the importance of this aspect in ONIHL, over and above other personal factors such as genetic predisposition.

Although significant, the findings should be interpreted carefully, taking cognisance of methodological limitations. The data that we reviewed were exclusively drawn from one large-scale mine, from the miners' diagnostic audiometry records, and revealed three critical limitations. Firstly, the shortcoming associated with the use of secondary data is that some interpretations of our findings are based on assumptions. Secondly, the occupational hygienist's data were not included in the records that we reviewed; thus, additional exposures and duration thereof were not included in the data that we reviewed. Our results therefore reflect only a narrow view of the diagnostic audiometry data set. Thirdly, the miners' medical surveillance records regarding TB and HIV status could not be accessed. This compromised our review, as we could not comment on the broader spectrum of the hearing health risks associated with the miners' ONIHL. This exclusion of data from the medical surveillance database indicates that the mine did not necessarily view TB, HIV and their medications as risk factors for hearing loss and therefore did not consider them in their HCP strategies. Finally, the non-classification of noise exposure levels according to risk rankings (Franz & Phillips, 2001) implies that the mine may be applying a blanket intervention for miners exposed to noise levels of ≥85 dBA.

Conclusion

Our findings, guided by the ADBA technique, which was recommended by Franz and Phillips in 2000, indicated that the mine was using an adaptation of a technique that was recommended more than 15 years ago. This resulted in the mine's hearing conservation practitioners considering noise exposure as the sole occupational hazard for ONIHL. Other occupational exposures associated with ONIHL were excluded. Nonetheless, the effort towards keeping records for the miners at risk of developing ONIHL was commendable.

A lower baseline referral PLH score should be used to identify miners at risk of ONIHL early, also allowing for early intervention to be instituted. The mining company is encouraged to add the miner's data on burden of diseases such as TB and HIV as part of the miners' audiometry monitoring programmes. This would facilitate proactive management of miners at risk of developing any type of hearing loss, including ONIHL. The current data management system used by the mine has the potential to be integrated into, and used together with, the new 2014 HCP milestones, to monitor the miners' hearing function across all frequencies. It is probable that the mines are not achieving the desired outcomes of tracking miners' hearing loss accurately, because they are using the PLH levels to report miners at risk for ONIHL, rather than STS. We recommend that the mines implement the new milestones (use of STS) across all stages of HCP reporting, to ensure that all new baselines are based on STS levels. This will ensure early identification of ONIHL instead of focussing on PLH, which is concerned with compensation after a disability has occurred.

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Competing interests

The authors declare that they have no financial or personal relationships which may have inappropriately influenced them in writing this article.

Authors' contributions

L.N. conceptualised the idea for the research, as well as the design and methodology adopted, with assistance from G.N. and K.K.-S. L.N. collected the data for the study and analysed these with supervision from G.N. and K.K.-S. L.N. was the lead author of the manuscript, which was critically reviewed by G.N. and K.K.-S. All three authors read and approved the final manuscript.

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Data availability statement

Data sharing is not applicable to this article as no new data were created or analysed in this study.

Disclaimer

The views and opinions expressed in this article are those of the authors and do not necessarily reflect the official policy or position of any affiliated agency of the authors.

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Appendix 4: Predicting standard threshold shifts for occupational hearing loss among miners at a large-scale platinum mine in South Africa (in press)

Predicting standard threshold shifts for occupational hearing loss among miners at a large-scale platinum mine in South Africa

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Synopsis

The prevalence of occupational noise-induced hearing loss is high in South African mines. We investigated the relationship between standard threshold shift (STS) and exposure to noise and dust and developed a predictive model for STS for miners at a platinum mine in South Africa from demographic data and five years of audiometry, noise, and dust data, by means of a linear mixed effects regression model.

More than 70% of the miners were exposed to > 85 dBA noise, and 58% were exposed to dust levels ranging from 1.5 to 2.99 mg/m³. Changes in hearing level ranged from 8.3 at baseline (2014/2015) to 10 dBHL in 2016 (high-frequency average, HFA234); with no changes thereafter. The linear mixed effects model estimated exposure associated with sex (male) was 27% and 21% for the left and right ears, respectively. The estimated effect of age, percentage loss of hearing, noise exposure, and years of exposure was < 10% for each variable. There was no statistically significant association between dust exposure and STS in hearing.

The combined effects of age, sex, years of exposure to noise, and noise exposure levels can be used to predict STS for this group of miners. Our findings may be used to gauge the efficiency of the mine's hearing conservation programme and assist the prevention of occupational noise-induced hearing loss among miners.

Keywords

occupational noise-induced hearing loss, noise, platinum mine dust, standard threshold shift.

Introduction

In 2005, the most recent year for which data is available 16% of global disabling hearing impairment, which affects about four million adults, was due to occupational noise; with the burden ranging from 7% to 21% in different subregions.(Nelson *et al.*, 2005) The estimated prevalence in African countries was 18% (12–23%).(Nelson *et al.*, 2005) In the USA, the estimated prevalence of occupational noise-induced hearing loss (ONIHL) in the mining industry for the period 2006–2010 was reported to be 24% (Masterson *et al.*, 2015). For South African mines during the same period a prevalence of 30% was reported (Mine Health and Safety Inspectorate, 2017). ONIHL is common in South Africa across all mining commodities. The prevalence in the gold mining sector was estimated to be 17% in 2012 (Strauss *et al.*, 2012).

An improved understanding of risk factors for miners' hearing deterioration, in addition to those already established and considered in hearing conservation programmes (HCPs), is essential. Research on the associations of socio-demographic factors (age, sex, and race), genetic predisposition, recreational noise exposure, and occupational exposures (noise, platinum mine dust, and chemicals) (Pillay, 2020, Sepadi, Chadyiwa, and Nkosi, 2020) with ONIHL has been extensively conducted, globally (Khoza-Shangase, 2019; Campo, Morat, and Hong, 2013; 2019, Strauss *et al.*, 2012; Brits *et al.*, 2012; Grobler *et al.*, 2020). Research in South African mines has shown that age, sex (Strauss *et al.*, 2014), ototoxic drugs used for treatment of pulmonary tuberculosis (PTB) and human immunodeficiency virus (HIV) (Khoza-Shangase, 2019; Brits *et al.*, 2012), and noise exposure levels ≥ 85 dBA are associated with ONIHL (Edwards *et al.*, 2015; Strauss *et al.*, 2012; Balfour-Kaipa, 2014).

Although exposure to platinum mine dust (PMD), which contains below detectable levels of crystalline silica (Nelson and Murray, 2013; Biffi and Belle, 2003), is not directly associated with any occupational diseases, platinum miners exposed to PMD experience symptoms such as blocked nose, scratchy throat, itchy ears and eyes (Levene and Calnan, 1971; Fickl, 2007). All of these are allergic reactions that are associated with conductive hearing loss (Signia, 2018), which occurs when there is an obstruction of sound waves from the outer ear (pinna to tympanic membrane) to the middle ear; also due to a build-up of ear wax or fluid (Katz *et al.*, 2009). This type of hearing loss is treatable but causes temporary difficulty in hearing low-frequency sounds.

The prevalence of PTB in the South African mining industry is high (Mine Health and Safety Inspectorate, 2017), and has been associated with ONIHL in gold miners (Khoza-Shangase, 2019). PTB is also associated with exposure to silica dust in the gold mines (Nelson, 2013; Sepadi, Chadyiwa, and Nkosi, 2020). HIV is a also a risk factor for PTB (Ebonyi *et al*, 2016), and treatments for both PTB and HIV are ototoxic (Khoza-Shangase, 2019). Certain cancers are also treated with ototoxic drugs, *e.g.* cisplatin, which contains platinum salts (Lenntech, 2020). Although some research has been conducted on the association between NIHL and PTB in the South African mining industry (Khoza-Shangase, 2019), no investigation has examined the association of NIHL with exposure to PMD or ototoxic TB, HIV, and cancer treatments (Lenntech, 2020; Phanguphangu and Ramma, 2018). There is a dearth of knowledge among mine medical practitioners on the multifactorial effects of certain diseases and medical conditions, and their treatments, on the auditory system (Edwards, van Coller, and Badenhorst, 2010).

The South African HCP guideline states that programmes to prevent ONIHL should include seven pillars: noise measurement, engineering and administrative controls, hearing protection devices, risk-based medicals, medical surveillance, and audiometry (SANS, 2013). However, audiometry data and reports on miners' hearing conditions in the South African mines surveillance programmes are not integrated (Ntlhakana, Khoza-Shangase, and Nelson, 2020). Data regarding risk factors associated with miners' hearing loss, health data, and occupational hygiene data (including noise exposure measurements) is recorded in different data-sets (under the auspices of HCPs). Data on diseases such as cancer, TB, and HIV is recorded separately from audiometry data, and records are not linked for hearing conservation reporting (Khoza-Shangase, Moroe, and Edwards, 2020).

The identification of risk factors associated with hearing loss, coupled with pure-tone and distortion-product otoacoustic emissions (DPOAEs) audiometric tests, can assist in the early diagnosis of ONIHL (Moepeng, Soer, and Vinck, 2017). These two tests measure hearing thresholds across low (250 Hz) mid (1000 Hz), and high (2-8 kHz) frequencies (Feuerstein and Chasin, 2009). While both the DPOAE and pure tone tests are used in HCPs (Edwards, van Coller, and Badenhorst, 2010), it has been reported that DPOAE is more sensitive, feasible, and helpful for the early identification of ONIHL than pure-tone audiometry (Edwards and Kritzinger, 2012; Edwards, van Coller, and Badenhorst, 2010). Results from the two tests are recorded separately in the miners' audiometry records, and DPOAE results are not always available.

Workers exposed to high noise levels lose the ability to hear high-frequency sounds first (Edwards, van Coller, and Badenhorst, 2010; Grobler *et al.*, 2020). Hearing loss, as a decline in hearing thresholds, is measured by percentage loss of hearing (PLH) (Department of Labour, 2001) and standard threshold shifts (STS) (Department of Mineral Resources, 2016). The PLH is calculated from measured hearing thresholds (0.5, 1, 2, 3, and 4 kHz), and a baseline audiogram is recorded based on this value.(Department of Labour, 2001) This is the method that was used by South African hearing conservation practitioners to define hearing loss for compensation purposes from 2001 to 2016 (Department of Labour, 2001).

