OCCUPATIONAL EXPOSURE TO RADIOFREQUENCY ENERGY AND STATIC MAGNETIC FIELDS IN MRI UNITS IN THE PUBLIC SECTOR WITHIN MANGAUNG METROPOLITAN REGION

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DECLARATION OF INDEPENDENT WORK

DECLARATION WITH REGARD TO INDEPENDENT WORK

I, **PHOKA CAIPHUS RATHEBE**, identity number and student number , do hereby declare that this research project submitted to the Central University of Technology, Free State for the Degree DOCTOR OF PHILOSOPHY: ENVIRONMENTAL HEALTH, is my own independent work; and complies with the Code of Academic Integrity, as well as other relevant policies, procedures, rules and regulations of the Central University of Technology, Free State; and has not been submitted before to any institution by myself of any other person in fulfilment (or partial fulfilment) of the requirements for the attainment of any qualification.

_____ **20 November 2020**

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List of Abbreviations

µT- Microtesla

AAMP- American Association of Physicists in Medicine

ACR- American College of Radiology

dB- Decibel

EMFs- Electromagnetic Fields

EU- European Union

FDA- Food and Drug Administration

HCW- Healthcare workers

IARC- International Agency for Research on Cancer

ICNIRP- International Commission of Non-Ionising Radiation Protection

IEC- International Electrotechnical Commission

IEEE- Institute of Electrical and Electronics Engineers

IUD- Intrauterine device

M- Meter

MHz- Megahertz

MR- Magnetic resonance

MRI- Magnetic Resonance Imaging

mT- Millitesla

PPE- Personal Protective Equipment

RF- Radiofrequency field

SCENIHR- Scientific Committee on Emerging and Newly Identified Health Risks

SMFs- Static Magnetic Fields

T- Tesla

W/Kg- Watts per kilogram

W/min kg^{-1}- Watts per minute per kilogram

WHO- World Health Organisation

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Executive summary

The healthcare workers (HCWs) working with magnetic resonance imaging (MRI) units are constantly exposed to MRI-related electromagnetic fields, and epidemiological studies have confirmed association between exposure to emitted static magnetic fields (SMFs) and development of transient exposure-related health effects. The thermal effects associated with induced tissue heating from radiofrequency (RF) energy have also been confirmed, however, there is still controversy on non-thermal effects. The development of health effects among workers is dependent on the performance of activities in close proximity to MRI scanner in zone IV.

The aim of this study was i) to assess the exposure levels of SMFs and RF magnetic fields, including the health effects resulting from exposure to MRI-related EMFs among MR staff as well as MR safety risks. ii) the second aim was to develop a health and safety model that will reduce MR safety risks and exposure of MR staff to SMFs and RF magnetic fields emitted by 1.5 and 3.0 T MRI scanners. Transient health effects reported in others studies were assessed among radiographers, nurses, cleaners, medical physicists, radiologists, porters, medical doctors and maintenance engineers. The exposure levels of SMFs and RF magnetic fields were also measured in zone IV, in the MRI rooms using distance as an exposure surrogate. Different distance points were considered, particularly one and two meter; when patient examinations were performed. Furthermore, a health and safety model focussing on administrative controls as well as recommendations on the use of personal protective equipment (PPE) has been developed to guide the MRI facilities to reduce exposure, health effects and existing MR safety risks. This study was conducted in two public hospitals located in Bloemfontein, Free State Province of South Africa. The SMFs and RF

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magnetic fields exposure levels from two 1.5 and one 3.0 T MRI scanners in Pelonomi and Universitas hospitals.

The exposure levels were measured through spot monitoring when patients underwent brain, cervical spine and extremities scans. The measurements for SMFs were collected at 1 meter (m) and 2 meters away from the right, left and front side of the scanner gantry, in zone IV. The RF magnetic fields' measurements were collected at 1 m away from the scanner on the right and left side of the scanner gantry. A questionnaire survey based on transient health effects and safety perception of MR staff around MRI scanners was also administered. Additionally, interviews on MR safety risks were conducted with four staff members from Pelonomi and Universitas hospital. The existing health and safety measures in zone III and IV were reviewed through the use of baseline risk assessment and image quality control test results were benchmarked against the relevant ACR guidelines.

The results of chapter 3 demonstrated that the three scanners from two hospitals respect ICNIRP guidelines in terms of occupational exposure to both SMFs and RF magnetic fields. Configurations of scanners such as clinical setting, magnetic field shielding and magnet type influence propagation of stray static fields in zone IV. The emission of RF magnetic fields is influenced by scans performed, RF pulse design and sequence settings-lip angle. In chapter 4, a significant difference between job titles and safety around the scanners ($p< 0.0023$), as well as the number of years working in the MRI units ($p< 0.0002$) was observed. Headache was significantly associated with perceived MRI safety ($p< 0.014$). MR staff were more likely (OR 39.15, 95% CI: 4.91- 312.02) to experience transient health effects compared to the control group ($p <0.0001$), with radiographers being affected the most (OR 60.75, 95% CI: 5.99-616.67). SMFs exposure effects such as vertigo, feeling of instability and metallic taste

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were significantly associated with shift duration and movement of head/upper body in the scanner bore. However, RF exposure effects were mainly associated with job title and presence in the scanner room for longer durations of time. MRI safety policies, safety training of MR staff, demarcation of safety zones and absence of ferromagnetic detectors were identified as shortfalls in both hospitals. As reported in chapter 5, the results of risk assessment suggested that both hospitals scored a moderate risk score of 12.3 for hospital A and 13.1 for hospital B. Similar risks were observed; however, lack of demarcation of four MRI safety zones, ferromagnetic detectors, 5-gauss line and access control increased the risk rating in both facilities. Defective air-cooling systems influenced the ACD measurements performed from 1.5 T Siemens. Low contrast object detectability had 29 spokes for ACR T2, while the PIU for image intensity uniformity was 78.2% on a 3.0 T Philips.

The model designed in chapter 6 addresses exposure levels of SMFs and RF magnetic fields reported in Chapter 3, and transient health effects reported by MR staff and MR safety risks identified in Chapter 4. The model also provides solutions (once a re-test is performed) to health risks and safety hazards reported, using the baseline risk assessment discussed in Chapter 5. The major shortfalls identified in both MR facilities studied include insufficient MR safety training, performance of activities in close proximity to the scanner bore, and failure to follow relevant ACR guidelines appropriately.

Keywords: MRI scanners; priori health effects; SMFs; RF fields; health and safety

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Chapter 1
Introduction: Occupational Exposure to Radiofrequency Energy and Static Magnetic fields in the MRI units

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1.1. Introduction

Magnetic resonance imaging (MRI) has changed the way health care experts (radiologists, radiographers, nurses and medical physicists) visualise anatomy and physiology of the internal human body structure. Through improvements, it has made possible to acquire, in a matter of seconds, what used to take an hour or longer to obtain. MRI reached the medical field more than 20 years ago with the intention of creating better diagnostic images and advancement in new clinical diagnostic technology within the health care sector. Nowadays, the magnetic resonance (MR) scanners used for clinical imaging have static magnetic fields strength ranging from 1.5 to 3.0 Tesla (T) (Schaap *et al*., 2013; Frankel *et al*., 2019). Majority of MR units with magnetic strength of 7 T, 11 T and above are used for clinical research in Netherlands (Schaap *et al*., 2013) while 1.5 to 3.0 T are mostly used for clinical diagnosis in South African hospitals. In the MRI units, the healthcare staff who enters the MRI room, where scanner is located, may be exposed to a mixture of MRI-related electromagnetic fields (EMFs); static magnetic fields (SMFs), time-varying magnetic fields and pulsed radiofrequency (RF) fields (Gourzoulidis *et al*., 2015; Frankel *et al*., 2018). Pulsed RF fields are mainly emitted to heat up patients body tissues and excite the nuclei to produce an image (Acri *et al*., 2018) and, time-varying magnetic fields are produced by induced movement of workers in the MRI room (Hartwig *et al*., 2018). The MRI magnet emits the SMFs and the fields are always present in the MRI room. De Vocht *et al*. (2015) suggest that MRI-related EMFs have a potential to produce detrimental effects to human health, and many studies have focused more into transient health symptoms amongst MR radiographers. The health effects related to the use of MRI has never been a major concern before until studies looked a exposure

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and genetic damage among patients post MRI examinations (Simi *et al*., 2008; Lee *et al*., 2011; Yildiz *et al*., 2011; Fiechter *et al*., 2013).

The health risks among patients and potential safety hazards associated with the use of MRI scanners have been studied by authors such as Nazarian *et al*. (2017), Kurpad *et al*. (2017) and Erhardt *et al*. (2018). Studies have gone as far as to discuss the exposure effects of MRI-related magnetic fields on pregnant patients (Bulas and Egloff, 2013; Ray *et al*., 2016) and health risks associated with implantable pacemakers (Wilkoff *et al*., 2011; Russo *et al*., 2017). There is relatively no literature suggesting significant health risks among MR staff exposed to pulsed RF fields during interventional scanning procedures. Overtime, exposure and health studies have focused on the health effects of exposure to RF fields emitted by telecommunication devices (i.e. mobile phone devices, radio antennas, radar etc.). In recent years, researchers such as, not limited to, Bongers *et al*. (2016) and Schaap *et al*. (2014) have studied health effects of exposure to SMFs among MR staff in research and health care facilities in the Netherlands. This study seeks to evaluate the exposure hazards and risks associated with the use of MRI units among health care workers within public hospitals in the central region of South Africa.

1.2. Background

Every year, an estimate of about 60 million MRI scans are performed worldwide in both private and public healthcare facilities (Hartwig *et al*., 2018). In South Africa, there is significantly high number of MRI units in private healthcare sectors as compared to public hospitals (Van Schouwenburg *et al*., 2014). In the central region of South Africa, Free State, where the current study was conducted, there are only two 1.5 T scanners

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and one 3.0 T MRI scanners serving approximately 2 753 200 million people, amounting to 0.3 scanners per million population in public healthcare facilities (Kabongo *et al*., 2015). The MRI examinations in the Free State public healthcare facilities are mainly performed in Pelonomi and Universitas academic hospitals. Universitas hospital has two MRI scanners: 1.5 and 3.0 T (Theron *et al*., 2015) whereas Pelonomi hospital has only one 1.5 T scanner. In both settings, the head of clinical imaging (radiologist) is responsible to manage all the protocols in the MRI units. There are relatively few workers assigned to work in the MRI units; this include radiographers, medical physicists, nurses, cleaners and students undertaking their academic practical in the field of medical physics, radiography and nursing. The maintenance of MRI scanners is primarily undertaken by outsourced maintenance engineers, who assumes the responsibility as clinical engineers and are responsible to maintain the MRI scanners according to manufacturers' requirements. The MRI scanners included in this study are open bore designs and exposes healthcare occupations, including maintenance engineers to a mixture of MRI-related EMFs. Radiographers and nurses are exposed to SMFs and RF magnetic fields simultaneously when they enters zone IV during image acquisition, positioning or assisting patients with severe medical conditions. Exposure of MR staff to RF magnetic field only happen when patients are scanned, since MRI scanners use RF transit coils to produce RF fields. Maintenance engineers and medical physicists can be exposed to SMFs and RF magnetic fields when performing acceptable testing or quality control tests, and cleaners are only exposed to SMFs when cleaning in the MRI room, where scanner is located. Occupational exposure in the context of this study refers to an interaction of workers with MRI-related EMFs propagated in the MRI room, where MRI scanner is located (zone IV). Transient health effects refer to acute

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exposure-related effects experienced by MR staff following exposure to MRI-related EMFs.

Although MRI scanners are considered safe, they come with great exposure risks from magnetic fields (Sammet and Sammet, 2015). However, MR staff entering zone III and IV are subjected to strict safety precautions using MRI safety checklist designed in line with the requirements of American College of Radiology (2013). Chief radiographer, radiologist or MRI staff in charge in the MRI unit administer the safety checklist. In the MRI units included in this study, it is assumed that safety precautions are adhered to and MRI safety signs are visible, since the safety practices are guided by the American Association of Physicists in Medicine (AAPM). Further than guided safety practice in the MRI units, the health risks associated with MR clinical imaging is a concern. Exposure-related health risks have been investigated mainly in European countries (Schaap *et al*., 2013; Acri *et al*., 2014) and safety practices in Ghana (Piersson and Gorleku, 2017). The health effects experienced by MR staff due to exposure to MRI-related EMFs in South Africa during scanning procedures remain unknown. The scope of this study was to investigate transient health effects experienced by MR staff, exposure levels of SMFs and RF magnetic fields in the MRI room, where MRI scanner is located and MR safety risks.

1.3. Problem statement

There are concerns regarding MRI workers, particularly radiographers, MR testing personnel, nurses and cleaners constantly exposed to pulsed RF energy and SMFs exceeding regulatory limits stipulated by the European Directive (Hojgaard and Makarow, 2010) and subsequently the International Commission of Non-ionising

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Radiation Protection (ICNIRP). The exposure of workers to RF energy occurs infrequently and during interventional MRI examinations (Schaap *et al*., 2013). However, transient health symptoms as a result of exposure to MRI-related EMFs have been confirmed in many studies (De Vocht *et al.*, 2015; Schaap *et al*., 2016; Wilen and De Vocht, 2011; Zanotti *et al*., 2016). According to Fatahi *et al*. (2016), one of the major raised concerns for workers in MRI environment is the recurring and prolonged exposure to high SMF up to 8 Teslas (T) in the clinical settings and even more in research. Schaap *et al*. (2013) indicate that in clinical settings, MRI is used to produce thorough sectional images of the whole-body including head in any imaging plane; it uses pulsed RF fields to generate signal, which produces sensory effects (Gourzoulidis *et al*., 2015).

There has been a rapid growth in the usage of MRI scanners and increased field strength over the last decades (Schaap *et al*., 2013; Hussa *et al*., 2017). The common MRI scanners in the South African public hospitals are 1.5 T and in recent years, the 3.0 T scanners have been introduced. According to Schaap *et al*. (2016), if the strength of scanners increases, the exposure levels also increase and this suggest substantial development of transient health symptoms, which could potentially lead to long-term health effects that necessitate further investigations. Literature also indicates a positive correlation between the developments of exposure-related effects and magnetic strength of the MRI scanners (Wilen and De Vocht, 2011; De Vocht *et al*., 2015; Hussa *et al*., 2017). MRI staff experience transient health symptoms as a result of exposure to SMFs. Such symptoms include vertigo and metallic taste (Fatahi *et al*., 2016), dizziness, nausea, headache, concentration problem, blurred vision and magnetophosphenes (Schaap *et al*. 2016). Furthermore, black spots, irritated eyes,

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irritated skin, hot flashes, earache and palpitation have been reported as unrelated symptoms of MRI exposure that usually develops among MR staff (Schaap *et al*. 2016). Scholars such as McRobbie (2012), Hansson-Mild and Mattsson (2017) and Frankel *et al*. (2018) reported RF energy as a cause of thermal effects among patients and MRI staff. Many radiation protection agencies such as Food Drug Administration (FDA), European Union (EU) directive, ICNIRP and World Health Organisation (WHO) provide exposure limit values that seek to protect workers from developing exposure-related symptoms. However, due to increasing clinical needs exposure to SMFs and RF energy in the MRI environment is a concern. The prime objective of this study was to develop a health and safety model that protects MR staff working in the public hospitals within the central region of South Africa from exposure to SMFs and RF energy. The model is based on the recommendation of occupational hygiene (risk management control approach) measures that could be adopted.

1.4. Aim

Most studies that determined association between exposure to MRI-related magnetic fields and adverse health effects focused on patients' health and safety. Occupational exposure studies have only focused on the movement of MR radiographers in stray fields and health effects. However, this study primarily assessed the exposure levels of SMFs and RF magnetic fields, including the health effects resulting from exposure to MRI-related EMFs among MR and non-MR staff as well as MR safety risks. The second aim was to develop a health and safety model that will reduce exposure of MR and non-MR staff to SMFs and RF magnetic fields emitted by 1.5 and 3.0 T MRI scanners.

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1.5. Objectives

In order to achieve the aims, the objectives of this study were;

- To determine transient health effects and safety risks associated with exposure to SMFs and RF magnetic fields among the MR staff.
- To measure the exposure levels of SMFs and RF magnetic fields emitted by 1.5 and 3.0 T MRI scanners.
- To compare the recorded exposure levels against the ICNIRP guidelines.
- To evaluate the hazards and risks associated with the use of MRI scanners.
- To develop a health and safety model for occupational exposure to RF fields, SMFs and MR safety risks in the 1.5 and 3.0 T MR facilities.

1.6. Research questions

The main question that is answered by this study is:

1. Does exposure to SMFs and RF magnetic fields in the MRI scanner room affect the health and safety of the MR staff?

Sub questions:

i) Is there an association between working in the MRI room, where the scanner is located, and reporting of transient health effects and safety risks among MR staff?

ii) Does exposure levels of SMFs and RF magnetic fields emitted by 1.5 and 3.0 T MRI scanners exceed the ICNIRP occupational exposure limits?

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iii) Is the health and safety of MR and non-MR staff affected by the presence of hazards and risks in the MR zone III and IV?

Upon measuring exposure levels and assessed the health effects and MR safety risks, the health and safety model was recommended to mitigate the MR health and safety risks, exposure levels and exposure-related health effects among MR staff.

1.7. Hypothesis

H_A: Exposure to SMFs and RF magnetic fields from MRI scanners affects the health and safety of MR staff.

H_0: Exposure to SMFs and RF magnetic fields from MRI scanners does not affect the health and safety of MR staff.

1.8. Ethical clearance and approval

Prior to the commencement of this study, ethical clearance was obtained from ethics committee of the Faculty of Health Sciences of the University of the Free State (reference number: UFS-HSD2018/0438/3107) (Annexure R). Approval to conduct the study at the hospitals was obtained from the Free State Department of Health (reference number: FS201805 020) and the head of clinical imaging departments (Annexure Q). The study commenced once consent was obtained from study participants. The participants agreed to enrol voluntarily - no remuneration was offered to them, and they were not required to pay participation costs. All efforts were made to keep their personal information confidential and to ensure their anonymity in their participation. Each participant spent approximately 20 minutes completing the questionnaire, and they were given an option to withdraw from the study if they felt

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uncomfortable at any point. Because participants were asked to reveal confidential information regarding their health, anonymity was ensured by asking participants not to divulge their identity when completing the questionnaire. To ensure privacy, participants were asked to complete the questionnaire and put it in a non-openable box designed by the researcher. Data obtained from the questionnaires were further transferred to a password-protected Excel spreadsheet. An information letter containing the study details was issued to each participant. Informed written consent (signed by both participants and the researchers) was obtained from the participants (Annexure B). A signed consent was also obtained from all participants who were interviewed. A separate written consent (Annexure S) was also obtained from participants who agreed to be interviewed.

Prior to the interviews, the purpose of the study was explained to participants and they were informed that their participation was voluntary, and they were given the option to withdraw at any time without repercussions, should they feel uncomfortable to continue with participation. Participants were asked not to reveal their identities. Each interview lasted approximately 45 minutes. The interview responses were recorded on a voice recording device, transferred to a computer and coded for safe storage.

1.9. Structural layout of the thesis

Chapter 1: Introduction

The study is introduced in this chapter, including a background of MRI services in the public hospitals where the study was conducted.

Chapter 2: Occupational exposure to radiofrequency energy and static magnetic fields from MRI Scanners: a review

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An overview of MRI services is given, and exposure-related health effects among workers, MRI-related electromagnetic fields emitted by MRI scanners, and the current regulatory framework are discussed in a form of narrative review.

Chapter 3: Exposure levels of SMFs and RF magnetic fields in 1.5 and 3.0 T MRI units.

In this chapter the environmental measurements and results of RF magnetic fields and SMFs emitted by 1.5 and 3.0 T MRI scanners in zone IV of two public hospitals where this study was conducted are discussed.

Chapter 4: Health effects and safety risks among staff working with 1.5 and 3.0 T MRI scanners within public hospitals in Mangaung metropolitan region

The health effects experienced by healthcare workers assigned to work in the MRI come under scrutiny discussed in this chapter. The transient health effects were assessed using a self-administered questionnaire. The results of MR safety risk interviews conducted among four MR staff are also discussed in this chapter.

Chapter 5: Review of health and safety control measures and MR quality control results in the MRI units of two public hospitals within the Mangaung Metropolitan region

In this chapter, existing control measures in both hospitals are reviewed using a baseline risk assessment. The quality control results benchmarked with ACR requirements are also discussed here.

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Chapter 6: A health and safety model for occupational exposure to radiofrequency fields, static magnetic fields and MR safety risks in the 1.5 and 3.0 T MR facilities

This chapter is devoted to occupational hygiene measures needed to mitigate the health effects experienced by MR staff, MR health and safety risks, and the reduction of exposure levels in the MRI units.

Chapter 7: General discussions

The recommendation and conclusion of this study are based on the findings of MR health and safety risks, the assessment of exposure-related health effects and spot monitoring in hospitals where the study was conducted. Methodological limitations and strengths, the need for similar studies is emphasised, and possibilities, such as comparative studies on the exposure in MRI units and assembly facilities in South Africa are mentioned.

1.10. Scope of the study

This study was conducted in the field of environmental health and more specifically, occupational hygiene (with risk management control approach). The focus was on non-ionizing radiation spot measurements from the MRI scanners. The health effects were assessed among workers assigned to work in MRI units. Specifically, radiographers, radiologists, nurses, cleaners, medical doctors, maintenance engineers, medical physicists and porters performing their work in hospitals, where this study took place, participated. Control group was also included since the health symptoms that could be experienced by the general population were included in the questionnaire.

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The control group included radiographers who perform their duties in computerised tomography (CT) scans and X-rays imaging.

Recent developments in medical imaging have led to a significant increase in the use of MRI scanners, resulting in more involvement of healthcare workers in the MRI units and occupational exposure to MRI-related magnetic fields. Additionally, the ongoing trend of using MRI scanners with strong magnets has resulted in workers being exposed to high levels of SMFs and RF magnetic fields when assisting patients in the MRI room (Schaap *et al*., 2013). Previous studies, outside South Africa, reported exposure-related health effects among health care workers exposed to MRI-related EMFs (Batistatou *et al*., 2016; Bongers *et al*., 2018; Walker *et al*., 2020). Exposure assessments based on numerical modelling (Li *et al*., 2009), personal dosimetry (Schaap *et al*., 2016) and spot measurements (Acri *et al*., 2014) were performed to assess SMFs and time-varying magnetic fields in order to determine workers' exposure patterns in the MRI. There is scarcity of literature on the assessment of RF magnetic fields and models designed to mitigate exposure levels and exposure-related health effects among MR staff. The literature on South African MRI staff is relatively non-existent. This creates a need to understand how MRI-related EMFs affect the health and safety of MR staff in South African public hospitals.

This study focused on the measurements of SMFs and RF magnetic fields, quality control parameters of the scanners as well as health and safety risks in the MRI units within the central region of South Africa, namely the Free State Province. The study took place in MRI units of two public hospitals in

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Bloemfontein; Universitas (hospital A) and Pelonomi (hospital B) hospitals. Universitas hospital has two MRI scanners, 1.5 T Signa (GE medical services) and 3.0 T Ingenia (Phillips), while Pelonomi has one 1.5 T MAGNETOM Aera (Siemens). The transient health effects were assessed amongst 77 workers to determine if their presence in zone IV during image acquisition could be attributed to exposure-related health effects. Forty-nine MRI staff (exposed) and 28 radiographers (control) from CT and X-ray sections formed part of this study. The stray SMFs and RF magnetic fields were measured to evaluate if there are variations in terms of strength when different scan procedures were performed. The MR safety risk interviews were conducted with four MR staff members, namely; a chief radiographer, two radiologists and a medical physicist. A baseline risk assessment was conducted to evaluate health and safety risks in the MRI facilities. The quality control results from the two hospitals were also reviewed to evaluate compliance with American college of radiology (ACR) requirements. Furthermore, a health and safety model was designed to mitigate the peak exposure levels and exposure-related health effects.

1.11. Research outputs

All chapters included in this thesis are reported in an article format. Publications emanating from this thesis are as follow:

1) Two manuscripts from chapter two (literature review) were published in the international conference proceedings of the institute of electrical and electronic engineers (IEEE): i) Rathebe, P.C. 2018. A narrative review on occupational exposure to radiofrequency energy from magnetic resonance

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imaging: a call for enactment of legislation. Open Innovations Conference (OI) (pp. 170-175). IEEE. ISBN: 978-1-5090-1629-7/16/$31.00. and ii) Rathebe, P. 2019. Occupational exposure to static magnetic fields from MRI units in health care settings: a narrative review. Ural Symposium on Biomedical Engineering, Radioelectronics and Information Technology (USBEREIT) (pp. 9-12). IEEE, 25-26 April, Ural Federal University. ISBN: 978-1-5386-8364-4/19/$31.00.

2) Chapter 3: Rathebe, P., Weyers, C. & Raphela, F. 2021. Exposure levels of radiofrequency magnetic fields and static magnetic fields in 1.5 and 3.0 T MRI units. *SN Applied Sciences*. 3, 157 https://doi.org/10.1007/s42452-021-04178-3

3) Chapter 4 has been submitted for publication. Chapter 5: Rathebe, P.C. 2021. Health and safety control measures and MR quality control results in the MRI units of two public hospitals within the Mangaung metropolitan. *SN Applied Sciences*. 3, 734 (2021). https://doi.org/10.1007/s42452-021-04707-0

4) The contents of chapter 6 have been published: Rathebe, P., Weyers, C. & Raphela, F. 2020. A health and safety model for occupational exposure to radiofrequency fields and static magnetic fields from 1.5 and 3 T MRI scanners. *Health and Technology*. 10, 39–50. https://doi.org/10.1007/s12553-019-00379-4

5) Rathebe, P., Weyers, C. and Raphela, F. 2020. Some Health Effects of Exposure to Static Magnetic Fields and Radiofrequency Energy among MRI Staff Working with 1.5 and 3.0 Tesla Scanners In South Africa. *African Journal of Biomedical Research*. 23 (1), pp.57-63. *This manuscript was submitted for*

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publication before adjustments were made to participants' composition and research questionnaire used in chapter 4 (annexure M).

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Chapter 2
Occupational Exposure to Radiofrequency Energy and Static Magnetic Fields in MRI Units: a Narrative Review

Abstract

This review provides an informed discussion on the state of occupational exposure to radiofrequency energy and static magnetic fields emitted by MRI units, particularly from health care settings. The purpose is to create an understanding on the occupational health implications that develops as a result of exposure to electromagnetic fields from working with MRI scanners. The discussion is based on the exposure-related and biological effects, radiofrequency and static magnetic fields exposure limits by ICNIRP, projectile effects based on the strength of the magnet and lastly the magnitude and extend to which MRI staff is exposed. In this review, authors recognise that there is a shortage of literature that outlines the quantification of exposure from different MRI units when examinations are performed. Furthermore, there is also a scarcity of information on the health effects of exposure radiofrequency energy and static magnetic fields in the South African occupational settings.

Keywords: occupational exposure; static magnetic fields; radiofrequency fields; MRI-related electromagnetic fields; projectile effects

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2.1. Introduction

In 2017, there were more than 150 million magnetic resonance imaging (MRI) examinations worldwide (Bonello and Sammut, 2017) and the number of whole-body examinations has increased steadily in the last 10 years (Theysohn *et al*., 2014). There is existing potential risk of large number of patients and volunteers being exposed to MRI-related electromagnetic fields (EMFs), including staff who control scanners (Frankel *et al*., 2018). To date, the long-term health effects of workers performing repeated work near MRI scanners are not yet known (Hartwig *et al*., 2018). Contrary, the potential health hazards are gaining an increased attention due to rapid development in MRI technology (Shellock and Crues, 2014; Kim and Kim, 2017). The recent developments in the MRI resulted in MRI staff exposed to various MRI-related EMFs (Frankel *et al*., 2018); such fields include radiofrequency (RF) fields, static magnetic fields (SMFs) and time-varying magnetic fields (Acri *et al*., 2018). In extreme cases, the exposure of MRI staff may be equivalent to patients' exposure (Capstick, 2008), and this usually happens when staff injects medicinal substance, help patients with severe medical conditions or comfort anxious patients (Moore and Scurr, 2007). Studies related to exposure of MRI staff to EMFs have been carried out only recently (Schaap *et al*., 2016; Batistatou *et al*., 2016; Fatahi *et al*., 2017; Gobba, 2018).

In recent years, the sub-clinical exposure effects have been reported on MRI staff that are directly exposed to SMFs (Hansson-Mild *et al*., 2013; De Vocht *et al*., 2015). The increased risks of safety accidents among maintenance engineers have also been reported (Bongers *et al*., 2015). However, scientific

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literature on RF magnetic fields exposure and long-term health effects is non-existing and it cannot be ruled out that such effects may never occur. The objective of this review was to provide a comprehensive discourse with regard to occupational exposure to RF energy and SMFs emitted by MRI units. In this review, an effort has been made to discuss health effects of exposure to MRI related fields, effects on pregnant employees, safety conditions and exposure limit values as stipulated by the International Commission for Non-Ionising Radiation Protection (ICNIRP).

2.2. Literature search

The literature search was mainly conducted using Google scholar, which directed to other engines such as PubMed, EBSCOhost, NCBI and Science Direct to find relevant articles and guidelines used to compile this narrative review. Keywords such as MRI safety, health effects, radiofrequency energy, static magnetic fields and occupational exposure were used. All publications up to 2020 were considered. Only full text, peer-reviewed articles and guidelines were retrieved and considered for inclusion if they evaluated workers' exposure to MRI-related EMFs and safety of MRI scanners. Environmental exposures for RF energy were also included based on the scarcity of literature on MRI-related RF energy exposures amongst workers.

2.3. What is Magnetic Resonance Imaging?

The MRI was introduced in the diagnostic medical physics more than 25 years ago. In the 1990s, a SMF of 1.5 T was introduced with new possibilities that

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emerged; functional studies such as metabolism, associated tissue movements, molecular diffusion, capillary perfusion, etc. (Hartwig *et al*., 2018). Currently, MRI scanners with up to 3 T SMFs are used for common diagnostics and interventional procedures (Schaap *et al*., 2013). MRI units exist in different forms, 7 T scanners are used in research facilities with the new systems up to 11.7 T introduced lately (Schaap *et al*., 2013). MRI scanners do not expose the body to ionizing radiation; they use magnetic fields to obtain a detailed image (Ghadimi and Sapra, 2019). Magnetic fields in the MRI include switched gradient fields that are used for image coding and RF magnetic field created with a body coil that is integrated into the scanner (Hansson-Mild *et al*., 2019) as well as SMFs emitted by the magnet. Figure 2.1 below represents an image produced by 1.5 T and 3.0 T MRI scanner.

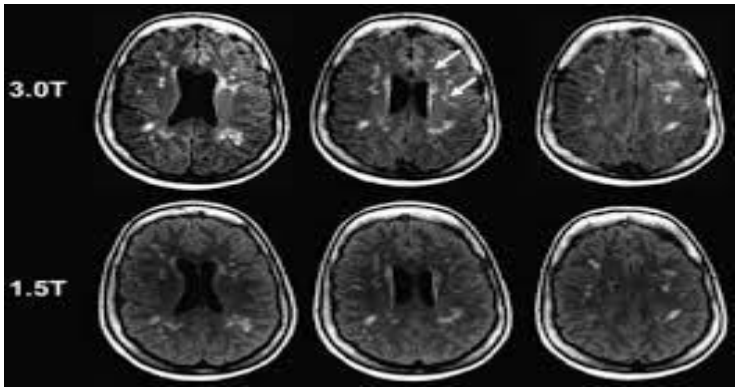

Figure 2.1: Structural imaging of the brain (Lymer, 2012)

Magnetic resonance imaging is used to produce a wide range of internal images, ranging from neuroimaging, cardiac imaging, musculoskeletal imaging, spectroscopy and functional imaging (Hansson-Mild *et al*., 2019). The RF energy is emitted to excite protons in the body tissues (Keevil, 2016),

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and once the nuclei are aligned in a direction of magnetic fields, the resonance is formed and image is produced. According to William and Faulkner (2015), the potential of induced tissue heating in MRI examination is a basic function of pulsed RF energy. Majority of human diagnostics MRI are based on cylindrical bore systems, and in close proximity MRI-related EMFs can be simultaneously present, with fringe fields outside the magnet bore extending up to several meters from the scanner (Hartwig *et al*., 2018). Due to inherent health risks of fringe fields, MRI staff should have sufficient knowledge on the purpose of safety zones (Sammet, 2016), potential risks related to their job and possibilities of exposure-related transient symptoms and sensations (Hartwig *et al*., 2018).

2.4. MRI safety zones

The team of experts from the American College of Radiology (ACR) have developed guidance document that enforces strict safety adherence in the MRI units (Kanal *et al*., 2013). To ensure safe practices in the MRI, the ACR defined trained MRI personnel according to different levels. According to Tsai *et al*. (2015), level one category of trained MRI personnel are regarded to have passed a minimum safety educational training to sufficiently protect themselves from safety accidents as they work in zone III. Level two personnel underwent extensive training and education in the broader aspects of MRI-related safety issues, while non–MR imaging personnel are those who do not comply with MRI safety instructions (Tsai *et al*., 2015). Furthermore, the MRI units are clearly labeled according to four safety zones (Sammet, 2016) (Figure 2.2).

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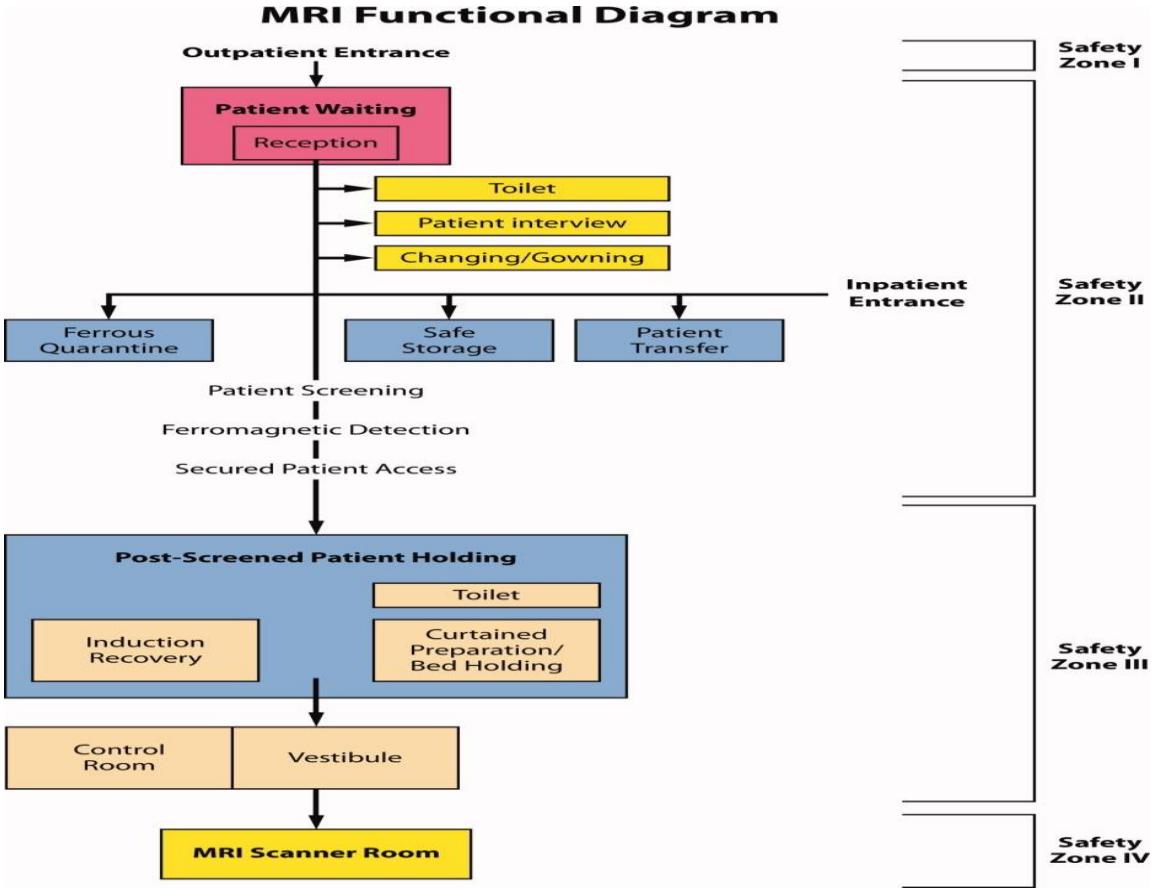

Figure 2.2: Four MRI safety zones (adopted from ARC, guidance document on MR safe practices; Kanal *et al*., 2013).

Zone I- This is an entrance to MRI facility, typically outside MRI units, and is freely accessible to the hospital general public. It is regarded as an area where magnetic fields poses no safety and health hazards.

Zone II- It is uncontrolled interface area between zone I, III and IV. This zone consist of reception area, dressing and screening rooms. Zone II includes the reception area, dressing rooms and MRI screening rooms. Trained MRI personnel provide supervision and administers safety questionnaire to patients.

Zone III- this area consist of MRI control room, only MRI personnel and patients that are screened are allowed. Access is restricted by means of

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physical barriers such doors with key locks, coded access or any other method that differentiate between MRI and non-MRI personnel. Non-MR personnel are not provided with access until they have underwent MRI safety training to become approved MRI personnel (Kanal *et al*., 2013).

Zone IV- this is the room where MRI scanner is located and there is a mixture of MRI-related EMFs. Ideally, this room is clearly demarcated as being potentially hazardous due to the presence of very strong magnetic fields (Kanal *et al*., 2013). Zone IV is designed to contain the 5 Gauss (G) line of the fringe magnetic fields from the magnet.

Sammet *et al*. (2010) suggest that MRI safety program should be established to train all MRI personnel and retrain non-MRI personnel about the presence magnetic fields and potential exposure hazards in the MRI suits, and also to warn about potential interference with implantable medical devices.

2.5. Static magnetic fields from MRI scanners and transient health symptoms among workers

Healthcare workers in hospitals are constantly exposed to SMFs and subsequently to time-varying magnetic fields from MRI scanners (Wiléna and De Vocht, 2011; Schaap *et al*., 2014). Exposure to pulsed RF energy is infrequent (Gourzoulidis *et al*., 2015). Personnel who operate 1.5 and 3 T MRI scanners are exposed to high levels of fringe SMFs surrounding the scanners and exposure symptoms like headaches, vertigo, nausea, metallic taste and concentration problems have been reported (Schaap *et al*., 2014; De Vocht *et al*., 2015; Schaap *et al*., 2016). This could be a common phenomenon

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among cleaning personnel when they move around the magnet bore. Studies suggest that exposure symptoms among of MR radiographers are related to the strength of the scanner (e.g. from 1.5 T to 3.0 T and more), duration and frequency of exposure (De Vocht *et al*., 2006; Schaap *et al*., 2014; Huss *et al*., 2017). Huss *et al*. (2018) suggested that MRI radiographers with intrauterine devices (IUDs) are at high risk of abnormal uterine bleeding than their co-workers without IUDs when exposed to static magnetic stray fields. According to De Vocht *et al*. (2007) and Wilen and de Vocht (2011), the development of all aforementioned health effects depend on the strength of scanners and duration of exposure. Furthermore, with rapid developments in the MR technology, potential health effects are gaining an increased attention (Kim and Kim, 2017).

In 2012, disturbed visual perception, hand-eye coordination and effects on balance amongst MRI staff exposed to 7 T magnetic stray fields were also reported by Van Nierop *et al*. (2012). Mian *et al*. (2013) reported vertigo as one of the health effects caused by exposure to SMFs and experienced by those in close proximity to MRI scanners. Headache and tiredness have been reported as symptoms that last for few minutes after exposure (Schaap *et al.*, 2013). However, insomnia has been reported to outlast exposure by night, following the exposure scenario (Wilen and de Vocht, 2011; De Vocht *et al*., 2015). Majority of symptoms are acute and disappear immediately the exposed subject exits the magnetic stray fields (De Vocht *et al*., 2006; Schaap *et al.*, 2013).

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2.6. MRI and medical implants

In 2017, Los Angeles, the study titled “assessing the risks associated with MRI in patients with a pacemaker or defibrillator was conducted by Robert *et al*. (2017). The founding aim of this study was to evaluate the health risks involved to patients with pacemakers or implantable cardiac valves that undergo 1.5 T MRI examinations. In the said study, 1000 pacemaker and 500 implantable cardio valve patients were referred to a non-thoracic MRI at field strength of 1.5 T. Before the advent of the measurements, devices were carefully examined and programmed so that no death, device failures, loss of capture or ventricular arrhythmias could occur. Changes in device impedance, pacing threshold, battery voltage, and P-wave and R-wave amplitude exceeding pre-specified thresholds were observed in small cases. However, a total device failure and death did not occur in any of the patients that were examined.

The above study outlines that to some extent, if not programmed, the interaction of MRI-related magnetic fields with implantable cardiac valves and pacemakers can disturb their functioning. What remains a known principle is that every device that enters the MRI room must be diamagnetic (Simmons and Hakansson, 2011). The static magnetic fields produced by magnets in the MRI magnetise every device that enters the MRI room if they do not have diamagnetic properties. Hence, every pacemakers and cardio-defibrillator have to be screened and in some cases be programmed. Kanal *et al*. (2012) argue that the hazards of examination on patients with pacemakers are direct results of procedures used in the MRI. According to Allaart and de Cock

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(2014), static magnetic field may produce mechanical forces on ferromagnetic components, leading to random magnetic sensor activation. The RF energy may heat cardiac tissues adjacent to the leap tip, leading to arrhythmias and over or under-sensing (Allaart and de Cock, 2014). It is known that RF energy heats up and damage the internal body tissues, which can subsequently be a contributing factor in the damaging of such devices by increasing the internal temperature.

Interactions of implantable MRI unsafe objects with magnetic fields can cause severe artifacts and heating (Sammet *et al*., 2013). However, there is unclear correlation between appearance, magnitude and implantable heating (Nordbeck *et al*., 2008). Contrary, Van Der Graaf *et al*. (2014) indicate that the latest implantable devices contain special components that are tested and approved for usage in the MRI units. The improved designs suggest reduced risks of complication, including heating. Moreover, the special MRI software is incorporated into implantable devices and once appropriate settings are activated, they switch on automatically.

2.7. Exposure to MRI-related magnetic fields, cancer and genetic damage

Compliance with occupational exposure limits gives protection against acute exposure symptoms (Sannino *et al*., 2017). However, exposure to significantly high SMFs could result in cumulative harmful effects among MRI workers (Sannino *et al*., 2017), necessitating research on the possibility of cancer and genetic material damage. A study by Lee *et al*. (2011) investigated

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exposure of human lymphocytes to MRI-related EMFs generated during clinical routine brain examination protocols, using three-channel head coil for 22, 45, 67 and 89 minutes respectively. A significant increase in the frequency of single-strand DNA breaks following exposure to 3.0 T MRI was observed. In 2008, Kimura *et al*. used experimental model metazoan *Caenorhabditis elegans* to study the effects of 3.0 and 5 T SMFs on gene expression. Following exposure to SMFs, transient induction of *hps12* family genes was observed. According to Sannino *et al*. (2017), a high SMFs strength has been measured where cell cultures and patients were exposed, and no clear conclusion was drawn. Vijayalaxmi *et al*. (2015) highlighted that SMF exposure levels, long-term effects and duration of exposure need to be compared in order to make a clear conclusion about the long-term effects.

The discussion on RF energy as a possible cause of cancer is based on weak assumptions and it uses the principles of ionising radiation to explain non-ionising radiation, which, according to Havas (2016) is inappropriate. The rationale put forward by many health agencies (WHO, 2014; National Cancer Institute U.S, 2016; ICNIRP, 2016; Health Protection Agency U.K, 2012; Health Canada, 2010) is that exposure to RF energy cannot cause cancer as it is a non-ionising radiation. Non-ionising radiation does not have enough energy to dislodge electrons and have weak electromotive force (Havas, 2016). Arguably, the statement by Havas (2016) consists of two contentions and are as follows: (1) for electrons to be dislodged there must be photon energy exerted and (2) electromagnetic force must be applied. In the ionising radiation “as a cause of cancer” photon energy is a critical criterion as it is

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needed to break the chemical bonds in the human cells. Exposure of tissues to non-ionising radiation results in the damaging of free radicals while ionising radiation directly damages the deoxyribose nucleic acid (DNA) (Havas, 2016).

2.8 Heating and safety regarding RF energy exposure in the MRI

According to Murbach *et al*. (2015), exposure to RF energy in the MRI environments is substantially high and requires special RF safety measures. Exposure to RF energy in the MRI is higher than the guidelines for general public exposure and has been reported to induce systemic thermal stress amongst workers and patients (Murbach *et al.,* 2015). Initiation of whole body thermoregulation and local thermoregulation processes around thermal hotspots has also been reported in several studies (Laakso and Hirata, 2011; Murbach *et al.,* 2015). Shellock (2000) indicates that thermoregulation takes place because of an elevated tissue temperature and studies on thermal effects of human exposure to RF energy produced by 1.5 T indicated a non-significant difference. The increase of tissue temperature due to absorbed RF energy is dependent on pulse sequence, repetition time, frequency and geometric tissue properties (Hartwig *et al*., 2010). Tissue heating among MRI technicians may primarily depend on their status of thermoregulatory system, duration of exposure and the rate at which energy is deposited, ambient conditions in the MRI environment and the underlying health conditions (Murbach *et al.,* 2015).

Radiofrequency fields are commonly referred to as B_1 while other fields (static) are referred to as B_0. The heating potential of RF energy is high and

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more significant at higher field strengths than at lower fields. According to Murbach *et al*. (2015), high-level RF energy exposures may induce systemic thermal stress. This include initiating whole-body thermoregulation and local thermoregulation processes around thermal hotspots (Laakso and Hirata, 2011; Murbach *et al*., 2014). Murbach *et al.* (2015) also indicate that the local RF deposition can reach higher magnitudes when the body is in close proximity to stray fields around the capacitors of the birdcage. This suggests the need to establish workers' exposure metrics in relation to RF stray magnetic fields present near MRI birdcage.

2.9 Effects of MRI fields on pregnant employees

There is lack of scientific evidence that as pregnant patients and MRI workers are at greater risk to harm their unborn foetus when exposed to magnetic fields from MRI scanners (MHRA, 2007). According to De Wilde *et al*. (2005) and Alorainy *et al*. (2006), potential sources of danger on pregnant patients include SMFs, gradient magnetic fields, RF magnetic fields and combination of these fields with contrast agents. Crook and Robinson (2009) suggest that pregnant MRI staff are not at greater risks of any harmful effects such as spontaneous abortion and pre-term delivery, however, the American College of Radiology argues that no special consideration should be given during any trimester in pregnancy (ACR, 2015). Two studies have reported evaluation models of SAR for pregnant MRI staff and patients exposed to RF energy (Pediaditis *et al*., 2008; Wang *et al*., 2009). The former models looked at exposure at a 28-week pregnancy period from RF fields of 64 and 127 MHz, while the other models focused on the whole-body exposure at a 30-week

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pregnancy period from radiofrequency fields of 13, 43, 64, 85, 127 and 170 MHz (Pediaditis *et al*., 2008). Hand *et al.* (2006) conducted a study to look at the local and whole-body exposure of 30-week pregnant females to MRI fields. In this study, it was shown that SAR averaged over 10 g of tissue exceeded 10 W/kg and reached 2 W/kg for extremities. However, it is still not clear with regard to RF energy heating as a prime cause of spontaneous abortion and pre-term delivery. Hence, ACR (2015) suggest that the risk to benefit ratio to perform examination pregnant patients must be evaluated by level II designated MRI personnel.

In 2015, Strizek *et al*. conducted a retrospective case-control study (2008-2012) of birth weights and the effects of acoustic noise on foetus exposed to 1.5 T MRI. The study included 751 neonates exposed to MR imaging in utero and a group of control comprising 10042 with no risk factors of hearing impairment at birth. No hearing defects in the exposed and un-exposed group were found. The study also revealed no effects on birth weight among neonates exposed to 1.5 T MRI. Reeves *et al*. (2010) performed a study to establish whether neonates exposed to acoustic noise generated by 1.5 T MRI is associated with cochlear injury and hearing loss. Hundred and three neonates who underwent MRI were identified and 96 of them completed hearing test. The study found that exposure of the neonates to 1.5 T MRI during the second and third trimesters of pregnancy is not associated with the risk of hearing defects. In a recent study, neonates exposed to acoustic noise generated by 3.0 T MRI scanners during pregnancy showed no adverse hearing effects and birth weight when compared to control group (Chartier *et*

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al., 2019). It has not been clear on how exposure to MRI-related EMFs can place foetus at risk during examination of pregnant females, if exposure data is extrapolated from animal studies (Brass and Copen, 2007).

2.10 Non-thermal effects including hypersensitivity of exposure to RF energy

Of great concern today in the EMF scientific society is the non-thermal effects of exposure to RF energy. Steward (2000) refers to these effects as those that occur below the guideline limits and also the long term effects with likelihood to lead to cancer. In many studies, an overall problem is that when exposure assessment for non-thermal effects has been conducted, the correlation between exposure and dose has not been given a pronounced attention (Wilen, 2002). In the case of exposure assessments from MRI, the only factors that are considered are time and dosage. However, Wilen (2002) indicated that non-thermal effects might not depend on time, but it will be a sound scientific approach to include time in the concept of dose. There have been assertions that other individuals are more sensitive to the effects of EMF than others but its scientific factualness has never emerged.

The hypersensitivity to EMF has always been a critical thought when dealing with the non-thermal effects. According to Raphela, Weyers and Shale (2013), the term electromagnetic hypersensitivity (EHS) refers to clinical conditions where people complain about health symptoms that are attributed to EMF exposures. Van Moorselaara *et al*. (2017) state that there is no accepted scientific definition of electromagnetic hypersensitivity (EHS), how

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to measure it and how to control it among those who are affected. However, in 2004, Röösli *et al*. conducted a questionnaire survey to determine the symptoms and number of people who are hypersensitive to EMFs. It was found that 56% of the participants claimed to develop symptoms within few minutes after being exposed. It is possible for individuals to be electromagnetic hypersensitive, but the sensitivity is highly dependent on the duration of exposure (short-time exposure). Leitgeb and Schröttner (2003) state that electromagnetic sensibility determines electromagnetic hypersensitivity. Individuals must first be sensitive to EMF exposures before they can develop hypersensitivity.

2.11 MRI scanners and emission of acoustic noise

Previous studies have suggested that acoustic noise emitted by MRI systems may induce hearing loss if exposed without hearing protectors (Govindaraju *et al*., 2011; Wang *et al*., 2015). Bongers *et al*. (2017) evaluated the effects of repeated exposure to MRI-related acoustic noise during scans. A total of 474 workers from MRI manufacturing facility formed part of the retrospective cohort study. Repeated exposure was found to be associated with exposure-dependent increased rate change of hearing. The increased rate change shown statistically significant difference for the frequencies; 500, 1000, 2000, 3000 and 4000 Hz in the right ear. Authors suggest that exposure to noise related to MRI scans resulted in a slight amount of hearing loss and the use of hearing protectors could have prevent hearing loss. In 2018, Song and Lim evaluated noise in the MRI scan and control rooms where 0.35 T, 1.0 T, 1.5 T and 3.0 T are situated. Different frequencies and waveforms characteristics

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were analysed using time history curves. Analyses revealed that the noise possessed the characteristics of steady and quasi-steady impulsive noises. It is suggested that the results of the study could be used to enforce MRI safety management regulations.

Scarabino *et al*. (2017), state that 3.0 T units have a considerable disadvantage of producing relatively more acoustic noise as compared to 1.5 T units, and may exceed 119 dB. Acoustic noise levels during MRI examination can exceed 80 dB (A) and at this exposure, hearing protection is normally recommended for patients and MRI personnel (Strizek *et al.,* 2015). Exposure levels are mainly dependent on the field strength and Hattori *et al*. (2007), indicate that noise levels are significantly higher in 3.0 T MRI systems. Occupational exposure to noise levels that has potential to cause hearing defects should be limited and according to Occupational Safety and Health Administration (OHSA) (2008), exposure intervals of 15 minutes per day should be considered.

2.12 Claustrophobia in the MRI environment

In the MRI units, patients are exposed to noise and encounter enclosed as well as isolated environment due to the nature and advances made to the MRI systems. Because of the design, patients tend to experience anxiety, distress and claustrophobia (Rai *et al*., 2013). In extreme cases, claustrophobic patients may refuse to complete the scan; hence, patients need to be informed on the MRI scan procedures (Ghadimi and Sapra, 2019). There is relatively no available literature that suggest MRI workers might experiencing

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claustrophobia in the MRI environment. According to kaur *et al.* (2017), older MRI machines have a very long scan times, up to 40 minutes, and the assistance of MRI staff to assist patients with mild claustrophobia may be necessary since they may be unable to complete the scan. This scenario could potentially expose MRI staff to a mixture of MRI-related EMFs.

Kaur *et al*. (2017) also suggest that the modern scanners have a short scan times and patients may find easy to tolerate the scan procedure. This implies patients undergoing scan procedures in 3.0 T scanners may experience less claustrophobia and anxiety. In 2017, Dundurs and Tarasova explored the noise influence on medical staff and patients in the departments of radiology. Of 150 study participants, 106 were women (70.7%, mean age 42 years) and 44 were men (29.3%, mean age 48 years). The study found that 54% of patients felt discomfort when undergoing MRI, while women associated discomfort with noise (p<0.036). Frequent reason for discomfort and claustrophobia was associated with noise and lying in the MRI scanner bore. Women experienced anxiety more often (p<0.05) and men tend to sleep during scan procedures (p<0.062). Dundurs and Tarasova (2017), suggested that discomfort could be reduced by sedating patients or giving them earplugs.

2.13 Specific absorption rates (SARs) for RF energy exposures

The RF frequency on a 1.5 T scanner is approximately 63.87 MHz and 127.74 MHz on a 3.0 T scanner (Frankel *et al*., 2018). The specific absorption rate (SAR) is the amount of RF energy absorbed per kilogram of body tissue, and

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SAR values are limited by the scanner to prevent patient overheating from RF energy (Frankel *et al*., 2018). The amount of SAR emitted by MRI scanners during patient examination is regulated by the International Electrotechnical Commission (IEC) standards (IEC, 2010). According to Frankel *et al*. (2018), during patient examination, the MRI operator may choose different scanning mode; normal operating mode with SAR that should not exceed 2.0 W/kg over an average six minutes period and the first-level controlled operating mode that allows SAR to reach >4.0 watts per kilogram (W/kg), and this is primarily used in research.

In a Sequence with an estimate of 1 W/kg over 6 minutes and a duty cycle of 1%, SAR would reach 100 W/kg in each pulse (Frankel *et al*., 2015). Since RF fields are significant in MRI scanning procedures (McRobbie, 2012), patient exposures at sequence and duty cycle described by Frankel *et al*. (2018) could result in induced tissue temperature, and subsequent tissue burns (Rathebe *et al*., 2020). The SAR values from 1.5 to 3.0 T scanners can potentially increase by a factor of four, if other parameters are kept equal (Tsai *et al*., 2015). An increase of field strength from 1.5 to 3.0 T suggest the risk of induced thermal effects to patients as well as MR staff who are present in close proximity to MRI scanner during patient examination. To reduce the induced tissue heating among patients, Food and Drug Administration (FDA) (2016) proposed exposure limit values (table 2.1).

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Table 2.1: SAR limits by Food and Drug Administration

Area	Dose	Exposure Time (minutes)	SAR (W/kg)
Whole body	**Averaged over**	15	4
Head	**Averaged over**	10	3
Head or torso	**Per gram of tissue**	5	8
Extremities	**Per gram of tissue**	5	12

Although FDA recommends the use of the above SAR limits in the medical field, particularly where MRI units are employed, the Radiation Protection Agency (RPA) in the North America suggests that all institutions that produce either non-ionising or ionising radiation to use guidelines that are published by the International Commission on Non-Ionizing Radiation Protection (ICNIRP). The ICNIRP is recognised by World Health Organisation (WHO), International Agency for Research on Cancer (IARC) and Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) for its expertise in this area. The guidelines receive worldwide support in America and European countries, including South Africa.

In the MR environment, an interest is to reduce high RF energy exposures by complying with the SAR limit values. According to Kwan-Hoong *et al*. (2003), if the MR examination takes up to 1 hour or more, the whole-body exposure should be limited to a total energy deposition of 120 watts per minutes per kilogram (W/min kg^{-1}) in order to avoid the overload of the thermoregulatory system. Any local area within the body, SAR should not exceed 60 W/min kg^{-}

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[1] averaged over the head, 120 W/min kg^{-1} averaged over the trunk, and 180 W/min kg^{-1} averaged over extremities. The limit values should be adhered to, provided that the instantaneous SAR does not exceed 4 W/kg^{-1} averaged over the head, 8 W/kg^{-1} averaged over the trunk or 12 W/kg^{-1} averaged over extremities.

The ICNIRP stresses the fact that exposure to RF fields with frequency range of 100 kHz to 10 GHz should not exceed the below basic restrictions. The reference levels are also specified in the ICNIRP guidelines of 1998 (updated to 2010). The major concern of reference levels is both electric and magnetic fields while basic restriction covers the SAR.

Table 2.2: ICNIRP Basic restrictions (100 kHz to 10 GHz)

General public exposures (W/kg)				**Occupational exposures (W/kg)**			**Reference levels**
Frequency	**Whole-body average**	**Localised SAR (head and trunk)**	**Localised SAR (limbs)**	**Whole-body average**	**Localised SAR (head and trunk)**	**Localised SAR (limbs)**	**Whole-body, Head and Trunk, Extremities**
100 kHz - 10 GHz	0.08	2	4	0.4	10	20	-
10-400 MHz (ICNIRP, 1998)	-	-	-	-	-	-	0.2 µT

Even though the FDA SARs are convenient due to time factor, the above ICNIRP classifies the limits for both workers and the general public. However, with regard to this study the ICNIRP basic restrictions avail its relevance.

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2.14 ICNIRP guidelines for SMFs exposures

Exposure to SMFs has an impact on the implantable medical devices such as cardiac pacemakers, ferromagnetic implants and implanted electronic devices, and 0.5 mT contour around the magnet should be clearly marked or access to that area should be restricted (Hansson-Mild *et al*., 2019). According to the ICNIRP (2009), a set of occupational exposure limits are based on avoiding the sensations of transient exposure effects that are induced by exposure to SMFs. The recommended exposure limits are also based on time-weighted average of 200 mT during an eight-hour working day, with a ceiling value of 2 T. The general public exposure limits has been set to 400 mT and this is determined by applying a reduction factor of five on 2 T, which has been proved to have no detrimental effects on humans (Zhang *et al*., 2017). Table 2.3 below shows occupational exposure limits that intent to reduce exposure to SMFs and subsequently protect workers from exposure effects.

Table 2.3: Occupational and general public exposure limits for SMFs

Exposure characteristics	**Magnetic flux density**
Occupational	
Exposure of head and of trunk	2 T
Exposure of limbs	8 T
General public	
Exposure of any part of the body	400 mT

Occupational exposure of head and trunk should not exceed a spatial peak magnetic flux of 2 T, however, in instances where the environment is

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controlled, exposures up to 8 T can be permitted. According to ICNIRP (2009), work applications where there is exposure of 2 T, it should be a controlled work environment and should not exceed 8 T. With regard to limbs, a maximum exposure of up to 8 T is permitted.

2.15 Environmental exposure to RF energy

Epidemiological studies on environmental exposure to RF energy (i.e. from RF signal base stations) and development of symptoms that were conducted until 2010, were all cross-sectional. Studies that were conducted on an estimated distance from base stations and exposure to RF fields by Baliatsas *et al*. (2011) and Blettner *et al*. (2009) revealed more associated symptoms, including sleep problems and reduced wellbeing. There were no consistent effects on the development symptoms or wellbeing of the exposed individuals in some studies where distance was objectively measured with RF fields' exposure (Baliatsas *et al*., 2011; Berg-Beckhoff *et al*., 2009; Heinrich *et al*., 2010; Thomas *et al*., 2008). However, when considering to evaluate environmental exposure to RF fields, geographical information and other considering factors (such as TV and radio transmitters and building characteristics) should be taken into account as they have shown to play a significant influence (Mohle *et al*., 2010). In the same study that was conducted in the USA on hypersensitivity by Mohler *et al*. (2010), 18% of the exposed to RF fields developed adverse health effects, while 8% was indicated to be hypersensitive to EMFs. The study found no indication that those affected perceived hypersensitivity differently than others.

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In 2010, Heinrich *et al*. performed a study to determine the acute symptoms and chronic well-being against RF fields exposure to children and adolescent group. The study was performed using exposimeter to assess personal exposure for the duration of 24 hours. Also in 2009, study of the same interest was conducted by Berg-Beckhoff *et al*. to measure exposure to RF fields in the home of participants. Different frequencies from different RF field sources (e.g. mobile phone handsets, base stations and TV antennas) were analysed and fields from mobile phones were purposefully excluded to investigate potential health effects from other environmental RF sources. However, no effects of exposure to RF environmental sources were observed but on the other hand sleep disturbance was attributed to RF base station exposures. Only 9% of the study participants showed acute health and sleep problems after RF fields exposure.

2.16 Static magnetic fields and projectiles (ferromagnetic objects)

The strong SMFs can attract objects with ferromagnetic properties towards the MRI scanner magnet, and the stray fields could affect the functioning of implantable medical devices (Ghadimi and Sapra, 2019). The ferromagnetic objects within the strong stray magnetic fields are primarily influenced by torque and translational force, and this is determined by the ferromagnetic object properties, strength and proximity of the object to the magnet (Heintz *et al*., 2018; Chandra *et al*., 2019). To date, ballistic effects of ferromagnetic objects in the MRI environment are considered potential risk factors, with severe safety injuries and few fatalities reported in the past (Kraff and Ladd, 2016).

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In study conducted by Güttler *et al*. (2015), 137 documented safety incidents caused by ferromagnetic objects were reported between 1992 and 2015. Authors indicated that these accidents were approximately 10 % of accidents (out of 1739) that occurred during that period. A growth of fivefold has also been reported by Gilk and Kanal (2015) between 2000 and 2009. Kraff and Ladd (2016) argue that the number of MRI installations has rapidly increased, and incident-reporting frequency does not reflect deterioration of safety vigilance in the MRI units. This has also been supported by discussion on design aspects relating to safety that could be taken into account to enhance efficiency of patients and healthcare staff during the new MRI planning phase (Gilk and Kanal, 2015).

2.17 MRI safety guidelines and policies in South Africa

There is dearth of literature on the safety practices within MRI units in South Africa. The medical physics profession is part of the multidisciplinary health care team that is responsible to uphold health and safety practices in the MRI units. In the absence of legislative framework that aims to protect the health and safety of MRI staff from MRI-related EMFs, South African healthcare sectors adopted the guidelines from Association of Physicists in Medicine (AAPM) and American College of Radiology (ACR). According to Clements *et al*. (2018), the primary role of medical physicists is to ensure safe and effective use of radiation in medicine as prescribed in the AAPM practice guidelines. Thus, this involves the use of non-ionizing radiation in diagnostic medical imaging such as MRI scan procedures. To ensure the safe use of non-ionizing radiation in the MRI, medical physicist often collaborates with physicians,

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maintenance engineers, nurses, radiographers and administrative staff (Clements *et al*., 2018).

Many aspects in the MRI are not regulated by the legislative framework but documents such as guidelines, standards and operating procedures are used (Mühlenweg *et al*., 2015). The planning, design and installation of the MRI suites are mainly undertaken by engineers and the International Electrotechnical Commission (IEC) 60601-2-33 regulates the operating instructions relating to safety. According to Schaefers and Mierau (2016), the IEC standard 60601-2-33 describes all safety precautions that must be undertaken for safe operation of the MRI systems. The safety precautions include MRI facilities requirements, workers, patients and volunteers' exposures as well as procedural requirements (IEC, 2010).

2.18 Conclusion and future studies

There are several guidelines, health recommendations and standards in place, addressing the safety of medical personnel in respect to the MR working environment. Some of the well-known recommendations include "*Strahlenschutzkommission*" from Germany, MR safety of the American College of Radiology (white paper), IEC 60601-2-33 standard and the European Directive (2013/35/EU) on the requirements regarding workers' exposure to the risks arising from electromagnetic fields. However, in South Africa, there is a need for special health and safety training of medical personnel, to classify the exposure limit values of RF energy and SMFs according to different field strength, development of safe working procedures

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for the MRI environment and risk assessment to address potential health hazards within zone IV of the MRI units. Furthermore, there is also a need for an appointment of health and safety professionals to ensure that procedures are in effect and enforced in order to realise health and safety in the MRI environment.

In South Africa, there is a need to quantify the stray RF magnetic fields and SMFs in the MRI suites in order to estimate and classify the exposure characteristics of workers. The existing exposure controls must be reviewed against the recommended safety guidelines in order to protect MRI staff from exposure-related health effects. Epidemiological studies are required to evaluate the development of long-term health effects such as cancer and chronic non-thermal health effects among MRI workers and other health care workers exposed to RF energy and SMFs. There is also a need to evaluate and characterise thermal and physiological responses of MRI staff in order to ensure that they are protected from high levels of RF energy and SMFs during MRI procedures.

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Chapter 3

Exposure levels of radiofrequency magnetic fields and static magnetic fields in 1.5 and 3.0 T MRI units

Abstract

Magnetic resonance imaging (MRI) staff is exposed to a complex mixture of electromagnetic fields from MRI units. Exposure to these fields results in the development of transient exposure-related symptoms. This study aimed to investigate the exposure levels of radiofrequency (RF) magnetic fields and static magnetic fields (SMFs) from 1.5 T and 3.0 T MRI scanners in two public hospitals in the Mangaung Metropolitan region, South Africa. The exposure levels of SMFs and RF magnetic fields were measured using the THM1176 3-Axis hall magnetometer and TM-196 3 Axis RF field strength meter respectively. Measurements were collected at a distance of 1 meter (m) and 2 m from the gantry for SMFs when the brain, cervical spine and extremities were scanned. Measurements for RF magnetic fields were collected at a distance of 1 m with an average scan duration of six minutes. Friedman's test was used to compared exposure mean values from two 1.5 T scanners and Wilcoxon test with Bonferroni adjustment was used to identify where the difference between exist. The Shapiro Wilk test was also used to test for normality between exposure levels in 1.5 and 3.0 T scanners. The measured peak values for SMFs from the 3.0 T scanner at hospital A was 1300 milliTesla (mT) and 726 mT from 1.5 T scanner in hospital B. The difference in terms of SMFs exposure levels were observed between two 1.5 T scanners at a distance of 2 m. The difference between 1.5 T scanners at 1 m were also observed during repeated measurements when brain, cervical spine and extremities scans were performed. Scanners' configurations, magnet type, clinical setting and location were identified as factors that could influence different propagation of SMFs between scanners of the same nominal B_0. The RF pulse design, sequence setting flip-angle and scans performed influenced the measured RF magnetic fields. Three scanners were complaint with occupational exposure guidelines stipulated by the ICNIRP, however, peak levels that exist at 1 m could be managed through adoption of occupational health and safety programmes.

Keywords: Static magnetic fields; radiofrequency fields; occupational exposure; MRI scanners; exposure levels

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3.1 Introduction

The World Health Organisation (WHO) has classified both magnetic fields (IARC, 2002) and radiofrequency (RF) fields (IARC, 2013) as a possible carcinogenic to humans, “group 2B”. Magnetic Resonance Imaging (MRI) has a complex mixture of electromagnetic fields (EMFs), ranging from static, low-frequency, and RF magnetic fields (Frankel *et al*., 2018). The MRI static magnetic fields (SMFs) range from 0.5 to 3 tesla (T) for clinical examinations and, in addition, the magnitude of RF fields (μT) produced gives rise to specific absorption rates (SAR) (Frankel *et al*., 2018), leading to increased tissue temperature and possible thermal damage (Golestanirad *et al*., 2017; Golestanirad *et al*., 2019). Transient effects resulting from exposure to MR-related EMFs have been well studied through health risk assessments in American and European countries (Bongers *et al*., 2016; Huss *et al*., 2017; Huss *et al*., 2018); however, current exposure scenarios in South African public health care sectors are not yet known (Rathebe, 2018; Rathebe, 2019). In exposure assessment studies conducted by Bongers *et al*. (2016) and Huss *et al*. (2017), an association was found between occupational exposure to SMFs and increased risks of commute-related accidents leading to injuries. Health risk assessments performed by Wilén and de Vocht (2011), Zanotti *et al*. (2015) and Schaap *et al*. (2016) suggest that exposure to MRI-SMFs is associated with unpleasant symptoms such as vertigo/ dizziness, nausea, unusual drowsiness, sleep disorders, severe headaches, and concentration problems. Similarly, SMFs-exposure effects were also reported by Schaap *et a*l. (2013) and De Vocht *et al*. (2015). It should be noted that performing personal exposure measurements during the execution of a magnetic resonance (MR) exam involves considering exposure conditions that require the presence of an operator in the MR room during the exam in order to assess the entire exposure scenario. The

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MR operator may only be present in the MR scanner room during interventional procedures or when assisting patients with severe medical conditions. According to Karpowicz *et al*. (2007), Gourzoulidis *et al*. (2015), Frankel *et al*. (2018), and Rathebe (2018), exposure to RF fields is associated with thermal effects and excitation of electro-sensitive tissues, which could lead to thermoregulatory failure.

The present guidelines focus on limiting occupational exposure to SMFs (ICNIRP, 2009), high RF EMFs (ICNIRP, 2020) and time-varying magnetic fields (ICNIRP, 2014) that produces induced health outcomes as a result of movement of workers in the MRI (ICNIRP, 2014; Hartwig *et al*., 2018). According to SCENIHR (2015) and Frankel *et al*. (2018), little attention has been given to cases where there is exposure to different MRI-related EMFs at the same time. In this study, RF magnetic fields and SMFs were quantified from 1.5 and 3.0 T MRI scanners to present an exposure scenario that could lead to induced thermal effects and SMF-related health outcomes. In 2017, Andreuccetti *et al*. investigated the exposure levels of SMFs near 1.5, 3.0 and 7 T MRI scanners. The exposure data in 1.5 and 3.0 T were compliant with 2013/35/EU Directive exposure limit values for static fields and ICNIRP-2014 basic restriction aimed at preventing vertigo. Contrary to this, findings made by Wilén and de Vocht (2011), Heinrich *et al*. (2013), and Schaap *et al*. (2016) suggest that health complaints are significantly related to the strength of the magnet, particularly on both 1.5 and 3.0 T scanners. This pointed the need to find out if exposure levels of RF magnetic fields and SMFs in hospitals within the central region of South Africa could present health and safety risks amongst staff working closer to 1.5 and 3.0 T MRI scanners.

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3.2 Problem Statement

In South Africa, relatively little literature exists regarding exposure of MRI staff to EMFs in the MRI units. Available studies suggest that exposure to SMFs poses health risks for radiographers, nurses, cleaners, medical physicists and maintenance technicians, with little attention to RF magnetic fields. This indicates a need to quantify the exposure levels of SMFs and RF magnetic fields in the MRI units in order to recommend compliance where necessary. The research problem I endeavoured to solve, therefore was to determine whether the strength of the fields could change during various scan procedures performed in hospitals included in this study. To find answers to the research problem the exposure levels of SMFs and RF magnetic fields were assessed.

3.3 Methodology

3.3.1 Study design

This study adopted a descriptive, quantitative design to describe the exposure levels of RF magnetic fields and SMFs emitted by the MR scanners in two hospitals. Since there is a well defined number of MR scanners per hospitals, a total sampling was used to measure exposure levels of RF magnetic fields and SMFs emitted by 1.5 and 3.0 T MRI scanners present in hospitals A and B within Bloemfontein. Measurements were collected from MR zone IV where MRI scanners are located. The emission data was measured from two 1.5 T scanners in hospital A (Signa GE medical systems) and B (MAGNETOM Aera, Siemens), and one 3.0 T scanner in hospital A (Philips). Ethical clearance and permission from Free State department of health were obtained prior commencement of this study (outlined in chapter 1).

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3.3.2 Piloting the instrument: spot measurements

The measurements were piloted on a 1.5 T scanner in hospital B when two brain scan procedures were performed in June 2018. The THM1176 3-Axis hall magnetometer was used to measure SMFs and a TriField meter model XE100 to measure RF magnetic fields. Due to incompatibility of the Trifield meter, TM-196 3 Axis RF Field strength meter was used. Measurements were first conducted in zone III of the MRI unit and no readings were obtained for SMFs at a distance of 1 m and 2 m outside the wall of zone IV (MRI scanner room), in the control room. Readings were noted for RF magnetic fields; however, there was no distinction of whether the fields were emitted by the scanner or communication devices in zone III. Measurements were further conducted in zone IV at a distance of 1 m and 2 m from the scanner for both RF magnetic fields and SMFs. Readings were obtained at a distance of 1 m; however, at 2 m, no readings were obtained for RF magnetic fields when patients were scanned for brain and extremities.

3.3.3 Measurements: SMFs and RF fields in MR zone IV

Prior data collection, the measurement technique was discussed with the clinical engineer who is responsible for acceptable testing and maintenance of the 3.0 T MRI scanner in hospital A. MRI chief radiographers in hospital A and B also assisted in determining days when brain, cervical spine and extremities scans were performed. At the time of data collection, 2018, an average of 20 patients were scanned per day in both facilities. This included patients mostly scanned for brain and cervical spines on neurosurgery day (6 to 10 patients per day) and an average of three whole-body scans. Upon obtaining this information, the measurement procedure was then conducted in two rounds. Measurements for SMFs were collected in the first round

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and RF magnetic fields followed in the second round, with the absence of MRI personnel in zone IV.

3.3.4 Static magnetic fields measurements: round one

Spot measurements were collected using distance as an exposure surrogate. Distance points were chosen as realistic exposure pathways where MRI staff move and perform duties around the scanners and also when entering zone IV. The purpose was to obtain exposure levels at different distances across MR zone IV. A manufacturer calibrated THM1176 3-Axis hall magnetometer was used to measure the exposure levels for SMFs. The magnetometer has a range from low fields to 20 T, DC to 1 kHz, and provide ±1 % accuracy. Exposure levels were measured at a distance of 1 m and 2 m away from the scanner, similar to a technique used by Sakurazawa *et al*. (2003). The magnetometer height and distance: 1 m and 2 m on the front, left and right side (Figure 3.1) of the scanner were determined using a cloth measuring tape with linear-measurement markings. A THM1176 3-Axis hall magnetometer was positioned at a height of 1 m from the ground, with probe sensor facing the scanner magnet. The height was chosen to representative where most of the MRI activities are performed and as an approximate height chosen in a study conducted by Bonutti *et al*. (2016) and Fatahi *et al*. (2017).

A single THM1176 3-Axis hall magnetometer was mounted to aluminium tripod and rotated between different measurement spots once every scan was completed. Measurements were taken on an average of 30 minutes on each spot and the hold button on magnetometer was pressed when time expired. The maximum exposure value (max. B) displayed directly from the magnetometer was noted manually on a data-recording sheet. Sixty measurements were collected at a distance of 1 m and 60

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measurements at a distance of 2 m from the gantry. During measurement collection, MRI personnel was situated in the control room (zone III) scanning the patients. Scanners included in this study use passive shimming to correct static magnetic fields inhomogeneity and because of temperature sensitivity of shim materials, B_0 may shift during gradient-intensive sequences (Jezzard, 2006), resulting in each patient placed within the scanner creating a unique pattern of inhomogeneity. Based on this reasons and also to homogenize the measurement approach between SMFs and RF magnetic fields, exposure levels of static stray fields were only recorded when brain, cervical spine and extremities were scanned from 1.5 and 3.0 T scanners. Twenty spot measurements were recorded during brain scan, 20 during cervical spines and 20 when extremities were scanned. Throughout the entire measurement period, a total 720 measurements were collected from hospital A, with 360 measurements collected from each scanner. In hospital B, 360 measurements were collected from the 1.5 T scanner, amounting to a total of 1080 measurements collected for SMFs emissions.

3.3.5 Radiofrequency magnetic fields measurements: round two

A manufacturer calibrated TM-196 3 Axis RF Field strength meter was used to measure the RF magnetic fields. The tenmars (TM) -196 can measure the RF fields ranging from 10 MHz to 8 GHz. Prior to measurement collection, the TM-196 3 Axis RF Field strength meter was mounted on the aluminium tripod at a height of 1 m from the ground, with the sensor facing the MRI scanner. The exposure levels for RF magnetic fields were measured at distance of 1 m from the MRI scanner gantry on right and left side. Based on the specific absorption rate (SAR) limit values for a duration of six minutes (International Electrotechical Commission, 2010), exposure levels were measured on an average of six minutes and recorded on a data-recording sheet in microTesla (µT). A stopwatch timer was used to determine the recording time

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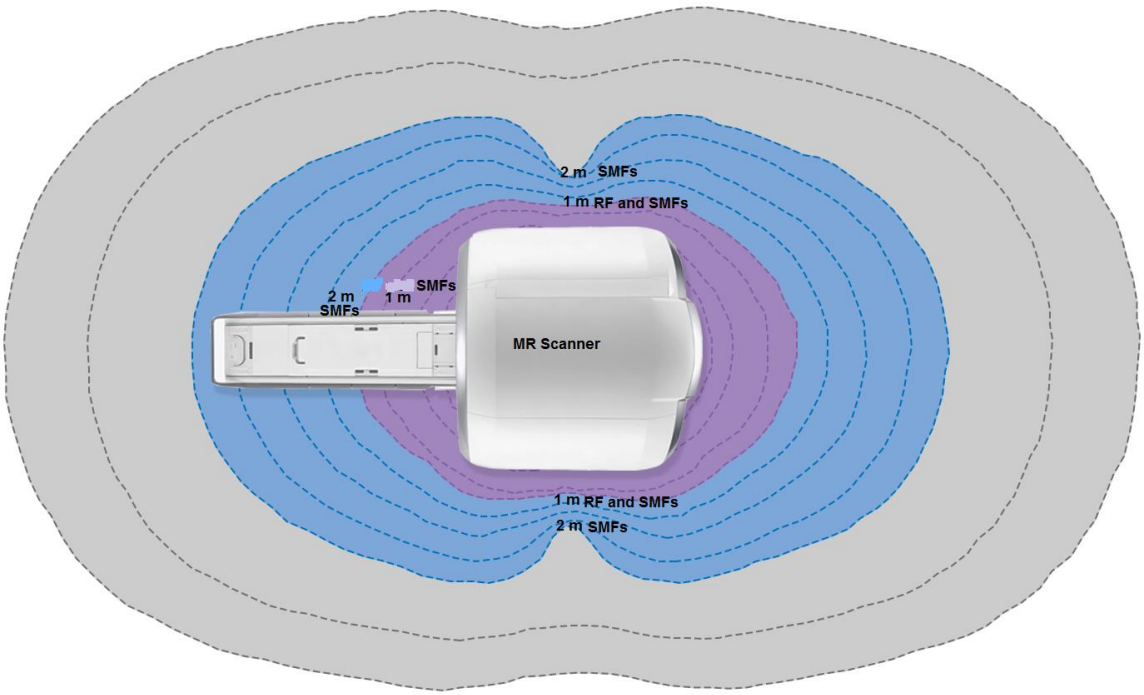
once the MRI personnel start to actuate the RF pulse. The measurements were collected at a distance of 1 m only when MRI scans were performed on patients. In each side of the scanner, 30 measurements were collected when brain scans were performed, 30 during cervical spines and 30 during extremities scans. A total of 180 measurements from each scanner, which resulted to 540 measurements, collected for RF magnetic fields exposures from the three scanners in both hospitals.



***SMFs spot monitoring: measurements on the left and right side were collected adjacent to the magnet housing. Front measurements were collected next to the patient table. All measurements were taken in zone IV. **RF magnetic fields spot monitoring: measurements were collected adjacent to the magnet housing (gantry).**

Figure 3.1: SMFs and RF magnetic fields sampling positions

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3.3.6 Calibration checks of measurement instruments

The THM1176 3-Axis hall magnetometer and TM-196 3 Axis RF Field strength meter were within a valid calibration period of the manufacturer: which is 18 months for magnetometer and 12 months for the RF Field strength meter. The calibration status check was performed on both meters. The THM1176 3-Axis hall magnetometer probe was placed on the zero gauss chamber (ZGC) to eliminate any offset errors by zeroing the readings. The RF Field strength calibration status was validated by crosschecking the meter's battery life, temperature and humidity operating conditions against operating requirements of the manufacturer.

3.3.7 Data analysis

Data was captured electronically by the researcher on SPSS version 26.0. Parametric tests were performed to test for normalities using the Shapiro-Wilk test. The independent t-test was performed using Levene's test of equality of variance. To compare emission levels based on scans performed, pairwise comparison tests were performed. Non-parametric tests were also performed using Friedman's test followed by Wilcoxon test and a statistical significance level (α) of 0.05 was used. Prior performing Wilcoxon test, Bonferroni adjustment was applied at a statistical significance level (α) of 0.02 to avoid type I statistical error.

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3.4 Results

3.4.1 Static Magnetic Fields emissions

The strength of stray static fields was measured in selected distance spots from MRI scanners. Common scan procedures performed in both hospitals were considered when measuring stray static fields. This included evaluating if stray static fields could change during different scan procedures. Periodic maintenance of the MRI scanners included in this study is conducted every second year, followed by acceptable testing performed four times annually by maintenance engineers of respective MRI vendors. Medical Physicists also conduct quality control tests weekly on the scanners included in this study. In order to evaluate compliance, exposure mean values from three scanners were benchmarked with ICNIRP (2009) guidelines under occupational exposure. Exposure mean values measured at different distances from two 1.5 T scanners were compared (Table 3.1). Further comparisons were made when brain, cervical spine and extremities were scanned. Similar comparisons were made for the 3.0 T scanner (Table 3.2).

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Table 3.1: The measured values of SMFs exposure at 1 and 2 m from two 1.5 T scanners in hospital A and B

Hospitals	Sampling position and scan performed	Mean (mT) and Std. Deviation	Minimum	Maximum	Range	Occupational exposure limits
Hospital A	Front Brain 1 m Right Brain 1 m Left Brain 1 m	623.30 ± 64.13 619.0 ± 48.07 602.10 ± 43.04	504 551 515	684 694 641	180 143 126	< 2 T for the head and trunk as well as 8 T for limbs
	Front Cervical spine 1 m Right Cervical spine 1 m Left Cervical spine 1 m	644.70 ± 40.55 653.0 ± 34.0 657.0 ± 39.56	586 590 598	699 706 705	113 116 107	
	Front Extremities 1 m Right Extremities 1 m Left Extremities 1 m	603.20 ± 66.16 582.60 ± 56.19 613.70 ± 65.39	522 509 508	697 697 695	175 188 187	
	Front Brain 2 m Right Brain 2 m Left Brain 2 m	297.10 ± 43.16 312.80 ± 34.37 281.0 ± 48.38	229 257 227	343 348 349	114 91 122	
	Front Cervical spine 2 m Right Cervical spine 2 m Left Cervical spine 2 m	341.40 ± 18.99 337.4 ± 24.01 330.3 ± 22.64	311 300 302	370 368 368	59 68 66	
	Front Extremities 2 m Right Extremities 2 m Left Extremities 2 m	294.20 ± 28.36 295.70 ± 26.72 297.40 ± 33.44	255 251 256	337 331 343	82 80 87	
Hospital B	Front Brain 1 m Right Brain 1 m Left Brain 1 m	669.90 ± 25.66 651.40 ± 31.53 653.60 ± 36.61	631 609 603	709 700 710	78 91 107	
	Front Cervical spine 1 m Right Cervical spine 1 m Left Cervical spine 1 m	672.70 ± 25.85 690.30 ± 30.93 676.30 ± 33.06	635 647 636	713 732 726	78 85 90	
	Front Extremities 1 m Right Extremities 1 m Left Extremities 1 m	650.10 ± 39.45 644.70 ± 23.13 650.90 ± 36.72	601 619 610	709 681 708	108 62 98	
	Front Brain 2 m Right Brain 2 m Left Brain 2 m	323.0 ± 15.73 336.60 ± 14.86 330.50 ± 12.97	302 308 309	341 352 345	39 44 36	
	Front Cervical spine 2 m Right Cervical spine 2 m Left Cervical spine 2 m	349.80 ± 8.24 342.50 ± 8.46 343.10 ± 8.91	334 333 332	362 357 358	28 24 26	
	Front Extremities 2 m Right Extremities 2 m Left Extremities 2 m	319.0 ± 13.10 327.80 ± 24.03 341.40 ± 12.33	300 300 318	342 354 355	42 54 37	

3.4.1.1 *Comparison of the 1.5 T scanners in hospital A and B*

The stray SMFs emissions were compared between hospital A and B from two different 1.5 T MRI scanners. Parametric analysis were performed using the Shapiro-Wilk test to assess underlying differences between exposure levels recorded from the front of both scanners in 1 and 2 m. Exposure mean values recorded for different scan

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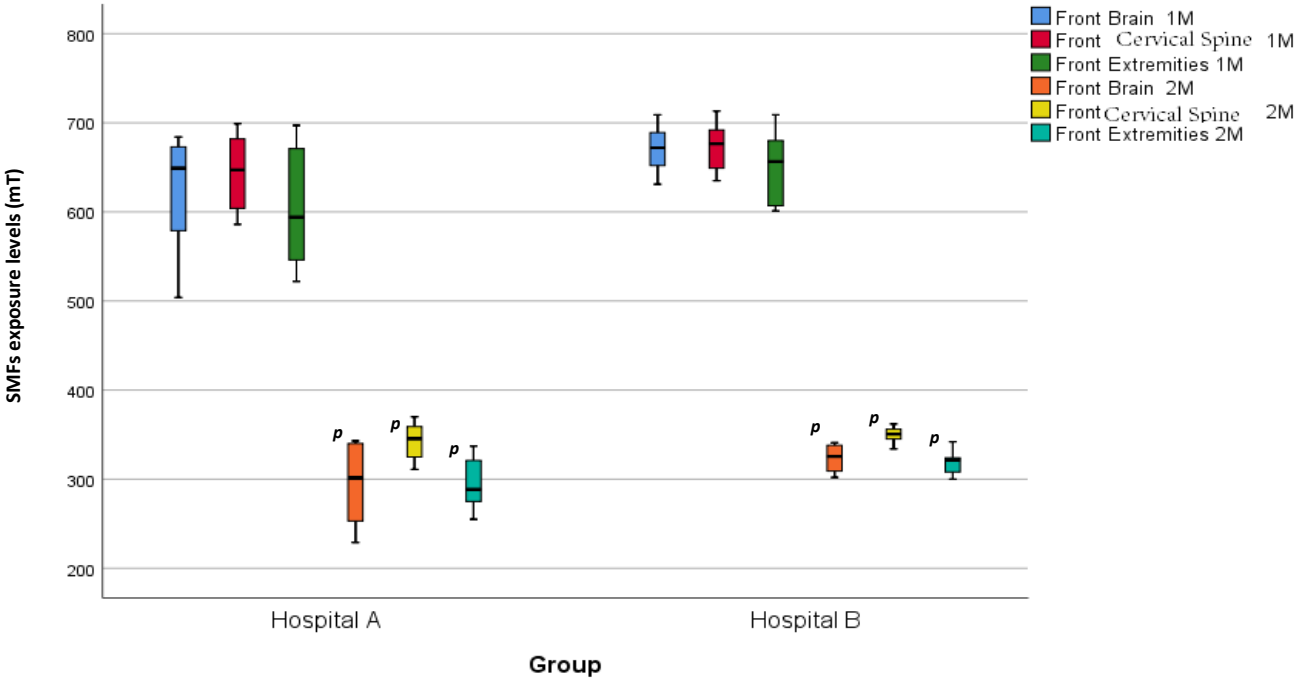
procedures. i.e. brain, cervical spine and extremities were considered and no significant differences were observed. However, the independent sample test performed using Levene's test for equality of variance suggested a statistical significant difference for extremities at 2 m (p<0.026). Similar comparisons made for 1.5 T scanners in both hospitals for the right side suggested a statistical significant difference when exposure levels recorded for extremities at a distance of 2 m (p<0.012) were performed (Figure 3.2b). In contrast, exposure levels recorded on the left side of both scanners in 1 and 2 m when brain, cervical spine and extremities were scanned shown a statistical non-significant difference (Figure 3.2c).