The STS method is based on an International Organization for Standardization (ISO) standard (ISO1999:2013) which specifies that a decline of 8 dB in the STS indicates early ONIHL. The STS method has been used by South African mines since 2016 to benchmark miners' hearing and to track STS deterioration as a function of hearing loss (Strauss *et al.*, 2012; Grobler *et al.*, 2020). In 2008, the Department of Mineral Resources and Energy (DMRE) set NIHL milestones for the mining industry, stating that, after December 2008, the HCP implemented by the industry 'must ensure that there is no deterioration in hearing greater than ten per cent amongst occupationally exposed individuals' (Msiza, 2014; Department of Mineral Resources and Energy, 2008). However, hearing loss prevention efforts were not successful (Edwards and Kritzinger, 2012) and the DMRE revised the milestones in 2014 (Chamber of Mines, 2016), stating that, by December 2016 no employee's STS will exceed 10 dBHL from the baseline when averaged at 2000, 3000, and 4000 Hz in one or both ears (MHSC, 2015).

Thus, STS was prioritized in the measurement of hearing loss for miners. Normal hearing is recorded as 0 dBHL (Chamber of Mines, 2016). A STS is defined as an average shift in hearing threshold of 10 dBHL. Although there is no hearing loss at this stage, any shift > 10 dBHL should be reported, and warrants investigation and intervention (Chamber of Mines, 2016). A shift in the hearing threshold of ≥ 25 dBHL for one or both ears indicates hearing loss. Thus, diagnostic audiometry is required in order to confirm hearing loss (Department of Mineral Resources and Energy, 2016). Worldwide, STS has been used to describe the hearing function of workers exposed to excessive noise levels since the early 2000s (Masterson *et al.*, 2016; Heyer *et al.*, 2011). The South African mining industry's hearing loss prevention efforts, as per the NIHL 2016 milestones, are now aligned with first world countries such as the USA. However, the success of these interventions will only be assessed in 2024 (MHSC, 2015).

The purpose of our analysis was to examine the association of STS with exposure to noise and PMD, and to develop prediction model for STS for miners employed at one of South Africa's large platinum mines, using demographic data and five years of audiometry, noise, and dust data.

Methods

The results of individual miners' hearing screening tests and occupational hygiene data from 2014 to 2018 were analysed. Data on diseases was not available. We accessed 24 321 hearing screening records and 15 769 occupational hygiene records (noise exposure levels) from the mine's two available data-sets. The hearing screening data-set contained audiometry screening records from examinations conducted by a qualified audiometrist (occupational health nurse) according to the South African National Standard (SANS) 10083:2013.(SANS, 2013), bilateral audiometry results at frequencies of 0.5, 1, 2, 3, 4, 6, and 8 kHz, calculated PLH, and averaged bilateral STS. The occupational hygiene data-set contained information about occupation (job title), noise exposure levels (dBA), and total PMD exposure measurements (mg/m³) for each miner, collected by a qualified occupational hygienist. Both data-sets included the miner's employee number, age, and sex. These three variables were used to combine the data-sets using STATA (version 15.1). The data was further categorized using the mine's risk rankings as follows: PLH as low (0–2%), moderate (2.1–5%) and high (>5%); noise exposure levels as 0–81.99 dBA, 82–84.99 dBA, 85–104.99 dBA, and 105–160 dBA; dust exposure levels as 0–0.299 mg/m³, 0.3–1.499 mg/m³, 1.5–2.99 mg/m³, and 3–100mg/m³, as well as the standard hearing loss classifications of mild (26–45 dBHL), moderate (46–55 dBHL), moderately-severe (56–70 dBHL), severe (71–90 dBHL), and profound (>90 dBHL) (Katz *et al*., 2009).

Permission to use the miners' data was granted by the mine management, and ethical clearance was obtained from the University of the Witwatersrand's Human Research Ethics Committee (clearance certificate no. M180273).

The combined data-set contained 17 304 electronic records (Figure 1). A total of 4 675 duplicate records, records with no employee numbers, records with no initial dates of employment, records with more than two baseline PHL values, and records with > 50% PLH (invalid calculations) were excluded. The number of records included in the analysis differed from year to year – 12 605 for 2014, 12 602 for 2015, 12 599 for 2016, 12 591 for 2017, and 12 592 for 2018.

Data analysis

Frequencies and percentages were used to describe miners' sex, age group, noise exposure and PMD levels, and PLH and STS categories. Medians and ranges were used to describe continuous PLH and STS scores. Differences in male and female miners' STS were graphically depicted by age group and PLH category.

A linear mixed effects model was used to estimate the effects of different exposure factors on the bilateral STS, using continuous data from all the variables with the exception of sex.

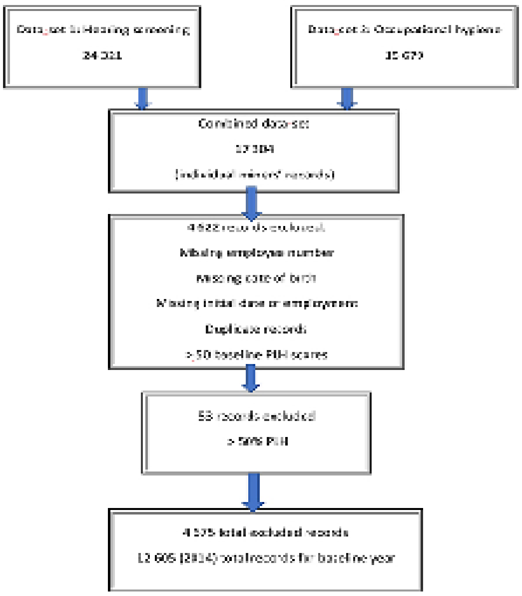

Figure 1—Individual miners' records excluded from merged data-set

Distributions of selected variables, including bilateral STS, were assessed to ascertain skewness before fitting the model. The bilateral STS (left and right) data were skewed and were therefore log-transformed before fitting the model. For the mixed effects model, when fitting the bilateral STS levels to predictor variables, a random intercept was assumed. The estimates are reported with 95% confidence intervals. Significance for two-sided tests was set at $P < 0.05$. Goodness of fit of the final prediction model was tested using the likelihood ratio test.

Results

The characteristics of the miners in the 2018 cohort are shown in Table I. There were more males (n = 11 283; 89.6%) than females (n = 1 309; 10.4%); most (53.4%) were younger than 41 years, most (76.4%) had low PLH; 72.4% were exposed to noise levels of 85 dBA or higher; and 57.9% were exposed to 1.5–2.99 mg/m³ PMD. Approximately 10% of the miners had high PLH (> 5%) and STS ≥ 26 dBHL.

Table I

Miners' demographic, exposure, and hearing function characteristics (N = 12 592*)

Variable	n	%
Sex		
Female	1 309	10.4
Male	11 283	89.6
Age (years)		
≤ 40	5 243	53.4
41–55	3 766	38.4
≥ 56	810	8.3
*Noise exposure level (dBA)***		
0–81.99	1 239	11.2
82–84.99	1 813	16.4
85–104.99	8 015	72.4
*PMD exposure level (mg/m³)***		
0–0.299	3 004	28.4
0.3–1.499	1 454	13.8
1.5–2.99	6 116	57.9
*PLH (%)***		
Low (0–2)	9 619	76.4
Moderate (2.1–5)	1 706	13.5
High (> 5)	1 274	10.1
*STS (dBHL)****		
−10–25	11 287	89.6
26–45	1 029	8.2
46–55	176	1.4
56–70	93	0.7
71–90	27	0.2
> 90	2	0.01

* Based on 2018 data; ** risk-ranking scales used by the participating mine;
***range of hearing function (Katz *et al*., 2009)

Table II shows the medians and range used to describe the miners' hearing function measurements (PLH and STS). The median PLH did not change throughout the study period (1.2%); some miners had a maximum PLH range of up to 50%. The median STS was 8.3–10 dBHL, with a hearing deterioration (STS) of 1.7 dBHL from baseline to 2016 in the left ear, and to 2017 in the right ear. Some miners had a maximum STS range of up to 99 dBHL at baseline, which increased to 95 dBHL by 2018.

Figure 2 shows STS for the left ear for male and female miners of different age groups and PLH categories across the five

Table II

Median values for hearing function measurements (N = 12 592*)

Year	PLH (%)		STS left ear (dBHL)		STS right ear (dBHL)	
	Median	Range	Median	Range	Median	Range
2014	1.2	1.1–49.9	8.3	1.0–99.0	8.3	10.0–93.0
2015	1.2	1.1–49.7	8.3	–8.3–99.0	8.3	–6.6–97.6
2016	1.2	1.1–49.9	10.0	–10.0–93.3	8.3	–8.3–91.3
2017	1.2	1.1–50.0	10.0	–8.3–95.0	10.0	–8.3–93.3
2018	1.2	1.1–49.3	10.0	–10.0–95.0	10.0	–10.0–94.3

* Based on 2018 data

years of follow-up. There was a small increase in mean STS over the five years in the high PLH category for males > 41 years. Male miners in most PLH categories had higher mean STS levels than female miners in all years of exposure, across different age categories. The differences in mean STS between males and females were greatest in the high PLH and > 41 years age categories.