***Mean exposure values displayed in table 1; *p*= significant difference**

Figure 3.2a: Comparison of SMFs exposure levels measured on the front side at 1 and 2 m in hospital A and B

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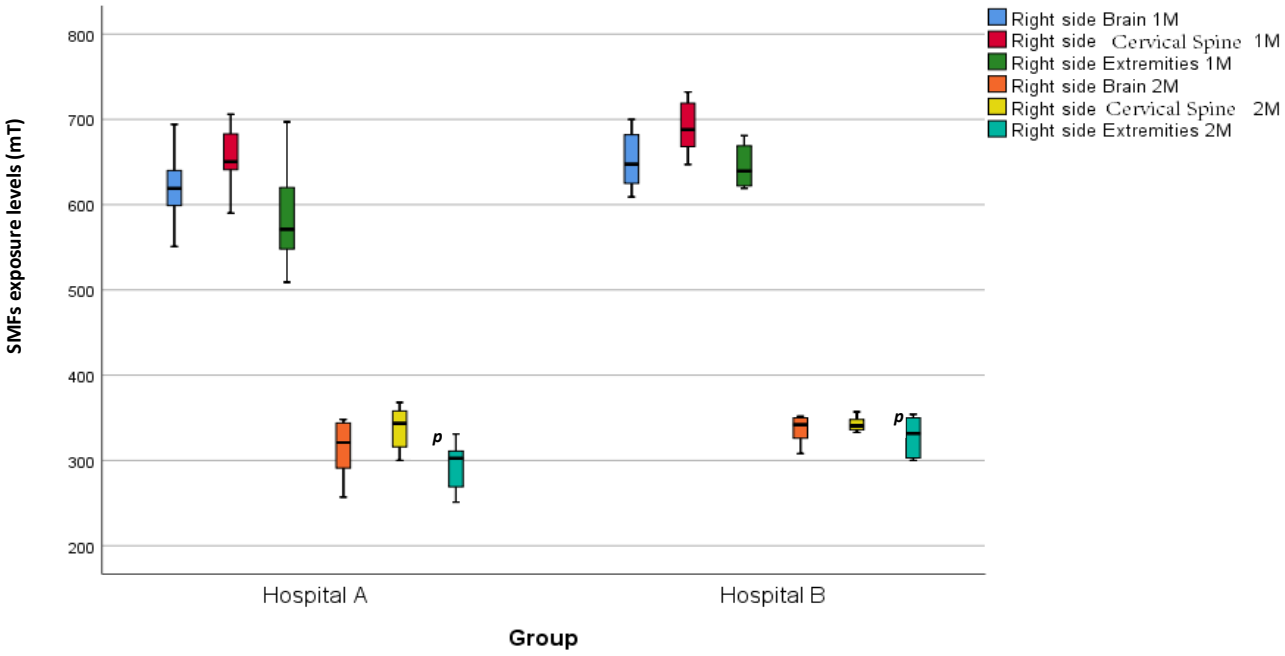

***Mean exposure values displayed in table 1; *p*= significant difference**

Figure 3. 2b: Comparison of SMFs exposure levels measured on the right side at 1 and 2 m in hospital A and B

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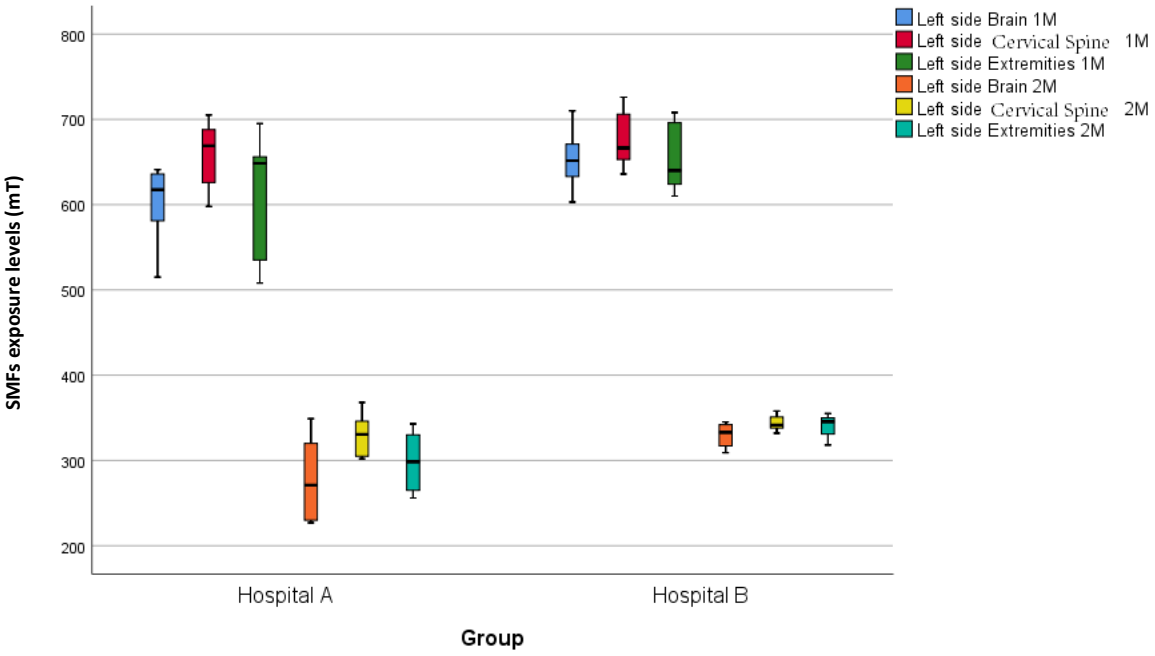

***Mean exposure values displayed in table 1**

Figure 3.2c: Comparison of SMFs exposure levels measured on the left side at 1 and 2 m in hospital A and B

A non-parametric Friedman's test was used to compare exposure mean values in all measurement positions when different scans were performed in both hospitals. At 1 m, a statistical significant difference in hospital A (p<0.014) for the left side and also hospital B for the right side (p<0.008) was found. At 2 m, both hospitals showed a statistical significant difference for the front side (p<0.025 and p< 0.001) and right side in hospital A (p<0.020). Furthermore, the Wilcoxon test was performed for all measurement sides and Bonferroni adjustment was applied (0.02). At 1 m in hospital B, the difference was observed between cervical spine and extremities (p<0.005) and in hospital A, there was a difference between cervical spine and the brain (p<0.013). At 2 m in hospital A, differences in the front side were observed between cervical spine and brain mean values (p<0.017) as well as extremities and cervical spine (p<0.013) (Figure 3.2a). Similarly, differences were observed between the cervical spine and

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brain (p<0.005) as well as extremities and cervical spine (p<0.005) in hospital B. On the right side, differences were only observed when exposure mean values for extremities were compared with cervical spine measurements (p<0.005). Pairwise comparisons with Bonferroni adjustment were performed between exposure mean values recorded for the brain, cervical spine and extremities' scans at a distance of 1 m. The difference was noted between cervical spine and extremities (p<0.0003) for the right side as well as cervical spine and brain (p<0.003) for the left side. There was also significant difference at 2 m between brain and cervical spine (p<0.001) as well as cervical spine and extremities (p< 0.0001) for the front side. A comparison between cervical spine and extremities (p< 0.0001) for the right side as well as brain and cervical spine (p<0.008) for the left side suggested a statistical significant difference.

3.4.1.2 *Comparison of measurements from 3.0 T scanner*

The Shapiro-Wilk test was performed to compare exposure levels resulting from different distances, taking into account different scans performed. A statistical significant difference was noted at 2 m, front side when brain scans were performed (p<0.02). A Friedman's test comparison between the brain, cervical spine and extremities' front mean values at a distance of 1 m indicated a non-significant difference. However, a difference was observed between brain, cervical spine and extremities (p<0.002) at 2 m. Using Bonferroni adjustment, the Wilcoxon test suggested a difference between cervical spine and extremities (p<0.013) at a distance of 1 m, brain and cervical spine (p<0.007) as well as cervical spine and extremities (p<0.005) at 2 m.

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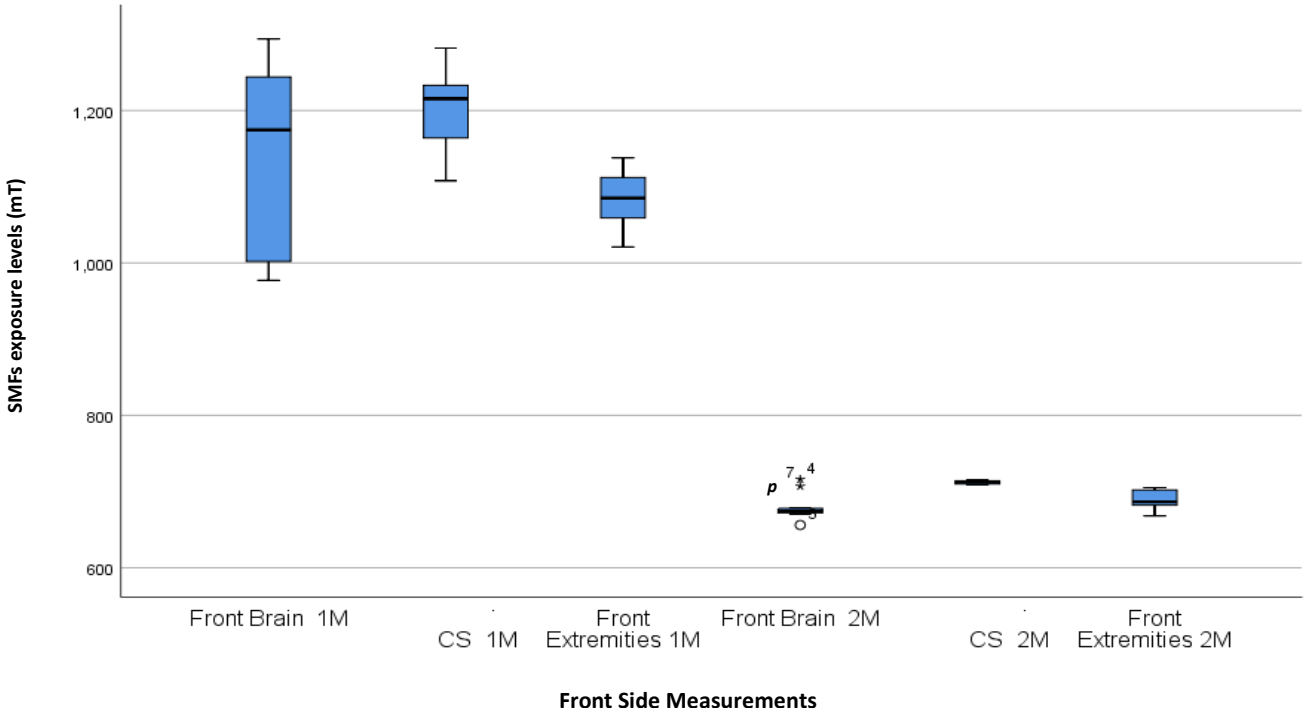
Table 3.2: The measured values of SMFs exposure at 1 and 2 m from 3.0 T scanner in hospital A

Hospitals	Sampling position and scan performed	Mean (mT) and Std. Deviation	Minimum	Maximum	Range	Occupational exposure limits
Hospital A	Front Brain 1 m Right Brain 1 m Left Brain 1 m	1139.0 ± 116.85 1196.50 ± 71.43 1081.30 ± 77.33	977 1076 995	1294 1300 1216	317 224 221	< 2 T for the head and trunk as well as 8 T for limbs
	Front Cervical spine 1 m Right Cervical spine 1 m Left Cervical spine 1 m	1199.80 ± 53.85 1236.40 ± 58.43 1211.40 ± 60.61	1108 1144 1135	1282 1300 1294	174 156 159	
	Front Extremities 1 m Right Extremities 1 m Left Extremities 1 m	1084.10 ± 37.72 1052.90 ± 55.43 1047.90 ± 48.72	1021 985 1000	1138 1131 1133	117 146 133	
	Front Brain 2 m Right Brain 2 m Left Brain 2 m	680.0 ± 17.84 690.30 ± 24.76 680.40 ± 17.42	656 660 655	716 719 706	60 59 51	
	Front Cervical spine 2 m Right Cervical spine 2 m Left Cervical spine 2 m	712.20 ± 2.15 710.70 ± 0.95 712.10 ± 1.97	709 709 709	715 712 715	6 3 6	
	Front Extremities 2 m Right Extremities 2 m Left Extremities 2 m	688.30 ± 13.43 685.70 ± 12.18 696.60 ± 4.40	668 672 690	705 702 704	37 30 14	



***CS= cervical Spine; mean exposure values displayed in table 2; *p*= significant difference**

Figure 3.3a: SMFs exposure levels measured on the front of 3.0 T scanner at 1 and 2 m

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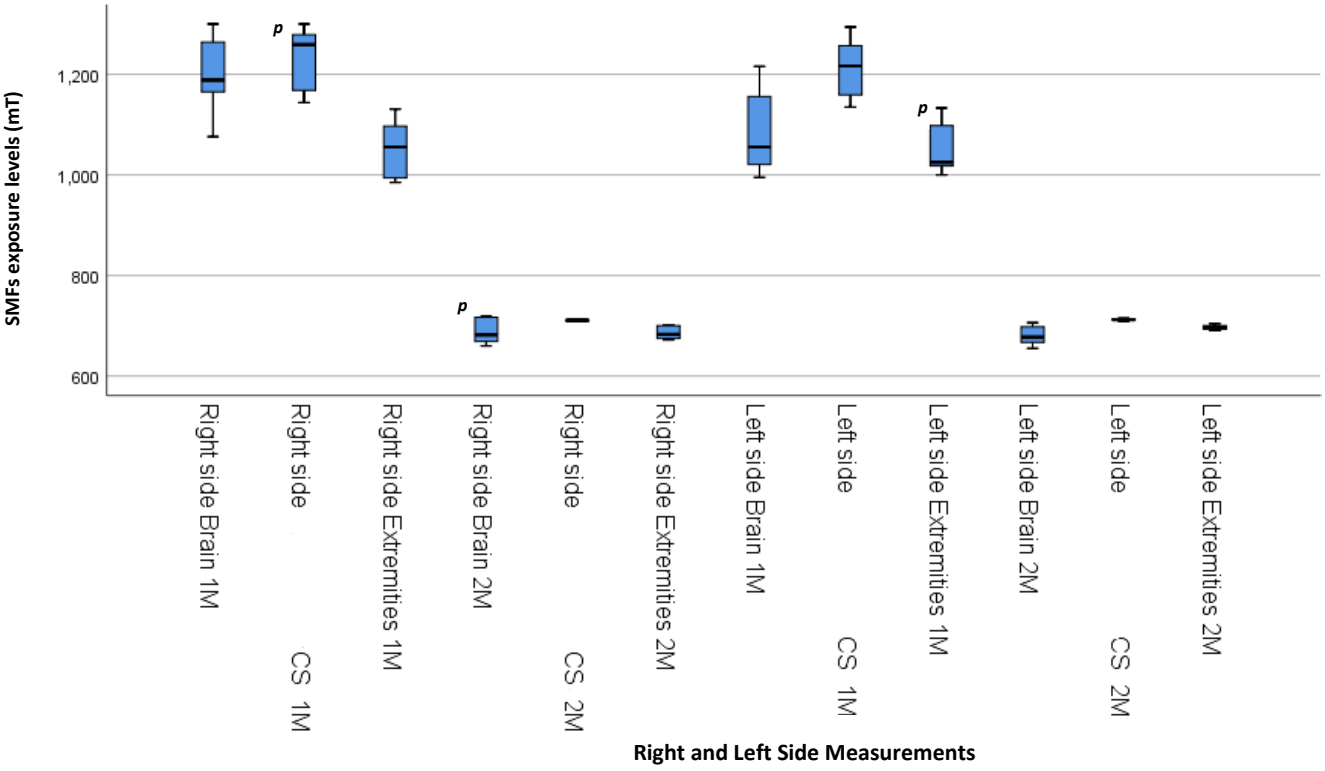

***CS= Cervical Spine; mean exposure values displayed in table 1; *p*= significant difference**

Figure 3.3b: SMFs exposure levels measured from the right and left side of 3.0 T scanner

When comparison was made for the right side exposure levels, a statistical significant difference was shown for cervical spine at 1 m (p<0.035) and brain at 2 m (p<0.038). The difference were also noted for the extremities at 1 m (p<0.013) for the left side exposure levels. The Friedman's test suggested a significant difference between brain, cervical spine and extremities at 1 m (p<0.001) and 2 m (p<0.027) for the right side measurements. To identify where there is a difference, the Wilcoxon test with Bonferroni adjustment was performed. A significant difference was shown between cervical spine and extremities (p<0.005) as well as extremities and the brain (p<0.007) at 1 m. Furthermore, the difference were also observed between extremities and

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cervical spine (p<0.005) at 2 m. Regarding comparison between exposure mean values at the left side, Friedman's test suggested a difference between brain, cervical spine and extremities at 1 m (p<0.003). The difference noted at 1 m existed between cervical spine and extremities (p<0.005). At 2 m, comparison between brain, cervical spine and extremities was significantly different (p<0.0004). Cervical spine measurements were different to the brain (p<0.005) and extremities were different to cervical spine measurements (p<0.005).

3.4.2 Radiofrequency fields emission

The RF magnetic fields emitted by two 1.5 T scanners were compared to evaluated compliance with ICNIRP of 2020, reference levels for local exposures averaged over 6 minutes (located in Table 3.3). The Incident H-field strength of 0.36 A m^{-1} occupational exposure limit was converted to 0.45 µT. Two 1.5 T scanners were compared to each other to assess if there is any difference with regard to RF magnetic fields emission on two sides of the scanners (right and left). Furthermore, RF emissions from 3.0 T scanner in hospital A were also measured to evaluate compliance. This was done by comparing exposure levels from different sides of the scanner when brain, cervical spine and extremities were scanned. Exposure levels were recorded for an average of 6 minutes at each measurement spot, when RF pulse was activated. The distribution of RF magnetic field levels is presented in Figure 3.4a and 3.4b below.

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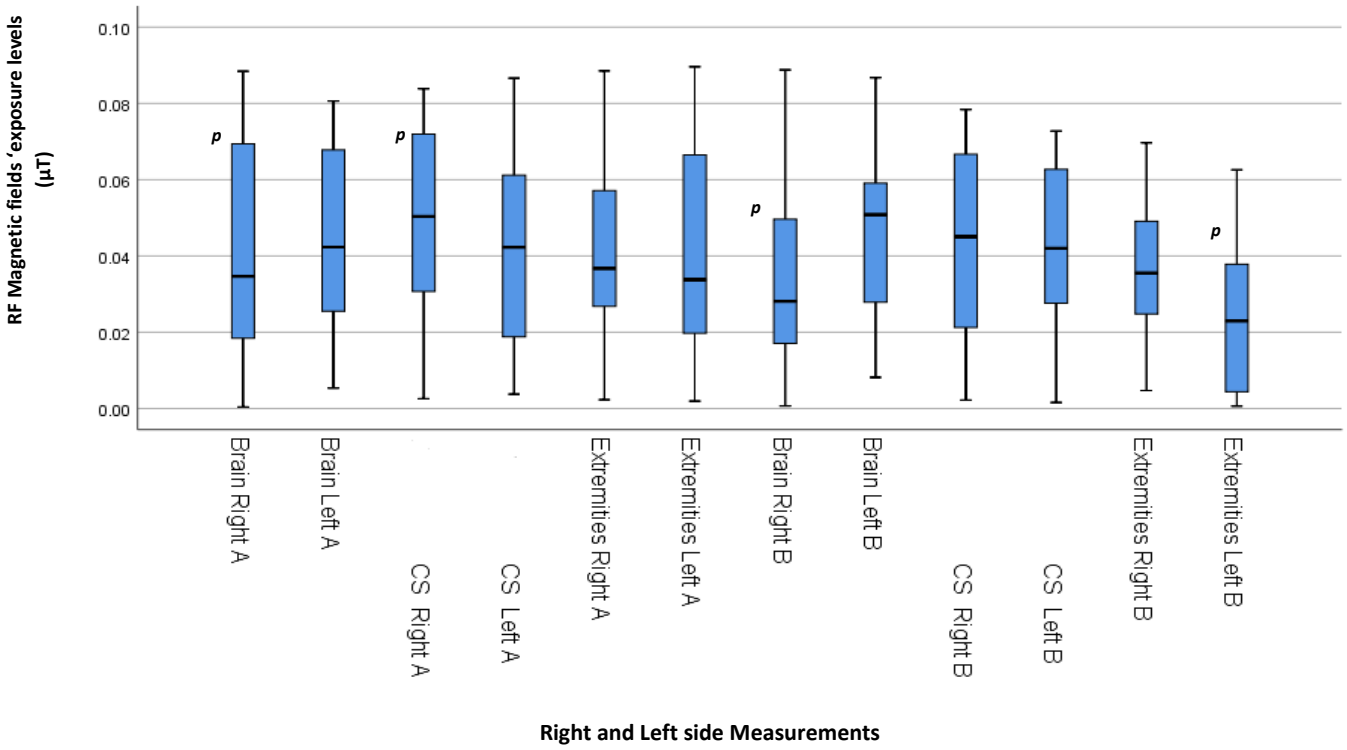

*CS= Cervical spine; A= Hospital A- mean 0.043 µT Std. 0.003; B= Hospital B- mean 0.039 µT Std. 0.008; *p*= significant difference

Figure 3.4a: Distribution of RF magnetic fields recorded at hospitals A and B from two 1.5 T MRI scanners

3.4.2.1 *Comparison between two 1.5 T scanners in hospital A and B*

Exposure levels recorded when brain, cervical spine and extremities scans were performed in both 1.5 T scanners were compared to one another. Similar comparisons were also performed between exposure levels recorded from the left and right side at a distance of 1 m from the scanners. Initially, Shapiro-Wilk test was performed to check for differences between exposure levels recorded during different scan procedures. In hospital A, significant difference was shown between repeated measurements taken at the right side of the scanner when brain (p<0.03) and cervical spine (p<0.04) scans were performed. The differences were also noted during brain scans (p<0.008) at the

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right side and extremities (p<0.02) at the left side in hospital B. The descriptive RF exposure values recorded in hospital A and B are described in table 3.3.

Table 3.3: The measured RF exposure values from two 1.5 T and one 3.0 T scanners in hospital A and B

Hospitals and magnetic flux	Scan performed	Sampling position	Mean µT and Std.	Minimum	Maximum	Range	Reference levels for local exposures averaged over 6 minutes
Hospital A 1.5 T scanner	Brain	Right	0.04 ± 0.03	0.0004	0.09	0.09	< Incident H-field strength of 0.36 A m^{-1} limit= 0.45 µT
		Left	0.05 ± 0.02	0.005	0.08	0.08	
	Cervical spine	Right	0.05 ± 0.03	0.003	0.08	0.08	
		Left	0.04 ± 0.03	0.004	0.09	0.08	
	Extremities	Right	0.04 ± 0.03	0.002	0.09	0.09	
		Left	0.04 ± 0.03	0.002	0.09	0.09	
Hospital B 1.5 T scanner	Brain	Right	0.04 ± 0.03	0.001	0.09	0.09	
		Left	0.05 ± 0.02	0.01	0.09	0.09	
	Cervical spine	Right	0.04 ± 0.02	0.002	0.08	0.08	
		Left	0.04 ± 0.02	0.002	0.07	0.07	
	Extremities	Right	0.04 ± 0.02	0.005	0.07	0.07	
		Left	0.02 ± 0.02	0.001	0.06	0.06	
Hospital A 3.0 T scanner	Brain	Right	0.1 ± 0.06	0.004	0.2	0.2	
		Left	0.11 ± 0.06	0.001	0.2	0.2	
	Cervical spine	Right	0.1 ± 0.06	0.005	0.2	0.2	
		Left	0.1 ± 0.06	0.003	0.2	0.2	
	Extremities	Right	0.1 ± 0.06	0.01	0.2	0.2	
		Left	0.1 ± 0.05	0.004	0.2	0.2	

The Friedman's test was used to compare right side exposure levels for all scans performed in hospital A and B, and statistical non-significant difference was found. However, the difference was shown when comparing exposure levels for the left side in hospital B (p<0.001). When using Wilcoxon test with Bonferroni adjustment, exposure levels for the extremities were different to the brain (p<0.001) and also extremities to the cervical spine (p<0.004). Paired samples correlation was performed to assess if exposure levels recorded from the left and right side of both scanners were

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correlated, and no correlation was found between the measured RF magnetic fields levels in both hospitals. Using Bonferroni adjustment, Wilcoxon test was performed to assess the difference between measurement sides in both hospitals. Exposure levels recorded from the left side during extremities' scans in hospital B were different to the ones recorded on the right side (p<0.01).

3.4.2.2 *Comparison of RF magnetic field levels from 3.0 T scanner in hospital A*

The repeated measurements recorded during brain scans varied significantly for the right (p<0.02) and left side (p<0.04), and also for cervical spine (p<0.05) on the left side of the scanner. Using a Wilcoxon's test to compare exposure levels recorded during brain, cervical spine and extremities' scans on the left and right side of the scanner, a non-significant difference was found. A paired samples correlation was performed to determine if exposure levels recorded on both sides of the scanner were correlated, and no correlation was found. Figure 3.4b below presents quantile distribution of RF fields during different scan procedures.

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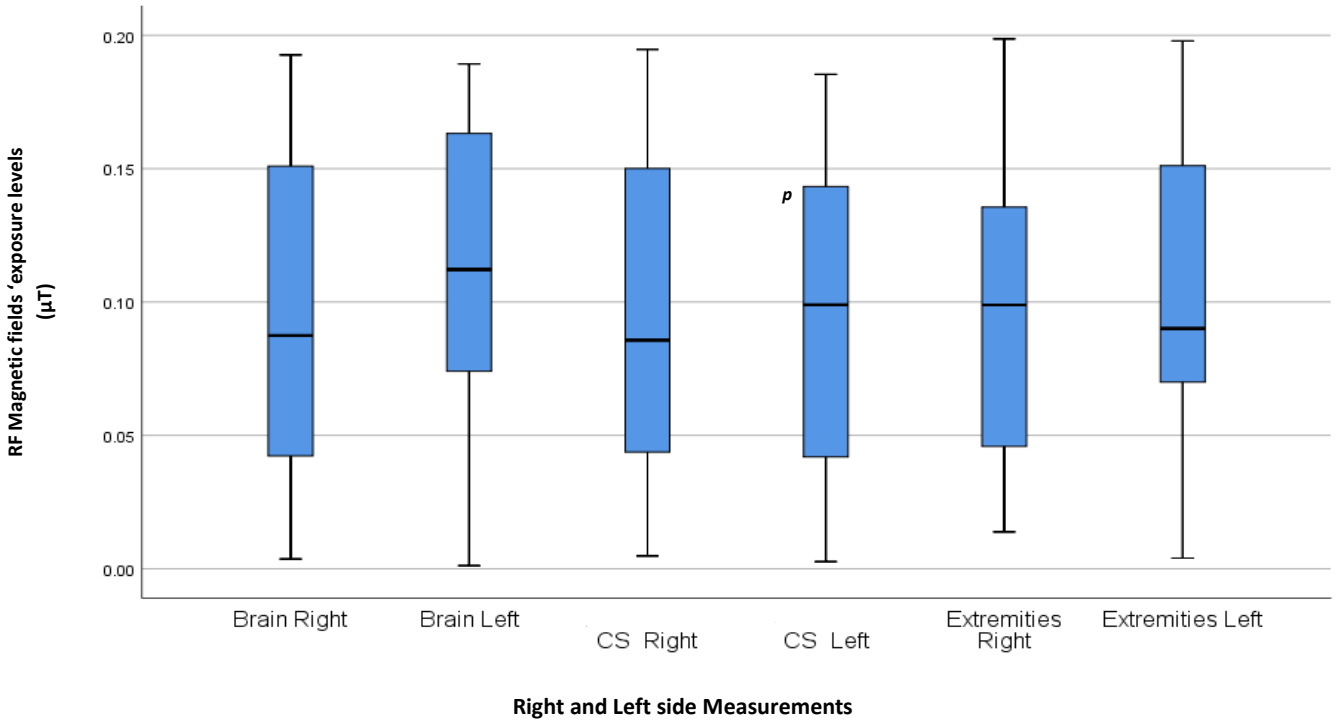

***CS= Cervical spine; Hospital A- Mean 0.1 µT Std. 0.006; *p*=significant difference**

Figure 3.4b: Distribution of RF magnetic fields recorded from 3.0 T MRI scanner

3.5 Discussion

3.5.1 Static Magnetic Fields emissions

The results of this study suggest that 1.5 T MRI scanners located in hospital A and B had different propagation of SMFs though the nominal B_0 is the same. This finding accords results of a recent study conducted in Italy by Hartwig *et al*. (2019). Riches *et al*. (2007) also indicated a significant difference between two 1.5 T scanners with a measured magnetic flux of 1540 mT in machine A and 700 mT in machine B. Although the measured stray fields from two 1.5 T scanners were different, it is worth noting that stray static fields were also different between two distance points, 1 m and 2 m from the scanners. This has also been observed in studies that quantified stray static fields in various distances from the scanner bore (Decat, 2007; Karpowicz *et al*., 2007; Acri

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et al., 2014). The significant difference was noted at a distance of 2 m when comparing both 1.5 T scanners. The 1.5 T and 3.0 T scanner rooms in hospital A are located adjacent to each and this could be a major influence of stray static fields measured at a distance of 2 m from both scanners. The variation noted in the levels of stray static fields cannot be attributed to different scans performed. However, since repeated measurements were recorded on different imaging days, it can be noted that stray static fields propagate non-uniformly from scanners of the same nominal B_0 (1.5 T included in this study). Both scanners are manufactured by different MR vendors and this suggest that configurations such as static magnetic field shielding, magnet type and clinical setting for installation are not similar.

Although this study used a spot monitoring, different to exposure assessment approaches used in other studies (spot measurement v/s personal monitoring), the recorded exposure levels correspond with exposure values reported by Groebner *et al*. (2011), Schaap *et al*. (2013), Andreuccetti *et al*. (2017) and Sannino *et al*. (2017). Since comparison between 1.5 T and 3.0 T scanners would have yielded significant results, exposure levels recorded from 3.0 T scanner were compared according to distance points. A major difference in the 3.0 T scanner was also observed at 2 m, and this could be attributed to its proximity to 1.5 T scanner. Though the scanner rooms are shielded, stray static fields could extend beyond the walls of zone IV into the control room (Schaap *et al*., 2013). The purpose of this study was to evaluate compliance for occupational exposure to SMFs in zone IV and the recorded exposure levels comply with occupational exposure guidelines stipulated under ICNIRP (2009). Although high exposure levels were detected at 1 m, none of them were above the exposure limit of 2 T for the head and trunk as well as 8 T for limbs.

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3.5.2 Radiofrequency fields emission

Studies reporting on the RF magnetic stray fields in the MRI units are far less available, and McRobbie (2012) has also noted the dearth of literature on RF magnetic fields in the MRI facilities. It has been noted in the literature that many studies are epidemiological, and they are based on a dose-response relationship between exposure and thermal effects (Hansson-Mild *et al*., 2012; Hartwig, 2015; Hansson-Mild and Mattsson 2017; Fiedler *et al*., 2018; Destruel *et al*., 2019). In this study, the RF magnetic fields were measured at a distance of 1 m from two 1.5 T and one 3.0 T scanners. Similar RF peak value of 0.09 µT were observed in both 1.5 T scanners and 0.2 µT from 3.0 T scanner. Capstick *et al*. (2008) reported a peak value of 0.08 µT when RF fields' measurements from a 3.0 T scanner were recorded, and this value correlates with a peak exposure value of 0.09 µT measured near a 1.5 T scanners included in this study. In addition, a mean value of 0.1 µT recorded from majority scans performed in 3.0 T scanner accords with exposure values reported in the aforementioned study.

This results of this study shows that emission of RF magnetic fields does not differ significantly between two 1.5 T scanners included in this study. The difference exist between 1.5 T and 3.0 T scanners as well as different scan procedures performed. This is in agreement with the findings made by Frankel *et al*. (2015), Frankel *et al*. (2019) and Hansson-Mild *et al*. (2019). Their results suggest that RF fields vary per strength of the scanner and the variation is influenced by the RF pulse design and sequence settings-flip angle. Frankel *et al*. (2018) also noted that scan protocols contain a number of sequences, which gives significant exposure differences between brain, cervical spine and extremities scans. Furthermore, RF magnetic fields recorded

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from the three scanners comply with the RF electromagnetic fields (EMF) ICNIRP guidelines (2020), reference levels for local exposures.

3.6 Conclusion

The results of this study demonstrate that the three scanners from two hospitals respect ICNIRP guidelines in terms of occupational exposure to both SMFs and RF magnetic fields. However, the configuration of scanners such clinical setting, magnetic field shielding and magnet type influence propagation of stray static fields in zone IV. The emission of RF magnetic fields is primarily influenced by factors such as scans performed, RF pulse design and sequence settings-flip angle. The limitation (fully discussed in chapter 7) represented by this study was including only three MRI scanners. In the central region of South Africa, Free State, MRI services are only performed in hospitals included in this study. For this reason, this study presented exposure levels of SMFs and RF magnetic fields that MR and non-MR staff could be exposed to in zone IV while attending patients in public hospitals. Peak exposure levels exist at a distance of 1 m from all three scanners, this represent a distance where most MRI staff are likely to perform their tasks. However, exposure to such fields could be managed through adoption of occupational health and safety programmes. Furthermore, measurement results presented in this study are likely to exemplify exposure scenarios in South African healthcare setting, since the use of 1.5 and 3.0 T scanners is common.

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Chapter 4
Health effects and safety risks among staff working with 1.5 and 3.0 T MRI scanners within public hospitals in Mangaung metropolitan region

Abstract

This study aimed to assess health effects associated with static magnetic fields (SMFs) and radiofrequency (RF) energy amongst MR staff and safety risks in 1.5 and 3.0 T MRI units. Data were collected through questionnaires completed by 77 MR staff members working in hospital A and B (49), as well as control group (28) in the Mangaung metropolitan region. Questionnaires also were administered to four MR staff members. The study participants comprised 57.14% females and 42.86% male participants with an average MRI experience of 5.41 years. The cross-tabulation followed by chi-square test and calculation of odds ratio were used to determine association between working in the MRI units, safety around MRI scanners, and development of transient health effect. Interview data consisting of operational safety, departmental policies and training programmes in the MRI units were transcribed and grouped into themes for thematic analysis. There was a significant difference between job titles and safety around the scanners ($p< 0.0023$), as well as the number of years working in the MRI units ($p< 0.0002$). Headache was significantly associated with perceived MRI safety ($p< 0.014$). MRI staff were more likely (OR 39.15, 95% CI: 4.91- 312.02) to experience transient health effects compared to the control group ($p <0.0001$), with radiographers being affected the most (OR 60.75, 95% CI: 5.99- 616.67). SMFs exposure effects such as vertigo, feeling of instability and metallic taste were significantly associated with shift duration and movement of head/upper body in the scanner bore. However, RF exposure effects were mainly associated with job title and presence in the scanner room for longer durations of time. MRI safety policies, safety training of MRI staff, demarcation of safety zones and absence of ferromagnetic detectors were identified as shortfalls in both hospitals. Performance of MRI-related activities in close proximity to the scanner bore and longer shift durations could prove SMFs and RF energy related health effects and perception of unsafety. Therefore, an MR safety programme and training of all MRI staff are necessary.

Keywords: Health effects; MRI safety; questionnaires; interviews; 1.5 and 3 T scanners

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4.1 Introduction

Magnetic resonance (MR) staff provides routine care to patients undergoing MRI procedures, and the implications for these patients are well-known and have been addressed in many studies. However, literature is scarce with regard to the occupational hazards and risks associated with the exposure of MRI staff to the magnetic fields emitted by MRI scanners (Gorlin *et al*., 2015). Several studies indicate that staff who works with MRI scanners commonly develop transient symptoms such as nausea, dizziness, a metallic taste, magneto phosphenes, severe headaches, tinnitus, and concentration problems in severe cases (De Vocht *et al*., 2015; Fatahi *et al*., 2016; Schaap *et al*., 2016). These symptoms are ascribed to exposure scenarios that include static magnetic fields (SMFs) (Schaap *et al*., 2014). For the purpose of this study, transient health effects refer to the short-term health effects experienced by MRI staff following exposure to SMFs and RF magnetic fields. According to Karpowicz *et al*. (2007), exposure to RF energy typically is associated with thermal effects and electro-sensitive tissue excitations, whereas possible adverse and transient health effects are associated with SMFs, especially in cases of chronic exposure to high fields (7 Tesla or more).

Exposure of MR staff to SMFs is a pressing concern, since fields are always on, even when patients are not being scanned (Schaap *et al*., 2013). Karpowicz and Gryz (2006) indicated that the most significant exposure occurs in the proximity of the magnet housing. Exposure to RF energy is also possible during patient examinations; however, this happens only in special cases, such as when staff assists patients with severe medical conditions, patients with claustrophobia, and children (Karpowicz and Gryz, 2006). Due to the minimal attention that has been paid to exposure of MR staff to electromagnetic fields (EMFs) in health care settings, Vijayalaxmi and Speck (2015)

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highlighted the need to investigate the long-term effects of different exposure levels encountered by health care workers in MRI areas. In 2015, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) expressed the same view regarding the need for epidemiological studies on exposure to RF energy and SMFs, which also were deemed important by the 2013 European Union directive. The study reported here investigated the transient health effects on MR staff exposed to SMFs and RF energy, as well as safety risks from 1.5 and 3 T MRI units in public hospitals in the Mangaung metropolitan region of South Africa.

4.2 Problem statement

Studies conducted in American and European countries have reported transient health effects following exposure to MRI-related EMFs (De Vocht *et al*., 2015; Schaap *et al*., 2014; Schaap *et al*., 2016). The health effects reported were primarily based on exposure to MRI-related EMFs emitted by scanners ranging from 0.5 to 7 T. In the South African public healthcare sector, 1.5 and 3.0 T MRI scanners are used for clinical imaging, and frequently, healthcare personnel enter the MRI scanner room to assist patients with severe medical conditions and inject contrast. This creates a need to assess the health effects among MR staff who enters the MRI scanner room during scanning procedures and safety practices. The objective of this study was to evaluate the health effects of exposure to RF energy and SMFs among MR staff and identify safety risks in 1.5 and 3.0 T MRI units.

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4.3 Methodology

4.3.1 Research design

This study adopted mixed methods design; quantitative for self-administered questionnaire survey (restrospective in nature) and qualitative for structured interviews. A descriptive, retrospective design was further used to investigate the health effects associated with the exposure to SMF and RF energy among MR staff during their work shifts. A structured interview was used to ensure that the MRI safety risks information received falls in line with the objective. The study took place in two South African public hospitals located within the Mangaung Metropolitan Municipality. The hospitals where the current study was conducted, provide MRI services in the central region of the Free State and they are situated in Bloemfontein. These hospitals are also regarded as referral facilities for patients who need radiological services, including MRI scans. Self-administered questionnaires (Annexure M) were used to collect data about SMFs and RF energy exposure-related symptoms experienced by the study participants. Eighteen-questions MRI safety risk interviews (Annexure J) were also conducted based on safety practices in the MRI suites. Prior to the commencement of the study, ethical clearance (subsequent approval) and permission from Free State department of health was obtained (see chapter 1).

4.3.2 Data collection tools

4.3.2.1 Questionnaire and interview questions development

Self-administered questionnaires were used to obtain information about exposure symptoms amongst MR workers. Transient health effects that have been investigated in previous studies (De Vocht *et al*., 2015; Schaap *et al*., 2016; Zanotti *et al*., 2016)

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and found to be associated with exposure to MRI fields were included. The questionnaire consisted of three sections collecting biographical, work and health-related information. The biographical information of the participants gathered included their age, gender and level of education. The work-related items gathered information about their working shifts, workloads, work activities in close proximity to MR scanners, health and safety training, job titles, and control measures to minimize exposure. The third section comprised questions that gathered data on health-related symptoms. The questions on transient health effects related to RF magnetic fields exposure included sensation of burning or irritated skin, and feeling warm and hot flushes. Static magnetic fields exposure symptoms included vertigo, nausea, seeing light flashes, feeling of instability, metallic taste, and so forth, while other unrelated effects, including itchy or watery eyes, headache and blurred or double vision were used to control for potential over-reporting of symptoms, similarly as reported by Fatahi *et al*. (2016). All health effects asked were rated on a five-point Likert-scale, ranging from “never” to “always” as a frequency of occurrence. Based on varying educational and linguistic backgrounds of study participants, the questionnaire was developed in three official languages of South Africa; English, Southern Sesotho and Afrikaans.

The interview questions were developed based on the context of operational safety in the MRI units, availability of departmental safety policy manuals and safety training programmes for MR staff. The questions asked were formulated from the American College of Radiology guidance document on MR safe practices: Updates and critical information of 2019 and the study conducted by Opoku *et al*. (2013). The interview questions were only developed in English, since the interviewees could understand and narrate in the English language.

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4.3.3 Piloting of instruments

The questionnaires were piloted among three subjects; one cleaning personnel member was given a Sesotho version of the questionnaire (Annexure O), one administration personnel member had an Afrikaans version (Annexure N), and one nurse from the orthopaedic section was given a questionnaire in English (Annexure M). This was done to ensure the validity and reliability of the instrument, and also to ensure that the questions were easy to answer in all three languages. The interview was piloted with one of the twelve radiologists who rotate between the hospitals where this study took place. The radiologist was chosen based on his involvement in the MRI units and his understanding of MRI safety protocols. Those who participated in the piloting of the instrument were not included in the main study.