Figure 3 shows STS for the right ear for male and female miners of different age groups and PLH categories, across the five years of follow-up. There was a small increase in mean STS over the five years in the high PLH category for males > 41 years. Male miners in most PLH categories had higher mean STS levels than female miners in all years of exposure, across different

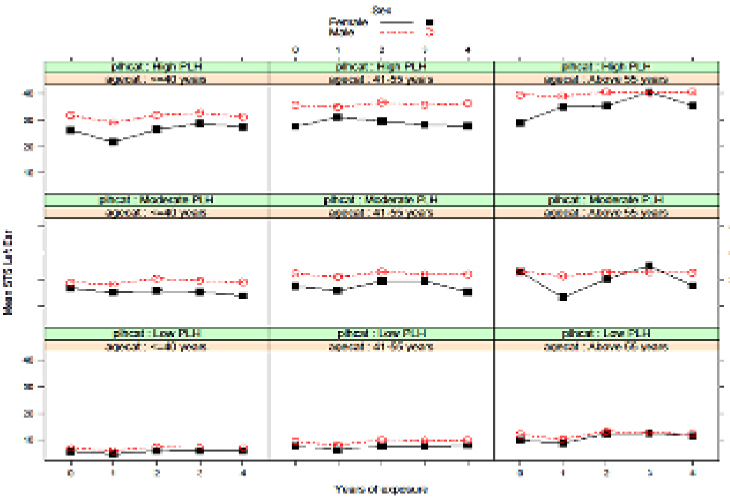

Figure 2—Mean STS for left ear by PLH level, age group, and sex for all years of follow-up

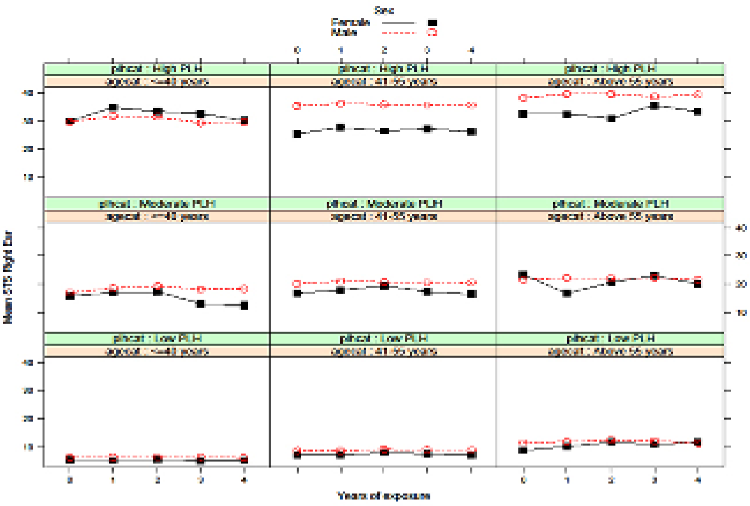

Figure 3—Mean STS for right ear by PLH level, age group, and sex for all years of follow-up

age categories. The differences in mean STS between males and females were greatest in the high PLH and > 41 years age categories.

Predicting standard threshold shifts for occupational hearing loss

The year 2014 was set as the baseline year; 2015, 2016, 2017, and 2018 represented cumulative years of noise and dust exposure. The log-transformed STS data was used in the mixed effects linear regression model as the outcome variable; the predictor variables were sex, age, PLH, noise exposure level, dust exposure level, and years of exposure (as described in Table III). The model showed that the estimated effect on STS for males was 27% and 21% higher than for females, for the left and right ear, respectively. The estimated effects on STS of a unit increase in PLH, age, duration of exposure, and noise exposure level were all < 10%, but nevertheless statistically significant. The effect of dust exposure on STS was not statistically significant. The likelihood ratio test showed that the predictive model was a good fit ($p < 0.001$).

Figure 4 shows an increasing effect of years of exposure on predicted STS for both male and female miners, controlling for age, PLH, and noise and dust levels. There was a steady increase in the predicted STS (and, therefore, a gradual hearing deterioration) for both the left and the right ears over time. Males start with a higher baseline STS and maintain higher STS levels across all years of exposure, compared to females.

Figure 5 shows the effect of increasing age on the predicted STS for males and females, when years of exposure, PLH, and noise and dust levels were controlled for. For males, the predicted STS increased steadily, and was higher than that for females for both the left and right ears. Again, males start with a higher baseline STS than females, which is consistent across all ages.

Discussion

Although the STS milestone (Regulation 839) was introduced by the DMRE and due to be updated in 2024 ('by December 2016, no employee's STS will exceed 10 dB from the baseline when averaged at 2000, 3000 and 4000 Hz in one or both ears') (Chamber of Mines, 2016), our study is the first to evaluate the progress made by this platinum mine. By analysing the mine's data we were able to benchmark miners' hearing, track STS deterioration, and identify miners at risk of developing hearing loss.

In this group of miners, both age and sex were associated with deterioration in hearing, measured by increases in STS in the high frequencies. This supports the findings of Grobler *et al.* (2020) that male gold miners older than 40 years and exposed to excessive occupational noise had hearing deterioration in the high frequencies. Bilateral loss of hearing, measured by STS (HFA234) was generally worse in male than female miners. This may be due to differences in genetic susceptibility (Sliwinska-Kowalska and Pawelczyk, 2013), recreational noise exposure (Gates *et al.*, 2000), previous occupational noise exposure (Grobler *et al.*, 2020), diagnosis of conductive hearing loss (Ntlhakana, Khoza-Shangase, and Nelson, 2020), or medical conditions such as TB and HIV, and treatments thereof (Khoza-

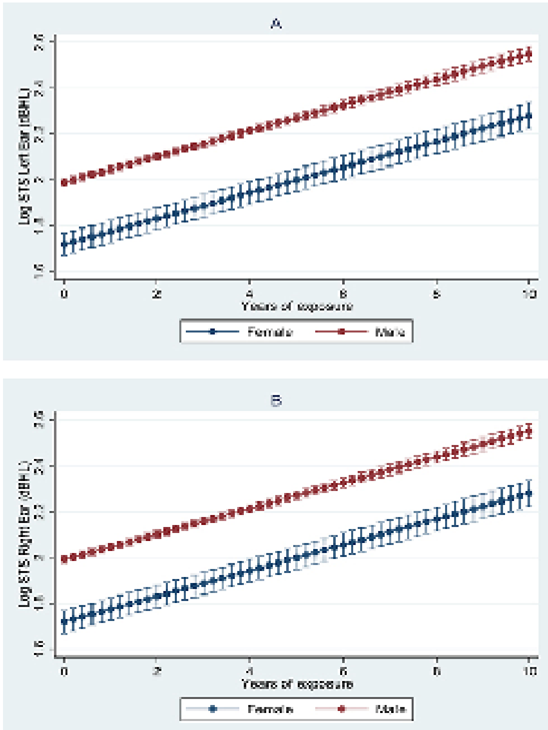

Figure 4—Prediction of STS for males and females, over 10 years (A and B) 95% CI predictive margins

Table III

Average predicted STS for miners from 2014 to 2018

	Standard threshold shifts (dBHL)					
	Left ear			Right ear		
Variable	**Estimated effect (%)**	**95% CI**	**p value**	**Estimated effect (%)**	**95% CI**	**p value**
Sex (male)	0.27	0.220–0.323	< 0.001	0.21	0.162–0.261	< 0.001
PLH	0.08	0.078–0.083	< 0.001	0.08	0.075–0.079	< 0.001
Age (years)	0.03	0.0357–0.040	< 0.001	0.04	0.038–0.041	< 0.001
Duration of exposure from 2014 (years)	0.03	0.0524–0.059	< 0.001	0.03	0.024–0.031	< 0.001
Noise level (dBA)	0.01	0.003–0.008	< 0.001	0. 00	0.002–0.007	0.002
Dust level (mg/m³)	0.02	–0.094–0.1538	0.270	–0.01	–0.132–0.109	0.850

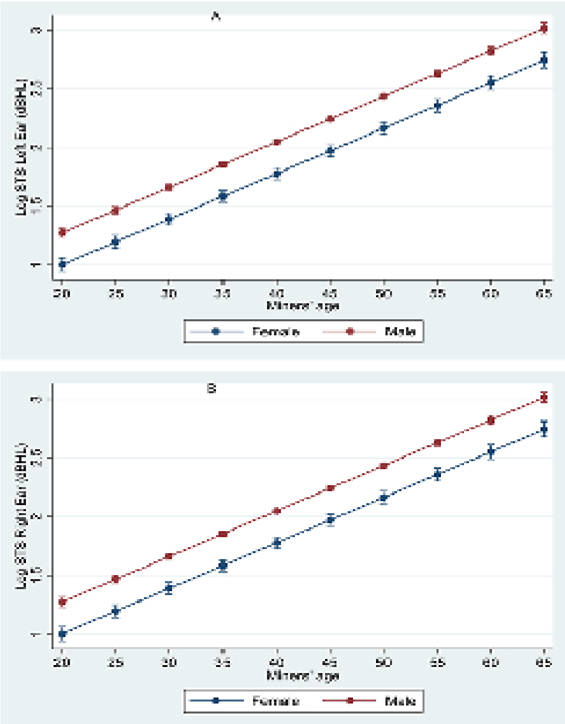

Figure 5—Prediction of STS for males and females over time, by age (A and B) 95% CI predictive margins (95% CI are too narrow to be depicted)

Shangase, 2019). Recently, coronavirus (COVID-19), associated with otitis media (Fidan, 2020) and otitis media, have been included among the risk factors that affect South African miners (Ntlhakana, Khoza-Shangase, and Nelson, 2020). Exclusion of this data from the audiometry records may lead to an under-estimation of the miners' hearing deterioration.

Hearing threshold changes and hearing deterioration that is due to a combination of various factors, including occupational noise exposure, are gradual and incremental. This has been reported previously in South African gold mines (Strauss *et al.*, 2014; Grobler *et al.*, 2020). Some miners had presented with hearing loss in 2018, ranging from 26 dBHL to 90 dBHL, which may prevent the mine from achieving the NIHL milestone target for 2024. Furthermore, some miners' pure-tone air conduction data was not available for every year, so the mine did not consistently follow audiometry requirements for individual miners who were at risk of developing ONIHL. Standard threshold shifts and hearing severity classification scales should be used together, from baseline, to measure miners' hearing deterioration and for early identification of at-risk miners. Our findings may be used by the participating mine to achieve the targets for the NIHL milestone for 2024.

Although the participating mine's noise exposure records showed a maximum noise exposure level (105 dBA) that was below the DMRE's targeted level of 107 dBA for 2024 (Chamber of Mines, 2016), more than 70% of the miners in the cohort were exposed to > 85 dBA over the five-year period. This is a concern as acoustic pressure at > 85 dBA damages the auditory system (Rodrigue, 2020; Grobler *et al.*, 2020). Cumulative exposure to high noise levels had a negative impact on miners' auditory systems, as some of the miners in our study presented with STS that ranged between 26 dBHL and >90 dBHL (Ntlhakana, Khoza-Shangase, and Nelson, 2020). High noise exposure levels will continue to increase the miners' risks of ONIHL.

There are no studies on the effects of dust exposure on hearing loss, which may be due to the fact that dust exposure levels in the South African platinum mines are lower than the regulated occupational exposure level (OEL) of 3 mg/m³ (Belle and Stanton, 2007). Although more than half of the miners in the database were exposed to 1.5–2.99 mg/m³ PMD, which is classified as 'significant' according to the mine's PMD risk ranking scale, we found no effect of PMD on hearing function. However, some platinum miners have reported irritation of the throat, nose, ears, and eyes (Levene and Calnan, 1971), which are allergic reactions to PMD that are associated with conductive hearing loss (Levene and Calnan, 1971). Therefore, other types of hearing loss such as conductive hearing loss should be considered to avoid an over-estimation of ONIHL as well as to account for different types of hearing loss that affect miners (Sebothoma, 2020). The findings of this analysis also have implications for preventive audiology in the form of early identification of hearing impairment in miners, and interventions to both reduce the risk of progressive hearing loss in those already affected and prevent hearing loss in miners who are not yet affected (Khoza-Shangase, Moroe, and Edwards, 2020).

Despite the fact that some studies have reported effects of PTB and HIV treatment on miners' hearing function (Khoza-Shangase, 2019), and that certain treatments for these diseases and cancer are ototoxic (Khoza-Shangase, 2019; Lenntech, 2020; Phanguphangu and Ramma, 2018), we were not able to access miners' medical records on PTB, HIV, and cancer treatment, as these records were in a database that was separate from the audiometry data. A lack of integration of the miners' PTB, HIV, and cancer data with audiometry data limits understanding of the miners' hearing function and deterioration.

Hearing changes due to occupational and individual characteristics occur gradually over time and reflect the mine's HCP efficiency. Our findings were similar to those of Strauss *et al.* (2014) and Grobler *et al.* (2020) in that hearing thresholds of males were more adversely affected than those of females. We predicted that the estimated effect on STS associated with being males was more than that of PLH, age, years of exposure, and noise exposure, although all were statistically significant. Our model showed that age had a small effect on STS compared to sex, which was surprising because studies on South African gold miners have reported age to be associated with ONIHL (Strauss *et al.*, 2014; Grobler *et al.*, 2020). There was also evidence that males started with higher STS than females, when years of exposure and age were controlled for, and thus were more susceptible to hearing loss from baseline than females. Furthermore, our model predicted a gradual STS deterioration over 10 years which, without intervention, will continue. Although we used five years (2014–2018) of data in our analysis, the mean duration of employment and noise exposure for platinum miners was more than five years (Ntlhakana, Khoza-Shangase, and Nelson, 2020). The model showed that combined exposure variables produced an effect on the bilateral STS over a period of time. This presents an opportunity for the mines to use our prediction model and to include miners' exposure variables (age, sex, noise, dust exposure levels, and duration of exposure) to predict hearing deterioration, with the hope of identifying miners at risk of occupational hearing loss.

Most investigations of the prevalence of ONIHL among miners have used cross-sectional study designs (Khoza-Shangase, 2019; Moepeng, Soer, and Vlnck, 2017; Strauss *et al.*, 2012, 2014; Brits *et al.*, 2012; Campo, Morata, and Hong, 2013; Masterson *et al.*, 2016; Heyer *et al.*, 2011). These have provided limited evidence for synergistic risk factors in occupational hearing loss, and no time-specific information associated with the onset and development of ONIHL. We conducted a retrospective cohort analysis that used the miners' longitudinal data to understand risk factors associated with hearing function. However, prospective cohort longitudinal studies would improve our understand of the development of ONIHL and its associated risk factors over time (Seixas *et al.*, 2012; Worku and Ohaju, 2004).

Strength and limitations

A strength of our study was the use of large data-sets that included miners' occupational exposures and audiometry data to understand the mine's recording of occupational exposure and audiometry data to determine trends in the miners' hearing function.

The main limitation was the unavailability of the miners' medical surveillance records linked to the data-sets used in the study. We could therefore not include medical conditions that cause conductive hearing loss (*e.g.* allergies, COVID-19), chronic medical conditions such as PTB and HIV, and medications used to treat PTB and HIV, in the analysis and in the predictive model. This mine cited the POPI and Medical Ethics Acts as stumbling blocks to providing the miners' medical records, which are classified as confidential with limited rights of access. Thus, effects due to ototoxicity were not factored into our analysis. In addition, there was no information about other factors associated with NIHL, such as recreational noise exposure and previous occupational noise exposure. It is therefore possible that we overestimated the prevalence of ONIHL. This mine's HCP data was not integrated, and some miners' records omitted demographic and audiometry data, hence 2014 was used as the baseline year, which was not necessarily a true baseline for miners in this study.

Conclusion

This is the first study conducted at a South African mine that includes miners' audiometry and occupational exposure data to predict hearing changes over a period of time. We showed that demographic characteristics (age and sex) and occupational exposures (noise) can be used to predict occupational hearing deterioration and calculated the contribution of each variable over a period of time. We showed that miners' STS changes are gradual over time and are due to a combination of risk factors, not only noise exposure. These findings may be used to evaluate HCP efficacy at this and other mines.

The miners' demographic data and risk ranking categories for occupational and audiometry data may be useful for development of the HCP data repository for this and other South African mines. We have highlighted gaps in the literature on the potential association of exposure to PMD and conductive hearing loss in the South African platinum mines. Our results reinforce the need to shift the focus from ONIHL prevention only towards HCPs that will address different types of hearing loss.

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Appendix 5: Using big data to predict occupational hearing loss for platinum miners in South Africa: A case study of data sharing practices and ethical challenges in the mining industry (invited manuscript – under review)

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Abstract

Background**:** Big data requires machine learning systems (MLSs) to automatically classify and predict outcomes, and to ensure protection of personal information. Relevant legislation have paved the way for data handling and sharing. However, ambiguous big data handling and sharing practices hinder healthcare delivery and medical research.

Objectives**:** We reviewed personal health data in hearing conservation programs to investigate personal data protection processes used by a South African platinum mine, and to describe the use of big data in a MLS, which may lead to ethical pitfalls.

Methods**:** This was a semi-qualitative cross-sectional study design, which entailed analysing miners' records from 2014 to 2018. Data were accessed from the audiometry medical surveillance database (n = 480), the hearing screening database (n = 24 321), and the occupational hygiene database (n = 15 769). Ethical principles related to big data protection and sharing were explored.

Results**:** Some audiometry screening and occupational hygiene records were incomplete and/or inaccurate (N=4 675). The database containing medical disease and treatment records could not be accessed. Ethical challenges included lack of clarity regarding permission rights when sharing big data, and no policy governing divulgence of miners' personal and medical records for research.

Conclusion: This case study illustrates how research can be effectively, although not maliciously, obstructed by the over-zealous protection of employee medical data. Efficient MLSs require good quality big data underpinned by medical ethics. Clearly communicated company policies should be developed for sharing of miners' records in the mining industry, to improve HCPs.

Keywords: electronic data, occupational exposures, personal data, audiometry, healthcare providers, machine learning systems, ethical principles

INTRODUCTION

Hearing conservation programs (HCPs) are an occupational noise induced hearing loss (ONIHL) prevention measure. A company's HCPs contains workers' personal information, and audiometry medical surveillance and occupational noise exposure records to monitor risks for ONIHL, the number of workers diagnosed with ONIHL, and the effectiveness of surveillance programs. [1] Globally, HCP data accessed from various occupational settings have been used to highlight the high prevalence of ONIHL as a result of exposure to high noise levels. [2] In a systematic review, Chen et al. (2020) [3] concluded that HCPs records show complex interactions of risks for ONIHL. Nevertheless, prevention measures implemented by various industries have reduced ONIHL morbidity but have not prevented ONIHL. [4]

Occupational noise induced hearing loss is a widely researched public health problem. [2] In 2005, the global prevalence of hearing loss due to exposure to noise in the workplace was estimated to range from 7% in high income countries to 21% in low and middle income countries (LMICs). [5] In LMICs, mining, agriculture and construction industries have been reported to produce the most excessive noise exposure levels and to present with the highest prevalence rates of ONIHL. [3,5,6] In South Africa - a LMIC - the mining industry reported a higher prevalence rate of ONIHL than this (30%) in 2016/2017. [7] Despite noise reduction and other measures (for example, noise surveillance and audiometry medical surveillance) implemented in South African mines over the last 12 years, the industry continues to struggle to prevent ONIHL. [8]

Mines' HCPs, designed to prevent ONIHL, constitute big data, which focus on noise exposure measurements, as well as noise monitoring and reduction strategies. Hearing conservation programs also incorporate the premise that noise exposure for any worker should not exceed 85 decibels (dB) averaged over an eight-hour working period (8-hour time-weighted average (TWA)). [9] However, for a HCP to be efficient and effective, other HCP pillars, in addition to noise reduction, must be adhered to. [10] These include administrative controls, HCP training and education, use of hearing protection devices (HPDs), risk-based medical examinations, and audiometry and medical surveillance. [10] Big data comprise massive volumes of highly diverse information, which includes personal information, and occupational and medical history of individuals and large cohorts. [11] Thus, South African mines' HCPs datasets constitute copious amounts of miners' electronic records collected for risk assessment related to occupational exposures, and prevention of associated medical conditions. Opportunities for medical research, using machine learning systems (MLSs) and algorithms to predict health risks, may seem limitless for the mining industry, but such opportunities have not been extensively explored. [12,13]

Electronic data recording uses MLSs with artificial intelligence (AI) capabilities, which automatically classify and predict outcomes by applying various algorithms to datasets. [14] Since the South African mines use electronic data to monitor occupational exposures and diseases, as well as to support medical decisions, it is imperative that occupational health and safety (OHS) practitioners understand MLSs and the relevant algorithms used for data collection, access and analysis, to compile OHS compliance reports. [3]

The lack of familiarity by end-users of MLSs impacts negatively on the quality of data. The fact that end-users cannot measure outcomes based on the collected data hinders hearing healthcare delivery, medical decision-making, and HCP planning. [3] Good quality audiometry data and audiometrists who are skilled in interpreting automated audiometry test results are essential, however, the quality of both has been questioned by some researchers in South Africa. [16,17] The quality of audiometry records is a critical indicator of the effectiveness of an HCP, thus it is imperative that audiometrists record data meticulously in order to enable accurate analysis for the reporting of valid results to inform medical decisions and to improve hearing healthcare delivery. Thus, consistent and accurate audiometry medical surveillance may not exist in some instances, which negatively affects the quality of HCP data as well as hinders accurate prediction and prevention of ONIHL. No studies in South Africa have assessed audiometrists' MLSs skills, or standards of data recording, which are essential for programs aimed at predicting and preventing ONIHL.