4.3.2 Participants enrolment

The study population consisted of workers of different races who were employed full-time and were assigned to work in the MRI units. The control population was also included in the study through convenient sampling. This population is based in the same department, but different unit/ section, as the MR staff. Participants who performed certain activities in the MRI units, zone IV, were considered exposed group and 28 radiographers from both hospitals (hospital A= n15 and hospital B= n13) who worked in the CT scan and X-ray departments were classified as control group. Since this study aimed to assess transient health effects among staff working in the MRI units, a purposive sampling was used to enrol all participants who indicated to have worked in the MRI units during their workweek. Such participants included maintenance engineers (two) from Philips and Siemens, two cleaning personnel

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members who rotated shifts in hospital A, MRI unit, and four radiographers who were assigned to work in the MRI units of both hospitals. An additional nine radiographers (one from hospital A and eight from hospital B), who were identified to have received in-house MRI safety training and frequently worked in the MRI room (where the scanner is located), also were enrolled for the study. Two medical physicists, both stationed in their respective hospitals, and four radiologists who were available at the time of data collection, were approached for participation. Of the latter group, only three reported to rotate between the two hospitals.

A specially designed MRI suite entrance register (Annexure L) was used to enrol those participants who entered zone IV, and they were given a questionnaire to complete. From the register, thirteen nurses and three medical doctors, who brought patients for MRI scanning were identified in the two hospitals, provided with consent forms and requested to complete the questionnaires. Two cleaners from hospital B who assisted (occasionally) in cleaning the MRI suite, eight porters who, sometimes, brought to or fetched patients from the MRI units (zones III or IV) in both hospitals also were included. A total of 49 exposed and 28 unexposed individuals participated in the questionnaire survey. Only four MR staff (chief radiographer, medical physicist, and two radiologists) agreed to be interviewed.

4.3.3 Administration of questionnaires and interviews

Prior to the completion of the questionnaire, the purpose of the study and structure of the questionnaire were discussed with the head of the clinical imaging department and chief radiographers in both hospitals. A second meeting was held with radiologists to discuss the structure and contents of the interview. The researcher administered the

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questionnaires once consent was obtained from all the participants. Completed questionnaires were placed in two sealed boxes, named hospital A and hospital B, and the researcher later categorised the questionnaires according to the groups (exposed and control) the respondents represented. Since the questionnaire reflects past exposure of the last workweek, participants were asked to complete their questionnaires on Monday morning prior commencement of their new workweek. The questionnaire data were collected for three months, from August to October 2020.

The first round of structured interviews was conducted (within four days) with two radiologists in hospitals A and B (separately). Based on the responses of the radiologists, it was considered necessary to conduct interviews with other participants (chief radiographer and medical physicist) as well. Two separate interviews thus were conducted with the medical physicist and chief radiographer in hospital B. Since radiologists, medical physicists and the chief radiographer are actively involved in the MRI operations, it was considered the best way to obtain detailed and comprehensive information about MRI safety risks. The four interviews were electronically recorded, transcribed and questions were grouped into themes (operational safety, availability of departmental policy manual and training programmes for MRI) and analysed.

4.3.4 Ethical considerations

The participants agreed to enrol voluntarily - no remuneration was offered to them, and they were not required to pay participation costs. All efforts were made to keep their personal information confidential and to ensure their anonymity. Each participant spent approximately 20 minutes completing the questionnaire, and they were given an option to withdraw from the study if they felt uncomfortable at any point. There were

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no risks and benefits for participation. Because participants were asked to reveal confidential information regarding their health, anonymity was ensured by asking participants not to divulge their identity when completing the questionnaire. To ensure privacy, participants were asked to complete the questionnaire and put it in a sealed box designed by the researcher. Data obtained from the questionnaires were transferred to a password-protected Excel spreadsheet. An information letter containing the study details was issued to each participant. Informed written consent (signed by both participants and the researchers) was obtained from the participants. Signed consent was also obtained from all participants who were interviewed and a separate written consent was obtained.

Prior to the interviews, the purpose of the study was explained to participants and they were informed that their participation was voluntary, and they were given the option to withdraw at any time without repercussions, should they feel uncomfortable to continue participation. Participants were requested not to reveal their identities. Each interview lasted approximately 45 minutes. The interview responses were recorded on a voice recording device, transferred to a computer and coded for safe storage.

4.3.5 Validity and reliability

To ensure validity of the questionnaire and reliability of results, the questions were compiled using questionnaire-based studies by Fatahi *et al*. (2016), Schaap *et al*. (2016) and De Vocht *et al.* (2015). These studies used baseline questionnaires to obtain data on the subjective health effects of exposure to SMFs. Furthermore, subjective reference symptoms from the Lund Subjective Health Complaint Inventory (SHC) questionnaire (Eriksen *et al*., 1999) were also included in the study to compare

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commonly reported symptoms between MR staff and the control group. According to De Vocht *et al*. (2015), the SHC questionnaire is a validated instrument used to obtain information about the commonly reported subjective health symptoms within the general population. The interview questions used in this study were also asked in the form of a questionnaire used in the study conducted by Opoku *et al*. (2013).

4.3.6 Data analysis

The questionnaire data were captured electronically by the researcher in Microsoft Excel (2016). Further analyses were done using SAS version 9.2, where descriptive statistics, namely frequencies and percentages were calculated for categorical data. The cross-tabulation and chi square test for independence were used to determine whether there was any association between the prevalence of transient health effects and working in the MRI units. Odds ratio at a confidence level of 95% also was used to determine the probability of transient health effects between the exposed and control groups. A significance (α) level of ≤ 0.05 was used. The interview responses were transcribed and data were grouped into themes for further thematic analysis.

4.4 Results

The results of this study are discussed according to how they were reported on the questionnaire and how participants responded during the interview. The categorical data in terms of frequency and percentages are discussed based on responses from biographical descriptions and work-related information. The responses on health effects were based on a five-point Likert-scale and associations with MRI work and perceived risks of working with scanners. All health effects included in this study were

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associated with exposure to SMF and RF energy in several studies conducted previously. Effects unrelated to exposure were also included to compare with the control group. The interview responses are discussed in terms of operational MRI safety, availability of safety policies, and safety training programmes for MR staff.

4.4.1 Questionnaire survey

4.4.1.1 Biographical data and work-related information

The total number of participants in the questionnaire survey were 77 (exposed group [49]; control group [28]), comprising 57.14% females (44) and 42.86% males (33). The age of the participants ranged from 21 to 61 years (ave. 34.6; std. deviation 8.56), with one female participant who did not indicate her age. A degree in radiography was reported most frequently (40.26%), as opposed to other educational qualifications. Of the 77 study participants, two maintenance engineers were employed by the MRI machine vendors (Philips 3.0 T and Siemens 1.5 T), three radiologists rotated between two hospitals (one indicated not to rotate between hospitals), 48.05% of other participants were employed by hospital B and 45.45% by hospital A. Apart from maintenance engineers and radiologists, study participants comprised medical physicists, nurses, and other participants such as medical doctors, porters and cleaners, with radiography being the most frequently reported job title. Regarding the intensity of their work, 1.30% of participants considered their workload as light, 68.83% called it moderate and 29.87% tiring. The results of the demographic and work-related information collected through the questionnaire is given in Table 4.1.

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Table 4.1: Results of collected data (n=77)

Descriptions	Number (n)	%
Job titles		
Maintenance Engineer	2	2.60%
Medical physicist	2	2.60%
Nurse	13	16.88%
Other	15	19.48%
Radiographer	41	53.25%
Radiologist	4	5.19%
Gender		
Female	44	57.14%
Male	33	42.86%
Used disinfectants or solvents during work		
Yes	76	98.70%
No	1	1.30%
Strong chemical smell or vapour	5	6.49%
Not a strong chemical smell or vapour	34	44.16%
Both	37	48.05%
Tiring workweek		
Hardly tiring	1	1.30%
A little tiring	49	63.64%
Very tiring	27	35.06%
Alcohol consumed during the past 24 hours		
0	56	72.73%
1 Glass	10	12.99%
2 Glasses	4	5.19%
3 Glasses	2	2.60%
4 Glasses	2	2.60%
6 Glasses	2	2.60%
9 Glasses	1	1.30%
Cigarettes per day		
0	61	79.22%
5	4	5.19%
7	1	1.30%
10	9	11.69%
15	1	1.30%
20	1	1.30%

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Medication		
Yes	24	31.17%
No	53	68.83%

N=Number of participants; **%**= percentage of participants

4.4.1.2 Working in the MRI units

Participants were asked whether their job involved working in the MRI room where the scanner is located and out of the 77 participants, 49.35% indicated to work in the MRI room where the scanner is located and 50.65% did not work in the MRI scanner room. Out of the 49.35 %, two participants did not indicate their years of experience in the MRI units. Reported years of working in the MRI units ranged from one to fifteen, with an average experience of 5.41 years (std. deviation 4.07) and the most years of experience reported was five (9.09%). Among those working in the MRI room, 32.47% reported to work shifts, while one participant did not indicate the duration of the shifts, 2.60% worked for only one hour, 2.60% for two hours, and 28.57% for eight hours per shift.

4.4.1.3 Workers' presence in the MRI scanner room

Of the 77 participants, 64.94% reported to have been present in the MRI room where the scanner is located during their shift, and on average 19.48% were in the MRI room for one day a week; 12.99% for two days; 7.79% for three days; 2.60% for four days, and 19.48% for five days respectively. Participants were asked to indicate which scanner they worked on during their shift: 35.06% worked on 1.5 T scanner

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(Siemens); 25.97% worked on 3.0 T scanner (Philips), and 2.60% indicated to have worked on both scanners. Table 4.2 below provides the results of the different scanners the professionals worked on during their shifts.

Table 4.2: Results of professional categories in hospitals A and B, the strength of the scanners worked on, and shift duration

Job title	Hospitals and participants	Scanner strengths	Average number of days per week spent in the MRI units	Average shift duration per day (hours) in the MRI units
Nurse	Hospital A (7)	3.0 T Philips	3.6	3.4
	Hospital B (6)	1.5 T Siemens	3.3	2.3
Radiographers	Hospital A (3)	3.0 T Philips	5	8
	Hospital B (10)	1.5 T Siemens	4.2	7.2
Maintenance engineers	Hospital A (1)	3.0 T Philips	2	NA
	Hospital B (1)	1.5 T Siemens	2	8
Radiologists	Hospital A and B (3)	3.0 and 1.5 T (Philips and Siemens)	1.3	5.3
	Hospital B (1)	1.5 T Siemens	NA	NA
Medical physicists	Hospital A (1)	3.0 T Philips	5	8
	Hospital B (1)	1.5 T Siemens	5	8
Others (medical doctors)	Hospital A (2)	3.0 T Philips	1	NA
	Hospital B (1)	1.5 T Siemens	1	NA
Others (cleaners)	Hospital A (2)	3.0 T Philips	1	1
	Hospital B (2)	1.5 T Siemens	1	2
Others (porters)	Hospital A (3)	3.0 T Philips	1.3	NA
	Hospital B (5)	1.5 T Siemens	1.4	NA

NA= participants did not indicate shift duration or number of days per week in the MRI units

Irregularities or incidents such as cleaning of the 1.5 T scanner on certain days, changes in patients' drips, or assisting patients with claustrophobia have caused 19.48% of participants to stay in the scanner room longer than usual. Such participants included nurses, porters, and cleaners in both hospitals, and two radiographers in hospital B. Furthermore, 11.69% of participants were present in the scanner room during image acquisition once, 9.09% two times, 5.19% three times and 1.30% four

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times during their work shifts in a week. Among those who were present in the scanner, 20.78% moved their head or upper body into the scanner bore once, 5.19% two times, 1.30% three times, and 1.30% four times when cleaning the scanner, positioning phantoms or coils and changing patients' drips.

4.4.1.4 Training and safety of MRI scanners

The results for perceived MRI safety are presented in Figure 4.1. The responses of participants ranged from very safe to very unsafe. Out of 67.53% respondents, 15.58% felt very safe, while 35.06% felt moderately safe, and 5.19% felt slightly safe around MRI scanners. Only five (6.49%) participants felt slightly unsafe and 5.19% felt neutral, and none of the participants reported to have felt moderately and very unsafe.

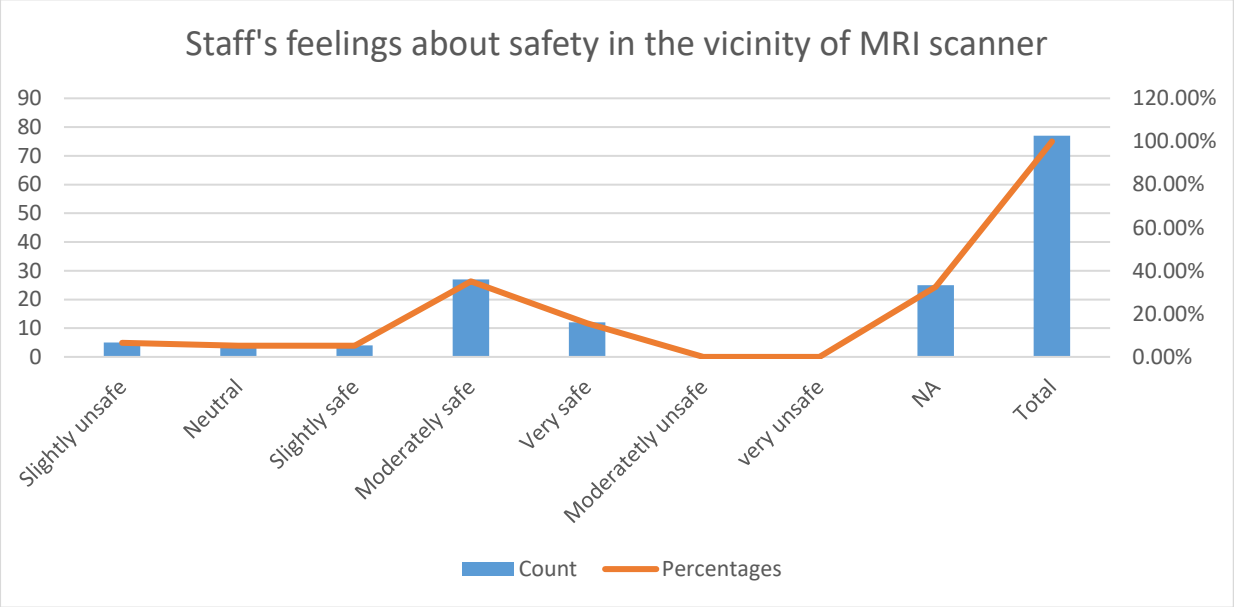

Figure 4.1: Perceptions of MRI scanner safety among MRI staff

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Out of the 52 respondents, four females and one male felt slightly unsafe, three females and one male felt neutral. Two females and two males felt slightly safe, 16 females and 11 males felt moderately safe. There were only five females and seven males that felt very safe around MRI scanners. A chi-square test for independence was performed to find associations between gender, job title, years of experience, scanner strength and feelings of safety around MRI scanners. Results suggested no significant association between male and female participants, and how safe they felt around MRI scanners ($p< 0.58$). However, a significant association was found between different job titles and safeness around the scanners ($p< 0.0023$). All maintenance engineers, medical physicists and radiologists felt much more safe around both MRI scanners (1.5 and 3.0 T) than other participants. One radiographer and a cleaner working with the 3.0 T scanner, as well as a nurse, a cleaner and a radiographer working with the 1.5 T scanner felt slightly unsafe. The majority of participants - radiographers (n=10) and nurses (n=8) - felt moderately safe.

No significant difference was found between participants working with scanners with different strengths (i.e. 1.5 T and 3.0 T, and both), and how safe they felt around the scanners ($p< 0.12$). However, when comparing the number of years working in the MRI units and safeness around the scanners, a significant difference was found ($p< 0.0002$). The majority of participants (n=26) felt safe (moderate and very safe) around MRI scanners, while only three felt slightly unsafe, and three were neutral. Participants who had between five and six years of experience working in the MRI units felt safer (moderately) around MRI scanners than other participants. The difference in years of experience in the MRI and feeling safe around scanners is depicted in Figure 4.2.

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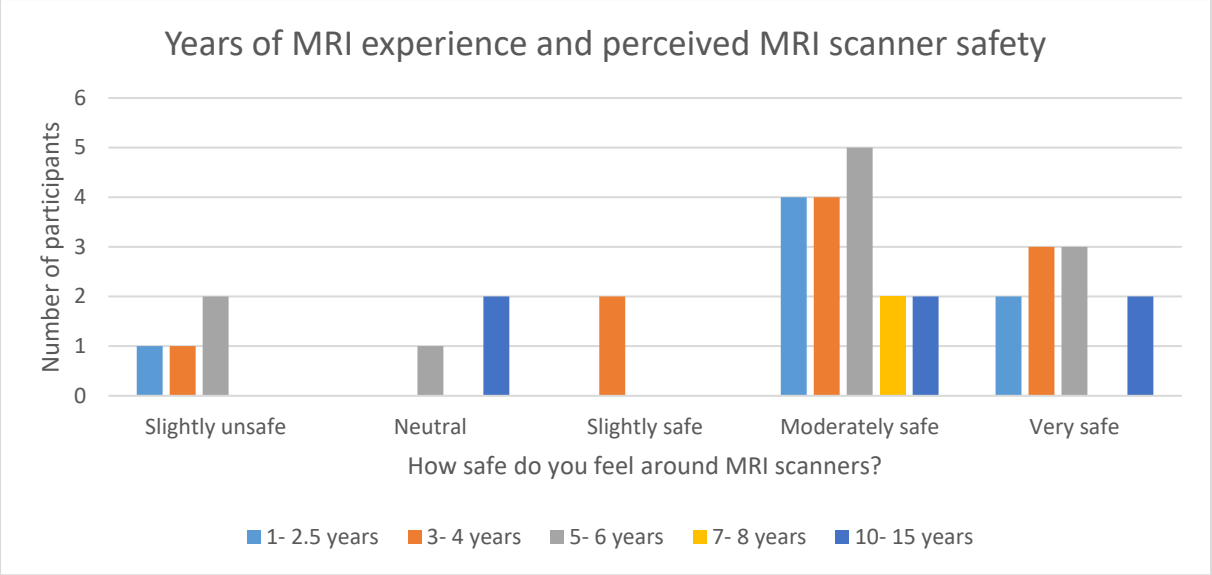

Figure 4.2: Years of experience in the MRI units and safeness around MRI scanners

Regarding training on the safety of personnel working in the MRI units, thirty-four (44.16%) participants indicated that they had received training about the safety of personnel in the MRI units, and 45.45% received training on the health effects of exposure to SMFs and RF energy. Maintenance engineers and medical physicists (6.49%) suggested that there were control measures in place to minimize harmful effects of exposure to SMFs and RF energy from MRI scanners.

4.4.1.5 Health effects responses

The responses on health effects experienced by participants were based on the five-point Likert scale, ranging from “never” to “always”, and of 77 participants, 38.96% (30) reported to have experienced the health effects. One participant did not indicate any response, while 59.74% indicated not to have experienced any health effects. Only one participant, who was part of the control group, experienced transient health effects. Participants were further asked if any of the transient health effects they had

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felt affected their work practice, and none of them indicated his/her work practice to have been affected by the effects they experienced. Table 4.3a depicts the health effects experienced by participants during their work in the MRI units.

Table 4.3a: Health effects experienced by participants when working in the MRI units

Symptoms experienced	Likert Scale				
	Never	Seldom	Half of the time	Usually	Always
Tinnitus or sensation of ringing in ears/head [a]	45	16	2	0	0
Earache [c]	63	0	0	0	0
Headache [c]	41	21	0	1	0
Concentration problems [a]	60	3	0	0	0
Tiredness or sleepiness [c]	60	2	0	1	0
Nausea [a]	43	17	3	0	0
Vomiting [c]	63	0	0	0	0
Involuntary muscle contractions [a]	61	1	1	0	0
Palpitations [c]	63	0	0	0	0
Tingling sensation [a]	63	0	0	0	0
Sensation of glowing, burning or irritated skin [b]	61	2	0	0	0
Suddenly feeling warm/hot, hot flushes [b]	50	13	0	0	0
Itchy, watery or red eyes [c]	63	0	0	0	0
Seeing black spots or having a temporary loss of vision [c]	63	0	0	0	0
Seeing light spots or light flashes [c]	63	0	0	0	0
Blurred or double vision [c]	63	0	0	0	0
Sensation of dizziness or vertigo [a]	34	15	14	0	0
Feeling lightheaded or weightless [a]	49	14	0	0	0
Feeling of instability when standing, walking or moving [a]	34	16	13	0	0
A metallic taste [a]	34	9	19	1	0

a Transient health effects related to exposure to SMFs; b Transient health effects related to exposure to RF energy; c Exposure unrelated symptoms

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Study participants experienced at least eight transient health effects related to SMFs, with the majority experiencing the effects seldomly and half of the time. Only one participant experienced a metallic taste in the mouth frequently (usually). A number of participants (13) seldomly experienced a sudden feeling of warmth and a sensation of burning or irritated skin (2) as effects related to RF energy exposure. Participants also reported to experience exposure-unrelated symptoms such as headache and tiredness seldomly and frequently (usually). Some medication taken by participants (31.17%) on a daily basis had side effects such as dizziness, nausea and headaches, which are effects reported in other studies to be associated with exposure to SMFs (De Vocht *et al*., 2015; Schaap *et al*., 2016). Exposure symptoms such as blurred or double vision, light flashes, temporary loss of vision, itchy or red eyes, earache, vomiting, palpitations and tingling sensations were not reported. No female participants reported to have worked in the MRI while they were pregnant. Transient health effects experienced by participants were measured against shift duration, presence in the MRI room during work shifts, safeness of MRI scanners, and job title to establish associations. Furthermore, movement of head or upper body in the scanner bore, as well as years of experience in the MRI units were also measured against transient health effects experienced.

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Table 4.3b: Comparison between exposed and control group regarding health effects they experienced

Symptoms experienced	Exposed	Control	Never experienced/ Missing data
Tinnitus or sensation of ringing in ears/head [a]	18	0	59
Earache [c]	0	0	77
Headache [c]	21	1	55
Concentration problems [a]	3	0	74
Tiredness or sleepiness [c]	3	0	74
Nausea [a]	20	0	57
Vomiting [c]	0	0	77
Involuntary muscle contractions [a]	2	0	75
Palpitations [c]	0	0	77
Tingling sensation [a]	0	0	77
Sensation of glowing, burning or irritated skin [b]	2	0	75
Suddenly feeling warm/hot, hot flushes [b]	13	0	64
Itchy, watery or red eyes [c]	0	0	77
Seeing black spots or having a temporary loss of vision [c]	0	0	77
Seeing light spots or light flashes [c]	0	0	77
Blurred or double vision [c]	0	0	77
Sensation of dizziness or vertigo [a]	29	0	48
Feeling lightheaded or weightless [a]	14	0	63
Feeling of instability when standing, walking or moving [a]	29	0	48
A metallic taste [a]	29	0	48

a Transient health effects related to exposure to SMFs; b Transient health effects related to exposure to RF energy; c Exposure unrelated symptoms

The odds of experiencing transient health effects among participants who reported to have worked in the MRI units (exposed), and those who did not work in the MRI units (control) were calculated. Those working in the MRI room, where the scanner is located, were highly likely (OR 39.15, 95% CI: 4.91- 312.02) to experience transient health effects as compared to those who were not working in the MRI room (*p*

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<0.0001). Furthermore, exposed radiographers reported more transient health-related effects (OR 60.75, 95%CI: 5.99- 616.67) than radiographers in the control group (*p*< 0.0005).

4.4.1.6 Transient health effects: shift duration and job title

The chi-square test of independence was performed to determine if the prevalence of transient health effects is associated with shift duration. Table 4.4 gives the reported health effects reported on the Likert-scale and in association with shift duration.

Table 4.4: Reporting of transient health effects and associated shift duration

Symptoms experienced	Likert Scale					Chi-square test associations with shift duration
	Never	Seldom	Half of the time	Usually	Always	
Tinnitus or sensation of ringing in head [a]	45	16	2	0	0	*p*< 0.3
Headache [c]	41	21	0	1	0	*p*< 0.213
Concentration problems [a]	60	3	0	0	0	*p*< 0.992
Tiredness or sleepiness [c]	60	2	0	1	0	*p*< 0.998
Nausea [a]	43	17	3	0	0	*p*< 0.364
Involuntary muscle contractions [a]	61	1	1	0	0	*p*< 0.999
Sensation of glowing, burning or irritated skin [b]	61	2	0	0	0	*p*< 1
Suddenly feeling warm/hot, hot flushes [b]	50	13	0	0	0	*p*< 0.61
Sensation of dizziness or vertigo [a]	34	15	14	0	0	**p*< 0.002
Feeling lightheaded or weightless [a]	49	14	0	0	0	*p*< 0.56
Feeling of instability when standing, walking or moving [a]	34	16	13	0	0	**p*< 0.0016
A metallic taste [a]	34	9	19	1	0	**p*< 0.0032

***Significant association between transient health effects and shift duration; a Transient health effects related to exposure to SMFs; b Transient health effects related to exposure to RF energy; c Exposure-unrelated symptoms**

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A significant association between experiencing a metallic taste and shift duration (p< 0.0032) was found. Participants who had a shift duration of 8 hours per day in the MRI units significantly experienced a metallic taste. Seven participants reported to experience a metallic taste seldomly during their 8-hour shift and another seven experienced it half of the time during their work shift. Only one participant reported to have a metallic taste frequently (usually) during an 8-hour shift. One participant who does not work shifts in the MRI, two with 1-hour shifts and two with 2-hour shifts experienced a metallic taste frequently (usually) during their shifts. The feeling of instability when standing, walking or moving was also associated with shift duration (p< 0.0016). Ten participants who experienced instability seldomly had a shift duration of 8 hours, and two had 2-hour shifts, followed by five participants experiencing it half of the time. One participant who had no shifts in the MRI and two with shift durations of one hour each experienced instability half of the time. The feeling of lightheaded or weightless was not associated with shift duration (p< 0.56).

Sensations of dizziness or vertigo were associated with shift duration (p< 0.002). Vertigo was experienced seldomly by participants (nine) who worked a shift of 8 hours. Two participants who spent at least two hours in the MRI room seldomly experienced vertigo. Six participants working 8-hour shifts reported to have experienced vertigo half of the time, followed by two who spent one hour in the MRI room and one who did not indicate his/her shift duration. Although eight participants working 8-hour shifts and one who spent one hour per week in the MRI room reported to have experienced a sudden feeling of warmth seldomly, this was not associated with the shift duration (p< 0.61). Sensations of glowing, burning or irritated skin also was not associated with shift duration. Only one participant, working 8-hour shifts, reported to have had sensations of burning or irritated skin. Though the majority of transient health effects

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were most reported by participants with shift duration of 8 hours, tinnitus, headaches, concentration problems, tiredness, nausea and involuntary muscle contractions were not associated with any of the recorded shift durations.

The chi-square test of independence was also used to determine the difference between prevalence of reported transient health effects on the Likert-scale within different job titles. Table 4.5 depicts the prevalence of transient health effects within different job titles.

Table 4.5: The reported transient health effects between different job titles

Symptoms experienced and Job title	Likert Scale (n)						Chi-square test associations between Job titles
	No response	Never	Seldom	Half of the time	Usually	Always	
Tinnitus or sensation of head ringing							
Maintenance Engineer	0	1	1	0	0	0	$p< 0.0804$
Medical physicist	0	1	1	0	0	0	
Nurse	0	6	7	0	0	0	
Other	0	13	2	0	0	0	
Radiographer	11	23	5	2	0	0	
Radiologist	3	1	0	0	0	0	
Headaches							
Maintenance Engineer	0	0	2	0	0	0	
Medical physicist	0	1	1	0	0	0	*$p< 0.014$
Nurse	0	4	9	0	0	0	
Other	0	13	2	0	0	0	
Radiographer	11	22	7	0	1	0	
Radiologist	3	1	0	0	0	0	
Concentration problems							
Maintenance Engineer	0	2	0	0	0	0	
Medical physicist	0	2	0	0	0	0	
Nurse	0	12	1	0	0	0	$p< 0.233$
Other	0	15	0	0	0	0	
Radiographer	11	28	2	0	0	0	
Radiologist	3	1	0	0	0	0	
Tiredness or sleepiness							
Maintenance Engineer	0	2	0	0	0	0	
Medical physicist	0	2	0	0	0	0	$p< 0.53$
Nurse	0	12	1	0	0	0	
Other	0	15	0	0	0	0	
Radiographer	11	28	1	0	1	0	
Radiologist	3	1	0	0	0	0	
Nausea							
Maintenance Engineer	0	2	0	0	0	0	
Medical physicist	0	1	1	0	0	0	
Nurse	0	5	7	1	0	0	$p< 0.144$
Other	0	12	3	0	0	0	
Radiographer	11	22	6	2	0	0	
	3	1	0	0	0	0	

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Radiologist							
Involuntary muscle contractions							$p< 0.567$
Maintenance Engineer	0	2	0	0	0	0	
Medical physicist	0	2	0	0	0	0	
Nurse	0	13	0	0	0	0	
Other	0	15	0	0	0	0	
Radiographer	11	28	1	1	0	0	
Radiologist	3	1	0	0	0	0	
Sensation of glowing, burning or irritated skin							
Maintenance Engineer	0	0	2	0	0	0	*$p< 0.00$
Medical physicist	0	2	0	0	0	0	
Nurse	0	13	0	0	0	0	
Other	0	15	0	0	0	0	
Radiographer	11	30	0	0	0	0	
Radiologist	3	1	0	0	0	0	
Suddenly feeling warm/hot, hot flushes							
Maintenance Engineer	0	0	2	0	0	0	*$p< 0.003$
Medical physicist	0	1	1	0	0	0	
Nurse	0	8	5	0	0	0	
Other	0	14	1	0	0	0	
Radiographer	11	26	4	0	0	0	
Radiologist	3	1	0	0	0	0	
Sensation of dizziness or vertigo							$p< 0.066$
Maintenance Engineer	0	0	1	1	0	0	
Medical physicist	0	0	1	1	0	0	
Nurse	0	3	5	5	0	0	
Other	0	10	3	2	0	0	
Radiographer	11	20	5	5	0	0	
Radiologist	3	1	0	0	0	0	
Feeling lightheaded or weightless							*$p< 0.04$
Maintenance Engineer	0	1	1	0	0	0	
Medical physicist	0	2	0	0	0	0	
Nurse	0	7	6	0	0	0	
Other	0	13	2	0	0	0	
Radiographer	11	25	5	0	0	0	
Radiologist	3	1	0	0	0	0	
Feeling of instability when standing, walking or moving	0	0	1	1	0	0	
Maintenance Engineer	0	0	1	1	0	0	
Medical physicist	0	3	5	5	0	0	$p< 0.06$
Nurse	0	10	3	2	0	0	
Other	11	20	6	4	0	0	
Radiographer	3	1	0	0	0	0	
Radiologist							
A metallic taste							
Maintenance Engineer	0	0	1	1	0	0	$p< 0.084$
Medical physicist	0	0	1	1	0	0	
Nurse	0	3	2	8	0	0	
Other	0	10	1	4	0	0	
Radiographer	11	20	4	5	1	0	
Radiologist	3	1	0	0	0	0	

n= Number of participants; *Significant associations

The majority of reported transient health effects were not significantly different amongst job titles except for headaches, sensation of glowing, burning or irritated skin

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and feeling of lightheaded or weightless. The reporting of headaches among participants was significantly different (p< 0.014). The majority of nursing staff (9) and a few radiographers (six exposed and one control) reported to experience headaches seldomly with only one radiographer experiencing headaches frequently (usually). Furthermore, headaches that occurred seldomly also were prevalent among maintenance engineers, two cleaning personnel, medical physicist from hospital A and one radiologist.

A sensation of glowing was only experienced seldomly by maintenance engineers (p< 0.00). However, the feeling of light-headedness or weightlessness was mostly prevalent among nurses (six) and radiographers (five) from hospital B, who experienced it seldomly. Additionally, one maintenance engineer working with the 1.5 T scanner and two cleaning personnel from hospital B also reported a feeling of light-headedness or weightlessness that occurred seldomly.

4.4.1.7 Transient health effects: Presence in the MRI room and safety of MRI scanners

The chi-square test of independence was used to determine if there was any association between reported health effects and presence in the MRI room during work shifts in the venue where the scanner is located (Table 4.6). The association between the prevalence of transient health effects and perceived safety of MR personnel on MRI scanners also was determined.

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Table 4.6: Presence in the MRI room and prevalence of transient health effects

Symptoms experienced	Presence in the MRI room	Likert Scale (n)						Chi-square test associations: Presence in the MRI room*
		No response	Never	Seldom	Half of the time	Usually	Always	
Tinnitus or sensation of head ringing	Yes	4	29	15	2	0	0	0.003
	No	10	16	1	0	0	0	
Headache	Yes	4	26	20	0	0	0	0.001
	No	10	15	1	0	1	0	
Concentration problems	Yes	4	43	3	0	0	0	0.01
	No	10	17	0	0	0	0	
Tiredness or sleepiness	Yes	4	44	2	0	0	0	0.01
	No	10	16	0	0	1	0	
Nausea	Yes	4	27	16	3	0	0	0.002
	No	10	16	1	0	0	0	
Involuntary muscle contractions	Yes	4	44	1	1	0	0	0.02
	No	10	17	0	0	0	0	
Sensation of glowing, burning or irritated skin	Yes	4	44	2	0	0	0	0.01
	No	10	17	0	0	0	0	
Suddenly feeling warm/hot, hot flushes	Yes	4	33	13	0	0	0	0.01
	No	10	17	0	0	0	0	
Sensation of dizziness or vertigo	Yes	4	18	15	13	0	0	0.001
	No	10	16	0	1	0	0	
Feeling lightheaded or weightless	Yes	4	33	13	0	0	0	0.002
	No	10	16	1	0	0	0	
Feeling of instability when standing, walking or moving	Yes	4	18	16	12	0	0	0.001
	No	10	16	0	1	0	0	
A metallic taste	Yes	4	18	9	18	1	0	0.001
	No	10	16	0	1	0	0	

n= Number of participants; * =significant difference

Presence in the MRI room during work shifts did not necessarily result in the development of transient health effects. However, occurrence of irregularities or incidents that caused MR staff to be present, or in close proximity of the scanner, and to stay in the MRI room longer than usual during image acquisition, as well as the comforting of patients with claustrophobia resulted in participants experiencing transient health effects. Of 64.94% (50) of participants who reported to have been in the MRI room where a scanner is located during their shifts, one participant was part of the control group. Twenty-seven (35.06%) participants (control group) were not in

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the MRI room during their work shifts. There was a significant difference among participants who reported to have been in the MRI room during their work shift (exposed), prevalence of transient health effects and those who were not in the MRI room (control). The majority of participants who were in the MRI room during their shifts reported to experience health effects very seldomly, with headaches being reported the most. However, the majority of participants reported to experience vertigo, a feeling of instability when standing, walking or moving, and a metallic taste half of the time when they were in the MRI room. Those who experienced transient health effects half of the time included nurses, radiographers and cleaners from hospital B.

Table 4.7: Safety of MRI scanners and prevalence of transient health effects

Symptoms experienced	Safety of MRI scanners	Likert Scale (n)					Chi-square test associations: perceived safety
		Never	Seldom	Half of the time	Usually	Always	
Tinnitus or sensation of head ringing	Slightly unsafe	4	1	0	0	0	$p< 0.70$
	Neutral	2	1	0	0	0	
	Slightly safe	3	1	0	0	0	
	Moderately safe	15	9	1	0	0	
	Very safe	4	4	1	0	0	
Headache	Slightly unsafe	3	1	0	1	0	*$p< 0.014$
	Neutral	1	2	0	0	0	
	Slightly safe	4	0	0	0	0	
	Moderately safe	13	12	0	0	0	
	Very safe	3	6	0	0	0	
Concentration problems	Slightly unsafe	5	0	0	0	0	$p< 0.31$
	Neutral	3	0	0	0	0	
	Slightly safe	4	0	0	0	0	
	Moderately safe	24	1	0	0	0	
	Very safe	7	2	0	0	0	
Tiredness or sleepiness	Slightly unsafe	4	0	0	1	0	$p< 0.13$
	Neutral	3	0	0	0	0	
	Slightly safe	4	0	0	0	0	
	Moderately safe	23	2	0	0	0	
	Very safe	9	0	0	0	0	
Nausea	Slightly unsafe	4	1	0	0	0	$p< 0.21$
	Neutral	0	3	0	0	0	
	Slightly safe	3	1	0	0	0	
	Moderately safe	15	9	1	0	0	
	Very safe	4	3	2	0	0	

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Involuntary muscle contractions	Slightly unsafe	5	0	0	0	0	$p< 0.68$
	Neutral	3	0	0	0	0	
	Slightly safe	4	0	0	0	0	
	Moderately safe	24	1	0	0	0	
	Very safe	8	0	1	0	0	
Sensation of glowing, burning or irritated skin	Slightly unsafe	5	0	0	0	0	$p< 0.1$
	Neutral	3	0	0	0	0	
	Slightly safe	4	0	0	0	0	
	Moderately safe	25	0	0	0	0	
	Very safe	7	2	0	0	0	
Suddenly feeling warm/hot, hot flushes	Slightly unsafe	5	0	0	0	0	$p< 0.2$
	Neutral	2	1	0	0	0	
	Slightly safe	4	0	0	0	0	
	Moderately safe	18	7	0	0	0	
	Very safe	4	5	0	0	0	
Sensation of dizziness or vertigo	Slightly unsafe	3	1	1	0	0	$p< 0.13$
	Neutral	0	2	1	0	0	
	Slightly safe	2	2	0	0	0	
	Moderately safe	11	7	7	0	0	
	Very safe	1	3	5	0	0	
Feeling lightheaded or weightless	Slightly unsafe	4	1	0	0	0	$p< 0.26$
	Neutral	1	2	0	0	0	
	Slightly safe	4	0	0	0	0	
	Moderately safe	18	7	0	0	0	
	Very safe	5	4	0	0	0	
Feeling of instability when standing, walking or moving	Slightly unsafe	3	1	1	0	0	$p< 0.16$
	Neutral	0	2	1	0	0	
	Slightly safe	2	1	1	0	0	
	Moderately safe	11	9	5	0	0	
	Very safe	1	3	5	0	0	
A metallic taste	Slightly unsafe	3	0	2	0	0	$p< 0.28$
	Neutral	0	1	2	0	0	
	Slightly safe	2	1	1	0	0	
	Moderately safe	11	4	10	0	0	
	Very safe	1	3	4	1	0	

*** Significant difference**

As observed in Table 4.7 the majority of participants who experienced health effects seldomly reported to feel moderately safe around MRI scanners, with some participants (10) reporting to experience a metallic taste, but still felt moderately safe when they were close to the MRI scanners. The perception of MRI scanner safety among participants was not associated with the majority of transient health effects they experienced when working with MRI scanners. However, experiencing headaches was significantly associated with the perception of safety in the vicinity of MRI scanners

($p< 0.014$). This could be attributed to one participant (control group) who reported to have experienced headaches frequently (usually) when in the MRI room, and a lack of training on the health effects of exposure to MRI-related electromagnetic fields.

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4.4.1.8 Transient health effects: Movement of head/upper body in scanner bore, and years of experience

Participants were asked if they had moved their head/upper body into the scanner bore during their work shifts. The responses from those who had moved their head/upper body in the scanner bore, included the following as reasons: changing patients' drips, positioning patients, cleaning scanner bore, and repositioning phantoms. The number of times that participants moved their head/upper body into the scanner bore was compared with the reporting of transient health effects (Table 4.8) in order to determine if there is any association.

Table 4.8: Movement of head/upper body in the bore and health effects

Symptoms experienced	Number of times head/upper body moved	Likert Scale (n)					Chi-square test associations
		Never	Seldom	Half of the time	Usually	Always	
Tinnitus or sensation of head ringing	0 times	22	2	0	0	0	*p< 0.001
	1 time	5	9	2	0	0	
	2 times	2	2	0	0	0	
	3 times	0	1	0	0	0	
	4 times	0	1	0	0	0	
Headache	0 times	19	5	0	0	0	*p< 0.012
	1 time	6	10	0	0	0	
	2 times	1	3	0	0	0	
	3 times	0	1	0	0	0	
	4 times	0	1	0	0	0	
Concentration problems	0 times	24	0	0	0	0	*p< 0.0002
	1 time	14	2	0	0	0	
	2 times	4	0	0	0	0	
	3 times	0	1	0	0	0	
	4 times	1	0	0	0	0	
Tiredness or sleepiness	0 times	23	1	0	0	0	p< 0.83
	1 time	15	1	0	0	0	
	2 times	4	0	0	0	0	
	3 times	1	0	0	0	0	
	4 times	1	0	0	0	0	
Nausea	0 times	19	4	1	0	0	*p< 0.00001
	1 time	5	10	1	0	0	
	2 times	2	2	0	0	0	
	3 times	0	0	1	0	0	
	4 times	1	0	0	0	0	
Involuntary muscle contractions	0 times	24	0	0	0	0	p< 0.60
	1 time	14	1	1	0	0	
	2 times	4	0	0	0	0	
	3 times	1	0	0	0	0	
	4 times	1	0	0	0	0	
Sensation of glowing, burning or irritated skin	0 times	24	0	0	0	0	*p< 0.000003
	1 time	15	1	0	0	0	
	2 times	4	0	0	0	0	
	3 times	1	0	0	0	0	

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	4 times	0	1	0	0	0	
Suddenly feeling warm/hot, hot flushes	0 times	23	1	0	0	0	*p< 0.0005
	1 time	8	8	0	0	0	
	2 times	2	2	0	0	0	
	3 times	0	1	0	0	0	
	4 times	0	1	0	0	0	
Sensation of dizziness or vertigo	0 times	18	5	1	0	0	*p< 0.0001
	1 time	0	8	8	0	0	
	2 times	0	2	2	0	0	
	3 times	0	0	1	0	0	
	4 times	0	0	1	0	0	
Feeling lightheaded or weightless	0 times	22	2	0	0	0	*p< 0.002
	1 time	8	8	0	0	0	
	2 times	3	1	0	0	0	
	3 times	0	1	0	0	0	
	4 times	0	1	0	0	0	
Feeling of instability when standing, walking or moving	0 times	18	6	0	0	0	*p< 0.0001
	1 time	0	7	9	0	0	
	2 times	0	3	1	0	0	
	3 times	0	0	1	0	0	
	4 times	0	0	1	0	0	
A metallic taste	0 times	18	5	1	0	0	*p< 0.0001
	1 time	0	4	11	1	0	
	2 times	0	0	4	0	0	
	3 times	0	0	1	0	0	
	4 times	0	0	1	0	0	

*** Significant difference**

The development of transient health effects, particularly SMFs and RF energy effects, is significantly associated with the movement of upper body/head in the MRI scanner bore. However, tiredness (exposure unrelated) (p< 0.83) and involuntary muscle contraction (p< 0.60) were not associated with movement of upper body/ head in the scanner bore. The majority of participants who experienced transient health effects seldomly reported to have moved their upper body/ head in the MRI scanner bore at least once (one time). Symptoms associated with SMFs exposures such as tinnitus, nausea, vertigo, feeling of instability when standing, walking or moving, and metallic taste were experienced half of the time. Only one participant (maintenance engineer; 3.0 T scanner) experienced the metallic taste frequently (usually). Symptoms associated with RF energy exposures were more prevalent among nurses, medical physicists, maintenance engineers, a few radiographers and medical doctors. Exposure to RF energy happened as a result of repositioning of phantoms during acceptable testing, injection of contrast, and positioning of patients during image acquisition. Leaning in the scanner bores during cleaning services and assisting

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patients with severe medical conditions as reported by radiographers in hospital B, cleaning personnel, and hospital porters, resulted in substantive exposure to SMFs.