High quality data are also essential for robust scientific research regarding HCPs and ONIHL prevention. However, there is no clarity on practices or policies, in by the mining industry for seamless and transparent data sharing with embedded ethical principles of confidentiality and beneficence. The implementation of the PoPI Act of 2013, enacted in 2020 [15], has paved the way for companies in South Africa to maintain the integrity and confidentiality of workers' records and has set the stage for national debate on the use of big data protection and sharing for healthcare and research.

Silo reporting of occupational exposure risks and health risks

Silo reporting (referred to reluctance to share information with other from different divisions) [18] of risks associated with ONIHL may impede efforts directed towards the prediction and prevention of ONIHL. There are factors, other than noise, that are associated with hearing loss [8,19], such as ageing, being male and black, genetic predisposition, exposure to recreational noise [19], and treatments for tuberculosis and HIV. [19,20,21,22,23] Exposure to chemicals (nitrogen sulphide and carbon monoxide) emitted during some mining processes have also been reported to increase the risk of hearing loss, but research on this is limited in the South African mining industry. [24] Studies using miners' HCP records have shown that data on common medical conditions (tuberculosis, cancer and HIV) and treatments thereof [22], as well as data on occupational exposures (dust and chemicals) that are associated with ONIHL, are often kept separately from HCP data. [17,19]

Using MLSs to capture and analyse data, and report health risks

Data recording and data sharing practices by the mines' healthcare practitioners are governed by the HPCSA's ethical principles for good practice [25,26] (specifically, confidentiality and beneficence), and the OHS Act (Act No.85 of 1993) [27], respectively. The South African mines, in their annual occupational diseases' reports submitted to the Department of Mineral Resources and Energy (DMRE) [8], showed a decrease in the number of ONIHL cases from 2015/16. In the same report [8], the South African mines showed a lack of integrated reporting of all occupational exposures (e.g. dust, nitrogen, carbon-monoxide) that are associated with hearing health risks, and interventions to mitigate these risks. The decrease of ONIHL cases in 2015/16 may have been due to reasons other than improvements in HCPs (e.g. practitioners' lack of training in and understanding of MLSs which in turn may lead to incomplete HCP records, and/or inconsistencies in HCP data capturing). [16,17] A lack of integrated reporting of HCP findings inhibits the practical implementation of the HPCSA guidelines which guide recording of patient data (Booklet 9). [25] There are no evidence-based studies on interactions between ethical rules that govern miners' health record keeping and reporting of occupational diseases.

Electronic occupational health records governance

Legally, access to workers' medical records, e.g. medical conditions and treatments, and personal information, is restricted to medical practitioners employed by the company. [26]

Legislation and rules that govern the reporting of, and access to, workers' data include the PoPI Act of 2013 [15], the National Health Act (Act No.61 of 2003) [28], and Booklet 5 of the HPCSA (Confidentiality: Protecting and Providing Information). [26] In addition, according to the Health Professions Act, 1974 (Act No. 56 of 1974) [29], healthcare practitioners hold rights and privileges with regard to patients' personal and medical information. Although individual companies may design specific data access and protection guidelines suitable for their needs and their multidisciplinary context, there may be governance challenges around privacy, transparency, security, and quality assurance of the big data collected by the mines, which should be investigated.

Table 1 summarises the basic ethical principles that guide data sharing for healthcare practitioners, as applied to mine employees' data.

Table 1. Summary of ethical principles

Ethical principle	Definition	Explanation
Confidentiality	Personal information will be held in confidence. Guidelines in Booklet 5 of the HPCSA state that a practitioner may divulge patient information under certain confidential conditions.	Miners' personal and medical information must be confidential and sharing of the medical information may be at the discretion of the medical practitioner.
Beneficence	Duty to do more good than harm	Research using miners' audiometry data must be shared confidentially and miners' identity must be protected to address scientific questions.

Adapted from Flite and Harman (2013) [30]

While protection of miners' data is ensured by these Acts and rules [15,24,26,28], the mining companies impose additional restrictions to data access for external medical practitioners and researchers, citing protection of miners' medical information as the reason for doing so.

In this case study, we reviewed the personal health data (exposure and audiometry data) in an HCP, to investigate the personal data protection processes followed by a South African platinum mine, and to describe the use of big data in a MLS, which may lead to ethical pitfalls.

METHODS

This was a case study of a large platinum mine in South Africa. We reviewed individual miners' personal and exposure data from electronic audiometry medical surveillance, hearing screening and occupational hygiene records (stored in three datasets) from 2014 to 2018. A semi-qualitative cross-sectional study design was used. [31]

The data collection process comprised two phases. First, data were extracted from the three Microsoft Excel databases, which were designed by the mine's hearing conservation practitioners. Second, the ethical principles applied by the company, with regard to data sharing, were explored.

Hearing screening (dataset 1, N = 24 321): Hearing screening, to assess risk for hearing loss, is conducted annually on each individual miner, by a qualified audiometrist. [8] The dataset comprised the bilateral audiogram records of 24 321 miners, and included the results of testing at frequencies of 0.5, 1, 2, 3, 4, 6 and 8 kHz that were used to calculate percentage loss of hearing (PLH) scores and bilateral standard threshold shifts (STSs). Six data points per audiogram (three frequencies per ear) were used to estimate risk for hearing loss (STS).

Audiometry medical surveillance (dataset 2, N = 480): This data set, accessed from the occupational medical practitioner (OMP), contained results from screening audiograms of miners with a PLH > 2.5% from baseline and those of some miners who presented with ear-related conditions (indicating risk for ONIHL). [8] The dataset comprised 480 miners who were referred to the OMP by the audiometrist, but 10 audiometry medical surveillance records were missing from the OMP's dataset. Seventy-six miners in the dataset were compensated for ONIHL.

Occupational hygiene (dataset 3, N = 15 769): Occupational hygienists collect data on exposures (including noise) that are associated with adverse health effects. [32] These data were stored in a separate database, which included data on occupations (job titles), noise exposure levels (dBA), and platinum mine dust (PMD) exposure levels (mg/m^3). Approximately 96 data points were used to measure noise exposure for individual miners, based on a noise reading every five minutes for an 8-hour shift.

Figure 1 illustrates the three datasets used in the study, all of which included the miners' employee number, age and sex. These three variables were used to merge the three datasets, using STATA (version 15.1). The numbers in Figure 1 refer to data collected in 2014.

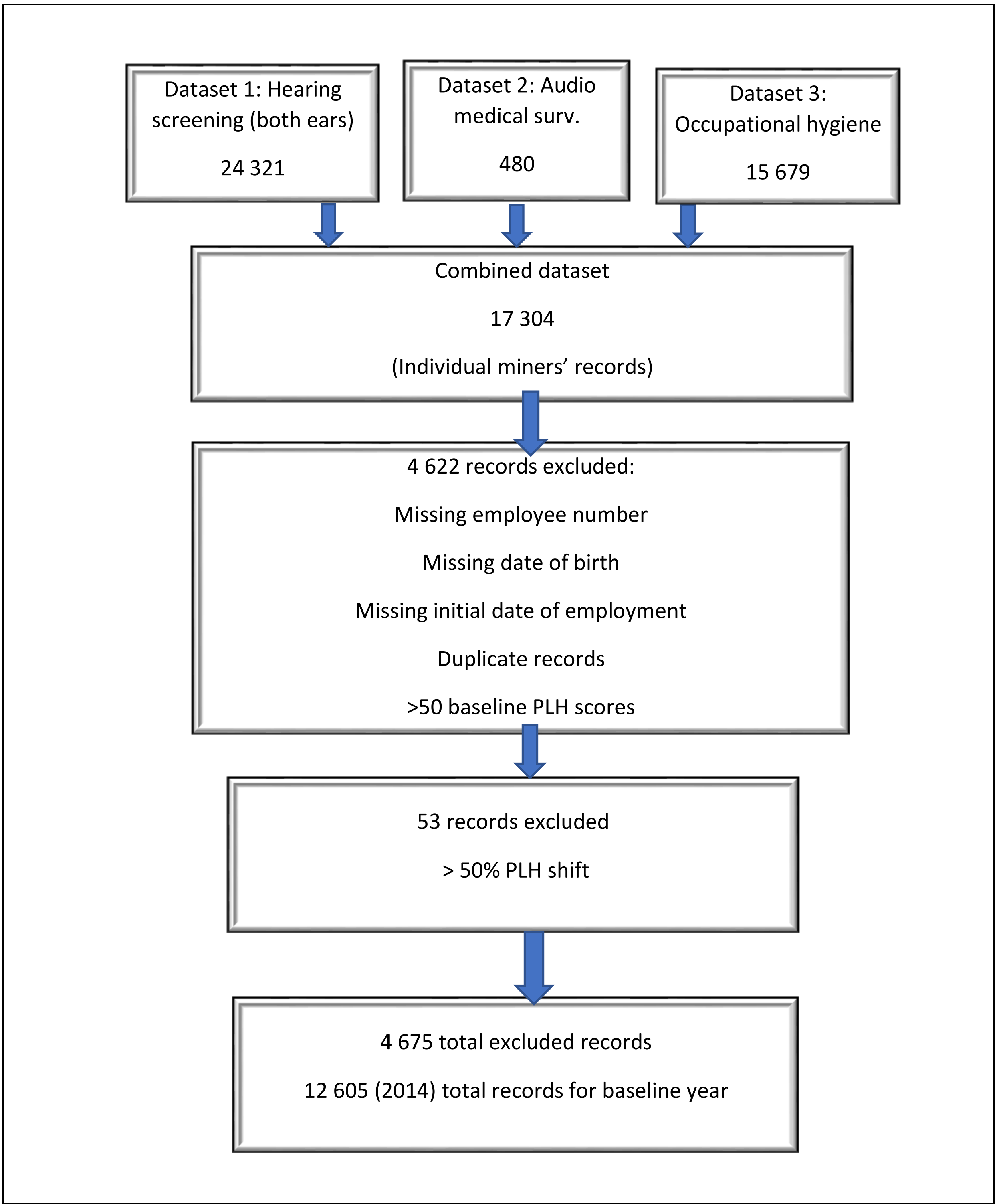

Figure 1. Data management process followed showing individual miners' records included and those excluded from merged dataset font is different