A few participants reported to never have moved their upper body/head in the scanner bore during their work shift, but reported to have experienced transient health effects. This could be attributed to performance of some activities that required them to be in close proximity of the scanner. Such activities include cleaning the outer part of the scanner machine (gantry and scanner table), injecting patients with contrast, and assisting those with severe medical conditions.

The chi-square test of independence also was performed to determine whether the years of experience working in the MRI was associated with the prevalence of MRI-related transient health effects. A feeling of dizziness or vertigo ($p< 0.007$), a feeling of instability when standing, walking or moving ($p< 0.009$), and a metallic taste ($p< 0.01$) were significantly associated with years of experience working in the MRI units. These effects were more prevalent among participants with five years of experience working in the MRI units and who reported to have experienced the SMFs exposure-related effects half of the time when working with MRI scanners. Only one radiographer with six years' MRI experience experienced vertigo frequently (usually).

4.4.2 Interview responses

A structured interview was conducted with four staff members (hospital A = n1, and hospital B= n3), who were directly involved in the MRI units and agreed to be interviewed at the time of data collection. The MR staff members who were interviewed included a medical physicist, the chief radiographer assigned to work in the MRI unit, and two radiologists. These participants also participated in the questionnaire survey.

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Interviewing these staff members who were more involved in the operations within the MRI units was considered the best way to obtain detailed and comprehensive information about MRI safety risks. The interview consisted of sections A, B and C. Each question in the MRI safety interview questionnaire required a “Yes” or “No” option, followed by comments that the interviewee could make with regard to the specific question asked. The interview report, therefore, was structured into a part one and part two. Part one indicates the interviewees’ responses to the “Yes” or “No” options in three sections of the interview questionnaire (Table 4.9). Part two comprised the comments made by the interviewees and followed on the “Yes” or “No” option.

Table 4.9: MRI safety risks: Interview responses

Questions	Chief Radiographer (B)	Medical Physicist (B)	Radiologist (B)	Radiologist (A)
SECTION A: OPERATIONAL SAFETY AT MRI UNIT				
1. Have all medical devices brought into Zone III and Zone IV in the MRI units undergone standardized evaluations and labelling to determine their status as being MR Safe, MR Conditional, or MR Unsafe?	No	No	Yes	Yes
2. Are there proximity access doors and an emergency exit door in the MRI unit?	Yes	Yes	Yes	No
3. Does the equipment used in the MRI unit have colour codes to identify ferrous material and MRI safety material?	No	No	No	No
4. Is there a routine maintenance of the MRI scanners, according to manufacturers’ requirements?	Yes	No	Yes	Yes
5. Do all MR personnel undergo an MR screening process as part of their employment agreement to ensure their safety in the MR environment?	No	No	No	No
6. Is there a careful screening for ferromagnetic materials by direct inspection and use of a ferromagnetic detector prior to entering Zone IV?	No	No	No	No
7. Is there a screening procedure for all non-MR personnel who accompany a patient into the MRI scanner room (Zone IV)?	No	No	Yes	No

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8. Are there lockers to store personal belongings of MR and non-MR personnel that may be ferrous in nature or have magnetic strips in the MRI Unit?	No	No	No	Yes
9. Is there a restricted access for everyone who comes to the MRI Suite?	Yes	(Not really)	Yes	Yes
10. Do MR and non-MR personnel wear personal protective equipment to protect themselves from MRI-related electromagnetic fields when entering Zone IV?	Yes	No	No	No
SECTION B: AVAILABILITY OF DEPARTMENTAL POLICY MANUAL				
1. Are there updated MR Safety policies and procedures in place?	No	No	No	No
2. When introducing any changes in the safety parameters of MRI units (e.g. hardware or software upgrade), do you update your safety policies or procedures?	No	No	No	Yes
3. Is there a written procedure to report the occurrence of all MR-related adverse events, safety incidents, or “near incidents”?	No	Yes	Yes	No
4. Is there a standard operating procedure for cleaning the MRI facility with respect to infection control?	No	Yes	No	No
5. Are there policies and procedures for emergency management in the MRI units?	No	Yes	No	No
SECTION C: TRAINING PROGRAMMES FOR MRI				
1. Are all individuals working in the MRI units aware of the four MRI safety Zones?	Yes	Yes	No	Yes
2. Are all individuals responsible for safety in Zones III or IV of the MRI units documented as being successfully educated about MR safety issues?	No	No	No	No
3. Is there an ongoing and documented MR safety educational programme for MR staff?	No	No	No	No

***A= hospital A; B= hospital B**

Table 4.9 indicates that there were questions to which the interviewees responded differently and this may be related to the different post levels of participants for example, the chief radiographer’s point of view differed from a radiologist’s point of view. In order to get clarity on the above “Yes” or “No” responses, the comments of the interviewees were compared.

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4.4.2.1 Comparison of the comments made by the interviewees

I. Section A: Operational safety at MRI unit

According to the responses of interviewees, it does not seem that medical devices brought into Zone III and IV in the MRI units undergo standardised evaluations. The medical physicist stated that all equipment brought into MRI units are MR safe and staff assigned to work in the MRI units ensures that metal or ferromagnetic objects do not enter the zones. Labelling of the equipment brought into Zone III and IV is not verified. The view of medical physicist was that MRI vendors are responsible to check the labelling and manuals of all equipment during their periodic maintenance, and according to their latest maintenance checks report, all equipment in the MRI units was indicated MR safe. The chief radiographer made a similar point, indicating that medical equipment such as access monitors and injector pumps are all MR safe, and no other equipment is brought into zone III and IV without their knowledge. The two radiologists in hospital A and B answered *yes*, indicating that their understanding was that all equipment should undergo standardised evaluation and be labelled prior to being brought into the MRI units.

Proximity access doors and an emergency exit door are found in the MRI units of both hospitals; however, interviewees responded differently to this question. The chief radiographer indicated that there is a proximity access door, as well as an ‘escape door at the back’, while the medical physicist indicated that there is a double door on the entrance of zone IV, as well as an exit door on the ‘other side’ of zone IV. The radiologist in hospital A indicated that there is an operational and emergency door, whereas the radiologist in hospital B indicated that there is only an access door.

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Although the ACR guidelines (2020) suggest that all equipment used in the MRI units must be colour coded, the equipment used in the MRI units of both hospitals have no colour codes to identify ferrous material and MRI-safe material. According to the medical physicist and chief radiographer, staff assigned to work in the MRI units are regarded as specialised and follow their own working systems. Their knowledge would allow them to differentiate between ferrous and non-ferrous materials. The two radiologists indicated that there should be no ferrous material, according to their knowledge; however, equipment is not colour coded.

The question on whether routine maintenance of the MRI scanners is done according to manufacturers' requirements, the chief radiographer indicated that periodic maintenance was done, but in terms of a service contract. However, a maintenance schedule for the MRI scanner in hospital B was missing. Once every quarter a maintenance engineer from an MR manufacturing company does maintenance work on the machine. It was further indicated that a week prior to periodic maintenance, the relevant MR staff members are informed to clear patient list. The medical physicist indicated that, according to quality control directives for scanner manufacturers, an annual test has to be performed in order to determine whether changes to the system are required. The two radiologists also indicated that routine maintenance was done.

All interviewees indicated that no standardised screening was done on every personnel member who entered the MRI units, and that they had never undergone a screening process as part of their employment stipulations to ensure their safety in the MR environment. According to the chief radiographer and radiologist in hospital B, there is no screening of ferromagnetic materials by direct inspection and there is no metal detector test done prior to entering zone IV. The medical physicist answer *no*, for two reasons. The first reason was that a static magnetic field does not change with

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time; therefore, it is “not necessary” for screening to take place. The second reason was that all MR staff received training (by the medical physicist), so it is assumed that staff is informed about MRI safety. The radiologist in hospital A indicated that the ferromagnetic detector was not working and no direct inspection was done.

There is no screening procedure in place for all non-MR personnel who accompany a patient into the scanner rooms of both hospitals. The chief radiographer stated that no screening checklist or questionnaire was in use and non-MR personnel are merely warned verbally. The medical physicist explained the procedure for dealing with a situation when non-MR personnel (e.g. a nurse) brings a patient from, for instance, casualty to the MRI. “Normally, the MR nurse will take over from the other nurse and if she needs help, she will be assisted by the other two MR staff members. However, an outsider can come in, because it is only a magnetic field, and therefore it poses no threat.” It is assumed that MRI-related EMFs does not pose any harm to non-MR personnel. The two radiologists indicated that a screening procedure exists in the sense that patients have to fill in a questionnaire, but this is not required from MR staff. Regarding lockers for personal belongings, MR and non-MR personnel members do not have lockers in which to store personal belongings that might be ferrous in nature or have magnetic stripes. The chief radiographer and medical physicist emphasised that patients’ cell phones and keys are taken care of; however, there are no lockers for staff. Staff members leave their belongings in non-lockable cubicles in Zone II. The radiologists also responded negatively, indicating that both MR and non-MR staff do not have lockers, but that a space is provided where patients can put their belongings, which is at a safe distance from the scanner in Zone III.

Restricted access applies to anyone who comes to the MRI Suite. According to the chief radiographer, the access door to Zone IV is kept locked when the scanner is not

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used and nobody may come to Zone III or IV without a valid work reason. The medical physicists responded, “Not really”, indicating that all radiographers may enter the control console of the unit if there is work to be done there. He further indicated that restricted access is not in place, because MRI scanners are considered safe. The radiologist indicated that restricted access applies in hospital B. The radiologist in hospital A indicated that restricted access applied for patients, but not for personnel. In response to the question whether MR and non-MR personnel members wear personal protective equipment to protect themselves from MRI-related electromagnetic fields (EMFs) when entering Zone IV, the participants responded as follows: The chief radiographer indicated that they only put on earmuffs “occasionally” when they are in Zone IV during image acquisition to protect their hearing from the loud noise generated by the scanner. The medical physicist and two radiologists answered no, indicating that they do not have any form of personal protective equipment for MRI-related EMFs.

II. Section B: Availability of departmental policy manual

According to interviewees, there are no updated MR safety policies and procedures in place. The medical physicist indicated that updated MR safety policies were not in place, because magnetic fields emitted by the MR scanner do not pose any significant safety risk. Furthermore, policies only are drafted, when new equipment is bought, when physicist will draw up daily and weekly quality assurance checks on the MRI, and also draft safety precautions for cleaning and training. “The only safety policy available is on pregnancy, because the sound generated by the scanner could pose significant risk to the foetus.” The chief radiographer and two radiologists indicated that they had never seen the policy.

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The question was asked whether updates of policies or procedures occurred when changes in the safety parameters of MRI units (e.g. hardware or software upgrade) are introduced. According to the chief radiographer, there has never been any upgrade because their MR machine (1.5 T) is a new model. The medical physicist indicated that there was no need for updated safety policies when software upgrade is done; however, there has never been any hardware upgrade in hospital B. The two radiologists indicated that they have never seen any software or hardware upgrade in their respective hospitals. The question about the existence of written procedures to report the occurrence of all MR-related adverse events, safety incidents, or "near incidents" was answered as follows: The chief radiographer indicated that a procedure did exist; however, it is not MRI specific, and it is a standardised hospital incident report procedure. The medical physicist indicated that they did have such a procedure, and the radiologist in hospital B said that an incident questionnaire did exist; however, there was no procedure on how to report the incidents. The radiologist in hospital A answered *no*, indicating that there was no procedure specifically for MRI units. In response to the question whether there was a standard operating procedure for cleaning the MRI facility taking cognisance of infection control, the chief radiographer indicated *no*. He indicated that they cleaned the machine every Friday, because then they are not very busy. Only the two of them (radiographers) cleaned the machine and mopped the floor in zones III and IV. Since an incident in 2014 when a cleaner used a mop with a ferromagnetic handle, they prefer to clean the scanner room themselves. The other challenge is that they have to train all the cleaners on a regular basis, and the training does not happen consistently (chief radiographer). The medical physicist indicated that a standard operating procedure exists, but it is mostly applicable to

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nursing staff. The two radiologists, on the other hand, indicated that there was no standardised protocol, but that cleaners were designated to clean the MRI room.

To the question whether there are policies and procedures for emergency management in the MRI units, the participants responded as follows: The chief radiographer indicated *no*, stating that in case of an emergency in the MRI room they called the doctors or trauma unit. The medical physicist indicated *yes*, stating that they trained dedicated students (radiographer and medical physics) to assist with emergency situations. The two radiologists said *no*, there were no policies and procedures for emergency management in the MRI facilities.

III. Section C: Training programmes for MRI

When asked about it, the chief radiographer indicated that all individuals working in the MRI units were aware of the four MRI safety zones. Only two radiographers are assigned to work in zones III and IV, and they are familiar with the zones in which they work. The medical physicist also responded affirmatively, and added that he trained MR staff to be aware of the four zones. The radiologist in hospital B indicated *no,* and the radiologist in hospital A indicated *yes*, stating that there were four zones and only the outside zone was marked; however, as staff moved closer, there were no specific demarcations of other zones. To the question whether all individuals responsible for safety in zones III or IV of the MRI units documented, have been successfully educated about MR safety issues, the chief radiographer responded *no,* as they had not received any training or endorsement on MRI safety. The medical physicist indicated that there are no essential aspects of MRI safety in medical physics, because magnetic fields cannot pose any health threat. Two radiologists also indicated *no*,

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stating that they only did a physics course on how the MRI works and safety aspects were not part of the training.

The final question of the interview inquired whether permanent, continuing, documented MR safety training of MR staff took place. The chief radiographer indicated *no*, without further comments. The medical physicist said that training was ongoing; however, they relied on the interaction with dedicated staff, who are specialists, to communicate it if any safety issues were experienced. The two radiologists also indicated *no,* without saying anything more.

4.5 Discussion

4.5.1 Questionnaire survey

According to literature, this is the first study to assess safety perceptions and transient health effects among 1.5 and 3.0 T MR workers in South Africa. Although transient health effects among MR staff were prevalent, the results of this study showed that the majority of MR staff working with both 1.5 and 3.0 T scanners (50.64%) perceived MRI scanners to be safe. Their perception of the safety around MRI scanners was not affect by the health effects they experienced during their work shifts in the MRI room. Similar observations were made in a study conducted in Europe among 7 T MR workers (Fatahi *et al*., 2016). This could be attributed to their knowledge of MRI scanners and years of experience working in the MRI units. It was noted, although not statistically measured, that the majority of participants (68.83%) reported their workload to be moderate and that their workweek was *a little tiring* (63.64%). This indicates that the prevalence of transient health effects was not related to the perceived workload or a tiring occupation. This is in accordance with the findings made

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by Wilén and De Vocht (2011). In addition, some participants from both the exposed and control group reported to have consumed alcohol, used disinfectants and medication, and smoked cigarettes, but such factors were not related to reporting any SMFs or RF-related health effects. Transient health effects were more prevalent among those who worked in the MRI room, where the scanner was located.

4.5.1.1 Training on and safety of MRI scanners

Gender played a non-significant role in terms of how safe MR staff perceived scanners to be. This study noted that the only factor that distinguished participants' perception on safety of MRI scanners, was the job title. Only five professionals felt safe (moderate and very) around MRI scanners, namely maintenance engineers, medical physicists, nurses, radiologists and radiographers (exposed). Professionals such as cleaners, porters, medical doctors and a few radiographers felt slightly unsafe, slightly safe and neutral. The perception of being unsafe around MRI scanners could be attributed to participants not being sufficiently trained (Fatahi *et al*., 2016), and lack of experience working with MRI scanners. Van Dongen *et al*. (2011) compared the perception of health risks of electromagnetic fields (EMFs) among MR radiographers and airport security officers. MR radiographers indicated a low risk perception and felt more positive towards EMF sources than security officers due to training in the occupation of EMF sources (MRI).

The strength of the scanner was not perceived as a safety risk. The perception of safety of MRI scanners among participants working with 1.5 T, 3.0 T, and both scanners was similar. The only factor that influenced how MRI staff perceived the safety of MRI scanners was their years of experience working in the MRI units.

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Participants who had mid-age (5-6) experience working in the MRI units perceived MRI scanners to be safe. The mid-age experience constitutes of professionals who felt safe (moderate and very) around MRI scanners. None of the participants from the control group rated the safety of MRI scanners.

4.5.1.2 Transient health effects: Shift duration and job title

The majority of participants who experienced transient health effects worked shifts of eight hours each in the MRI units. This is an indication that within their work shift, they spent more time in the scanner room, where high stray static magnetic fields exist. This has been suggested in previous studies (Antunes *et al*., 2012; Mian *et al*., 2013; Fatahi *et al*., 2016). In this study, participants experienced SMF exposure-related effects such as a metallic taste, a feeling of instability when standing, walking or moving, and dizziness or vertigo on various shift durations (eight, two and one hour); however, these effects were more prevalent among those who worked eight-hour shifts. Four MR staff who had a shift duration of one and two hours experienced the metallic taste frequently (usually), and this could be attributed to the performance of activities in close proximity to the scanner. According to Antunes *et al*., (2012) and Fatahi *et al*., (2016), strong magnetic fields are the main contributing factor to evoke most of the acute transient symptoms experienced by those in close proximity to the scanners. Apart from the prevalence of SMF exposure-related effects among those who spent more hours in the MRI units (eight hours), the feeling of instability when standing, walking or moving was experienced half of the time by seven participants who had a shift duration of two hours and two participants with one-hour shifts. Six participants who spent eight hours, and two who spent one hour per shift in the MRI

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units experienced dizziness or vertigo half of the time. Only two participants who worked two-hours shifts in the MRI units reported to experience vertigo seldomly.

When stratifying all shift durations and the reporting of transient health effects, it is noted that a metallic taste was experienced frequently (usually) among participants working in all shift durations, the feeling of instability when standing, walking or moving, and dizziness or vertigo was experienced half of the time. However, there were instances where participants experienced dizziness or vertigo seldomly and this occurred among those who spent only two hours in the MRI units. One staff member who does not work shifts in the MRI also indicated to have experienced a metallic taste frequently (usually), and a feeling of instability and vertigo half of the time. This participant (medical doctor) reported to have been in close proximity to the scanner (3.0 T) when accompanying a patient.

Although a sudden feeling of warmth was not statistically associated with shift duration, nine participants reported to experience it seldomly. Eight of these participants worked shifts of eight hours and one participant spent one hour per shift in the MRI units. These participants reported to have either repositioned the phantom during acceptable testing or fixed patients' drips during image acquisition. Hansson-Mild *et al*. (2019) suggest that MR personnel could be exposed to RF energy when performing interventional procedures to levels similar as those to which patients are exposed. In this study, a sudden feeling of warmth was classified as a RF exposure-related transient effect. Karpowicz and Gryz (2006) suggested that exposure to RF energy among MR personnel is significant in close proximity to the scanner, particularly when patients are scanned. In addition, exposure to RF energy could rise the tissue temperature and result in thermal effects (Frankel *et al*., 2015).

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Transient health effects such as headaches (exposure unrelated), a sensation of glowing (RF exposure-related), and a feeling of light-headedness or weightlessness (SMF exposure-related) were significantly associated with job titles. Headache was more prevalent among nurses (nine) and radiographers (eight). One radiographer from the control group reported to have experienced headaches. Although headache was classified as an exposure-unrelated symptom, as indicated in the Lund Subjective Health Complaint Inventory (SHC) Questionnaire (Eriksen *et al*., 1999), it was reported to be experienced by both exposed and unexposed study participants, and MR staff, and was also reported in studies conducted by De Vocht *et al*. (2015) and Schaap *et al*. (2014). It is therefore assumed that experiencing headaches might be related to exposure to SMFs or side effects of medication participants take. Many of the self-reported symptoms in this study, like headaches, and the way in which they occur, remain unknown (*cf.* De Vocht *et al*., 2015), and a perception threshold may exist for certain effects (Cavin *et al*., 2007). The sensation of glowing was experienced by two maintenance engineers, but seldomly. Maintenance engineers are more likely than other professionals to experience exposure effects of RF energy when performing acceptable testing and periodic maintenance of MRI scanners' components.

The seldomly experienced feeling of light-headedness or weightlessness was more prevalent among nurses (six) and radiographers (six). Two cleaners and one maintenance engineer reported a seldomly experienced feeling of light-headedness or weightlessness. Nurses reported to have been in close proximity to the scanner magnet when fixing patients' drips, and radiographers when cleaning the 1.5 T scanner on certain days, as well as assisting porters to lift patients from the scanner bed. Cleaners indicated that their job in the MRI room included mopping the floor and cleaning inside the scanner bores, while the maintenance engineer got very close to

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the scanner when performing acceptable tests. Schaap *et al*. (2014) suggest that MR personnel performing activities in close proximity to the scanner magnet are likely to report SMF exposure-related symptoms.

4.5.1.3 Transient health effects: Presence in the MRI room and safety of MRI scanners

The MR staff included in this study were more likely (OR 39.15, 95%CI: 4.91- 312.02) to report MRI-related transient health effects than non-MR staff (control group). Moreover, radiographers that reported to have been in the MRI room during their shifts, where the scanner is located, reported more transient health-related effects (OR 60.75, 95%CI: 5.99- 616.67) ($p< 0.0005$) than other radiographers (control group). When cross-tabulating transient health effects and presence in the MRI room, headache was mostly reported among MR staff members who had been in the MRI room during their work shifts. Nurses, radiographers and cleaners reported to have experienced vertigo, a feeling of instability when standing, walking or moving, and a metallic taste half of the time. Presence in the MRI room, where the scanner is located, could aggravate the exposure and core symptoms of SMFs (Wilén and De Vocht, 2011). The difference in the findings regarding transient health effects and increased exposure (from 1.5 to 3.0 T scanners) was not observed. These results are in accordance with the finding of De Vocht *et al*. (2015), and this could be attributed to a small sample size, since other studies included an exposure range from 0 up to 7 T (Gilles *et al*., 2013; Heinrich *et al*., 2014). Headache was the only transient health symptom associated with the perception of safety around MRI scanners when compared to other effects, and one radiographer (control group) experienced it usually.

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4.5.1.4 Transient health effects: Movement of head/upper body and years of experience

Movement of head/upper body in the MRI scanner bore during image acquisition was significantly associated with all SMF and RF exposure effects. These effects were experienced by participants when moving their head/ upper body at least once (one time) in the scanner bore. All SMF exposure-related symptoms were experienced half of the time, and only a maintenance engineer working with 3.0 T scanner experienced a metallic taste frequently (usually). Symptoms associated with RF energy exposures were mainly experienced by nurses and medical doctors who frequently fix patients' drips during image acquisition, medical physicists and maintenance engineers during repositioning of phantoms, and radiographers when assisting to position patients with severe medical conditions. Tiredness and involuntary muscle contraction were not associated with movement of upper body/ head in the scanner bore.

The feeling of dizziness or vertigo among those with five years' MRI experience was reported by two radiographers (seldomly) and two nurses (half of the time). The same participants also reported to experience instability when moving, standing or walking. Two participants reported this happened seldomly, and two said it happened half of the time. A metallic taste was prevalent with three radiographers (seldomly), and three nurses (half of the time). No study could be found that attempted to associate transient health effects with years of experience in the MRI units. Although studies (Schaap *et al*., 2014; De Vocht *et al*., 2015) have shown that transient health effects resulting from exposure to MRI-related EMFs last for a short duration of time across all MR staff, this study shows that transient health effects were more prevalent among those with mid-year (five years') experience (mostly reported, namely 9.09%). This is due to the fact

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that the majority of participants had an average work experience in the MRI of between five and six years.

4.5.2 Interview responses

In this study a difference was observed in the knowledge of the medical physicist, radiographer and radiologists about MRI safety risks. This might be ascribed to the different functions they perform in the MRI units that determines the extent to which their job involves safety risk observations. The finding of this study indicated that there are no updated MRI safety policy documents in either of the hospitals, and it is clear that this is associated with the knowledge gap on safety issues regarding MRI. This finding is in accordance with results of a study on MRI safety practices conducted in Ghana (Opoku *et al*., 2013). Opuku *et al*. (2013) suggested that there was a lack of effective and efficient policy documents and guidelines in the radiography department where the study was conducted, and that attributed to the knowledge gap on MRI safety. Hughes and Ferrett (2011) regard safety policies in the workplace as a cornerstone for efficient safety practices. It is essential for all MR staff to realize safety aims, objectives, and targets for all safety issues in the MRI units (Piersson and Gorleku, 2017). It was also noted that when changes or upgrades, either in hardware or software, were brought about to the MR machine, safety policies were not updated. This was due to the perception that the scanner in hospital B was very recent and no upgrades had been due at the time of the study. The ACR guidance document on MR Safety Practices (2013) stipulates that MR safety policies and procedures should be reviewed and updated if there are any significant changes in the safety parameters of the scanner, either software or hardware. It is important for both hospitals to have a

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copy of ACR guidelines in place in order to compile their own tailor-made safety procedures and policies when upgrades are needed.

The system of standardised evaluation and classification of equipment by labelling them MR safe, conditionally safe or unsafe is not used by staff in either hospital; rather, as indicated by participants, this is a responsibility left in the hands of the relevant MRI vendors. The ACR manual on MR safety (2020) indicates that all equipment prior to being brought into the MRI units must undergo standardised evaluation and labelling to classify them as MR safe, conditionally safe or unsafe. This, however, in both hospitals is done by MRI vendors when conducting periodic maintenance. Although many MRI incidents occur as a result of improper screening or inappropriate access control (Piersson and Gorleku, 2017), it was noted that in both hospitals, there is restricted access to anyone entering the MRI suite. The responses of participants revealed that MR and non-MR staff members are allowed to enter zone III or IV without undergoing safety screening, consequently putting them at risk of exposure to magnetic fields (exposure levels are provided in chapter 3). A similar observation was made among nurses, anaesthetics and medical doctors in Opoku *et al*.'s study (2013) who merely were asked to remove their metallic possessions without being subjected to mandatory screening. Close observation during the study revealed that no single staff member that entered zone III or IV was screened by direct visual inspection or passed a well-working ferromagnetic detector in either hospital. This might be due to the absence of a ferromagnetic detector in hospital B, and one malfunctioning detector in hospital A. Shellock and Spinazzi (2008) suggest that a standardised screening form, coupled with visual observation and the use of ferromagnetic detectors is important in identifying objects or materials that may be potentially harmful in the static magnetic fields environment.

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It was noted that infection control does exist in the MRI units of both hospitals in a form of cleaning MRI units. However, the chief radiographer in hospital B indicated that cleaning of the MRI units on certain days is undertaken by radiography staff. This is based on inconsistence of training of MRI cleaning staff that could potentially put them in danger. Training on MRI safety is recommended to all persons working in the MRI units (Hood, 2020). The MRI radiographers and radiologists are required to undergo annual advanced MRI safety training (The Joint Commission, 2015) and non-MR staff who are constantly in the MRI units must have basic annual training (Hood, 2020). The MR staff members who sometimes work in the MRI units must undergo a quick screening conducted by an MR radiographer or radiologist.

Though the maintenance schedule for hospital B was missing (according to the chief radiographer), it was indicated that the maintenance of MRI scanners in both hospitals is conducted periodically, according to the maintenance schedule by respective MRI vendors. This is in accordance with the requirements of the International Electrotechnical Commission (2010), namely that the periodic maintenance of MR scanners should strictly be adhered to by the MR manufacturer. It was also reported that there is no demarcation of the four MR safety zones. Sammet (2016) recommends that the four MRI safety zones should be clearly demarcated as this will ensure strict adherence to MRI safety (Kanal *et al*., 2013). This study further revealed that there is no procedure to report safety accidents or near incidents specific to the MRI units in either hospital, although it was indicated that there is a procedure in hospital B, but there is no guidance on how to report the results. This could mainly be attributed to the lack of policies for emergency management in the MRI units. Two studies have suggested that the majority of healthcare professionals are not prepared for medical emergencies (Fowkes *et al*., 2010; Gowing *et al*., 2017). Kanal *et al*. (2013)

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recommend emergency preparedness plans to be part of the organisational safety culture, and that healthcare professionals should be equipped with the required knowledge and skills in order to deal with emergency situations (MedPro, 2016; American Heart Association, 2017).

The only PPE reported to be worn (occasionally) when entering zone IV is earmuffs to reduce exposure to acoustic noise. This is consistent with the findings of an earlier study that reported the availability and use of earmuffs and earplugs in the MRI units (Piersson and Gorleku, 2017). The use of hearing protective devices, such as earmuffs and earplugs, is mandatory when entering zone IV (Kanal *et al*., 2013). However, it was noted that other forms of PPE to protect staff from MRI-related EMFs were not available. This could have been influenced by the perception of the medical physicist who provided in-house training to all MR staff, that static magnetic fields cannot pose any harm to the health and safety of MR staff.

4.6 Conclusion

This is one of the relatively few studies investigating the prevalence of transient health effects among MRI staff working with 1.5 and 3.0 T scanners, and the first such study in South Africa. The results presented in this study report support the findings of previous studies that routine work in the MRI room, where the scanner is located, is associated with reports on SMF-exposure related effects; while this study is the first to report on RF energy transient effects. The findings of this study suggest that perceptions of safety risks of MRI scanners are similar among staff members, whether they work with 1.5 scanners, 3.0 T scanners, or both. Reporting on transient health effects was not influenced by the perception of the safety of MRI scanners, nor the

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strength of the scanner; however, it was primarily influenced by longer shift duration in the MRI room and performance of activities in close proximity to the scanner bore (limitations are discussed in chapter 7). Irregularities or activities that caused MR staff to stay in the MRI room for longer than usual, as well as moving the upper body/ head in the scanner bore evoked SMFs and RF energy-exposure related effects. It was observed that maintenance engineers, medical physicists and radiologists perceived MRI scanners to be safer than other MR staff did. This suggest that more intense training is needed to all staff in the MRI units.

In terms of MRI safety risks, both hospitals complied with the ACR guidelines in some areas; however, there are shortfalls that need to be addressed. In order to address the identified shortfalls, this study recommends that both hospitals should establish the following: (i) MRI-specific safety policies that could be updated when there are any changes that need to be effected to MRI scanners; (ii) MR safety training to be given to all MR staff, including the development of guidelines on how to report MRI-related incidents; (iii) the installation of ferromagnetic detectors that should be coupled with the MRI safety questionnaire for non-MR and MR staff; (iv) demarcation of all MRI safety zones and strict access restrictions to all non-MR personnel, and (v) the training of MR staff on the use of PPE in zone IV, and MRI-related health effects.

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4.7 References

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Chapter 5
Review of health and safety control measures and MR quality control results in the MRI units of two public hospitals within the Mangaung Metropolitan region

Abstract

This study aimed to assess the health and safety compliance of two MRI units and scanners with quality performance in Mangaung Metropolitan region. This study adopted an observational-descriptive design. Baseline risk assessment was used to review existing control measures and compliance with MRI health and safety requirements in the MRI units of hospitals A and B. The availability of MRI Health and Safety Measures were benchmarked against ACR MRI safety requirements. Furthermore, probability and consequence scores were rated according to Exeter MRI risk assessment. Weekly quality control test results obtained from both facilities were measured against the ACR QC acceptable criteria. The results of risk assessment suggested that both scored a moderate risk score of 12.3 for hospital A and 13.1 for hospital B. Similar risks were observed; however, lack of demarcation of four MRI safety zones, ferromagnetic detectors, 5-gauss line and access control increased the risk rating in both facilities. Defective air-cooling systems influenced the ACD measurements performed from 1.5 T Siemens. Low contrast object detectability had 29 spokes for ACR T2, while the PIU for image intensity uniformity was 78.2% on a 3.0 T Philips. High and moderate risks observed in both facilities could be reduced by implementation of an effective health and safety programme. Ambient temperature within the scanner room should be maintained at 21^{O}C to attain well-performing ADC measurements and RF subsystems should be visually inspected and maintained regularly to obtain optimal image quality.

Keywords: risk assessment; quality control; hazards; risks; magnetic resonance imaging

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5.1 Introduction

The acquisition of an image from the magnetic resonance (MR) scanner is unique and mainly depends on the inherent behaviour of hydrogen protons bound to tissues and fluids to produce an image contrast (Tsai *et al*., 2015). The use of magnetic fields and radiofrequency coils presents a variety of safety challenges that are different from other radiological imaging processes (Tsai *et al*., 2015). With the increasing clinical demands for MRI, there is a need for MR workers to be trained in MRI safety to protect themselves, patients, and other healthcare workers (Sammet, 2016). Despite the need for comprehensive safety training, health and safety hazards arising from main static magnetic fields leading to projectile force and transient effects, RF magnetic fields associated with heating and gradient magnetic fields producing acoustic noise still exist (Kraff and Ladd, 2016). In order to mitigate the safety risks present in the MRI units, risk assessment is necessary to identify all hazards that could affect the health and safety of MR staff, patients and related healthcare workers. Quality control tests are also used to form the basis of MRI safety protocols in the MRI units. In this study, risk assessment was conducted in the 1.5 and 3 T MRI units of two public hospitals to identify all risks and hazards present in the units. Though this study focused on occupational health and safety risks, the results of quality control tests performed in both hospitals were also benchmarked with the ACR quality control guideline document (Safety ACR, 2020).

There is scarcity of literature regarding hazards identification and risks assessment in the MRI units. With the increasing use of 3.0 T, MR staff should never assume MR compatibility or safe information about any device brought into the MRI units, especially if it is not clearly documented in writing (Kanal *et al*., 2013). Durbridge (2011) suggests that screening must be compulsory for all persons entering the MRI

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units, details of implantable devices must be known, and access to the area containing the 5-G line and the magnet room must be restricted. Since the MRI safety risks are unique and require an understanding of hardware and electromagnetic (EM) principles, the inherent risks could potentially be minimized through the development of a safety culture that relies on MR staff to develop policies that suit their individual facilities (Tsai *et al*., 2015). In this study, comparison of hazards and risks was drawn between two facilities, one with a 1.5 and the other with a 3.0 T MRI scanner, in order to assist in tailoring a health and safety model for the MRI units.

5.2 Problem statement

A dearth of literature exists regarding the assessment of possible risks and hazards that could affect the health and safety of health care workers in the MRI units. Available literature suggests that control measures are in place to protect patients from MRI safety risks. However, in the recent clinical applications, the most common magnetic strength used ranges from 1.5 to 3.0 T, and the risks attributed to the use of these radiological modalities have never been quantified in South Africa. In the context of workers' health and safety, a need exists to assess the effectiveness of existing control measures, hazards and risks associated with the use of MRI scanners. To evaluate risks and hazards in the MRI units included in this study and the effectiveness of existing control measures, a risk assessment and comparison of quality control results were performed to find answers to the research question.

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5.3 Methodology (design)

The study was quantitative in nature and adopted an observational-descriptive design. This was based on having to quantify risks and hazards on the risk assessment, and the quality control measurements. An observation tool was used to collect risks and hazard related information in the MRI units. To ensure validity, a checklist consisting of all possible risks and hazards was designed according to the ACR manual on MR safety (Safety ACR, 2020). A walk-through survey was conducted to observe possible existing hazards as well as risk in zones III and IV of the MRI units. A discussion was also conducted with the medical physicists and maintenance engineers as part of the walk-through survey of the maintenance interval of the MRI scanners and presence safety guidelines in the MRI units. The information recorded on the checklist was fed into a health and safety baseline risk assessment. Results of quality control tests performed by medical physicists in both hospitals also were reviewed.

5.3.1 Data collection tool

5.3.1.1 Checklist

An observational checklist (Annexure K) was designed as part of a tool used to identify the presence of hazards in zone III and IV of hospital A and hospital B. The checklist consisted of three columns: a brief description of hazards, a column for *yes* and a column for *no*. Descriptions of the hazards found in the checklist were compiled based on safety requirements stipulated in the ACR guideline of 2020. The focus was on the occupational safety requirements. The hazard-related items contained in the checklist included factors such as the presence of ferromagnetic detectors, the use of hearing protection devices by MR and non-MR personnel, demarcation of the 5-Gauss line

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and four MRI zones, as well as lockers to store personal belongings of MR staff. Other factors included in the checklist were the screening of non-MR personnel entering zones III and IV, health and safety policy, exposure of staff to MRI-related electromagnetic fields, access control, as well as “final stop and final check” requirements.

This study received approval and ethical clearance in 2018 prior ammendments that required subsequent approval.

5.3.1.2 Discussion on maintenance intervals and presence of safety guidelines

A discussion was held with two maintenance engineers of two service providers (Philips and Siemens) to check the maintenance interval of the MRI scanners and validate with maintenance schedules. During a walk-through survey the engineers were asked how often the MRI scanners were serviced. The previous maintenance schedules were provided to check if they corroborated with the answers given during the walk-through survey discussion. Both engineers indicated that they performed quality assurance tests four times annually, followed by a comprehensive service of the scanners every second year. Medical physicists from both hospitals were asked to provide the results of the quality control tests performed on MR scanners in their respective hospitals.

5.3.1.3 Presentation of weekly quality control test results

Quality control procedures were performed on two MR scanners in hospitals A and B. In hospital A weekly quality control tests were performed on a 3.0 T Philips Inguena using an ACR phantom that contains structures for measuring geometric accuracy,

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high-contrast spatial resolution, slice thickness accuracy, slice position accuracy, image intensity uniformity, percent signal ghosting and low-contrast detectability. In hospital B, tests only were performed for apparent diffusion coefficient. Therefore, quality control tests of two 1.5 T scanners in hospital A and B could not be compared since 1.5 T in hospital A has been discontinued. Quality control tests on the 3.0 T scanner had been performed once in February 2018 (no quality control data could be provided for subsequent months). The apparent diffusion coefficient test results of the 1.5 T (Siemens, MAGNETOM) for 2018 were compared with the new established limit values of 2018. The ACR phantom used to perform tests had an inner length of 148 mm and diameter of 190 mm, filled with a solution containing 10 mM $NiCl_2$ and 75 mM NACl.

On a 3.0 T Philips scanner, phantom images were analysed according to ACR instructions and the results were compared with the ACR specifications. Geometric accuracy was determined by measuring known distances in the images, while high contrast spatial resolution was evaluated visually based on hole-array pairs with hole diameters of 0.9 mm, 1.0 mm and 1.1 mm. Image intensity uniformity was calculated from pixel values inside the region of interest in a slice containing uniform material, and ghosting values were calculated from the region of interest placed outside the phantom in the image. Furthermore, low-contrast object detectability was visually assessed and this was done by calculating the number of objects visible in images with gradually decreasing contrast and object size. Slice positioning accuracy was measured based on wedge visualization and slide thickness was calculated from a known ramp angle.

Since hospital B performs the diffusion weighted imaging (DWI), the ADC was conducted on a 1.5 T scanner (Siemens), and the protocol was applied with the

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scanner operating in a regular mode (25 mT m^{-1} and slew rate of 40 T m^{-1} s^{-1}). The phantom was secured within the head coil and left in the magnet bore for few minutes, prior to the scanning procedure. Diffusion sensitization was applied independently in the three orthogonal directions; superior–inferior (SI), anterior–posterior (AP) and right–left (RL), and the directional ADC image was calculated. The ADC measurements were obtained at the centre of the images, with a region of interest (ROI) of 20×20 pixels. The spherical phantom (10 mmol nickel chloride solution containing 45 mmol sodium chloride to simulate biological conductivity) was kept inside the scanner room at all times in order to minimise the movement and to acclimatize it to the temperature of the environment. The ADC measurements were recorded for a given ROI on the ADC map. Furthermore, ADC values were calculated automatically by the software and displayed as a parametric map that reflected the degree of diffusion of water molecules. Images were acquired at b = 1000 s/mm^2.

5.3.1.4 Development of base-line risk assessment tool

Risk assessment was designed using data obtained from observational checklist to review existing control measures (Annexure P). The risk assessment template consisted of sections that required descriptions of tasks, hazards, risks, indication of whether a hazard is related to health or safety, consequence, probability, risks rating and outcome, existing control measures, as well as emergency action required. The probability and consequence scales were adopted from the Exeter MRI risk classification scheme. The probability scale ranged from “improbable” on a scale of one to “very likely” classified as five, while consequence ranged from a classification scale of one as “minimal effect” to five as “irreversible effect”. To determine risk rating,

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the probability score was multiplied by the consequence score and this resulted in the determination of the overall risk outcome. The risk outcome was classified in terms of high, moderate, low or no risk. The derivation to overall risk score was based on the outcome or total score of the risk rating. Regarding the score values for risk outcome, if the risk rating was >15, the risk outcome was classified as high, >5 ≤15 was moderate, ≤five was low risk, and zero being no risk. The emergency action required to improve controls was determined by the risk rating score; a score factor of >five led to the recommendation of emergency action to improve safety controls.

5.4 Results

5.4.1 Risk assessment

This study reports on the results of base-line risk assessment conducted in the MRI units of two hospitals housing two different strengths of MRI scanners. Hospital A's 3.0 T MRI unit had a total of ten safety risks and four health risks, whereas nine safety risks and three health risks were identified from the 1.5 T MRI unit in hospital B. In both hospitals, factors such as demarcation of four safety zones, presence of ferromagnetic detectors and performance of final stops and checks of personnel entering the scanner room (zone IV) were identified as high risks (>15), since they either did not exist, were very likely to pose health and safety risks to MR and non-MR staff, or were not in accordance with the requirements of the ACR guideline of 2020 (Tables 5.1 and 5.2). Moderate risks (>5 ≤15) also were identified in both hospitals, and these were classified based on the observational probability that they could occur and existing control measure in place to mitigate the risks. Low risks (≤5) were classified only if the probability of risk was observed to be minimal. Demarcation of the 5-gauss line, access control, lockers for MR and non-MR staff to store their

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belongings, workers' exposure to MRI-related electromagnetic fields, visibility of a health and safety policy, use of hearing protectors during patients' examination, safety screening, and a red illuminated sign, reading *Magnet is always ON,* were rated moderate risks in both hospitals.

Hospital A had a low-risk classification on fading of the 5-gauss line demarcation on the floor of zone IV, and this influenced the health and safety overall risk rating of the hospital (A). The health and safety in the MRI units of both hospitals were rated moderate risks (>5 ≤15), and emergency control measures required to relegate the risk score to low risk (≤5) are indicated in Tables 5.1 and 5.2.

Table 5.1: Base-line risk assessment outcomes for hospital B, 1.5 T MRI unit

Task	Hazards	Risks	*H/S	Probability	Consequence	Risk rating (C*P)	Risk outcome	Existing control measures in the MRI unit	Emergency action required
MRI services in Pelonomi hospital (Scanner: 1.5 T Siemens)	Four MRI zones are not demarcated	*Non-MR personnel may access zones III and IV without supervision of MR personnel and possibly not observe safety protocols. *Non-MR personnel may pass zones II to III without screening and bring along projectile ferromagnetic objects.	**S**	**4**	**4**	**16**	High risk	All zones are separated from each other by physical barriers but require individuals with knowledge on MRI suites to be able to distinguish the zones.	All four MRI zones must be visible and clearly demarcated to allow all non-MR personnel to identify the zones.