The second phase of data collection comprised completing a checklist, as shown in Table 2, to record information about the ethical principles that were applied to miners' data reporting and access, guided by Booklet 9 of the HPCSA [25], the National Health Act [28] and the PoPI Act. [15] Information was collected during discussions with the mine's three hearing conservation practitioners, viz. the OMP, the audiometrist and the occupational hygienist.

Table 2. Checklist of ethical considerations used from data accessed

		Dataset to which ethical considerations applied		
Ethical consideration	**Guiding document**	**1**	**2**	**3**
Confidentiality	*†‡	√	√	√
Anonymity	*	√	√	√
Protection of personal information	‡	√	√	√
Complete and consistent records	*†‡	√	√	√
Standardized electronic records	‡	√	√	√
Computer stored records	*†‡	√	√	√
Data access for research (external users)	*†‡	√	√	√

*HPCSA; †National Health Act; ‡PoPI Act;

A fourth set of data (**dataset 4)**, which was stored in a QMed format, could not be accessed. QMed is the mine's integrated big data health management system, which allows for complex machine learning analysis. It is used by the hearing conservation practitioners and had stricter data access restrictions than those that applied to the three MS Excel datasets. The database comprised a comprehensive record of each miner, which medical practitioners could access, and included key items such as scheduling for medical examinations, medical surveillance, primary healthcare, anti-retroviral treatment (ART), and disease management data. The QMed system was developed in line with best-practice guidelines with the intention of providing an integrated healthcare management solution. [33] QMed enables 1) the efficient medical care of miners, 2) medico-legal compliance, and 3) healthcare compliance needs of the mine, in line with the Mines Health and Safety Act. [34]

Figure 2 illustrates the ethical considerations followed in the data collection process to show rigor during data collection.

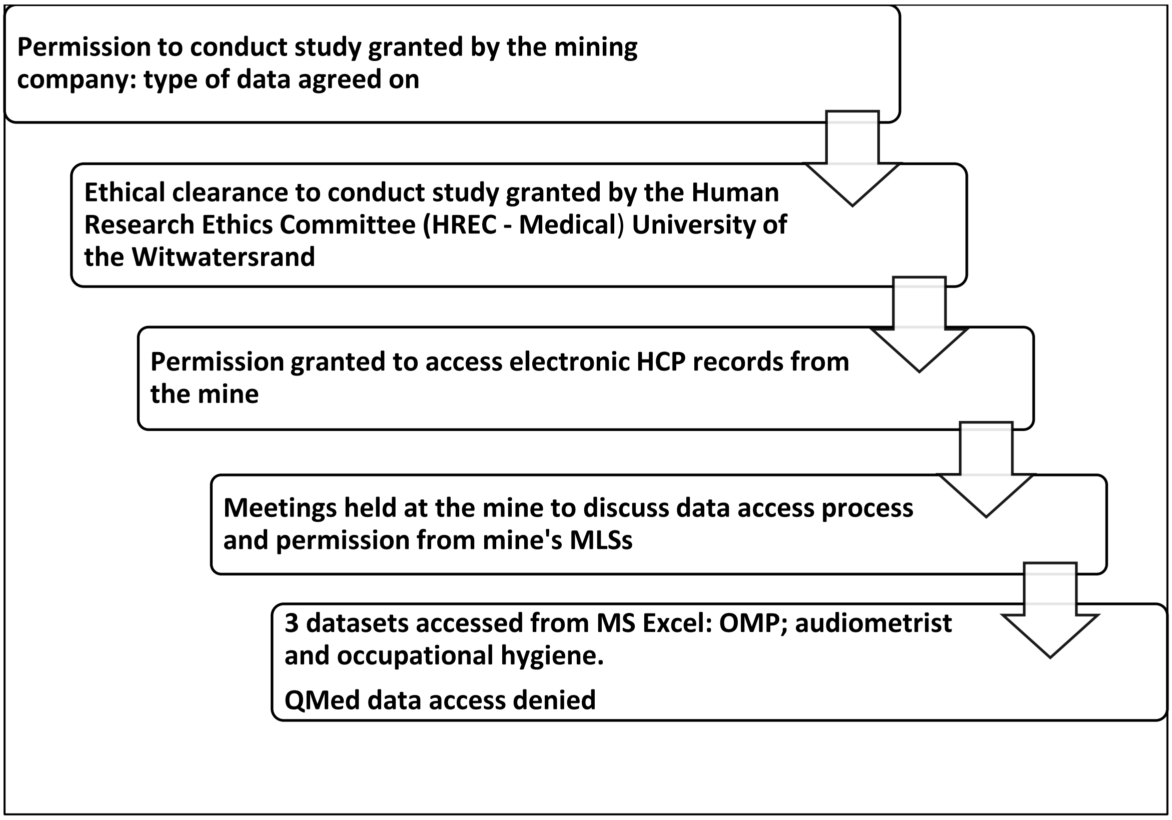

Figure 2. Ethical considerations in the data collection process

Ethical clearance was obtained from the University of the Witwatersrand's Human Research Ethics Committee (clearance certificate no. M180273).

RESULTS

The mine's hearing conservation practitioners used a two-step process of HCP record keeping. Step1 involved daily recording of miners' complete HCP data in MS Excel spreadsheets. In step 2, some of the miners' records were transferred to the QMed system. The hearing conservation practitioners maintained both the MS Excel and QMed datasets.

Access to audiometry medical and occupational hygiene surveillance data

Many of the audiometry medical and occupational hygiene surveillance records accessed from MS Excel were incomplete and/or inconsistent. A total of n=4 675 individual miners' records were excluded from the analysis due to employee numbers which were missing or incomplete; the initial date of employment was missing for some; there were several employees for whom more than one baseline PLH score was recorded without explanation; and some had a PLH shift score of > 50% with no specified follow-up by the OMP (n=53).

Although permission to use the QMed dataset was initially granted by the mine, access to the data was later denied, based on conditions of confidentiality as stated in the PoPI Act. [15] Information about some of the miners' ear-related conditions and treatments which would have been accessed from QMed were excluded from the analysis. Miners' records stored in the QMed system (all miners), which included data on medical conditions such as tuberculosis, HIV, diabetes, cancer and treatments thereof, could not be accessed due to restrictions applied to external users for research purposes.

Accessing miners' audiometry medical surveillance records – ethical challenges

The application of the ethical principles of justice, beneficence and confidentiality ensures protection of miners' personal and medical information. However, this resulted in challenges with regard to accessing data from the MS Excel and QMed databases.

Justice

Fair equitable treatment for all (miners) was ensured. All workers who were exposed to occupational noise and were at risk of developing ONIHL accessed hearing health services from audiometry medical surveillance designed to prevent ONIHL.

Beneficence

The use of MLSs ensured that miners' audiometry surveillance records could be accessed, and complied with the HPCSA guidelines in Booklet 5, Section 9.1.1.1. [26] The MLSs were used as registries to monitor hearing and ear-related medical conditions and treatments thereof.

Confidentiality

The confidentiality rule is central to trust between practitioners and patients. [25,30] Confidentiality of miners' audiometry medical records was ensured by hearing conservation practitioners by, for example, password encryption, and all data were anonymised before we received them for analysing.

DISCUSSION

In this case study, we reviewed the use of personal health data (exposure and audiometry) in an HCP to establish risk assessment practices, and explored the application of personal data protection processes used by a South African platinum mine. Our intent was to start a debate on the use of big data in MLSs and data sharing, which may lead to ethical challenges.

Worldwide, occupational hearing health research is impeded by data access restrictions – due to both legislation and guidelines that are designed to ensure privacy and confidentiality of workers' information, and/or company-specific information. This case study illustrates how research can be effectively, although not maliciously, obstructed due to over-zealous protection of employee medical data by a company. Specifically, access to (and therefore analysis of) the data of several thousand miners for research aimed at predicting occupational hearing loss was hindered by tensions between the application of ethical principles that govern workers' medical data, such as ethical guidelines for good practice, confidentiality and protection of personal information, and access to data for research purposes.

The use of machine learning systems to improve data quality and protection has been legislated in South Africa [15, 24] but automation still comes with challenges. The participating mine used MS Excel and QMed to record miners' data. According to Luy [35], MS Excel is inappropriate for the processing and analysis of large datasets as it lacks programming functions and falls short of the requirements for machine learning. On the other hand, the QMed system allows for big data risk assessment analysis and medical research. [36] Thus, using different MLSs, with different capabilities impeded data access and restricted hearing health research. While this was a case study of a single large mine in South Africa, the findings are likely to apply to other mines and, perhaps, industries in this and other countries.

Justice

All miners undergo medical surveillance as a mandatory procedure to identify early signs of occupational diseases. The mines follow risk management protocols that are designed to efficiently monitor all miners and prevent occupational diseases. [7,37] Indeed, the mine in this case study conducted annual audiometry surveillance to identify miners at risk of developing ONIHL, and therefore to prevent ONIHL.