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MRI services in Pelonomi hospital (Scanner: 1.5 T Siemens)	5 Gauss line not demarcated in zone IV	*MR-staff may fail to observe or define a border to which the magnetic field could affect implantable devices and to warn non-MR staff about potential interference of magnetic fields with implantable devices.	**S**	**2**	**4**	**8**	Moderate risk	Every person entering the MRI unit, zones III and IV is under the supervision of MR radiographers.	The 5 Gauss line must be demarcated on the floor in the MRI scanner room to delineate the boundary between areas where SMF strength is greater than 5 Gauss.
MRI services in Pelonomi hospital (Scanner: 1.5 T Siemens)	No adequate access control of non-MR personnel to zone III	*MRI safety protocols may not be observed and non-MR personnel may bring along projectile ferromagnetic objects to zone III.	**S**	**3**	**4**	**16**	Moderate risk	*Every person entering zone III is under the supervision of MR radiographer. *There is access control, but there is no passkey locking system.	There should be a physical restriction to access zone III by means of a reliable, physically restricting method, such as a passkey locking system.
MRI services in Pelonomi hospital (Scanner: 1.5 T Siemens)	Exposure of MR staff to MRI-related electromagnetic fields when present in zone IV during image acquisition.	*Potential exposure to static magnetic fields and RF magnetic fields and development of exposure-related effects. *Movement of workers in the MRI scanner room might expose them to time-varying magnetic fields and developing exposure-related effects.	**H**	**5**	**2**	**10**	Moderate risk	MR and non-MR staff are not always present in the scanner room during image acquisition. *The Siemens 1.5 T MR scanner has been certified to operate in accordance with the IEC 60601-2-33 MR safety standard.	*There must be an appointment of a health and safety officer in the MRI suite. *There should be ongoing performance of exposure assessment when there are changes in the MRI software or hardware.

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MRI services in Pelonomi hospital (Scanner: 1.5 T Siemens)	No ferromagnetic detectors	*Non-MR personnel may bring along projectile ferromagnetic objects that are likely to cause safety accidents in zone IV.	**S**	**5**	**4**	**20**	High risk	*The MRI safety questionnaire is administered only to patients and verbal interview. *In-house MRI safety training to MR staff is provided by the Medical Physicist.	A ferromagnet detection syste should be installed, capa of detecting ve small ferromagnetic objects externa MR and non-M staff, and differentiate between ferromagnetic non-ferromagr materials.
MRI services in Pelonomi hospital (Scanner: 1.5 T Siemens)	No visible health and safety policy on the wall	*Contravene with Occupational Health and Safety Act, 85 of 1993 in terms of providing a clear overarching statement on how the MRI department approaches safety issues and who is responsible for particular safety issues.	**S**	**3**	**4**	**12**	Moderate risk	There is an occupational health and safety policy for the whole clinical imaging department.	A health and safety policy providing safety approaches in the MRI unit must be posted on the wall and be visible to all MR and non-MR staff.
MRI services in Pelonomi hospital (Scanner: 1.5 T Siemens)	No lockers to store staff belongings	*MR and non-MR staff could potentially assume MRI compatibility or safety on devices that are not MRI safety tested and then bring along items in zone III and IV.	**S**	**3**	**3**	**9**	Moderate risk	MR and non-MR staff leave their belongings in zone III under the supervision of MR radiographer.	Lockers must be installed in zone II, to store personal belongings, particularly the ones that are ferromagnetic in nature.

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MRI services in Pelonomi hospital (Scanner: 1.5 T Siemens)	No screening of non-MR personnel entering zones III and IV	*MRI safety protocols may not be observed and non-MR personnel may bring along projectile ferromagnetic objects to zone III.	**S**	**3**	**4**	**12**	Moderate risk	Non-MR staff leave their belongings in zone III under the supervision of MR radiographer.	MRI safety questionnaire must be designed for non-MR staff and be completed prior to entering zone III. This should be coupled with passing through ferromagnetic detection system, visual safety inspection and safety verbal interview.
MRI services in Pelonomi hospital (Scanner: 1.5 T Siemens)	MR staff does not wear hearing protection *all the time* when entering zone IV during patient examination.	*MR staff may be exposed to loud noise for short duration of time, leading to temporary changes in hearing or tinnitus.	**H**	**4**	**3**	**12**	Moderate risk	Hearing protectors (ear muffs) are present in the scanner room.	Ear muffs must be placed in zone III and always be worn prior to entering zone IV when examination is taking place. All MR and non-MR personnel entering zone IV during image acquisition must be provided with their own ear muffs capable of reducing noise levels below 85 dB(A).
MRI services in Pelonomi Hospital (Scanner: 1.5 T Siemens)	No *"final stop and final check"* performed by MRI radiographer on non-MR personnel	*Non-MR staff may not observe MRI safety protocols and may bring along projectile ferromagnetic objects in zone III.	**S**	**4**	**4**	**16**	High risk	Non-MR staff is under supervision of MR radiographer in zone III.	Prior to passing the ferromagnetic detection system into zone III, MR staff should administer MRI safety questionnaire coupled with visual safety inspection

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									and verbal interview.
MRI services in Pelonomi Hospital (Scanner: 1.5 T Siemens)	Clearly marked and red illuminated sign, stating "The Magnet is always On".	*Non-MRI personnel may not observe MRI safety protocol in zone IV, and bring along projectile ferromagnetic objects and become exposed to static magnetic fields when zone III is not sufficiently illuminated.	**H and S**	**3**	**3**	**9**	Moderate risk	A red sign indicating, "The magnet is on" is posted on the door allowing entrance to the scanner room.	A red illuminated sign stating "The magnet is always on" must be installed and be visible before entering the scanner room. This could provide safety caution if zone III is not sufficiently illuminated.

*H= Health; S= Safety

Hospital B scored an average risk rating of 13.1 and was classified as moderate risk. A factor that influenced the risk-rating score included the lack of demarcation of the fourth MR safety zone. Through a walk-through survey, it was observed that none of the four MR safety zones was labelled accordingly and this could make it difficult to identify zones, especially to non-MR staff and newly appointed MR staff who had not received in-house MR safety training. The ferromagnetic detector was not installed, there was no final stop and checks performed on non-MR staff entering zone III and IV, and a 5-gauss line was not marked on the floor in zone IV. This does not comply with the latest requirements of the ACR MR safety rules. Although some factors were classified as a moderate risk, appropriate and substantial alternative control measures were used to reduce the identified health and safety risks.

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Table 5.2: Base-line risk assessment outcomes for Hospital A, 3.0 T MRI unit

Task	Hazards	Risks	*H/S	Probability	Consequence	Risk rating (C*P)	Risk out-come	Existing control measures in the MRI unit	Emergency action required
MRI services in Universitas Hospital (scanner: 3 T Philips)	Ferromagnetic detector is not functioning	*Non-MR personnel may bring along projectile ferromagnetic objects that are likely to cause safety accidents in zone IV.	**S**	**5**	**4**	**20**	High risk	* MRI safety questionnaire and verbal interview are administered only to patients. *In-house MRI safety training to MR staff provided by the Medical Physicist	Ferromagnetic detection system should be maintained according to manufacturer's requirements. The use of ferromagnetic detection system should be coupled with staff MRI safety questionnaire and verbal interview prior to entering zone III.
MRI services in Universitas Hospital (scanner: 3 T Philips)	No visible access restriction to zone IV when MRI scanner is not in use	*Non-MRI personnel may not observe MRI safety protocol in zone IV, bringing along projectile ferromagnetic objects and becoming exposed to static magnetic fields.	**H and S**	**3**	**4**	**12**	Moderate risk	Non-MR personnel are under the supervision of MRI radiographer in zone III.	Non-magnetic barrier chain should be used to restrict access to zone IV when the scanner is not in use.

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MRI services in Universitas Hospital (scanner: 3 T Philips)	No lockers to store staff belongings	*MR and non-MR staff could potentially assume MRI compatibility or safety of devices that are not MRI safety tested and brought along to zone III.	**S**	**3**	**3**	**9**	Moderate risk	MR and non-MR staff leave their belongings in zone III under supervision of the MR radiographer.	Lockers must be installed in zone II, to store personal belongings, particularly those that are ferromagnetic in nature.
MRI services in Universitas Hospital (scanner: 3 T Philips)	Exposure of MR staff to MRI-related electromagnetic fields when present in zone IV during image acquisition.	*Potential exposure to static magnetic fields and RF magnetic fields and development of exposure-related effects *Movement of workers in the MRI scanner room might expose them to time-varying magnetic fields and developing exposure-related effects.	**H**	**5**	**2**	**10**	Moderate risk	MR and non-MR staff are not always present in the scanner room during image acquisition. *The Philips 3.0 T MR scanner has been certified to operate in accordance with the IEC 60601-2-33 MR safety standard. .	* A health and safety officer must be appointed in the MRI suite. *There should be ongoing performance of exposure assessment when there are changes in the MRI software or hardware.
MRI services in Universitas Hospital (scanner: 3 T Philips)	No physical access control of non-MR personnel to zone III	*MRI safety protocols may not be observed and non-MR personnel may bring along projectile ferromagn	**S**	**4**	**4**	**16**	Moderate risk	Every person entering zone III is under the supervision of the MR radiographer. *There is access control, but there is no	There should be a physical restriction to access zone III by means of a reliable, physically restricting method, such as a passkey

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		etic objects to zone III.						passkey locking system.	locking system.
MRI services in Universitas Hospital (scanner : 3 T Philips)	No visible health and safety policy on the wall	*Contravene with Occupational Health and Safety Act, 85 of 1993 in terms of providing a clear overarching statement on how the MRI department approaches safety issues and who is responsible for particular safety issues.	**S**	**3**	**4**	**12**	Moderate risk	There is an occupational health and safety policy for the whole imaging department.	A health and safety policy providing safety approaches in the MRI unit must be posted on the wall and be visible to all MR and non-MR staff.
MRI services in Universitas Hospital (scanner : 3 T Philips)	The four MRI zones are not demarcated	*Non-MR personnel may access zones III and IV without supervision of MR personnel and possibly do not observe safety protocols. *Non-MR personnel may pass zone II to III without screening and bring along	**S**	**4**	**4**	**16**	High risk	All zones are separated from each other by physical barriers but require individuals with knowledge on MRI suites to be able to distinguish the zones.	All four MRI zones must be visibly and clearly demarcated to allow all non-MR personnel to identify the zones.

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		projectile ferromagnetic objects.							
MRI services in Universitas hospital (Scanner : 3.0 T Philips)	No screening of non-MR personnel entering zone III and IV	*MRI safety protocols may not be observed and non-MR personnel may bring along projectile ferromagnetic objects to zone III.	**S**	3	4	**12**	Moderate risk	Non-MR staff leave their belongings in zone III under the supervision of MR radiographer.	MRI safety questionnaire must be designed for non-MR staff and be completed prior to entering zone III. This should be coupled with passing through a ferromagnetic detection system, visual safety inspection and verbal safety interview.
MRI services in Universitas Hospital (scanner : 3 T Philips)	The 5-gauss line demarcation on the floor is fading	*MR-staff may fail to observe or define a border to which the magnetic field could affect implantable devices and to warn non-MR staff about potential interference of magnetic fields with implantable devices.	**S**	**2**	**2**	**4**	Low risk	Every person entering the MRI unit, zone III and IV is under the supervision of MR radiographers.	The 5-gauss line demarcation on the floor must be revamped; this will provide a clear delineation of the boundary between areas where SMF strength is greater than 5 Gauss.

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MRI services in Universitas Hospital (scanner: 3 T Philips)	MR staff does not always wear hearing protection devices when entering zone IV during patient examination.	*MR staff may be exposed to loud noises for a short duration of time, leading to temporary changes in hearing or tinnitus.	**H**	**4**	**3**	**12**	Moderate risk	Hearing protectors (ear muffs) are present in the scanner room.	Ear muffs must be placed in zone III and be worn all the time prior to entering zone IV when examination is taking place. All MR and non-MR personnel entering zone IV during image acquisition must be provided with their own ear muffs capable of reducing noise levels below 85 dB(A).
MRI services in Universitas Hospital (scanner: 3 T Philips)	There is no "final stop and final check" performed by MR radiographer on non-MR personnel	*Non-MR staff may not observe MRI safety protocols and may bring along projectile ferromagnetic objects in zone III.	**S**	**4**	**4**	**16**	High risk	Non-MR staff are under supervision of the MR radiographer in zone III.	Prior to passing the ferromagnetic detection system into zone III, MR staff should administer staff MRI safety questionnaire coupled with visual safety inspection and verbal interview.
MRI services in Universitas Hospital (scanner: 3 T Philips)	Clearly marked and red illuminated sign, stating "The Magnet is On".	*Non-MR personnel may not observe MRI safety protocol in zone IV, and bring along projectile	**H and S**	**3**	**3**	**9**	Moderate risk	A red sign indicating, "The magnet is on" is posted on the door leading to the	A red illuminated sign stating "The magnet is always on" must be installed and be visible prior

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	ferromagnetic objects and become exposed to static magnetic fields.		scanner room.	to entering the scanner room. This could provide safety if zone III is not sufficiently illuminated.

*H= Health; S= Safety

Hospital A had a low-risk score on the 5-gauss line, influencing the average risk rating of the entire MRI unit to 12.3 (moderate risk). Similar to hospital B, hospital A had non-compliant factors that influenced the risk-rating scores to high risks. Such factors included a non-functioning ferromagnetic detector, non-demarcated MR safety zones and final stop and checks. The majority of risks observed were safety related, which is a major concern in terms of ACR MR Safety Guidelines. However, it was noted that the majority of control measures in place were acceptable and capable of reducing the identified health and safety risks to low and moderate.

5.4.2 Quality control

5.4.2.1 A 3.0 T Philips Inguena

On a 3.0 T scanner, the results of quality control for geometric accuracy, high spatial resolution, slide thickness and slice position accuracy are illustrated in Table 5.3 below. Image intensity uniformity, percentage signal ghosting and low contrast object detectability were also determined, and a summary of the results are found in Table 5.4.

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Table 5.3: Summary of results for geometric accuracy, high spatial resolution, slide thickness and slice position accuracy on a 3.0 T Philips scanner

	Geometric accuracy					High spatial resolution			
	Vertical (mm)	**Horizontal (mm)**	**45^{O} 325^{O}**	**Limit**	**Test status**	**Vertical (mm)**	**Horizontal (mm)**	**Limit**	**Test status**
ACR T1 Slice 1	189.32	189.92		190 ± 2 mm	Pass	1	1	<= 1	Pass
ACR T1 Slice 5	188.73	189.02	*188.32 189.24	190 ± 2 mm	Pass	1	1	<= 1	Pass
Localizer	146.2			148 ± 2 mm	Pass				

	Slide thickness					Slice position accuracy					
	Top (mm)	**Bottom (mm)**	**ST**	**Limit**	**Test status**		**Left (mm)**	**Right (mm)**	**Difference (mm)**	**Limit**	**Test status**
ACR T1	79.92	44.45	5.6	5 ± 0.7 mm	Pass	**Slice 1**	33.35	32.22	-1.13	<= 5	Pass
						Slice 11	31.32	28.62	-2.7	<= 5	Pass
ACR T2	98.63	36.12	5.3	5 ± 0.7 mm	Pass	**Slice 1**	30.66	33.6	2.98	<= 5	Pass
						Slice 11			0	<= 5	Pass

*45^{O}

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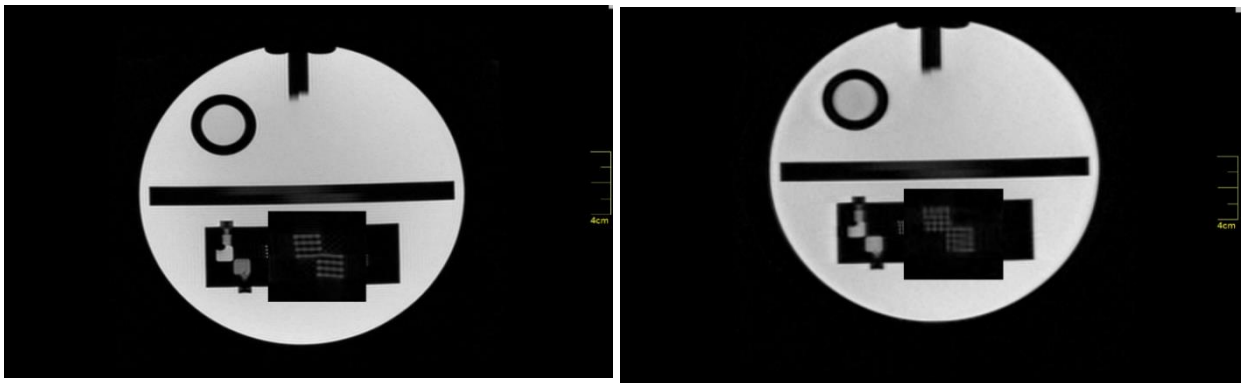
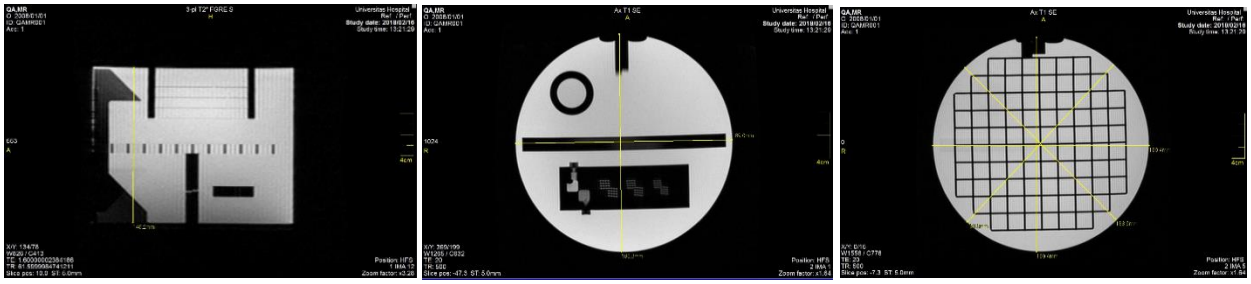
The geometric accuracy test was performed to assess whether geometric distortion could occur during the scanning process. The phantom dimensions in the image were similar to the true dimensions. As prescribed by the ACR procedure, the phantom dimensions were measured in the localizer, slice 1 and slice 5 of the axial series and the localizer presented an accuracy of 146.2 mm. The absolute value for the percentage of geometric distortion did not exceed 2% (Figure 5.1.b). The real inner diameter of the phantom was 190 mm and the inside end-to-end length was 148 mm, meeting standards of the ACR guidance (Ron *et al*., 2015), which allows for a ± 2 mm deviation. With a resolution insert located in slice 1, a high contrast spatial resolution test was conducted to determine the scanner's ability to resolve small high-contrast objects within close proximity of each other. Furthermore, the field of view and matrix size for the axial series were chosen to produce a resolution of 1.0 mm in both directions (Figure 5.1.a). The measured resolution of both axial series was 1.0 mm in both directions.



5.1 a) High spatial resolution



5.1 b) Geometric accuracy

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Figure 5.1: a) High spatial resolution b) Geometric accuracy

On both ACR series the measured slice thickness was 5.6 mm and 5.3 mm, resulting in the scanner passing the slice thickness test (5.0 mm ± 0.7 mm) (Figure 5.2.a). The radiofrequency (RF) amplifier nonlinearity did not cause any distorted RF pulse shapes and no thickness error was identified on either ACR series. The absolute bar length difference for slice 1 and slice11 (Figure 5.2.b) for position accuracy was less than 5 mm.

5.2 a) Slide thickness

5.2 b) **Slice positioning accuracy**

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Figure 5.2: a) Slide thickness; and b) Slice positioning accuracy

The high and low signal levels within a large water-only region of the phantom were measured for both ACR T1 and T2 series. To obtain the region of lowest signal in the ROI, the display window was set to its minimum and the level was lowered until the entire area inside the large ROI was white. The levels were raised until a small region (1 cm^2) of white pixels remained inside a large ROI to obtain the highest signal. The percentage Integral uniformity (PIU) for ACR T1 was 85.3% and 78.2% for ACR T2, failing the test (Table 5.4).

Table 5.4: Summary of results for image intensity uniformity, percentage signal ghosting, and low contrast object detectability on a 3.0 T Philips scanner

Image intensity uniformity					
	High signal ROI	**Low signal ROI**	**PIU (%)**	**Limit 3T (%)**	**Test status**
ACR T1	1672.58	1244.38	85.3	>= 82	Pass
ACR T2	1644.56	1055.83	78.2	>= 82	Fail
Percentage signal ghosting			**Low contrast object detectability**		
Parameters	**Values**	**Slice**	**Spokes T1**	**Spokes T2**	**Ideal**
Large ROI	1494.44	8	10	9	
Top ROI	2.09	9	10	10	
Bottom ROI	22.89	10	10	10	
Left ROI	2.71	11	10		
Right ROI	2.01				
GR	0.00678				
Limit	<= 0.025	**Total**	40	29	>= 37

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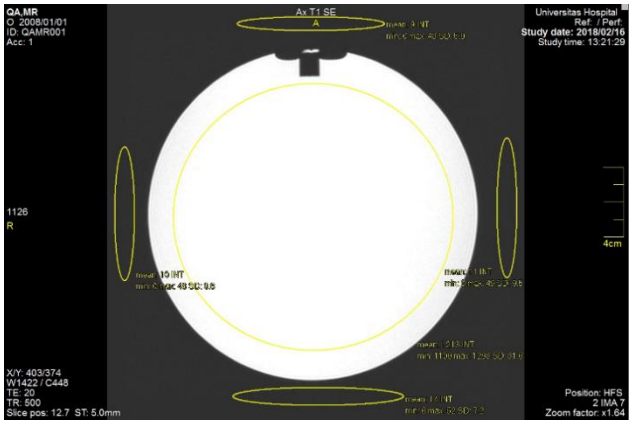
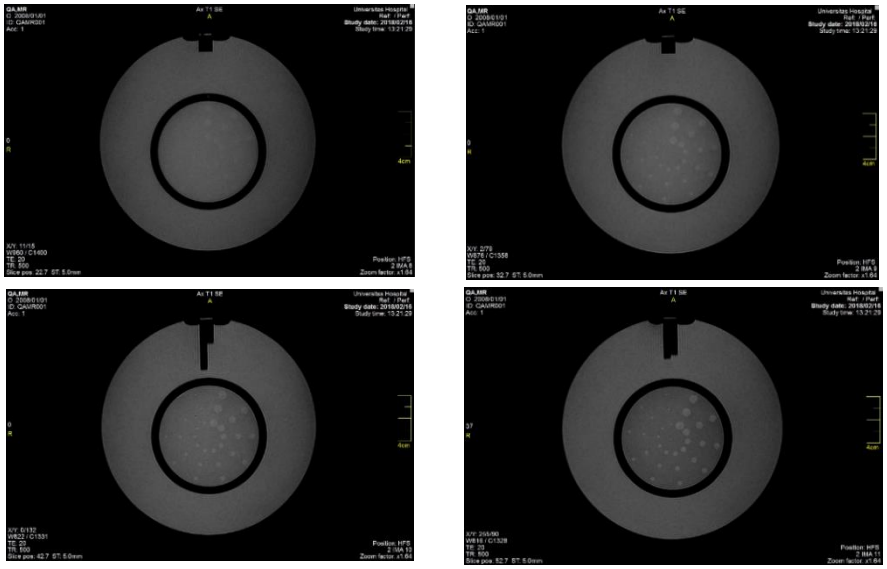
Status	Pass	Pass	Fail

In order to determine ghost ratio, five intensity measurements were made for the ACR T1 series; the average intensity in the image of the phantom, as well as the average intensity in the background at four locations outside of the phantom. The ghosting ratio was 0.00678, being less than the acceptable ghost ratio value of less than or equal to 0.025 (2.5%).



5.3 a) Percentage signal ghosting



5.3 b) Low object detectability

Figure 5.3: a) Image uniformity intensity, and b) Low contrast object detectability

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Measurements were made for ACR T1 and T2 series using four slices for low contrast detectability. In each slice, the low contrast objects appeared as rows of small disks, from the centre of a circle. All the disks on each slice had the same level of contrast. In order, the contrast values were 1.4%, 2.5%, 3.6%, and 5.1% (Figure 5.3.b). All the disks in a given spoke had the same diameter. The measurements comprised counting the number of complete spokes seen in Figure 3.b. The ACR T1 had a total score of 40 spokes, while T2 failed with a total of 29 spokes (ideal >= 37).

5.4.2.2 A 1.5 T Siemens MAGNETOM

The ADC measurements were taken when the phantom acclimatized to an approximate temperature of 21^{O}C; however, the calculated average temperature for the period of 2018 when measurements were performed was 22.8^{O}C. The measured average ADC values in the same period was 0.00204 μm^2/s (Std ± 0.000132), this was on the computed values for X, Y and Z. In order to establish the ADC values, each non-zero b-value (on the ADC maps) was computed using formula (1):

$$ADC_b = \frac{1}{b}\ln\left[\frac{S_o}{S_b}\right], \quad (1)$$

where S_0 is the b = 0 image and S_b is the isotropically weighted DWI at the given b-value. The calculated ADC values for S_0, S_b, X, Y and Z are found in Table 5.5 below.

S_o	**S_b**	**ln**	**b**	**ADC values (μm^2/s)**

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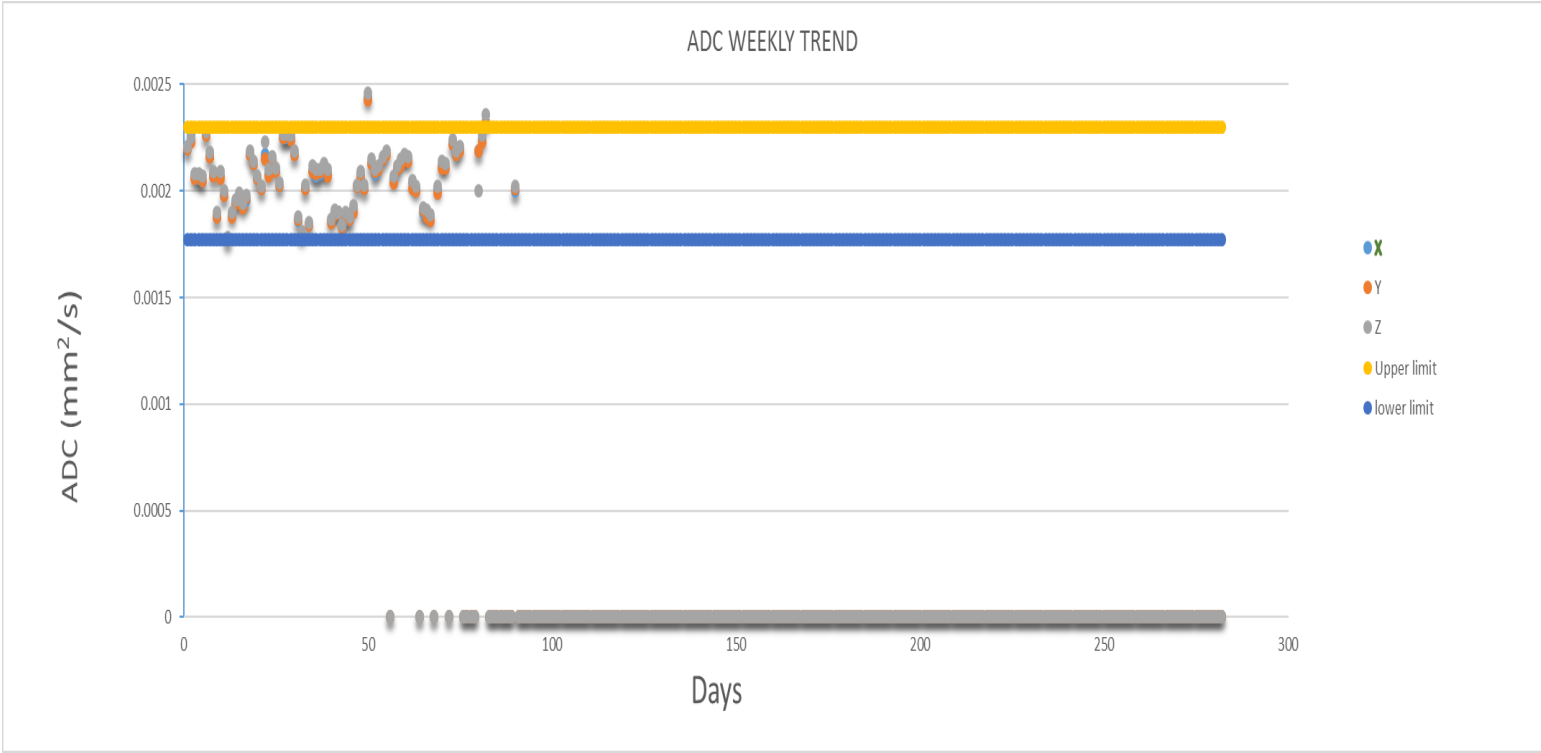
1216	164.5	2.000411492	1000	Y (A/P)	0.00200
1237.2	166.3	2.006812655	1000	Z (S/I)	0.00201
1244.9	165.9	2.015425287	1000	X (R/L)	0.00202

Table 5.5: The measured ADC values for 1.5 T Siemens

The ADC values were well within the acceptable range; however, it was noted that some measurements were influenced by varying temperatures on certain days (Figure 5.4). None of the measurements were below the low acceptable limit.



* **X (R/L); Y (A/P); Z (S/I)**

***Upper limit: 0.002301; Lower limit: 0.001773**

Figure 5.4: Apparent diffusion coefficient weekly trend for 2018

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On day 57 of the measurements the ADC values for X, Y and Z were 0.00244 $\mu m^2/s$, 0.00243 $\mu m^2/s$ and 0.00246 $\mu m^2/s$ respectively. These values were noted to be higher than the acceptable upper limit and the recorded room temperature was 37.7^{O}C. The rise in temperature was influenced by the defective air-cooling system in the scanner room. After maintenance of the air-cooling system, the measured ADC values for X, Y and Z were significantly lower: 0.00188 $\mu m^2/s$ 0.00186 $\mu m^2/s$ and 0.00189 $\mu m^2/s$, with measured room temperature of 15.9^{O}C. Also, on day 94, the measured room temperature was 30.6^{O}C and the ADC values for X (0.00232 $\mu m^2/s$), Y (0.00232 $\mu m^2/s$) and Z (0.00236 $\mu m^2/s$) were significantly higher, above the acceptable upper limit.

5.5 Discussion

5.5.1 Base-line risk assessment

There is a dearth of literature on the assessment of health and safety risks in the clinical MRI units, and this is the first study in South Africa that evaluated risks related to occupational health and safety in the MRI units of two public hospitals. The results show that there are similar risks and hazards that exist in the MRI units of hospital A and B. A relatively small number of high risks were classified compared to moderate and low risks in both hospitals. However, it was noted that the overall risks rating (safety performance) was relatively lower in hospital A (12.3) compared to hospital B (13.1). This has been influenced by the demarcation of the 5-gauss line on the floor of zone IV (scanner room). Hospital A scored a risk rating of four (low risk) due to a fading 5-gauss line on the floor, while hospital B had no demarcated line to provide delineation of the boundary between areas where static magnetic field (SMF) strength is greater than 5-gauss. The American experts on MR safety indicated that areas where SMFs' strength exceeds 5-gauss, they should be clearly marked as potentially

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hazardous (Kanal *et al*., 2013; Keevil, 2016; Sammet & Knopp, 2013). Restoring the 5-gauss line in hospital A, therefore is necessary to relegate the overall risk rating score.

It was noted from the outcome of the risk assessment that hospital B did not have a ferromagnetic detector and this contravenes with the safety requirements of ACR. The ACR MR Safety Committee (2020) requires all MRI facilities to have a ferromagnetic detector before one may enter zone III, and the use of such a detector should be coupled with a visual safety inspection. Apart from screening using ferromagnetic detectors, Keevil (2016) recommends that MR facilities must establish and mark the four MRI zones, have strict access control, and ensure safety screening prior to entering zone III (Simmons and Hakansson, 2011; Cross *et al*., 2018). These factors were observed to constitute moderate risks in both hospitals. Improper use of hearing protectors and absence of red illuminated signs, indicating, “Magnet is always on” was noted to be a risk. Heismann *et al*. (2015) maintain that the switching of magnetic field gradients creates vibration that generates acoustic noise and patients would experience an average sound pressure level ranging from 80 to 109 dB. In order to reduce exposure to acoustic noise and avoid hearing impairments, Kraff and Ladd (2016) recommend the use of earmuffs or earplugs during patients’ scanning. Regarding illuminated signs, Sammet (2016) purports that special warning signs indicating the strong magnetic field and its associated hazards must be present in MRI facilities. In both hospitals MR safety signs are found indicating the magnet is always on, however, they are not illuminated. This might be a safety risk especially when zone III is not properly illuminated.

Both facilities do not have a visible MR safety policy in place. However, it was noted during a walk-through survey that there was a health and safety policy for the entire

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clinical imaging department. Similar MR safety non-compliance has also been noted in a Ghanaian study (Piersson and Gorleku, 2017). Since both facilities have no strict access control to zones III and IV, there is a likelihood of exposure to MRI-related EMFs among non-MR and MR staff who enter the scanner room, and increased odds of experiencing transient health effects. To reduce these risks, it is essential for both facilities to adhere to the ACR guidance document on MR safe practices (2019).

5.5.2 MR quality control

A comprehensive assessment of the performance of two MRI scanners was provided in this study. A 3.0 T scanner complied with the majority of the image quality features that were assessed. However, image intensity uniformity and low contrast objectivity did not meet the ACR acceptable criteria. The 1.5 T scanner performed well with regard to ADC and the majority of measurements were within the low and upper acceptable limit. A defective air-cooling system in the 1.5 T scanner room resulted in elevated temperatures that influenced the ADC measurements. The current study showed that under normal, controlled room temperature, the ADC measurements were stable and within the acceptable range, and this accords with the results obtained from a study that compared the DWI results using a phantom (Lavdas *et al*., 2014). However, since the phantom was stored in the scanner room prior to ADC measurements, the room temperature was unstable, and significantly high ADC measurements were obtained. Lavdas *et al*. (2013) have shown that the stability of ADC measurements could be attained when the phantom is stored in temperature-controlled environments.

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The ACR T2 failed the low contrast object detectability with 29 spokes while the PIU for image intensity uniformity was 78.2%, lower than the acceptable ACR quality control (QC) criterion. According to Chen *et al*. (2004), failure in a uniformity test could potentially be caused by poor phantom positioning, head coil failure and ghosting. Vibration of unstable phantom could create ghosting signals that influence the image intensity. In this study, failure in the low contrast detectability test could have been caused by intermittent ghosting or a tilting phantom. Persistence of this failure would require a medical physicist to repeat the tests and if it continues, a maintenance engineer should be consulted to establish the cause. Since poor signal uniformity suggest that the RF coil has a significantly greater variation in image intensity than normal (Price, Allison and Clarke, 2015), failure of the image uniformity test in this study could have been caused either by a defective RF coil or by underlying RF subsystem faults.

5.6 Conclusion

This study showed that many areas within MRI units of both hospitals comply with occupational health and safety requirements. Although the results of risk assessment suggest that moderate risks exist within the facilities, according to the risk classifications, areas of high risk require urgent attention. Such an area is found where the lack of clear demarcation holds a high risk of potential safety accidents, and safety inspections using visual inspections, a safety questionnaire and ferromagnetic detectors should be employed. It is recommended that both facilities develop a health and safety programme (as recommended in chapter 3) with the aid of the risk

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assessment template used in this study to identify risks and hazards, and improve compliance with health and safety according to ACR MRI safety requirements.

To ensure optimal image quality performance of hospital A, a maintenance engineer of a respectable MR vendor should be consulted to inspect and service the RF sub-systems of the scanner. Furthermore, stability of phantom should be maintained at all times to avoid MRI QC test failures. Failure of the air-cooling system in the scanner room of hospital B (1.5 T Siemens) resulted in temperature variability which subsequently influenced the ADC measurements. It has been shown that desired ADC measurements could be best obtained if the measured temperature of the scanner bore is approximately 21^{O}C (Delakis *et al*., 2004). It is therefore recommended that prior to performing ADC measurements, it must be ensured that the air-cooling system is working efficiently and the scanner bore temperature does not exceed 21^{O} C. The methodological strengths and limitations of this chapter are discussed in chapter 7.

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Chapter 6
A health and safety model for occupational exposure to radiofrequency fields, static magnetic fields and MR safety risks in the 1.5 and 3.0 T MR facilities

Abstract

The aim of developing this model was to provide tailored health and safety solutions to health and safety challenges present in the MR facilities of hospitals A and B. This model addresses exposure levels of SMFs and RF magnetic fields reported in Chapter 3, and transient health effects reported by MR staff and MR safety risks identified in Chapter 4. The model also provides solutions to health risks and safety hazards reported, using the baseline risk assessment discussed in Chapter 5. The major shortfalls identified in both MR facilities studied include insufficient MR safety training, performance of activities in close proximity to the scanner bore, and failure to follow relevant ACR guidelines appropriately. It is recommended that both hospitals develop occupational health and safety programmes that address all challenges reported in Chapters 3, 4 and 5. Furthermore, medical physicists should assume their roles as MR safety officers in order to ensure compliance with relevant ACR guidelines in their respective MR facilities.

Keywords: Health and safety; occupational exposure; safety risks; SMFs; RF energy

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6.1 Introduction

Magnetic resonance imaging (MRI) technologies have an increased use of strong SMFs, and subsequently induced RF energy (Hartwig *et al*., 2018). In the current healthcare system, and particularly in South African public hospitals, 1.5 and 3.0 T scanners are used for diagnostic purposes, while 7 T is mainly used for research in European countries (Hartwig *et al*., 2018). New MRI systems with magnetic fields strength reaching 11.7 T also are used (Schaap *et al*., 2013). Advances in clinical imaging science have led to health risks gaining increased attention, with some of the studies looking at the safety of ferromagnetic objects, tissue heating caused by RF energy above recommended SAR limits, and stimulation of peripheral nerve and temporary hearing damage due to acoustic noise (Shigemitsu and Ueno 2017; Shellock and Crues, 2014). In this chapter, mitigation measures necessary to reduce exposure levels of SMFs and RF energy, magnetic resonance (MR) safety risks and transient health effects among MR staff are discussed.

The use of MR devices such as the MRI scanner is associated with increased occupational exposure to static magnetic fields as it produces high intermediate magnetic fields (Karpowicz and Gryz, 2007; Mild *et al*., 2009). Few studies assessing the health risks for exposed MR staff have been published, and occurrence of transient symptoms such as tinnitus, nausea, vertigo, dizziness, severe headache and concentration problems have been highlighted in studies focusing on 1.5, 3.0 and 7 T scanners in MRI units (De Vocht *et al*., 2015; Schaap *et al*., 2016). According to Hartwig *et al*. (2018), the long-term health implications of the reported transient symptoms among MR workers are not yet known. The safety of MRI scanners with regard to scans taken during pregnancy and the potential risks to obstetric patients have also been extensively discussed in some studies (Alorainy *et al*., 2006;

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Patenaude *et al*., 2014). However, there is a pressing need to define and develop methods to mitigate health and MR safety risks, and this should be done together with providing guidelines for safe working procedures and training for MR workers (Sammet, 2016).

6.2 Problem statement

In the public hospitals of South Africa, 1.5 and 3.0 T scanners are used for MR clinical diagnostics and they are primary sources of exposure to RF energy and SMFs among MR staff. Although strong fields are produced by 3.0 T, induced exposure levels exist near both scanners and this indicates higher exposures in close vicinity. Lack of compliance with the requirements of ACR guidance on safety has also presented health and safety risks in MR facilities. The objective of this chapter was to develop a health and safety model to reduce occupational exposure of MR staff to RF energy and SMFs present in close proximity to 1.5 and 3.0 T MR scanners. In addition, the aim is to reduce exposure-related transient health effects among MR staff, and to improve health and safety practices within MR facilities included in this study (hospitals A and B).

6.3 Development of a health and safety model to reduce RF energy and SMFs exposures, and MR safety risks

In order to reduce occupational exposure to RF energy and SMFs among MR workers and provide protection against the discussed and known potential health effects, the International Commission for Non-ionising Radiation (ICNIRP) has developed safety guidelines to limit occupational exposure levels. These guidelines recommend

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exposure levels below which no adverse health effects should occur in healthy adult workers (Hartwig *et al*., 2018). The American College of Radiology (ACR) has developed guidance documents to improve health and safety in the MR facilities and also to restrict access of non-MR personnel to MR safety zones. The purpose of developing this model was to guide MR facilities and staff working with 1.5 and 3.0 T MR scanners on how to reduce exposure to RF energy and SMFs, thereby preventing the occurrence of transient health effects and potential MR safety risks. According to Raphela (2013), the first step in developing a model of this kind is to recognise electromagnetic fields (EMFs) as hazard in the workplace, and this should be followed by the assessment of exposure levels, health and safety risks, and prevalence of transient health effects among workers. Exposure levels of RF magnetic fields and SMFs remain significantly high, but below recommended occupational exposure limits, in close proximity to MR scanners. The MR safety risks pose a major challenge in the MR facilities, and a prevalence of transient health effects among staff occurs, hence the development of this model.

This model is based on the hierarchy of controls for occupational hygiene, which include elimination, substitution, engineering, administration controls and the use of personal protective equipment (PPE) to mitigate occupational risks and hazards. However, due to the effectiveness of existing control mechanisms in hospital A and B, this model is based on administrative controls with few recommendations made on the use of PPE. Figure 6.1 below illustrate control measures applicable in hospital A and B.