The South African mines are guided by Acts (Mine Health and Safety Act No. 29 of 1996; PoPI Act of 2013) to ensure the aspect of justice, where miners have frequent and regular annual medical examinations to reduce occupationally-related health risks and, in turn, benefit from best practice medical surveillance. [34] However, the use of different MLSs (rather than a single MLS), viz. Excel and QMed, in this case study, to capture annual audiometry medical surveillance records may hinder accurate tracking of the miners' hearing function, subsequent medical decisions, and research efforts related to hearing loss prevention.

Ethical challenge: big data regarding hearing health medical conditions and treatment for tuberculosis and HIV from the QMed system could not be accessed, which prevented comprehensive data analysis for this case study and possibly restricted the mine's implementation of actions for early prediction and prevention of occupational hearing loss.

We recommend that this, and other mines store data in a single database, using one health management system to track the health of individual miners.

Beneficence

The mine HCP reports refer to audiometry surveillance big data records. The HCP reporting is based on occupational noise exposure levels, and hearing deterioration is calculated using a PLH score. [38] Other risk factors, such as tuberculosis and HIV treatments, and ear diseases such as otitis media, otitis externa, and impacted cerumen, were included in the QMed dataset (to which access was refused), but not in the records that were accessed for this study. Miners' PLH scores can be influenced by these ear- and hearing-related risk factors (tuberculosis, HIV, otitis media, otitis externa, impacted cerumen, and their treatments) [22,23], which may not have been taken into consideration when assessing hearing deterioration and planning ONIHL prevention strategies. While the exclusion of miners' medical information from the audiometry surveillance records may be based on maintaining confidentiality of medical records and adhering to the mine's privacy policies, it hinders efforts to prevent ONIHL. [17,19,23]

The Mine Health and Safety Act (MHSA) has legislated the reporting of HCP data to the DMRE to ensure accurate tracking of miners at risk of ONIHL, and the reporting of cases of ONIHL. [34] However, evidence-based research has shown that the South African mines use different HCP databases, which presents challenges such as missing records, and inconsistent recording of noise measurements and PLH scores. [16,17] The individual mines and the government departments that publish the annual occupational and medical reports should undertake quality assurance of the HCP reports submitted to the DMRE.

Ethical challenges: Incomplete records and inaccurately entered records lead to poor quality surveillance data, which in this case may lead to inequitable hearing healthcare for individual miners. This also has the potential to negatively affect the accurate prediction and prevention of occupational hearing loss.

It is recommended that companies develop and communicate transparent policies regarding big data access and sharing processes with all hearing conservation practitioners, and miners , to empower miners to take ownership of their hearing health and to ensure equitable hearing health care and accurate monitoring of hearing health trends.

Confidentiality

The mine adhered to the rules that govern patient confidentially and protection of personal information with regard to occupational medical record keeping. [24] The National Health Act [26], Booklet 5 of the HPCSA [24], the MHSA [34], and the POPI Act [15] clearly state that healthcare professionals are mandated to record health data for all users (patients and/or employees), and to design electronic information systems to ensure security of health records. By using MLSs for big data storage, the mine complied with these requirements.

The OMP is responsible for ensuring that the mine's medical surveillance programs and MLSs are designed to monitor miners' occupational hazards associated with health conditions, to evaluate intervention strategies used to mitigate risk, and to prevent occupational diseases. [26] Furthermore, the MHSA [34], the PoPI Act and HPCSA [26] all require the application of privacy control measures for the protection of workers' health records. For example, the mines are mandated to report occupational hazards and medical conditions affecting miners to the DMRE's medical inspectors, and to ensure that miners' identifiable information is anonymised. [34] In our assessment of the mine's HCP records, there was a lack of clarity (in the mines' annual health and safety reports) about which database(s) was used to report audiometry medical surveillance results to the DMRE, although confidentiality and protection of miners' records were maintained. [16,17] The PoPI Act had not been effected when our study was conducted, but the mine's medical officers applied the PoPI Act restrictions when denying our request to access the miners' medical records for research purposes.

Ethical challenge: Criteria used in the decision to share miners' confidential personal and medical records for medical research are provided in Booklet 5 of the HPCSA. [26] The application of the confidentiality rule is at the discretion of the mine's medical officer (Section 3.2), but this was not clear to the OMP in this case study. Restricted access to records for miners' medical conditions and treatments thereof may have been due to a misinterpretation /misunderstanding of Section 3.2 of Booklet 5. [26]

We recommend a transparent application of the privacy and confidentiality rules to all hearing conservation practitioners and employees who handle miners' data, to encourage big data sharing. Also, that health care practitioners are knowledgeable about the legislation pertaining to confidentiality and their understanding thereof.

General observations

There are multiple ethical principles (Figure 3) for the protection of personal and medical information used by the mine's hearing conservation practitioners for record keeping, reporting of ONIHL cases, and accessing data for research regarding ONIHL prediction and prevention. The PoPI Act [15] 'carries more weight' than the National Health Act and the HPCSA ethical guidelines. [25,26,29] Thus, the application of these ethical principles and data protection regulations shows respect for individual worker's rights with regard to the protection of their medical information, which was ensured by the healthcare professionals (OMP and audiologist).

Miners' audiometry hearing results are reported in such a way that they are easy to understand. For example, results are relayed as 'pass' (hearing within normal limits) or 'refer' (hearing problem, which may require further intervention, e.g. refer to OMP or refer for a repeat hearing screening). However, research has indicated that miners have limited understanding and knowledge regarding their hearing function. [39] Thus, although the hearing screening results may be easily understood by the miners, the use of four separate datasets by hearing conservation practitioners may hinder the understanding of the negative effects of other diseases and ear-related conditions (and their treatments) on hearing function – by both the miners and the health practitioners. Miners should be encouraged to understand their hearing health status from the audiometry medical surveillance programs. To facilitate this, audiometry results should be integrated with medical records and presented to miners in an easy-to-understand manner.

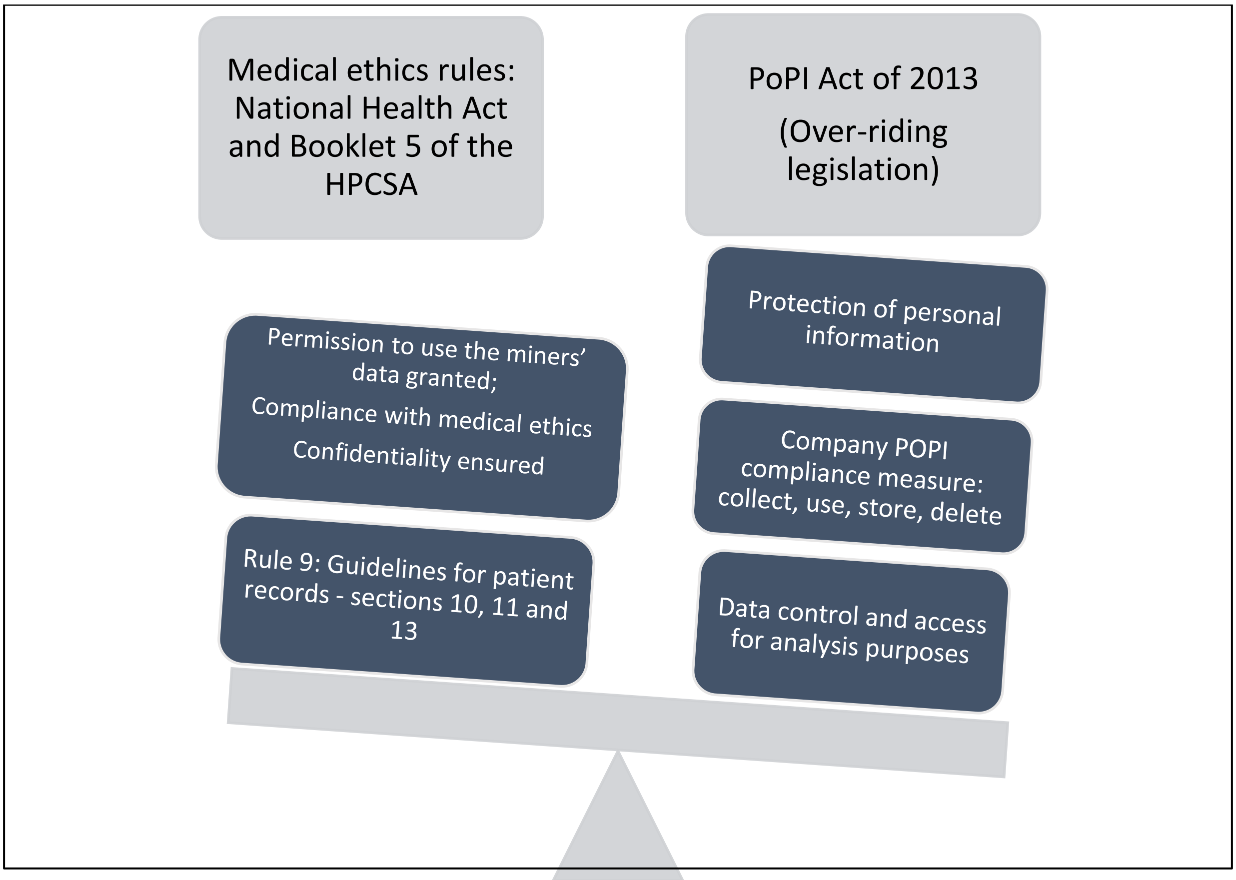

Figure 3. Illustration of medical ethics and personal protection regulations for access to personal data in MLSs

LIMITATIONS

This case study was based on findings from one large-scale mine in South Africa, and the challenges experienced might not apply when conducting research at other mines, large or small. However, it is likely that other mines have the same or similar approaches to data sharing for research purposes.

RECOMMENDATIONS

Mining company employees' should be well-informed about, and comprehensively understand, the legislation, rules, guidelines and policies that govern sharing of employee data for research (and other) purposes. While data sharing should be guided by ethical rules and company policies, the implementation of these rules and policies should ensure efficient surveillance programs and encourage medical research.