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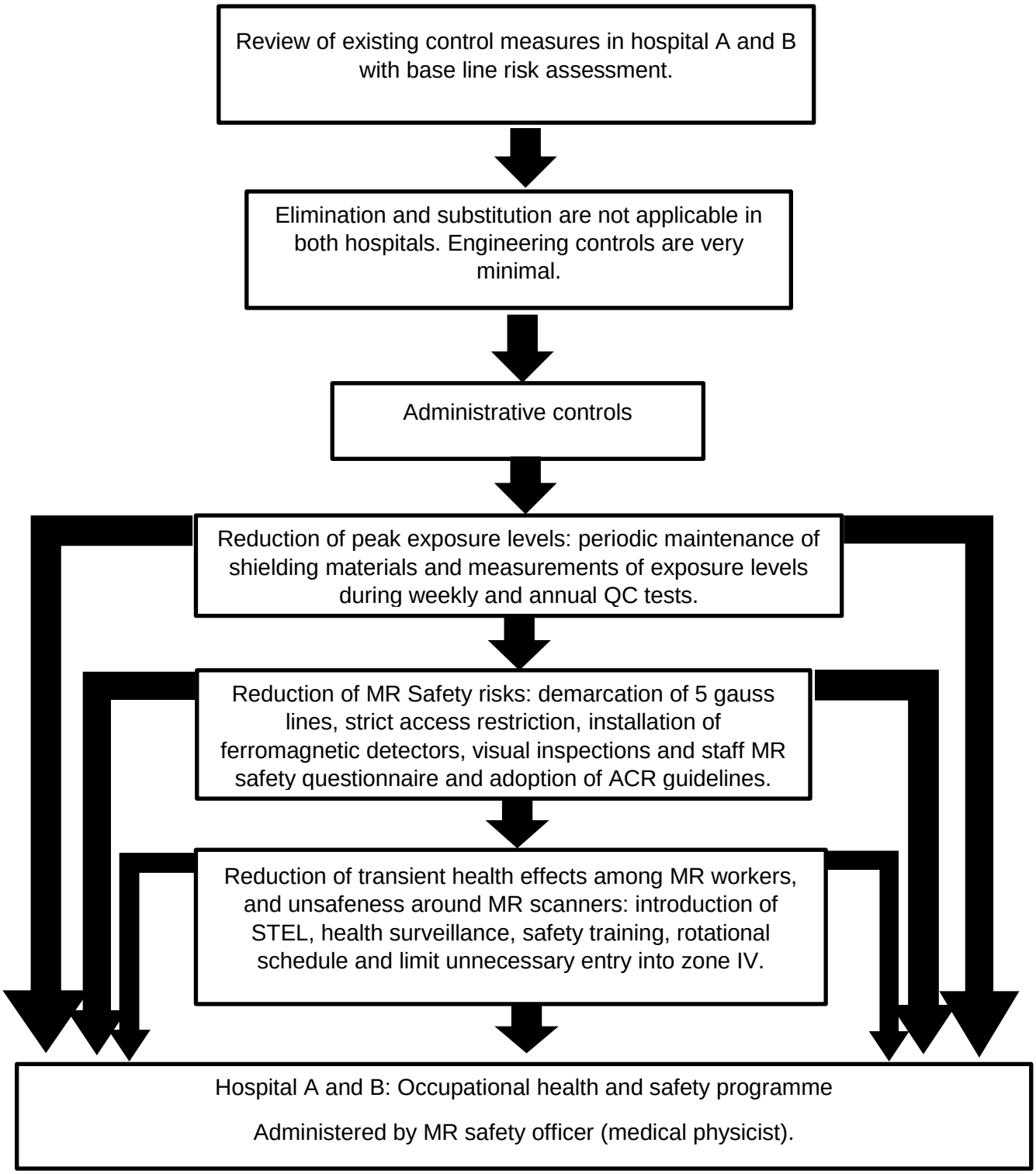

Figure 6.1 flow diagram of control measures for hospitals A and B

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6.3.1 Reduction of peak SMFs and RF magnetic fields exposure levels from 1.5 and 3.0 T MR Scanners

The SMFs and RF magnetic fields exposure values reported in Chapter 3 complied with occupational exposure limits set by the International Commission for Non-Ionizing Radiation Protection (ICNIRP). All the SMF exposure values measured at a distance of 1 m and 2 m from the scanner gantry of the two 1.5 T and one 3.0 T scanners were below 2 T for the head and trunk, and 8 T for limbs (ICNIRP, 2009). Furthermore, RF magnetic field exposure values measured near the scanner gantry (1 m) also were below the recommended reference levels for local exposure (< Incident H-field strength of 0.36 A m−1 limit= 0.45 μT) set in the latest guidelines for RF electromagnetic fields (EMF) in the ICNIRP Guidelines (2020). However, at a distance of 1 m from the scanner gantry, peak SMFs exposure levels were noted, and this is an area were MR staff moves, either assisting a patient, cleaning the scanner room, performing weekly quality control tests or quarterly maintenance of the scanner. In order to reduce peak stray static fields and avoid inhomogeneity in hospitals A and B, passive shims used to correct SMFs' inhomogeneity and reduce stray static fields should be replaced regularly when performing quarterly maintenance of the scanners. Regular replacement of shim materials is beneficial, since they are temperature sensitive and B_0 is more likely to shift during gradient-intensive sequences (Jezzard, 2006).

Every time quarterly maintenance of MRI scanners is performed, exposure measurements discussed in Chapter 3 should be performed in order to determine whether the shielding material needs to be replaced. Although the ACR Quality Control Manual of 2015 recommends RF coils checks and SMFs inhomogeneity checks be performed annually, it is recommended that these assessments form part of weekly

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quality assurance tests performed by medical physicists in both hospitals in order to detect if B_0 has shifted due to gradient-intensive sequences. During the risk assessment survey (see Chapter 5) it was observed that MR staff did not use any type of EMF-related personal protective clothing and no single study in the literature could be found that recommends the use of protective clothing among MR staff. However, EMFs-related protective clothing made of knitted fabric, coated either with Ag, Cu or Ni deposited on the textile surfaces to provide shielding effectiveness with a high contribution to absorption coefficient, reduced transmission, and reflection coefficients has been recommended by Brzezinski *et al*. (2009), Cheng *et al*. (2000) and Perumalraj *et al*. (2010). It is recommended that such protective clothing be used by MR staff in both hospitals when entering the MR scanner room during image acquisition in order to protect themselves against peak exposures that exist at a distance of 1 m from the gantry. Medical physicists, assuming the responsibility of MR safety officers, should provide the instructions on the use and maintenance of such protective clothing.

6.3.2 MR Safety risks and recommended health and safety controls in hospitals A and B

In the MRI facilities of hospitals A and B, similar health and safety challenges were observed in the results of the risk assessment reported in Chapter 5, and MR safety risks interviews reported on in Chapter 4. Both hospitals scored a moderate overall risk score in the risk assessment (hospital A= 12.3 and hospital B= 13.1). Non-compliance in terms of the ACR manual on MR safety (2020) was noted in both hospitals, resulting in moderate health and safety risks; however, MR safety protocols were in place. In order to reduce the health and safety challenges present in both

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hospitals, MR safety protocols should be developed in line with the requirements of the ACR manual on MR safety (2020).

In hospital B, the demarcation of the 5-Gauss line on the floor of zone IV was fading and hospital A had no demarcation at all. In order to avoid the risk of exposure to strong static fields, both hospitals should have a demarcation on the floor of the MR scanner room to delineate the boundary between areas where SMF strength is greater than 5-Gauss. In Chapter 3 of this study report, maximum SMFs exposure levels in hospital B, 1.5 T scanner at 1 m was 732 mT and 362 mT at 2 m. In hospital A (3.0 T scanner), at 1 m the maximum recorded exposure value was 1300 mT and 702 mT at 2 m. Kanal *et al*. (2013), Keevil (2016) and Sammet *et al*. (2013) suggest that where SMFs strength exceeds 5 gauss in MRI facilities, they should be clearly marked as potentially hazardous. Based on SMF measurements described in Chapter 3, it is recommended that the demarcation of the 5-Gauss line be beyond a distance of 2 m from the scanner gantry in both facilities, particularly in the entrance of zone IV.

No ferromagnetic detector was installed in hospital B, and the one installed in hospital A was defective. Although no safety inspections were done through the use of ferromagnetic detectors, both hospitals also did not administer staff MR safety questionnaires or performed visual safety inspections. It was observed that a ferromagnetic detector was present in zone III in hospital A, but it needs to be repaired to function properly. The ACR manual on MR safety (2020) requires all MRI facilities to have ferromagnetic detectors installed at the entrance to zone III, and to establish a comprehensive safety inspection. Hospital B thus should have a ferromagnetic detector installed in zone III, and the use of ferromagnetic detectors should be coupled with visual safety inspections and MR safety interviews prior to entering zone III. All MR and non-MR personnel should be subjected to these inspections. In both facilities,

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the four MR safety zones were not clearly marked; however, the zones are separated from each other by means of physical barriers, and they can only be identified by persons knowledgeable about MR safety protocols. In both hospitals all non-MR personnel entering the MR facilities are under direct supervision of the MR radiographer; however, supervision is conducted effectively only in zone III, since that is where MR radiographers are stationed. All the safety zones in MR facilities ought to be easily recognized; therefore, all zones must be demarcated and clearly marked (Keevil, 2016), as discussed in Chapter 2 of this study report.

Clearly marked zones in both hospitals will assist in restricting unauthorised access of non-MR personnel (Kanal *et al*., 2013) until they have undergone in-house MR safety training provided by medical physicists. Inconsistency in the use of hearing protectors and absence of red illuminated signs, indicating, *Magnet is always on,* were also noted to be safety risks in both facilities. In an event of short-term power-outage, illuminated safety signs could assist non-MR personnel to easily identify restricted areas such as zones III and IV when there is inadequate illumination. Although non-illuminated signs are present, it is recommended that both hospitals should use special warning signs indicating strong magnetic fields (such as illuminated signs) as suggested by Sammet (2016). Switching of magnetic field gradients creates acoustic noise that is likely to generate an average sound pressure level of between 80 and 109 dB (Heismann *et al*., 2015). Frequent exposure to such levels of noise might result in a temporary hearing shift of MR and non-MR staff who are entering MR scanners room during image acquisitioning (Chapter 5). It should be compulsory for every personnel member entering the MR scanner rooms of the facilities to wear earmuffs or earplugs to avoid experiencing hearing impairments. The importance of wearing hearing protectors during MR exams has also been noted by Kraff and Ladd (2016).

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As reported in Chapter 5 and in the interview results in Chapter 4, neither hospital A nor hospital B had MR safety policies in place. The only policy that could be found, was for the entire clinical imaging department, that is, the MRI, CT and X-ray rooms. Both facilities must develop their own health and safety policy, specifically for the MR facilities, and such policy should be developed in accordance with the ACR guidance document on MR safe practices (2019). The person who should oversee compliance with the requirements of this policy is the medical physicist who assumes the role of MR safety officer in both hospitals. However, additional safety training is required for medical physicists in both hospitals in order to be capacitated to comply with the requirements of the Occupational Health and Safety Act, number 85 of 1993 (South Africa, 1993) in the workplace. Safe working procedures should be developed for both MR facilities in order to ensure compliance with of the guidelines ACR manual on MR safety (2020). The safe working procedures should include a description of all four MR safety zones with specific restrictions on access, as well as clear safety demarcations. The procedures should specify the number of visits or entries to zone III and IV for all non-MR staff per day and a description of areas in zone IV where peak exposure levels of SMFs and RF magnetic fields occurs. In both facilities, safety procedures should include a list of personnel authorized to enter zones III and IV, as well as particulars of the medical physicist responsible for enforcing safety compliance.

When changes or upgrades are brought about, either in hardware or in software of both MR scanners, safety policies were not updated. Though it was reported that the MR scanner in hospital B was very recently installed and no upgrades were needed, it is highly recommended that MR safety policies in both facilities be reviewed and updated whenever there are significant changes in the safety parameters of the scanners. This is also a requirement in terms of the ACR guidance document on MR

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Safety Practices (Kanal *et al*., 2013). Infection control occurred in both facilities; however, MR radiographers in hospital B were responsible for cleaning the scanner room on certain days. There must be at least two permanent cleaning personnel members (working on rotational basis) designated to cleaning the MR scanner in hospital B. Prior to being designated for such a function, in-house MR safety training should be provided to them in order to avoid safety accidents. Furthermore, training on MR safety issues is recommended to all MR and non-MR personnel working or visiting MRI facilities (Hood, 2020) of both hospitals. Since MR radiographers and radiologists are required to undergo annual advanced MRI safety training (The Joint Commission, 2015), non-MR staff who are constantly in the MRI units must also receive in-house safety training conducted by medical physicists. Hospital B had a procedure in place to report safety accidents or near incidents specific to the MR facility; however, there was no guidance on how to report results. Hospital A had no existing procedure to report safety accidents or near incidents that occurred in the MR facility. In addition, there was a lack of policies for emergency management in both MR facilities. Medical physicists who assume the responsibility of MR safety officer in these facilities must develop an incident or safety accident-report form to be administered by all MR and non-MR staff when a safety accident occurs. This action should be supplemented by developing written procedures to be posted in visible areas in zone III on how accidents or near incidents should be reported and to whom. An emergency management policy should also be developed by the MR safety officer of both MR facilities and this should form part of the MR safety culture, as recommended by Kanal *et al*. (2013). Such a policy should address emergency response procedures, vital signs, and assembly points in an event of an emergency in the MR facility.

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The defective air-cooling system in the MR facility of hospital B affected the temperature of the phantom, which subsequently influenced the weekly ADC measurements. On certain days, the MR scanner room temperature increased to 37.7^{O}C, resulting in ADC measurements of above the recommended upper limit of 0.002301 μm^2/s for superior–inferior (SI), anterior–posterior (AP) and right–left (RL) directional ADC image, as reported in Chapter 5. To ensure accurate ADC measurements, air-cooling systems should be maintained regularly to ensure optimal ambient temperatures in the scanner room. The MR safety officer, as part of the visual inspection team, should check and record the room temperature on a regular basis, prior to performing ADC measurements. Alternatively, the ice-water phantom, proposed by Chenevert *et al*. (2011), could be used. The image quality test performed on a 3.0 T MR scanner in hospital A failed the low contrast object detectability with 29 spokes and the PIU for image intensity uniformity with 78.2%. This is lower than the acceptable ACR quality control criteria. Tilting of the phantom, as well as a defective RF subsystem were suspected to be the cause. It is therefore recommended that a medical physicist should at all times make reference to the ACR quality control manual prior to performing image quality tests. The defective RF subsystem should be reported to the maintenance engineer, be checked and repaired immediately. Beside systems checks performed quarterly by a maintenance engineer, it is also recommended that the RF coils be replaced every time the scanner is serviced.

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6.3.3 Reduction of transient health effects among MR workers, and unsafeness around MR scanners

Job titles were a significant indicator of how safe MR staff members felt in the vicinity of the MR scanner. As reported in Chapter 4, maintenance engineers, medical physicists, nurses, radiologists and radiographers perceived both 1.5 and 3.0 T scanners safe; however, professionals such as cleaners, porters, medical doctors and a few radiographers felt unsafe near the MR scanner. It is assumed that radiographers feeling unsafe might be due to their lack of work experience in the MR facilities, whereas others had insufficient safety training regarding MR scanners, as observed by (Fatahi *et al*., 2016). Although in-house training was given by medical physicists in hospitals A and B, it is recommended that safety training programmes be conducted at least once a week to all non-MR staff who frequently work in or enter the MR facilities, particularly those who perceive MR scanners to be unsafe. The MR safety refresher training should be conducted to all MR staff at least every two weeks. Such training programmes should focus more on the health effects of exposure to MRI-related EMFs, housekeeping of MR facilities, and avoidance of safety-related accidents or near incidents in the MR facilities. MR safety training always should be given when MR cleaning staff members rotate, return after a long absence, and after weekly quality assurance tests and quarterly maintenance of MR scanners. The MR safety officers in hospitals A and B should develop an MR safety manual in accordance with the requirements of the ACR Manual on MR safety (2020), and provide a copy to every non-MR staff member who frequent all four MR safety zones.

The majority of MR workers who had a shift duration of eight hours experienced SMF exposure-related effects such as a metallic taste, a feeling of instability when standing, walking or moving, and dizziness or vertigo. These effects were more prevalent among

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those with shift durations of eight hours compared to those reported with a shift duration of two or one hour, as reported in Chapter 4. Although these MR staff members did not spend the entire eight hours in the MR scanner room, it was observed that they experienced SMF exposure effects due to their performance of activities in close proximity of the scanner. In order to reduce SMF exposure-related effects among MR staff in both hospitals, a schedule that ensures rotation of workers should be designed with aimed at reducing the exposure time of MR staff. As recommended by the Occupational Health and Safety Act, number 85 (1993) (short-term exposure limit), exposure time in the MR scanner room should be limited to at most 15 minutes. The radiographers in the MR console, as well as the medical physicists should ensure that all MR and non-MR staff members in their respective hospitals do not spend more than 15 minutes in zone IV. An alternative method to ensure an effective rotational system in hospitals A and B is to adopt the heuristic job rotation procedures recommended by Sorawit and Suebsak (2008). These procedures are as follows: (i) A shift is divided into work periods of equal duration - in the case of hospitals A and B it could be one-hour shifts; and, (ii) the number of workers should be substantially more than required by the job to be performed, and as a result, some workers may be idle during some work shifts. Procedure (ii) is mostly applicable to cleaners, nurses who administer contrast, and maintenance engineers.

The RF-related exposure effects also were prevalent among two maintenance engineers who are responsible for maintenance of 1.5 and 3.0 T scanners in hospitals A and B. Since exposure to RF energy induces thermal effects and engineers have experienced the effects thereof when performing tests, maintenance engineers and medical physicists should regularly drink water, as this will assist in regulating their body temperature, which subsequently will reduce or prevent them from experiencing

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headaches, and the sensation of glowing and sudden hot flushes. Air cooling systems should be switched on when maintenance engineers and medical physicists perform activities that potentially expose them to RF energy, and, if possible, these activities should be performed during time of the day when the ambient temperature is not high (<20^{O}C). The reported health effects discussed in Chapter 4 are transient and could be associated with symptoms of undisclosed illnesses by participants. In order to ensure comprehensive exposure-effects reporting in both hospitals, a health surveillance programme should be developed aimed at the transient exposure effects reported by MR staff and non-MR staff who visit zone IV. Occupational health practitioners in hospitals A and B should recommend intervals at which MR staff and non-MR staff should undergo medical surveillance.

6.4 Conclusion

The health and safety challenges present in the MR facilities of hospitals A and B will be addressed if the ACR guidelines are followed appropriately. The safety training of non-MR and newly appointed MR personnel could change the perception of unsafeness around MR scanners. Both MR facilities need to develop an occupational health and safety programme in line with the contents of this model in order to address all the challenges reported on in Chapters 3, 4 and 5. The majority of MR modalities in South Africa are 1.5 and 3.0 T scanners for clinical imaging; this model therefore could be extended to other provinces to address similar challenges that they may experience. Compliance with relevant ACR guidelines in the MR facilities could be achieved with the assistance of medical physicists if they fulfil their role as MR safety officers.

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Chapter 7
General Discussion

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7.1 Main Findings

This thesis reported on a study conducted to determine the effects of occupational exposure to SMFs and RF magnetic fields by using environmental monitoring in the MRI facilities of two public hospitals in the central region of the Free State, South Africa. The health and safety risks in MRI facilities also were evaluated using baseline risk assessment, as well as MR safety risk interviews. The aim and objectives described in Chapter 1 (1.4 and 1.5) were achieved through four investigations. The first investigation, entailing exposure assessment, was conducted by evaluating the exposure levels of SMFs and RF magnetic fields in zone IV, using distance as an exposure surrogate. The second investigation of this research was aimed at evaluating transient health effects resulting from exposure to SMFs and RF magnetic fields among 49 MR staff in the two facilities, while an additional 28 radiographers were included as part of the control group. The interviews on MR safety risks also were conducted with four staff members from two hospitals who agreed to be interviewed. In the third investigation, baseline risk assessment was used to review existing control measures, and current safety hazards present in both facilities. Additionally, image quality control and apparent diffusion coefficient measurement results of 3.0 T and 1.5 T scanners in both facilities were evaluated. The last-mentioned investigation was based on the health and safety model which consists of recommendations that could be used to improve compliance with the health and safety regulations of MR facilities in hospital A and B.

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7.1.1 Objective I: Measurement of exposure levels of SMFs and RF magnetic fields emitted by 1.5 and 3.0 T MRI scanners

Environmental measurements were done in zone IV of the MR facilities in hospitals A and B to determine the exposure levels of SMFs at a distance of 1 m and 2 m, and for RF magnetic fields at 1 m from the scanner gantry. Measurements of SMFs were conducted from three sides (right, left and front) of the scanner in order to determine the distribution of stray fields where there is movement of MR staff, particularly when they enter the room and also in close proximity to the scanners. Radiofrequency magnetic fields measurements were only conducted from two sides of the scanner (left and right). The measurements were conducted from the three MRI scanner rooms, namely 1.5 T and 3.0 T in hospital A, and 1.5 T in hospital B. To homogenize the measurement approach, both SMFs and RF magnetic fields' measurements were only conducted when MRI examinations were performed on patients, particularly when the brain, cervical spine and extremities were scanned.

The magnet is always on, however, shim materials used to correct static magnetic fields' inhomogeneity are temperature sensitive and this may cause B_0 to shift during gradient-intense sequences, resulting in each patient placed within the scanner creating a unique pattern of inhomogeneity (Jezzard, 2006). Due to this, stray static fields also were measured during patient examination. Because of significantly different measurement values that could have been yielded when comparing 1.5 T and 3.0 T emissions, the SMFs and RF magnetic fields from the two 1.5 T scanners in hospitals A and B were compared with one another. The SMF results indicated that 1.5 T MRI scanners located in hospitals A and B had different propagation of SMFs though the nominal B_0 is the same. However, the RF magnetic field measurements between the two 1.5 T scanners were not significantly different.

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When comparing exposure values per distance interims, a significant difference was found. Since the 1.5 T and 3.0 T scanner rooms in hospital A are adjacent to each other, this type of clinical setting explains the difference in the measurement values obtained at a distance of 2 m. The difference noted in SMF exposure levels in the two 1.5 T scanners was not attributed to the MR examinations performed, but solely on the comparison between the two scanners from different manufacturers. The significant difference in RF magnetic field exposure values was noted due to variation in RF pulse design and sequence settings-flip angle when different patients were scanned. The peak SMF exposure levels measured on a 3.0 T scanner were 1300 mT at 1 m and 716 mT at 2 m. The 1.5 T scanner in hospital A had a peak exposure value of 716 mT at 1 m, and 370 mT at 2 m. The peak exposure values were 732 mT at 1 m, and 362 mT at 2 m for hospital B.

The peak RF magnetic field value of the 3.0 T scanner was 0.2 µT, and that of both 1.5 T scanners was 0.09 µT. Although high exposure levels were noted on a 3.0 T scanner, SMF spot measurements conducted in the three MR facilities suggest that the three scanners comply with reference levels set out by the ICNIRP (2010) for occupational exposure limit of < 2 T for the head and trunk, as well as 8 T for limbs. Furthermore, the measured RF magnetic field values of the three scanners were also compliant with the latest RF electromagnetic field (EMF) reference levels for local exposures (ICNIRP, 2020).

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7.1.2 Objective II: Transient health effects and safety risks among staff working with 1.5 and 3.0 T MRI scanners

A questionnaire survey based on the transient health effects experienced by MR staff exposed to MRI-related EMFs and the perception of safeness around MR scanners was conducted among 49 MR staff and 28 radiographers (control group) from hospitals A and B. The responses of participants were measured by means of a Likert-type scale. The investigation included MR radiographers, nurses, maintenance engineers, porters, cleaners, doctors, radiologists and medical physicists with varying MR work experience and levels of education. From the total of 77 participants, 49.35% indicated they worked in the MR room where the scanner was located, and 50.65% did not work in the MR scanner room. The reported years of working in the MRI units ranged from one to fifteen (average 5.41) years. A few participants (32.47%) reported to work shifts ranging from one, two and eight hours in the MR units. The reporting of transient health effects among MR staff was not influenced by the increase in the scanner strength (1.5 T to 3.0 T MR scanners). Participants experienced SMF exposure-related effects such as a metallic taste (frequently), a feeling of instability when standing, walking or moving (half of the time), and dizziness or vertigo (half of the time) on various shift durations (eight, two and one hour); however, these effects were more prevalent among those who worked an eight-hour shift. The SMF exposure-related effects were evoked by performance of activities in close proximity to the MR scanner bore.

The RF energy-related exposure effects, such as a sudden feeling of warmth and a sensation of glowing, were experienced by maintenance engineers, but seldomly. Other participants, such as nurses and medical doctors, who frequently adjusted patients' drips during image acquisition, medical physicists who reposition phantoms,

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and radiographers assisting in positioning patients with severe medical conditions experienced RF-related exposure effects. The MR staff members (OR 39.15, 95%CI: 4.91- 312.02) were more likely to report MRI-related transient health effects than non-MR staff (control group). Furthermore, radiographers that reported to have been in the MRI room, where the scanner is located, during their shifts, reported more transient health-related effects (OR 60.75, 95%CI: 5.99- 616.67) (p< 0.0005) than other radiographers (control group). Movement of head/upper body in the MR scanner bore during image acquisition was significantly associated with all SMF and RF exposure effects.

It was noted that the only factor that distinguished participants' perception on the safety of MRI scanners, was the job title. Professionals, such as maintenance engineers, medical physicists, nurses, radiologists and radiographers felt safe (moderate and very) around MRI scanners. Other participants felt slightly unsafe, slightly safe and neutral, and this could be attributed to lack of or insufficient training on MRI safety (Fatahi *et al*., 2016). The interviews also were conducted with four MR staff members from hospital A (1) and hospital B (3), who agreed to be interviewed during the data collection phase. Their responses confirmed that there were no updated MR safety policy documents in either hospital, and this could be associated with the knowledge gap in the safety issues regarding MRI. It was also revealed that MR and non-MR staff members in both hospitals were allowed to enter zone III or IV without undergoing safety screening, and MR radiographers in hospital B were responsible for cleaning the MR scanner room, thus putting them at risk of exposure to MRI-related EMFs. This study further revealed that there was no procedure to report safety accidents or near incidents specific to the MRI units in hospital A; however, hospital B has a procedure, but there is no guidance on how to report the results. This

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could be attributed to the lack of policies for emergency management in the MR units of both hospitals.

7.1.3 Objective III: Evaluation of safety hazards and risks associated with the use of MRI scanners

In this study, a baseline risk assessment was conducted to evaluate existing control measures, as well as health and safety risks in the MR units of hospitals A and B by using risk classification scores. The rating of probability and consequence was adopted from the Exeter MRI risk assessment. This study revealed that similar risks and hazards existed in the MR units of hospital A and hospital B. A relatively small number of high risks were identified in both hospitals when compared to moderate and low risks, leading to an overall risk rating (safety performance) of 12.3 in hospital A and 13.1 in hospital B, which is classified as moderate. There was no demarcation of the 5-Gauss line on the floor of zone IV in hospital B, and the demarcation line in hospital A was fading. It was also noted that hospital B did not have a ferromagnetic detector and the one in hospital A was defective, resulting in a less effective screening system. The four MR safety zones in both facilities were not marked as required by the ACR Committee on MR Safety (2020).

Improper use of hearing protectors and the absence of red illuminated signs indicating, *Magnet is always on* were also noted to be health and safety risks. In both facilities, MR safety signs were demarcated and clearly indicated that the magnet was always on; however, the signs are not illuminated, and this could pose a safety risk, especially when zone III is not properly lighted. Both facilities did not have a visible MR safety policy in place and there was no strict access control to zone III and IV by means of a

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pass-key locking system. Although MR and non-MR personnel members were under direct supervision of MR radiographers when entering zone III, the absence of strict access control could pose health and safety challenges. The 2018 image quality control test results from the 3.0 T scanner in hospital A, and the apparent diffusion coefficient measurements from the 1.5 T in hospital B were compared with the ACR quality control requirements. The 3.0 T scanner complied with the majority of the image quality features that were assessed; however, the image intensity uniformity (PIU= 78.2%) and low contrast objectivity (ACR T2 = 29 spokes) did not meet the ACR-acceptable criteria. A defective air-cooling system in the 1.5 T scanner room resulted in elevated temperatures (37.7^{O}C) on certain days that influenced the ADC measurements (X=0.00244 μm^2/s, Y=0.00243 μm^2/s and Z= 0.00246 μm^2/s).

7.1.4 Objective IV: Development of a health and safety model with recommendations to reduce occupational exposure to SMF and RF magnetic fields, and MR health and safety risks

In this sub-section, health and safety measures are recommended with guidelines to reduce stray static fields and RF magnetic fields from MR facilities in both hospitals. Recommendations also are made to reduce transient exposure effects among MR staff and MR safety risks in the MR units of both facilities. Regular maintenance of shim materials is recommended every time quarterly maintenance is undertaken in order to avoid B_0 from shifting due to elevated scanner temperatures. Furthermore, exposure assessment discussed in Chapter 3 must be conducted on a regular basis, particularly by medical physicists when performing quality control tests, in order to check RF coils and determine if static magnetic fields inhomogeneity occurs. The use of EMF-related protective clothing, coated either with Ag, Cu or Ni deposited on the

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textile surfaces was recommended for use since they provide shielding effectiveness with a high contribution to the absorption coefficient, reduced transmission and reflection coefficients.

The demarcation of the 5-Gauss line in hospital A is fading and hospital B is not demarcated. Furthermore, the four MR safety zones are not marked and safety screening systems are not effective. Based on the findings of this study, the demarcation of the 5-Gauss line and four MR safety zones was recommended. The use of ferromagnetic detectors coupled with visual inspection and the administration of a MR safety questionnaire to all MR and non-MR staff were recommended. The medical physicists in both hospitals must recognize their responsibility as MR safety officers and ensure compliance with the health and safety requirements of the relevant ACR safety guidelines. The introduction of a rotational system for the working hours of MR staff, safety training programmes for MR and non-MR staff, regular water intake, effective air-cooling systems, and short-term exposure in the MR units of both facilities were recommended to reduce transient exposure effects. The establishment of a medical surveillance process by responsible occupational medical practitioners was also recommended to ensure comprehensive reporting of transient exposure effects, as reported on in Chapter 4.

7.2 Methodological strengths and limitations

The report on both SMF and RF energy-related exposure effects did not show any differences among the participants working on different scanners, as reported in other studies (Gilles *et al*., 2013; Heinrich *et al*., 2014; Schaap *et al*., 2014), and this was due to a small sample size. Since the questionnaire survey required participants to

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reflect on the results of exposure they had experienced during their workweek, this was more likely to invite response bias. The use of certain medication with side effects similar to transient health effects reported in Chapter 4 and psychosocial influences might have affected the reporting patterns among individuals. Due to the unavailability of the head of the clinical imaging department at the time of the MR safety risks interview, different MR staff members were interviewed and their varying knowledge on MR safety might have influenced interview results. Different functions they performed in the MR units determined the extent to which their job involved safety risk observations. Due to COVID 19 outbreak, it was impossible to include measurements and study participants from private health care sectors around Mangaung metropolitan region were MRI services are rendered.

Blinding the study participants is not always possible, the experience of one colleague's risk perception, response and expectation might be similar to that of another colleague performing the same job tasks. Personal exposure measurements were not conducted for two reasons, namely i) none of the study participants agreed to have the magnetometer and RF strength meter attached to their bodies, head or extremities, and ii) budget constraints made it impossible to obtain a small personal dosimeter that could be attached on the study participants. The discontinued use of the 1.5 T scanner in hospital A (late 2018, after measurements were conducted) made it impossible to obtain quality control test results and exposure-related effects data among MR staff who might have worked on the scanner.

The use of 1.5 T and 3.0 T scanners are common in South African healthcare sectors, the results provided in Chapter 3 are likely to exemplify exposure scenarios in South African clinical MRI facilities. To obtain approximate exposure values, measurements were conducted in close proximity to the scanners, where most activities in zone IV

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took place. The questionnaire was developed in three languages predominantly spoken in Bloemfontein and this made it easier for all participants to respond to questions easily. Their experience of transient health effects was studied among MR staff with various job titles, providing a clear distinction among professionals with prevalent exposure effects. It was also possible to measure the association between the safety perceptions of MR scanners and reporting transient health effects - the first study of its kind in South Africa.

The results obtained from the risk assessment (developed from the ACR MR Safety requirements) in terms of health and safety risks were corroborated with MR safety risk interviews to address all health and safety challenges in both MR facilities. This study included participants with varying MR work experiences and this assisted in determining whether MR work experience could present a different pattern of reporting transient exposure effects among participants. An association was observed between transient exposure effects and shift duration, which indicated that spending more time in close proximity to the scanner evoked transient exposure effects.

7.3 Future Studies

This study emphasises the need of studies focusing on occupational exposure to MRI–related EMF in all clinical sectors that provide MRI services in South Africa. This should be coupled with a national survey investigating the effects of static magnetic fields in MRI scanner assembly plants in South Africa. The study of genotoxic effects also should be conducted to lay a sound foundation for establishing whether exposure to MRI-related EMFs could result in severe effects among MR staff. Such studies should include the examination of exposure to time-varying magnetic fields and metabolic

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responses. Studies of personal exposure should be considered in order to improve the understanding of different exposure patterns among MR staff, particularly those present in the scanner room during patients' examination.

7.4 Conclusion

A large number of health care workers worldwide are exposed to MRI-related EMFs due to the increasing use of MR scanners in clinical settings, and this is likely to keep on increasing over the coming years as MR scanners with strong magnets become fully employed. This thesis aimed at providing insight into the levels of SMFs and RF magnetic fields used in 1.5 T and 3.0 T in the South African clinical setting, as well as associated exposure effects among health care and other workers subjected to the wave-emitting devices. The health and safety aspects related to magnetic resonance imaging (MRI) were discussed in terms of the requirements of the ACR. The researcher believes that the study reported described in this thesis will contribute to providing regulatory measures such as the establishment of non-ionizing radiation exposure limits, like in Europe, for workers in the South African health occupations. The adoption of ACR requirements to design health and safety programmes in the MRI units will provide an MR environment with minimal risks and hazards.

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Annexures

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ANNEXURE A

INFORMATION DOCUMENT/LETTER

Study title: OCCUPATIONAL EXPOSURE TO RADIOFREQUENCY ENERGY AND STATIC MAGNETIC FIELDS IN MRI UNITS IN THE PUBLIC SECTOR WITHIN MANGAUNG METROPOLITAN REGION.

Introduction:

I am Phoka Caiphus Rathebe, student at the Central University of Technology, Free State. I am conducting a research on occupational exposure to radiofrequency energy and static magnetic fields emitted by MRI scanners, which forms part of a new knowledge in South Africa, and in the field of Occupational Hygiene. The purpose of this study is to protect workers from MRI safety risks and exposure to radiofrequency energy, and static magnetic fields from MRI scanners during patients examination. The protection of workers to radiofrequency and static magnetic fields, and MRI safety risks will be done through the development of a health and safety model.

Invitation to participate: We are asking/inviting you to participate in this research study by completing a questionnaire. Completion of a questionnaire will take approximately 20 minutes.

This study will be beneficial to all MR staff as it will be assessing the health effects of exposure to radiofrequency energy and static magnetic fields from MRI scanners. Through this study, safe working procedure will be developed and thus MR workers will have a safe and healthy work environment. All the risks associated with their work will be evaluated and appropriate control measures will be recommended. Also, a comprehensive model will be developed that will reduce workers' exposure to radiofrequency energy and static magnetic fields. All workers that will benefit from this study include (but not limited to): All MR staff such as medical physicists, maintenance engineers, nurses, radiologists, radiographers and cleaners, South African department of health and academic authors.

There are no risks associated with participation in the study.

Kindly note that your **participation is voluntary** and that you may withdraw from the study at any time.

No costs are payable by you to participate in the study, neither will you be **remunerated** for your participation.

The **expected duration of sampling** is **4 Months**

All efforts will be made to keep personal information **confidential** and to ensure **anonymity**.

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The **results** from the study may be **presented** at seminars/conferences related to the research and/or **published** in an applicable journal.

Contact details of researcher(s) – for further information/reporting of study-related issues, please contact:

23 February 2018

…….. ……

Signature of researcher Date

Contact details of Secretariat and Chair: Ethics Committee of the Faculty of Health Sciences, University of the Free State – for reporting of complaints/problems: Telephone number (051) 4052812.

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ANNEXURE B

CONSENT TO PARTICIPATE IN RESEARCH

PROJECT TITLE: OCCUPATIONAL EXPOSURE TO RADIOFREQUENCY ENERGY AND STATIC MAGNETIC FIELDS IN MRI UNITS IN THE PUBLIC SECTOR WITHIN MANGAUNG METROPOLITAN REGION

You have been asked to participate in a research study and you have studied the information letter about this study.

Kindly note that your participation in this research is voluntary, and you will not be penalised or lose benefits if you refuse to participate or decide to terminate participation.

If you agree to participate, you will be given a signed copy of this document as well as the information letter, which is a written summary of the research.

You may contact **Phoka Rathebe** at **0780830553/pcphoka@gmail.com** at any time if you need some clarity concerning the research study, or alternatively the Secretariat of the Ethics Committee of the Faculty of Health Sciences, UFS may be contacted at 051 4052812 if you have questions about your rights as a research subject.

_____

The research study, including the above information has been verbally described to me. I understand what my involvement in the study means and I voluntarily agree to participate.

23 February 2018

…… …….

Signature of researcher Date

…… …….

Signature of participant Date

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ANNEXURE C

REQUEST TO CONDUCT THE RESEARCH STUDY

Central University of Technology,
Free State
Department of Life Sciences
21 President Brand Street
9300

Free State Department of Health
Bophelo House
Cnr. Charles & Harvey Rd, City Centre
Bloemfontein, 9301

Dear Dr/Mr/Mrs

RE: REQUEST TO CONDUCT RESEARCH STUDY

I, Phoka Caiphus Rathebe hereby requests consent to conduct a research at Pelonomi and Universitas academic hospitals. The title of my study is “Occupational exposure to radiofrequency energy and static magnetic fields in mri units in the public sector within mangaung metropolitan region”. The main aim of this study is to develop health and safety model that will reduce the exposure of all MRI staff to radiofrequency energy and static magnetic fields emitted by MRI scanners. The duration of sampling will be four months and measurements will be conducted in the MRI units. All MR staff will be required to fill in self-administered questionnaires after environmental exposure measurements have been collected. A copy of the research proposal has been submitted to the Health Science Research Ethics Committee at the University of the Free State in Bloemfontein for approval.

I trust that you will consider the above request favourably.

Yours sincerely

Signature of researcher

© Central University of Technology, Free State

Kindly indicate your approval, or not by, marking the appropriate box below:

APPROVED ☐ **NOT APPROVED** ☐

…… ……

Signature of Clinical Head/ Head of Department

Date

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ANNEXURE D

REQUEST TO CONDUCT THE RESEARCH STUDY

Central University of Technology,
Free State
Department of Life Sciences
21 President Brand Street
9300

Pelonomi hospital
121 Dr Belcher Rd, Heidedal
Bloemfontein, 9301

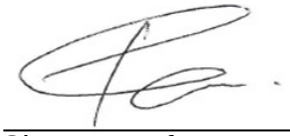
Dear Hospital CEO

RE: REQUEST TO CONDUCT RESEARCH STUDY

I, Phoka Caiphus Rathebe hereby requests consent to conduct a research at Pelonomi hospital. The title of my study is “Occupational exposure to radiofrequency energy and static magnetic fields in mri units in the public sector within mangaung metropolitan region”. The main aim of this study is to develop health and safety model that will reduce the exposure of all MRI staff to radiofrequency energy and static magnetic fields emitted by MRI scanners. The duration of sampling will be for four months and measurements will be conducted in the MRI units. All MR staff will be required to fill in self-administered questionnaires after environmental exposure measurements have been collected. A copy of the research proposal has been submitted to the Health Science Research Ethics Committee at the University of the Free State in Bloemfontein for approval.

I trust that you will consider the above request favourably.

Yours sincerely



Signature of researcher

© Central University of Technology, Free State

Kindly indicate your approval, or not by, marking the appropriate box below:

APPROVED ☐ **NOT APPROVED** ☐

…… ……

Signature of Clinical Head/ Date
Head of Department

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ANNEXURE E

REQUEST TO CONDUCT THE RESEARCH STUDY

Central University of Technology,
Free State
Department of Life Sciences
21 President Brand Street
9300

Universitas academic hospital
1 Logeman St, Universitas
Bloemfontein, 9301

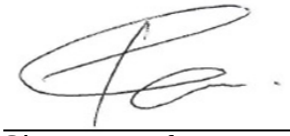
Dear Hospital CEO

RE: REQUEST TO CONDUCT RESEARCH STUDY

I, Phoka Caiphus Rathebe hereby requests consent to conduct a research at Universitas academic hospital. The title of my study is “Occupational exposure to radiofrequency energy and static magnetic fields in mri units in the public sector within mangaung metropolitan region”. The main aim of this study is to develop health and safety model that will reduce the exposure of all MR staff to radiofrequency energy and static magnetic fields emitted by MRI scanners. The duration of sampling will be for four months and measurements will be conducted in the MRI units. All MR staff will be required to fill in self-administered questionnaires after environmental exposure measurements have been collected. A copy of the research proposal has been submitted to the Health Science Research Ethics Committee at the University of the Free State in Bloemfontein for approval.

I trust that you will consider the above request favourably.

Yours sincerely



Signature of researcher

© Central University of Technology, Free State

Kindly indicate your approval, or not by, marking the appropriate box below:

APPROVED ☐ **NOT APPROVED** ☐

…… ……

Signature of Clinical Head/ Date
Head of Department

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ANNEXURE F

INLIGTINGS DOKUMENT / LETTER

Studie titel: Beroepsblootstelling aan radiofrekwente energie en statiese magnetiese velde in MRI-eenhede in Mangaung-metropolitaanse streek

inleiding:

Ek is Phoka Caiphus Rathebe, student aan die Sentrale Universiteit vir Tegnologie, Vrystaat. Ek is besig met 'n navorsing oor blootstelling aan radiofrekwente energie en statiese magnetiese velde wat deur vrygestel wordMRIeenhede, wat deel vorm van 'n nuwe kennis in Suid-Afrika en op die gebied van beroepshigiëne. Die doel van hierdie studie is om werkers te beskerm teen blootstelling aan radiofrekwente energie en statiese magnetiese velde teen MRI tydens die skandering van pasiënte. Die beskerming van werkers teen radiofrekwensie en statiese magnetiese velde sal geskied deur die ontwikkeling van 'n gesondheids- en veiligheidsmodel.

Uitnodiging om deel te neem: Ons vra / nooi u om deel te neem aan hierdie navorsingstudie deur 'n vraelys in te vul. Die voltooiing van 'n vraelys sal ongeveer 20 minute duur.

Hierdie studie sal voordelig wees vir alle MRI-personeel, aangesien dit die gesondheidseffekte van blootstelling aan radiofrekwensie-energie en statiese magnetiese velde van MRI-skandeerders beoordeel. Deur middel van hierdie studie sal veilige werksprosedures ontwikkel word en dus sal MRI-werkers 'n veilige en gesonde werksomgewing hê. Al die risiko's verbonde aan hul werk sal geëvalueer word en toepaslike beheermaatreëls word aanbeveel. Daar sal ook 'n omvattende model ontwikkel word wat werknemers se blootstelling aan radiofrekwente energie en statiese magnetiese velde sal verminder. Al die werkers wat by hierdie studie sal baat, sluit (maar nie beperk nie tot) die volgende in: alle MRI-personeel soos mediese fisici, onderhoudsingenieurs, verpleegkundiges, radioloë, radiograwe en skoonmakers, die Suid-Afrikaanse departement van gesondheid en akademiese skrywers.

Daar is geen risiko's verbonde aan deelname aan die studie nie.

Let daarop dat u deelname vrywillig is en dat u te eniger tyd aan die studie kan onttrek.

Geen koste is betaalbaar nie deur u deel te neem aan die studie, en u sal ook nie vergoed word vir u deelname nie.

Die verwagte duur van die steekproefneming is 4 maande

Alle pogings sal aangewend word om persoonlike inligting vertroulik te hou om anonimiteit te verseker.

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Die resultate van die studie kan aangebied word tydens seminare / konferensies wat met die navorsing verband hou en / of in 'n toepaslike tydskrif gepubliseer word.

Kontakbesonderhede van navorser (s) - vir verdere inligting / verslagdoening oor studie-verwante aangeleenthede, kontak:

23 Februarie 2018

....

Handtekening van navorser datum

Kontakbesonderhede van Sekretariaat en Voorsitter: Etiekkomitee van die Fakulteit Gesondheidswetenskappe, Universiteit van die Vrystaat - vir die aanmelding van klagtes / probleme: Telefoonnommer (051) 4052812.

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ANNEXURE G

TOESTEMMING OM NUUS TE deelneem aan die navorsing

PROJEK TITEL: Beroepsblootstelling aan radiofrekwente energie en statiese magnetiese velde in MRI-eenhede in Mangaung-metropolitaanse streek

Jou is gevra om aan 'n navorsingstudie deel te neem en jou het die inligtingsbrief oor hierdie studie bestudeer.