All databases that contain miners' health and safety records should be complete, accurate, comprehensive and integrated to ensure efficient risk management frameworks for occupational hazards, which will benefit all miners. The mines should consider implementing quality checks to ensure high quality data.

Mining companies should review their policies about data sharing for research purposes and communicate those policies clearly to employees. Such policies, stipulating access rights for researchers outside of the company, will encourage scientific research.

CONCLUSION

Efficient MLSs that are used to store and manage HCP big data depend on good quality data, accurate and consistent data input, clear checklists for all ethical principles, and comprehensive company regulations related to the recording of, and access to, data for medical research.

In this case study of one mine, there were discrepancies in the implementation of HCP checklists used for record keeping, which rendered big data inefficient for the prediction and prevention of ONIHL. In addition, there were ethical challenges that arose due to unclear data sharing practices, which, in turn, potentially hindered medical decisions regarding ONIHL prevention. There is a need for all the ethical principles to be integrated in the recording and sharing of big data, together with HCP checklists, in order to assist in the prediction and prevention of occupational hearing loss. This case study illustrates how research can be effectively, although not maliciously, obstructed due to over-zealous protection of employee medical data by a company. The findings may apply to other mines and industries in South Africa and other countries. Debates around the mines' HCP's big data should incorporate privacy and confidentiality, as well as the right to data access and sharing in order to improve medical research, which is aimed at preventive healthcare.

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Authors' contributions

Conception and design of the study: LN, KK-S, GN, ED

Data acquisition: LN

Data analysis: LN

Interpretation of the data: LN, GN, KK-S, ED

Drafting of the paper: LN

Critical revision of the paper: LN, GN, KK-S, ED

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Appendix 6: Permission Letter

Mine: **Date:**

Dear Sir/Madam

Re: Permission to carry out a research study with mine workers employed by the mine.

I am a PhD candidate in the School of Public Health at the University of the Witwatersrand. A requirement for the completion of the degree is to conduct a research study. The title for my study is: Exploring the incidence and health patterns of Noise Induced Hearing Loss: risk assessment of miners in South Africa.

The purpose of the study is to explore the incidence and health patterns of NIHL at one large-scale mine in South Africa. The study will enable me to determine whether the mine's hearing conservation programs are geared for the 2024 milestones of curbing: employee's standard threshold shift at 25dB bilaterally from baseline and reducing noise levels emitted by equipment used in the mines to 107dB and below.

The researcher will review past cohort employee records from 2014-2018. The following data will be collected: biographical data; medical conditions; ototoxic medications, noise dose, occupation type, use of hearing protection devices (HPDs), audiometry data and successful NIHL claims, in order to address the outlined objectives. Details of the study are contained in the attached proposal.

Upon completion of the study, the research report will also be made available to the mine. Information obtained from the mine will be treated with strict confidentiality. The participants' anonymity from the records reviewed will be guaranteed throughout the process of research process and beyond.

Your assistance will be greatly appreciated. We (myself and my supervisors) will be happy to answer any questions you have about this study. The University of the Witwatersrand Research Ethics Committee will approve this research study upon receipt your letter granting permission for the researcher to review miners' records. If you have questions about the research, you may also contact the principal investigator: Liepollo Ntlhakana on 060 426 1711.

Yours Sincerely,

Liepollo Ntlhakana

Appendix 7: Data collection sheet - Individual miner record review form

Personal details

1. Participant number

2. Date of birth DDMMYY

3. Study site
   - ☐ Amandelbult [1]
   - ☐ Union [2]

Work History

4. Date of first employment DDMMYY

5. Current job title
   - ☐ Loco/Winch driver [1]
   - ☐ Rock driller [2]
   - ☐ Pump attendant [3]
   - ☐ Generalist [4]
   - ☐ Boiler maker [5]
   - ☐ Supervisors [6]
   - ☐ Pump attendant [7]
   - ☐ Other……………………………………………
6. Mining work history Date started Number of months/years
   - ☐ Loco/winch driver
   - ☐ Rock driller
   - ☐ Pump attendant
   - ☐ Generalist
   - ☐ Boiler maker
   - ☐ Supervisor
   - ☐ Pump attendant
   - ☐ Other
7. Record all noise measurements and dates of measurement

<80 dB(A)	**[1]**
80-85 dB(A)	**[2]**
85+ dB(A)	**[3]**

Medical History

1. Diagnosed medical conditions and date diagnosed: DDMMYY

   - ☐ Diabetes [1]

- ☐ High blood pressure [2]
- ☐ HIV/AIDS [3]
- ☐ TB [4]
- ☐ Cancer [5]

2. Medication name date prescribed
   - ☐ Antibiotics (…cin) [1]
   - ☐ Anti-cancer drugs [2]
   - ☐ Diuretics [3]
   - ☐ Aspirin [4]
   - ☐ Other………………………… [5]

Hearing history

3. Date of audiometric baseline: DDMMYY

4. Name of mine where baseline was conducted: ______________________
5. Occupation at the time of baseline
   - ☐ Loco/Winch driver [1]
   - ☐ Rock driller [2]
   - ☐ Pump attendant [3]
   - ☐ Generalist [4]
   - ☐ Boiler maker [5]
   - ☐ Supervisor [6]
   - ☐ Pump attendant [7]
   - ☐ Other……………………………………..[8]
6. PLH % at baseline
   - ☐ 5% [1]
   - ☐ 7.5% [2]
   - ☐ 10% [3]
   - ☐ +10% [4]
7. Medical conditions related to hearing loss mentioned at baseline
   - ☐ Tinnitus [1]
   - ☐ Otitis externa [2]
   - ☐ Otitis media [3]
   - ☐ TM perforation [4]
   - ☐ Aural fullness [5]
   - ☐ Headaches [6]
   - ☐ Other….. [7]
8. Frequency of audiograms Dates
   - ☐ Audiogram 1
   - ☐ Audiogram 2
   - ☐ Audiogram 3
9. Exit audiograms Dates
10. Reason for exit
    - ☐ Retirement [1]
    - ☐ Retrenchment [2]
    - ☐ Medical boarding [3]
    - ☐ Resign [4]

- ☐ Other [5]

11. Exit PLH %
    - ☐ 5% [1]
    - ☐ 7.5% [2]
    - ☐ 10% [3]
    - ☐ +10% [4]
12. Exit PLH % shift
    - ☐ 5% [1]
    - ☐ 7.5% [2]
    - ☐ 10% [3]
    - ☐ +10% [4]
13. Provision of HPDs
    - ☐ Custom-made earplugs [1]
    - ☐ Disposable foam earplugs (yellow/orange) [2]
    - ☐ Earmuffs [3]

Adapted from: State of Arizona Risk Management Loss Prevention, Hearing Conservation Checklist (March 26, 2003) and Rand Mutual Assurance (RMA) RMDI-Disease-claim-form

Checklist Site Evaluation: Hearing Conservation Program Pillars

Pillar	Items / Areas	YES **1**	NO **2**	N/A
Noise measurement	Have all work areas been evaluated to determine actual noise levels daily?			
	Have all work areas been evaluated to determine if noise monitoring is warranted?			
	Have sound level measurements been taken in areas suspected of having noise levels that exceed 85dBA?			
	Has a noise monitoring program been developed and implemented?			
Engineering controls	Is noise monitoring reported when there is a change in equipment or controls?			
	Are employees notified of the new changes and results of the noise monitoring?			
	Is there evidence of regular maintenance and upgrade of equipment used by the employees?			

Administrative controls	Has 8-hour noise monitoring been done of employees performing jobs in noisy areas or working with loud equipment to identify which employees to include in a HCP?			
	Does the mine have measures in place to temporarily remove employees working in noisy areas or working with loud equipment in order to conserve their hearing?			
Personal protection	Has proper hearing protection been identified and provided at no cost to the employees?			
	Does the supervisor ensure that proper hearing protectors are worn by the affected employees?			
	Is a variety of hearing protectors provided for the employees to choose from?			
	Have the employees been trained in the proper use and care of the HPDs?			
Education, motivation and training	Has a training program been instituted for all employees in the HCP?			
	Is the training done annually?			
	Does the training include information on? The effects of noise on hearing?			
	The purpose, advantages and disadvantages of HPDs usage?			
	Introduction on selection, fitting and care of HPDs?			
	The various types of HPDs offered by the mine operator?			
	The mine operator's and miner's respective tasks in controlling the miner's exposure to noise?			
	The purpose of audiometric testing and explanation of test procedures?			
Risk-based medical examination	Are audiometric test records retained for the duration of the			

	affected employee's employment plus thirty years?			
	Do employees go through annual medical assessments?			
	Are the medical conditions and medications prescribing for as ear infections; head and neck surgeries; high-blood pressure; TB and HIV/AIDS recorded in the employee's medical files for further monitoring and evaluation?			
	Are there records of employee's previous and current chemicals exposure in the employment file?			
Medical surveillance and audiometry	Is audiometric testing conducted, at no cost, to all employees whose exposure is equal to or exceeds an 8-hour TWA of 85dBA?			
	Are baseline audiograms given within 30 days of an employee's first exposure to noise levels equal or exceeding the 85dBA?			
	Are annual audiograms provided to employees in the HCPs?			
	Are audiograms (screening and diagnostic) administered, reviewed and evaluated by competently trained professionals?			
	Are annual audiograms compared to the baseline to determine if a standard threshold shift (+10%) has occurred in an employee's hearing?			
	Are problem audiograms reviewed by an audiologist, otolaryngologist or occupational medical practitioner (OMP) to determine if further action is necessary?			
	Are all records relating to an employee's noise exposure provided to that employee or			

	employee representative upon request?			

Adapted from: State of Arizona Risk Management Loss Prevention, Hearing Conservation Checklist (March 26, 2003) and Rand Mutual Assurance (RMA) RMDI-Disease-claim-form

Additional Comments:

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Appendix 8: Turnitin Report

21 Sep 2021

Liepollo thesis 29 Mar 2021_1.docx

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