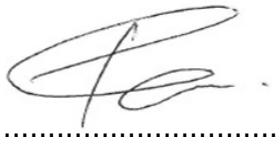
Let daarop dat jou deelname aan hierdie navorsing vrywillig is, en jou sal nie gepenaliseer word of voordele verloor as jou weier om deel te neem of besluit om deelname te beëindig nie.

As jou instem om deel te neem, kry jou 'n ondertekende afskrif van hierdie dokument, sowel as die inligtingsbrief, wat 'n skriftelike samevatting van die navorsing is.

Jou kan Phoka Rathebe op 0780830553 / pcphoka@gmail.com te eniger tyd kontak indien u duidelikheid oor die navorsingstudie benodig, of alternatiewelik kan die Sekretariaat van die Etiekkomitee van die Fakulteit Gesondheidswetenskappe, UV gekontak word by 051 4052812 indien jou vrae het oor jou regte as navorsingsonderwerp.

_____

Die navorsingstudie, wat bogenoemde inligting insluit, is mondelings aan my beskryf. Ek verstaan wat my betrokkenheid by die studie beteken en stem vrywillig daartoe in.



23 Februarie 2018

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Handtekening van navorser datum

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Handtekening van die deelnemer datum

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ANNEXURE H

LENGOLO LA TLHOKOMELISO / LITLHAKISO

Sehlooho sa thuto: Ho pepesetsoa hoa matla a radiofrequency le static magnetic fields li-unit tsa MRI kahare ho sebaka sa toropo ea Mangaung.

Selelekela:

Ke Phoka Caiphus Rathebe, moithuti Univesithing e Bohareng ea Theknoloji, Free State. Ke etsa patlisiso mabapi le ho pepesehela matla a radiofrequency le static magnetic fields li-unit tsa MRI, tseo e leng karolo ea tsebo e ncha Afrika Boroa, le lebaleng la bohloeki ba mosebetsi. Morero oa thuto ena ke ho sireletsa basebetsi hore ba se ke ba pepesetsoa ke matla a radiofrequency le static magnetic fields a tsoang ho MRI nakong ea ho hlahlojoa ha bakuli. Ts'ireletso ea basebetsi ho li-radiofrequency le matla a static magnetic fields e tla etsoa ka nts'etsopele ea mohlala oa bophelo bo botle le polokeho.

Memo ea ho nka karolo: Re o kopa / ho o mema hore u kenye letsoho thutong ena ea lipatlisiso ka ho tlatsa lipotso. Ho phetheloa ha lipotso ho tla nka metsotso e ka bang 20.

Phuputso ena e tla ba molemo ho basebeletsi bohle ba MRI kaha e tla be e hlahloba litlamorao tsa bophelo bo botle ba ho pepesetsoa ke matla a radiofrequency le static magnetic fields a tsoang ho li-skena tsa MRI. Ka thuto ena, ho tla ba le mekhoa e sireletsehileng ea ho sebetsa ka tsela e sireletsehileng, ka hona basebetsi ba MRI ba tla ba le tikoloho e bolokehileng le e phetseng hantle ea mosebetsi. Likotsi tsohle tse amanang le mosebetsi oa bona li tla hlahlojoa mme ho tla khothalletsoa mehato e loketseng ea taolo. Hape, ho tla hlahisoa mofuta o akaretsang o tla fokotsa ho pepesetsoa ha basebetsi ho matla a radiofrequency le static magnetic fields. Basebetsi bohle ba tla rua molemo thutong ena ba kenyelletsa (empa ha ba felle ho): Basebetsi bohle ba MRI joalo ka lingaka, baenjiniere ba tlhokomelo, baoki, litsebi tsa radiology, bahloekisi, lefapha la tsa bophelo bo botle le barutehi ba Afrika Boroa.

Ha ho na likotsi tse amanang le ho nka karolo thutong ena.

Ka mosa, hlokomela hore karolo ea hao ea boithatelo ke ea boithatelo le hore o ka tlohela ho nka karolo neng kapa neng ha o kgetha o etsa joalo.

Ha ho litšenyehelo tse lefuoang ke oena ho nka karolo thutong ena, ebile hahona moputsoa o olefang ka ho nka karolo.

Nako e lebelletsoeng ea ho qeta thuto ena ke likhoeli tse 4.

Ka honka karolo thutong ena, ho tla etsoa boiteko bohle ho boloka litaba tsa hao e le lekunutu.

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Liphetho tsa thuto li ka hlahisoa lithupelong / likopanong tse amanang le lipatlisiso le / kapa ho phatlalatsoa koranteng ae ditsibi.

Lintlha tsa ho ikopanya le bafuputsi: bakeng sa tlhaiso-leseling thutong ena/ ho tlaleha ha litaba tse amanang le thuto ena, ka kopo ikopanye le:

23 Pherekhong 2018

…….. ……

tekeno ea mofuputsi Letsatsi

Lintlha tsa ho ikopanya le Setsi sa Bongoli le molulasetulo: Komiti ea Boitšoaro ea Setsi sa Saense sa Bophelo, Univesithi ea Free State - bakeng sa ho tlaleha litletlebo / mathata: Nomoro ea mohala (051) 4052812.

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ANNEXURE I

TLHOKOMEDISO HO nka karolo lipatlisisong

TLHOKOMELISO E BONAHALANG: Ho pepesetsoa matla a radiofrequency le static magnetic fields li-unit tsa MRI ka har'a sebaka sa toropo ea Mangaung.

O kopiloe ho nka karolo mabapi le thuto ena.

Ka mosa hlokomela hore ho nka karolo ho etsa lipatlisiso thutong ena ke hoe ithaopa, 'me o ke ke oa fuoa kotlo kapa oa lahleheloa ke melemo haeba o hana ho nka karolo kapa o etsa qeto ea ho emisa ho nka karolo.

Haeba o lumela ho nka karolo, o tla fuoa lengolo le saennoeng la tokomane ena hammoho le lengolo la tlhaiso-leseling, e leng kakaretso e ngotsoeng ea lipatlisiso.

O ka ikopanya le Phoka Rathebe ho 0780830553 / pcphoka@gmail.com ka nako efe kapa efe haeba o hloka ho itseng mabapi le boithuto ba lipatlisiso, kapa ho seng joalo, Mongoli oa Komiti ea Litekanyetso tsa Lefapha la Saense ea Bophelo, UFS e ka ikopanya le 051 4052812 haeba o ka ikopanya le ena. ho ba le lipotso ka litokelo tsa hao joalo ka taba ea lipatlisiso.

_____

Boithuto ba lipatlisiso, ho kenyelletsa le tlhaiso-leseling e kaholimo li hlalositsoe ka botebo. Kea utloisisa hore na ho nka karolo ha ka thutong ho bolela eng 'me ke lumela ka boithatelo ho nka karolo.

23 Pherekhong 2018

…… ……

tekeno ea mofuputsi Letsatsi

…… ……

tekeno ea motho a nkang karolo Letsatsi

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ANNEXURE J

MRI Safety interview

Title: OCCUPATIONAL EXPOSURE TO RADIOFREQUENCY ENERGY AND STATIC MAGNETIC FIELDS IN MRI UNITS IN THE PUBLIC SECTOR WITHIN MANGAUNG METROPOLITAN REGION

The purpose of this study is to evaluate the health and safety risks of MRI staff working in the MRI units and to develop a model that will protect workers' safety and well-being.

This interview consist of questions adopted from the American College of Radiology guidance document on MR safe practices: Updates and critical information 2019

Section A: Operational safety at MRI unit

1. Are all medical devices brought into Zone III and Zone IV in the MRI units undergo standardized evaluations and labeling to determine their status as being MR Safe, MR Conditional, or MR Unsafe?

Yes ☐ No ☐

Comment……

2. Are there proximity access doors and an emergency exit door in the MRI unit?

Yes ☐ No ☐

Comment……

3. Does the equipment used in the MRI unit have colour codes to identify ferrous material and MRI safety material?

Yes ☐ No ☐

Comment……

4. Is there a routine maintenance of the MRI scanners, according to manufacturers' requirements?

Yes ☐ No ☐

Comment……

5. Are all MR Personnel undergo an MR screening process as part of their employment agreement to ensure their safety in the MR environment?

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Yes ☐ No ☐

Comment……

6. Is there a careful screening for ferromagnetic materials by direct inspection and use of a ferromagnetic detector prior entering Zone IV?

Yes ☐ No ☐

Comment……

7. Is there a screening procedure for all non-MR Personnel who accompany a patient into the MRI scanner room (Zone IV)?

Yes ☐ No ☐

Comment……

8. Are there lockers to store personal belongings of MR and non-MR personnel that may be ferrous in nature or has magnetic stripes in the MRI Unit?

Yes ☐ No ☐

Comment……

9. Is there a restricted access to everyone who comes to the MRI Suite?

Yes ☐ No ☐

Comment……

10. Do MR and non-MR personnel wear personal protective equipment to protect themselves from MRI-related electromagnetic fields when entering Zone IV?

Yes ☐ No ☐

Comment……

Section B: Availability of departmental policy manual

1. Are there updated MR Safety policies and procedures in place?

Yes ☐ No ☐

Comment……

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2. When introduction any changes in the safety parameters of MRI units (e.g. hardware or software upgrade), do you update your safety policies or procedures?

Yes ☐ No ☐

Comment……

3. Is there a written procedure to report the occurrence of all MR-related adverse events, safety incidents, or “near incidents”?

Yes ☐ No ☐

Comment……

4. Is there a standard operating procedure for cleaning the MRI facility with respect to infection control?

Yes ☐ No ☐

Comment……

5. Are there policies and procedures for emergency management in the MRI units?

Yes ☐ No ☐

Comment……

Section C: Training programmes for MRI

1. Are all individuals working in the MRI units aware of the four MRI safety Zones?

Yes ☐ No ☐

Comment……

2. Are all individuals responsible for safety in Zones III or IV of the MRI units documented as been successfully educated about MR safety issues?

Yes ☐ No ☐

Comment……

3. Is there an ongoing and documented MR safety educational among MRI staff?

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Yes ☐ No ☐

Comment……

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ANNEXURE K

Observational tool for existing health and safety controls in zone III and IV within MRI units

Existing health and safety controls	Description of a hazard	Yes	No
e.g. Posted safety signs			
e.g. MR staff: safety behavior			
e.g. Zone III and IV access restriction			

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ANNEXURE L

MRI suite (zone IV) entrance register for non-MR staff

Date	
Job title	
Signature	

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ANNEXURE M

Questionnaire

Title: OCCUPATIONAL EXPOSURE TO RADIOFREQUENCY ENERGY AND STATIC MAGNETIC FIELDS IN MRI UNITS IN THE PUBLIC SECTOR WITHIN MANGAUNG METROPOLITAN REGION

The purpose of this study is to evaluate the health effects of exposure to radiofrequency energy and static magnetic fields in MRI units and to develop a model that will protect workers' exposure.

This questionnaire is divided into three sections. Section A consists of biographical information, section B consists of work-related information and section C consists of health-related.

Instructions

Complete the questionnaire by ticking "√" next to the relevant answer where applicable and by writing answers in the dotted lines provided.

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Section A: Biographical information

1. What is your gender?

Male ☐

Female ☐

2. What is your age? ……..... years

3. What is your highest level of education? ……

Section B: Work-related information

4. At which facility are you currently employed? (Tick the applicable hospital)

a. Universitas hospital ☐ b. Pelonomi hospital ☐

5. What is your current job title? (Tick the applicable job title)

a. Nurse ☐ b. Radiographer ☐ c. Medical physicist ☐ d. Radiologist ☐

e. Maintenance Engineer ☐ f. Student Nurse ☐ g. Student Radiographer ☐

h. Student Medical physicist ☐ i. Other ☐ please specify……

6. Does your job involve working in the MRI room, where MRI scanner is located?

Yes ☐ No ☐ **if No**, kindly proceed to question 9.

7. How long have you been working in the MRI units…….years

8. Do you work shifts in the MRI units? Yes ☐ No ☐

8.1 **If Yes**, what is the duration of your shift?.....hours

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9. Have you ever been in the MRI room (where MRI scanner is located) during your work shifts?

Yes ☐ No ☐ **If No, kindly proceed to question 10.**

9.1 **If Yes**, how many days per week on average did you work with the MRI scanner which requires you to enter the scanner room? ……

9.2. At which scanner(s) did you work during your shifts this week? Please report scanner name and field (in Tesla)……

When answering question 9.3, think about things that went wrong or did not go according to plan; such as malfunctioning devices, repositioning of patient or coil, assisting patient with claustrophobia, emergency situations or having to clean the scanner.

9.3. During your shifts this week, did any irregularities or incidents occur that required you to stay inside the scanner room for a longer time than usual or to enter the room more often than usual? Yes ☐ No ☐

When answering question 9.4, count the total number of times, not number of procedures and reflect on your shifts this week. *Acquisition: The moment when the image is acquired; when the scan is being performed.

9.4. How many times were you in the scanner room during image acquisition?.....times

9.5. How many times did you move your head or upper body into the scanner bore this week?.....times

9.5.1 **If you have moved your head or upper body into the scanner bore, please describe the situation in which this happened.**

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……

……

……

……

10. How do you consider your workload? (Tick applicable answer)

a. Light ☐

b. Moderate ☐

c. Heavy ☐

11. How tiring do you consider this workweek to have been? (Tick applicable answer)

a. Hardly tiring ☐

b. A little tiring ☐

c. Very tiring ☐

12. Have you ever received training on the safety of MR personnel prior working with MRI scanners? Yes ☐ No ☐

13. How safe do you feel while working with MRI scanner?

a. Very safe ☐

b. Moderately safe ☐

c. Slightly safe ☐

d. Neutral ☐

e. Slightly unsafe ☐

f. Moderately unsafe ☐

g. Very unsafe ☐

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14. Have you received training on the health effects of exposure to static magnetic fields and radiofrequency energy from MRI units? Yes ☐ No ☐

14.1 If Yes, when last did you receive training?_____

Answer question 15 only if you are a Maintenance/ Service engineer, Medical physicist or student medical physicists.

15. Are there any control measures in place to minimize the harmful effects of static magnetic fields and radiofrequency energy from MRI scanners? Yes ☐ No ☐

Section C: Health-related information

16. Do you experience any of the symptoms (listed in the table below) when working with MR scanners?

Yes ☐ No ☐

If Yes, kindly use the following five Likert Scale (Never, Seldom, Half of the time, Usually, Always). If No, move to question 19.

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Symptoms that you experienced	Likert Scale				
	Never	Seldom	Half of the time	Usually	Always
Tinnitus or sensation of head ringing					
Earache					
Headache					
Concentration problems					
Tiredness or sleepiness					
Nausea					
Vomiting					
Involuntary muscle contractions					
Palpitation					
Tingling sensation in the body: please specify body part……					
Sensation of glowing, burning or irritated skin					
Suddenly feeling warm/hot, hot flashes					
Itchy, watery or red eyes					
Seeing black spots or having a temporary loss of vision					
Seeing light spots or light flashes					
Blurred or double vision					
Sensation of dizziness or vertigo					
Feeling lightheaded or weightless					
Feeling of instability when standing, walking or moving					
A metallic taste					

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17. Do you think that your work practice has been affected by the symptoms you experienced? Yes ☐ No ☐

17.1. **If Yes**, by which of the above listed symptoms was your work affected and in what manner?

……

……

……

……

18. Do you have any idea what caused these symptoms?

……

……

……

……

19. Do you use any disinfectants or cleaning agents (e.g. alcohol-based) during your workday? Yes ☐ No ☐ **If Yes**, indicate the following:

a. Cleaning agents that have a strong chemical smell or vapour, such as products containing bleach or volatile compounds) ☐
b. Cleaning agents that do *not* have a strong chemical smell or vapour, such as products made of soap (hand soap, detergent) ☐

20. Do you take any medication? **If Yes**, please mention what medication do you take and how much per day. Yes ☐ No ☐

……

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21. Do you smoke? Yes ☐ No ☐

21.1 **If Yes**, how many cigarettes do you smoke per day?.....

22. How much alcoholic consumptions you normally drink per week? _____Glasses

22.1 How much did you drink in the last 24 hours?.....Glasses

23. Have you ever worked in the MRI unit (where the MRI magnet is located) while you were pregnant? Yes ☐ No ☐

23.1 **If Yes**, indicate the pregnancy trimester: (tick the applicable trimester)

1st Trimester ☐ 2nd Trimester ☐ 3rd Trimester ☐

Thank you for participating in this study!

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ANNEXURE N

Vraelys

Titel: BEROEPTE BLOOTSTELLING AAN RADIOFREKWENSIE-ENERGIE EN STATIESE MAGNETIESE GEBIEDE IN MRI-EENHEDE IN DIE OPENBARE SEKTOR IN MANGAUNG METROPOLITAANSE STREEK

Die doel van hierdie studie is om die gesondheidseffekte van blootstelling aan radiofrekwente energie en statiese magnetiese velde in MRI-eenhede te evalueer en om 'n model te ontwikkel wat werknemers se blootstelling sal beskerm.

Hierdie vraelys is in drie afdelings verdeel. Afdeling A bestaan uit biografiese inligting, afdeling B bestaan uit werkverwante inligting en afdeling C bestaan uit gesondheidsverwante.

instruksies

Voltooi die vraelys deur te merk **"√"** langs die toepaslike antwoord, waar van toepassing, en deur antwoorde in die stippellyne te verskaf.

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Afdeling A: Biografiese inligting

1. Wat is jou geslag?

Manlik ☐

Vroulike ☐

2. Wat is jou ouderdom? …… .... jare

3. Wat is jou hoogste vlak van opleiding? .....

Afdeling B: Werksverwante inligting

4. By watter fasiliteit is jou tans werksaam? (Merk die toepaslike hospitaal af)

a. Universitas hospitaal ☐ b. Pelonomi hospitaal ☐

5. Wat is jou huidige pos? (Merk die toepaslike postitel)

a. Verpleegster ☐ b. radiografis ☐ c. Mediese fisikus ☐

d. radioloog ☐ e. onderhoudsingenieur ☐ f. Studenteverpleegster ☐

g. Studente Radiograaf ☐ h. Student Mediese fisikus ☐ i. ander

spesifiseer asseblief……

6. Behels jou werk in die MRI-kamer, waar die MRI-skandeerder geleë is?

Ja ☐ Nee ☐ **as Nee**, gaan asseblief na vraag 9.

7. Hoe lank werk jou in die MRI-eenhede ……..jaar

8. Werk jou skofte in die MRI-eenhede? Ja ☐ Nee ☐

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8.1 Indien Ja, wat is die duur van jou skof? ..... uur

9. Was jou al ooit in die MRI-kamer (waar MRI-skandeerder geleë is) tydens jou werkswisseling? Ja ☐ Nee ☐ **As Nee**, gaan dan asseblief na vraag 10.

9.1 As Ja, hoeveel dae per week het jou gemiddeld saam met die MRI-skandeerder gewerk, wat vereis dat jou die skandeerderkamer binnegaan? .....

9.2. By watter skandeerder (s) het jou hierdie week tydens jou skofte gewerk? Rapporteer die skandeerder se naam en -veld (in Tesla) ……

By die beantwoording van vraag 9.3, dink aan dinge wat verkeerd geloop het of nie volgens plan verloop het nie; soos toestelle wat nie funksioneer nie, die herposisionering van die pasiënt of die spoel, die pasiënt help met klaustrofobie, noodsituasies of die skandeerder moet skoonmaak.

9.3. Het daar gedurende jou skofte hierdie week onreëlmatighede of voorvalle plaasgevind wat vereis het dat jou langer as gewoonlik in die skandeerkamer moes bly, of om die kamer meer gereeld as gewoonlik binne te gaan? Ja ☐ Nee ☐

By die beantwoording van vraag 9.4, tel die totale aantal kere, nie die aantal prosedures nie, en besin oor u skofte hierdie week.* Verkryging: die oomblik wanneer die beeld verkry word; wanneer die skandering uitgevoer word.

9.4. Hoeveel keer was jou in die skandeerderruimte tydens beeldverwerwing? .....

9.5. Hoeveel keer het jou kop of bolyf hierdie week in die skandeerder ingetrek?.....

9.5.1 As jou kop of bolyf in die skandeerderboor beweeg het, beskryf dan die situasie waarin dit gebeur het.

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.....

.....

.....

10. Hoe beskou jou werklading? (Merk toepaslike antwoord)

a. ligte ☐

b. matige ☐

c. swaar ☐

11. Hoe vermoeiend beskou jou hierdie werkweek? (Merk toepaslike antwoord)

a. Skaars vermoeiend ☐

b. 'N Bietjie vermoeiend ☐

c. Baie uitputtend ☐

12. Het jou al ooit opleiding ontvang oor die veiligheid van MRI-personeel voordat jou met MRI-skandeerders gewerk het? Ja ☐ Nee ☐

13. Hoe veilig voel jou as met MRI-skandeerder werk?

a. Baie veilig ☐

b. Redelik veilig ☐

c. Effens veilig ☐

d. neutrale ☐

e. Effens onveilig ☐

f. Redelik onveilig ☐

g. Baie onveilig ☐

14. Het jou opleiding ontvang oor die gesondheidseffekte van blootstelling aan statiese magnetiese velde en radiofrekwensie-energie van MRI-eenhede?

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Ja ☐ Nee ☐

14.1 As Ja, wanneer laas het jou opleiding ontvang?_____

Beantwoord vraag 15 slegs as jou 'n onderhouds- / diensingenieur, mediese fisikus of studentemedisyns is.

15. Is daar beheermaatreëls in plek om die skadelike gevolge van statiese magnetiese velde en radiofrekwensie-energie deur MRI-skandeerders te verminder?

Ja ☐ Nee ☐

Afdeling C: gesondheidsverwante inligting

16. Ervaar jou enige van die simptome (gelys in die onderstaande tabel) as jou met MR-skandeerders werk?

Ja ☐ Nee ☐

Indien ja, gebruik die volgende vyf Likert-skaal (nooit, selde, die helfte van die tyd, gewoonlik, altyd). **As Nee**, gaan na vraag 19.

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Simptome wat u ervaar het	Likert-skaal				
	nooit	Selde	Die helfte van die tyd	gewoonlik	altyd
Tinnitus of gevoel van kopklank					
Oorpyn					
hoofpyn					
Konsentrasieprobleme					
Moegheid of slaperigheid					
naarheid					
braking					
Onwillekeurige spierkontraksies					
Trilling/ bewing					
Tintelingsensasie in die liggaam: spesifiseer asseblief liggaamsdeel ……					
Sensasie van gloeiende, brandende of geïrriteerde vel					
Skielik voel dit warm / warm flitse					
Jeukerige, waterige of rooi oë					
Om swart vlekke te sien of tydelik visie te verloor					
As u ligvlekke of ligflitse sien					
Vervaag of dubbelvisie					
Gevoel van duiseligheid of vertigo					
Voel lighoofdig of gewigloos					

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Onstabiliteit as jou staan, loop of beweeg					
'N Metaal smaak					

17. Dink jou dat werkspraktyk beïnvloed is deur die simptome wat jou ervaar het?

Ja ☐ Nee ☐

17.1. Indien wel, deur watter van die bogenoemde simptome is jou werk beïnvloed en op watter manier?

.....

.....

.....

18. Het jou enige idee wat hierdie simptome veroorsaak het?

.....

.....

.....

19. Gebruik jou ontsmettingsmiddels of skoonmaakmiddels (bv. Op alkohol) gedurende jou werksdag? Ja ☐ Nee ☐

Indien Ja, dui die volgende aan:

a. Skoonmaakmiddels met 'n sterk chemiese reuk of damp, soos produkte wat bleikmiddel of vlugtige verbindings bevat ☐
b. Skoonmaakmiddels wat nie 'n sterk chemiese reuk of damp het nie, soos produkte van seep (handseep, skoonmaakmiddel) ☐

20. Neem jou medikasie? As Ja, meld watter medikasie jou neem en hoeveel per dag.

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Ja ☐ Nee ☐

.....

21. Rook jy? Ja ☐ Nee ☐

21.1 As Ja, hoeveel sigarette rook jou per dag? ....

22. Hoeveel alkoholiese inname drink jou gewoonlik per week? _____

22.1 Hoeveel het jou die afgelope 24 uur gedrink? .....

23. Het jou al ooit in die MRI-eenheid (waar die MRI-magneet geleë is) gewerk terwyl jou swanger was? Ja ☐ Nee ☐

23.1 Indien Ja, dui die swangerskap trimester aan: (merk die toepaslike trimester aan)

1ste trimester ☐ 2de trimester ☐ 3de trimester ☐

Dankie dat u aan hierdie studie deelgeneem het!

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ANNEXURE O

Dipotso

Sehlooho: THUTO YAHO HLAHLOBA LITLAMORAO TSA MATLA A RADIOFREQUENCY LE STATIC MAGNETIC FIELDS BASEBETSING BASEBETSANANG LE LI MRI LIPETLELENG TSA MMUSO, MANGAUNG METROPOLITAN REGION

Morero oa thuto ena ke ho hlahloba litlamorao tsa bophelo bo botle ba ho pepesetsoa matla a radiofrequency le static magnetic fields li-unit tsa MRI le ho theha mofuta o tla sireletsa bophelo ba basebetsi.

Potso ena e arotsoe likarolo tse tharo. Karolo A e na le tlhaiso-leseling e mabapi le litaba tsa tlhaho, karolo ea B e na le tlhaiso-leseling e amanang le mosebetsi 'me karolo ea C e na le litaba tse amanang le bophelo.

Litaelo

Fana ka le tšoao **"√"** haufi le karabo e loketseng moo ho hlokahalang le ka ho ngola likarabo meleng e boletsoeng.

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Karolo A.

1. Bong ba hau ke bofe?

Ntate ☐

Mosali ☐

O lilemo li kae? …… ....

3. Boemo ba hau bo phahameng ka ho fetisisa ba thuto/magolo ke bofe? ……..

Karolo B: Tlhahisoleseling e amanang le mosebetsi

4. Hona joale o sebetsa sebakeng sefe? (Tšoaea sepetlele seo o sebetsang hosona)

a. Sepetlele sa Universitas ☐ b. Sepetlele sa Pelonomi ☐

5. Lebitso la hau la hona joale la mosebetsi ke lefe? (Tšoaea sehlooho sa mosebetsi seo o se sebetsang)

a. Mooki ☐ b. Radiograph ☐ c. Lingaka tsa bongaka ☐

d. Radiologist ☐ e. Moenjiniere oa Tlhokomelo ☐ f. Mooki oa Moithuti ☐

g. Radiograph ea moithuti ☐ h. Setsebi sa fisiks sa bongaka sa baithuti ☐

i. Tse ling, ka kopo hlakisa ……

6. Na mosebetsi oa hau o kenyelletsa ho sebetsa ka kamoreng ea MRI, moo ho beuoeng mochini wa MRI?

Ho joalo ☐ Che ☐ **haeba Che**, tsoela pele ka potso ea 9.

7. U qetile nako e kae u sebetsa li-unit tsa MRI ……..years

8. Na o sebetsa li chencheng li-unit tsa MRI? Ho joalo ☐ Che ☐

8.1 Haeba ho joalo, o sebetsa nako e kae ka letsatsi?.....

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9. Na o kile oa ba ka kamoreng ea MRI (moo mochini wa MRI oleng teng) nakong ea mosebetsi oa hao?

Ho joalo ☐ Che ☐ **Haeba ho joalo, tsoela pele ka potso 10.**

9.1 Haeba ho joalo, ke matsatsi a makae ka beke ka karolelano u sebelisitseng mochini oa skena oa MRI o hlokang hore o kene ka hara kamore moo skena seleng teng? ……

9.2. O sebellelitse pela skena kapa o sebelisitse skena nakong ya hao ya mosebetsi bekeng ee? Ka kopo tlaleha lebitso la skena le tšimo (ka Tesla) …….

Ha o araba potso ea 9.3, nahana ka lintho tse sa tsamaeeng hantle kapa tse sa tsamaeang ho latela moralo; joalo ka lisebelisoa tse sa sebetseng hantle, ho beha mokuli hantle, ho thusa mokuli ea nang le claustrophobia, maemo a tšohanyetso kapa ho tlameha ho hloekisa skena.

9.3. Nakong ea liphetoho tsa hao bekeng ena, na ho na le ho hloka toka kapa liketsahalo tse u hlokang hore o dule kahare ho kamore ea skena nako e telele ho feta tloaelehileng kapa ho kena ka phapusing hangata ho feta ho tloaelehileng?

Ho joalo ☐ Che ☐

Ha o araba potso ea 9.4, bala palo ea linako, eseng palo ea lits'ebetso mme o nahane ka liphetoho tsa hao bekeng ena.* Ho Fumana: Nako le tsela eo setšoantšo se fumanoang ka eona.

9.4. O kene ka makhetlo a makae ka kamoreng ea skena nakong ea ho nkuoa ha litšoantšo?

9.5. O sutumisitse hlooho kapa 'mele oa hao pakeng tsa skena ha kae bekeng ee?

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9.5.1 Haeba o ile oa tsamaisa hlooho kapa 'mele oa hao pakeng tsa skena, ka kopo hlalosa boemo boo sena se etsahetseng.

……

……

……

10. O nka mojaro oa hau oa mosebetsi joang? (Tšoaea karabo e nepahetseng)

a. Ole bobebe ☐

b. O leka-lekane ☐

c. Ole boima ☐

11. O nka mosebetsi ao hao ole boima hakae bekeng ee? (Tšoaea karabo e sebetsang)

a. Ha o khathatse ☐

b. O khathatsa hanyane ☐

c. O khathatsa haholo ☐

12. Na o kile oa fumana koetliso mabapi le polokeho ea basebeletsi ba MRI pele o sebetsa le li-skena tsa MRI? Ho joalo ☐ Che ☐

13. O ikutloa o sireletsehile hakae ha o ntse o sebetsa ka/ pela skena sa MRI?

a. Ke bolokehile haholo ☐

b. Ke sireletsehile ka tsela e itekanetseng ☐

c. Ke bolokehile hantle ☐

d. Ha ke nke lehlakore ☐

e. Ke sa bolokeha ☐

f. Ke sa sireletsehe ka tsela e itekanetseng ☐

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g. Ke sa sireletseha haholo ☐

14. Na o fumane koetliso ka litlamorao tsa bophelo bo botle ba ho pepesetsoa matla a static magnetic fields le radiofrequency ho tsoa li-unit tsa MRI?

Ho joalo ☐ Che ☐

14.1 Haeba ho joalo, u qetetse neng ho fumana koetliso?_____

Araba potso ea 15 ha feela o le moenjiniere oa Lisebelisoa tsa tlhokomelo / tšebeletso, Lingaka tsa fisiks kapa moithuti ao bongaka ba fisiks.

15. Na hona le mehato ea taolo e teng ho fokotsa litlamorao tsa matla a static magnetic fields le matla a radiofrequency ka hare ho li-unit tsa MRI?

Ho joalo ☐ Che ☐

Karolo C: Lintlha tse amanang le bophelo

16. Na o ba le matšoao afe kapa afe (a thathamisitsoeng tafoleng e ka tlase) ha o sebetsa le li-skena tsa MR?

Ho joalo ☐ Che ☐

Haeba ho joalo, sebelisa motjha o nang le karolo tse hlano tse latelang ho araba ka tsela eo o utloang matšoao ka teng (Likert- scale: Ha ho leka mohla, Ha nyane ka mehla, Halofo ea nako, Ha ngata, Ka mehla). Haeba che, fetela ho potso 19.

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Matšoao ao u fetileng ho ona	Sekala sa Likert				
	Ha ho leka mohla	Ha nyane ka mehla	Halofo ea nako	Ha ngata	Ka mehla
Tinnitus kapa maikutlo a molumo oa hlooho					
Ho opeloa ke tsebe					
Ho opeloa ke hlooho					
Mathata a ho tsepa misa monahano					
Ho khathala kapa ho robala					
Ho nyekeloa ke pelo					
Ho hlatsa					
Boiketsetso ba mesifa e kenang					
Ho thothomela					
Ho sithabela ha maikutlo 'meleng: ka kopo bolela karolo ea 'mele ……					
Phekolo ea letlalo le khanyang, le tukang kapa le sa khopiseng					
Ka tšohanyetso o ikutloa o futhumetse / o chesa, o tuka					
Mahlo a makatsang; a metsi kapa a mafubedu					
Ho bona matheba a sootho kapa ho lahleheloa ke pono ha nakoana					
Ho bona matheba a bobebe kapa mabone a khanya					
Pono e foufalitsoeng kapa e habeli					
Ho terekana					
Ho ikutloa o sena matla kapa o se na boima ba 'mele					
Boikutlo ba ho hloka botsitso ha o eme, o tsamaea kapa o sisinyeha					
Tatso ea tšepe ka hanong					

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17. Na o nahana hore tloaelo ea hao ea mosebetsi e amiloe ke matšoao ao u fetileng ho ona? Ho joalo ☐ Che ☐

17.1. Haeba ho joalo, ke matšoao afe a boletsoeng kaholimo a entseng hore mosebetsi oa hao o amehe?

……

……

……

18. Na o na le mohopolo o bakileng matšoao aa?

……

……

……

19. Na o sebelisa li-hloekisa ha ole mosebetsing?

Ho joalo ☐ Che ☐

Haeba ho joalo, bontša tse latelang:

a. Lisebelisoa tsa ho hloekisa tse nang le monko o matla kapa motsoako oa lik'hemik'hale, joalo ka lihlahisoa tse nang le li-bleach kapa metsoako e sa tsitsang ☐
b. Lisebelisoa tsa ho hloekisa tse se nang monko o matla oa lik'hemik'hale, joalo ka lihlahisoa tse entsoeng ka sesepa (sesepa sa matsoho) ☐

20. Na o noa meriana leha e le efe? Haeba ho joalo, ka kopo bolela hore na o sebelisa meriana efe le hore na o noa ha kae ka letsatsi. Ho joalo ☐ Che ☐

……

……

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21. Na oa tsuba? Ho joalo ☐ Che ☐

21.1 Haeba ho joalo, o tsuba lisakerete tse kae ka letsatsi? ……

22. Ha ngata o sebelisa lino tse tahang hakae ka beke? _____

22.1 O noele tse kae lihora tse 24 tse fetileng?.....

23. Na o kile oa sebetsa lekaleng la MRI (phaposing eo ho beueng mochini wa MRI teng) ha o ne o le moimana? Ho joalo ☐ Che ☐

23.1 Haeba ho joalo, bonts'a nako ea boimana: (tšoaea trimester e nepahetseng)

1Trimester ☐ 2 Trimester ☐ 3 Trimester ☐

Kea leboha ha o nkile karolo thutong ena!

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ANNEXURE P

RISK ASSESSMENT SHEET

Task	Hazards	Risks	H/ S	Probability	Consequence	Risk rating (C*P)	Risk outcome	Existing control measures in the MRI unit	Emergency action required
MRI services in Pelonomi hospital (Scanner: 1.5 T Siemens)									
MRI services in Universitas hospital (Scanner: 3.0 T Philips)									

***Overall risk: Average of risk rating**

Probability	Score A	Risk outcome	Overall risk score
Improbable	1	High risk	>15
Remote	2	Moderate risk	>5 ≤15
Possible	3	Low risk	≤5
Likely	4	No risk	0
Very likely	5		
Severity/ Consequence	**Score B**		
Irreversible effect	5		
Severely harmful	4		
Harmful	3		
Slightly harmful	2		
Minimal Effect	1		
No effect	0		

***H= Health and S= Safety**

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ANNEXURE Q

Permission from FSDOH

health
Department of Health
FREE STATE PROVINCE

11 July 2018

Mr. P Rathebe
20 Pres. Brandt Str.
Willows
BFN, 9300

Dear Mr. P Rathebe

Subject: Occupational exposure to radiofrequency energy and static magnetic fields in MRI units within Mangaung Metropolitan Region.

- Please ensure that you read the whole document, Permission is hereby granted for the above – mentioned research on the following conditions:
- Participation in the study must be voluntary.
- A written consent by each participant must be obtained.
- Serious Adverse events to be reported to the Free State department of health and/ or termination of the study
- Ascertain that your data collection exercise neither interferes with the day to day running of the Universitas or Pelonomi Hospital and Mangaung Metro Offices nor the performance of duties by the respondents or health care workers.
- Confidentiality of information will be ensured and please do not obtain information regarding the identity of the participants.
- **Research results and a complete report should be made available to the Free State Department of Health on completion of the study (a hard copy plus a soft copy).**
- Progress report must be presented not later than one year after approval of the project to the Ethics Committee of The University of the Free State and to Free State Department of Health.
- Any amendments, extension or other modifications to the protocol or investigators must be submitted to the Ethics Committee of The University of the Free State and to Free State Department of Health.
- **Conditions stated in your Ethical Approval letter should be adhered to and a final copy of the Ethics Clearance Certificate should be submitted to** sebeelats@fshealth.gov.za or lithekom@fsheatlh.gov.za **before you commence with the study**
- No financial liability will be placed on the Free State Department of Health
- Please discuss your study with the institution manager/CEOs on commencement for logistical arrangements
- Department of Health to be fully indemnified from any harm that participants and staff experiences in the study
- Researchers will be required to enter in to a formal agreement with the Free State department of health regulating and formalizing the research relationship (document will follow)
- You are encouraged to present your study findings/results at the Free State Provincial health research day

Trust you find the above in order.
Kind Regards

Dr D Motau
HEAD: HEALTH
Date: 9/07/2018

Head : Health
PO Box 227, Bloemfotein, 9300
4th Floor, Executive Suite, Bophelo House, cnr Maitland and, Harvey Road, Bloemfotein
Tel: (051) 408 1646 Fax: (051) 408 1556 e-mail:khusemj@fshealth.gov.za@fshealth.gov.za/chikobvup@fshealth.gov.za

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ANNEXURE R

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA

UFS·UV
HEALTH SCIENCES
GESONDHEIDSWETENSKAPPE

Health Sciences Research Ethics Committee

25-Jul-2018

Dear **Mr Phoka Rathebe**

Ethics Clearance: **Occupational exposure to radiofrequency energy and static magnetic fields in MRI units within Mangaung metropolitan region**
Principal Investigator: **Mr Phoka Rathebe**
Department: **CUT - Central University of Technology**
APPLICATION APPROVED

Please ensure that you read the whole document

With reference to your application for ethical clearance with the Faculty of Health Sciences, I am pleased to inform you on behalf of the Health Sciences Research Ethics Committee that you have been granted ethical clearance for your project.

Your ethical clearance number, to be used in all correspondence is:**UFS-HSD2018/0438/3107**

The ethical clearance number is valid for research conducted for one year from issuance. Should you require more time to complete this research, please apply for an extension.

We request that any changes that may take place during the course of your research project be submitted to the HSREC for approval to ensure we are kept up to date with your progress and any ethical implications that may arise. This includes any serious adverse events and/or termination of the study.

A progress report should be submitted within one year of approval, and annually for long term studies. A final report should be submitted at the completion of the study.

The HSREC functions in compliance with, but not limited to, the following documents and guidelines: The SA National Health Act. No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes (2015); SA GCP(2006); Declaration of Helsinki; The Belmont Report; The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services- (HHS), 21 CFR 50, 21 CFR 56; CIOMS; ICH-GCP-E6 Sections 1-4; The International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite), Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines, Constitution of the HSREC of the Faculty of Health Sciences.

For any questions or concerns, please feel free to contact HSREC Administration: 051-4017794/5 or email EthicsFHS@ufs.ac.za.

Thank you for submitting this proposal for ethical clearance and we wish you every success with your research.

Yours Sincerely

Dr. SM Le Grange
Chair : Health Sciences Research Ethics Committee

Health Sciences Research Ethics Committee
Office of the Dean: Health Sciences
T: +27 (0)51 401 7795/7794 | E: ethicsfhs@ufs.ac.za
IRB 00006240; REC 230408-011; IORG0005187; FWA00012784
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YUNIVESITHI YA FREISTATA

UFS·UV
HEALTH SCIENCES
GESONDHEIDSWETENSKAPPE

Health Sciences Research Ethics Committee

28-May-2020

Dear Mr Phoka Rathebe

Ethics Number: UFS-HSD2018/0438/3107

Ethics Clearance: **Occupational exposure to radiofrequency energy and static magnetic fields in MRI units within Mangaung metropolitan region**

Principal Investigator: **Mr Phoka Rathebe**

Department: **CUT - Central University of Technology**

SUBSEQUENT SUBMISSION APPROVED

With reference to your recent submission for ethical clearance from the Health Sciences Research Ethics Committee. I am pleased to inform you on behalf of the HSREC that you have been granted ethical clearance for your request as stipulated below:

- Minor Amendment:
  The data collection tool (questionnaire) has been modified and interview questions are also included.

The HSREC functions in compliance with, but not limited to, the following documents and guidelines: The SA National Health Act. No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes (2015); SA GCP(2006); Declaration of Helsinki; The Belmont Report; The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services- (HHS), 21 CFR 50, 21 CFR 56; CIOMS; ICH-GCP-E6 Sections 1-4; The International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite), Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines, Constitution of the HSREC of the Faculty of Health Sciences.

For any questions or concerns, please feel free to contact HSREC Administration: 051-4017794/5 or email EthicsFHS@ufs.ac.za.

Thank you for submitting this request for ethical clearance and we wish you continued success with your research.

Yours Sincerely

Dr. SM Le Grange
Chair : Health Sciences Research Ethics Committee

Health Sciences Research Ethics Committee
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ANNEXURE S

CONSENT TO PARTICIPATE IN RESEARCH: INTERVIEWS

Please initial each box below:

☐ I hereby give consent for my interview, conducted as part of the study stipulated in the information letter, to be audio-taped.

☐ I understand that my personal details and identifying data will be changed in order to protect my identity. The audio tapes used for recording my interview will be destroyed immediately after publication of the research.

☐ I have read this consent form and have been given the opportunity to ask questions.

_____	_____	_____
Name of Participant	Signature of Participant	Date
Phoka Rathebe		03 August 2020
Name of Researcher	Signature of Researcher	Date

Researcher's details: Name: Phoka Rathebe **Cell no:** 0780830553

It is hereby confirmed that **PC Rathebe** (student researcher) orientated and inducted..... (Study participant) through all the procedures of the study, its importance and potential risks to both the general population and/or the study participants. It is confirmed by the study participants that he/she participates voluntarily in the study, with NO any pressure/coercion or what so ever from the researchers. It is also confirmed that the student researcher explicitly notified the study participants of their right and autonomy to participates and withdraw from the study, it is agreed by both parties, on that effect, that the study participants will reserve their right to withdraw from the study at any stage of the study, even, without an explanation to the researcher, it is also agreed that the researcher shall impose no punitive measure by action nor omission on the study participants upon the study participants opting out of the study.

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Student Researcher: Phoka Rathebe Date: 03 August 2020 Place: Bloemfontein

Study participants :_____ Date:..... Place: .....

Separate Informed consent for the use of Audio recording device during interviews: Audio recording

It is hereby confirmed that PC Rathebe (student researcher) prepared and presented this as a separate document as required by law. This document serves as a contract of agreement for the student researcher to record..... (Study participants) during the conversation(s) related exclusively to the study interview(s). It is agreed that the recorded conversation(s) and/or responses shall be used only for the purpose of the study, during the conduct of the study and of which after the study all such data recorded shall be responsibly discarded by the student researcher.

Student researcher: Phoka Rathebe Date: 03 August 2020 Place: Bloemfontein

Study participants .....Date.....Place

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