# Perceived safety of MRI units in the two public hospitals within the central region of South Africa: A pilot study among four MR staff

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#### Abstract

Magnetic resonance scanners are considered safe but comes with substantive safety risks to patients seeking radiological diagnostics and health care professionals. This pilot study aimed to assess the safety compliance of MRI units commonly used in the clinical diagnostic imaging of two public hospitals in South Africa. Structured interviews were conducted with four MRI staff assigned to work in the 1.5 and 3.0 T MRI units. Their responses were benchmarked with ACR MR Safety guideline of 2019 to assess any safety compliance deviations. Thematic analysis was conducted by evaluating responses per themes and further expanding on comments provided on Yes or No options. There were few major shortfalls identified that include outdated safety policies, inadequate screening, nonexistence of demarcations and lack of training of MR and non-MR personnel of MRI safety. These challenges could be eliminated by introducing a comprehensive occupational health and safety program, specific to the MRI units.

#### **Keywords**

Interviews, MRI staff, operational safety, training, policies documents

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# Introduction

Magnetic resonance imaging (MRI) is considered safe but comes with substantive risks to patients seeking radiological diagnostics and health care professionals who are not properly trained, and may be exposed to magnetic fields. The well-known risks of MRI scanners range from the interaction of static magnetic fields (SMFs) with humans and ferromagnetic equipment, including exposure to radiofrequency fields (RF) and implant interference.<sup>1,2</sup> In South Africa, like many other African countries, the use of 1.5 and 3.0 T magnetic resonance (MR) scanners for clinical purposes is common.<sup>3</sup> This epitomizes similar exposurerelated scenarios and safety conditions found in other countries. Contrary to other countries, the specific number of 1.5 and 3.0 T MR scanners in both private and public hospitals of South Africa, is unknown. It has been found that South African health care sector has 2.9 MRI units per one million of the population,<sup>4</sup> and this assessment was conducted without providing the number of available and authorized MR units in South Africa. Therefore, a South African MR inventory study is required to provide reliable information on the authorized number of 1.5 and 3.0 T MR scanners in both private and public hospitals. Prior advocating for MR units in South Africa, inherent safety risks that comes with these scanners must first be understood.

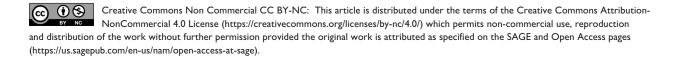
Since the release of the first safety guidance document by the American College of Radiology (ACR) in 2007, there has been only one study in Africa that investigated

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	Age	Gender	Number of years in the MRI units	Scanner worked on	Shift duration in the MRI unit	Tiring workweek	Workload
ob titles							
Radiographers	49	Μ	15	1.5 T	8h	Very tiring	Heavy
Medical physicists	31	Μ	3	1.5 T	8h	Little tiring	Moderate
Radiologist (A)	42	Μ	4	3 T	4h	Little tiring	Moderate
Radiologist (B)	32	F	3	1.5 T	4h	Little tiring	Moderate

 Table I. Description of study participants.

A: hospital A; B: hospital B.

safety standards of MRI in one of the tertiary hospitals in Ghana.<sup>5</sup> This study looked at operations of the MRI concerning safety policies, compatibility, and design elements of the MRI suites as well as safety-training needs of the MRI staff. The increasing demands for MRI services in the African continent suggest potential risks of safety noncompliances in the operations of MRI units. The perceived potential risks must be well studied in the health care population of South Africa, since there is an increased commissioning of MRI scanners. In the current study, the safety compliance of the MRI units, 1.5 and 3.0 T, from two tertiary hospitals in South Africa was measured against the latest ACR guidance document on MR safety.<sup>6,7</sup> The aim was to assess areas where there is a significant need to strengthen safety in the MRI units of different scanner strength.

## Materials and methods

The cross-sectional descriptive study design was employed to investigate the MRI safety risks using structured interviews. This study took place in the MRI units of two tertiary hospitals located in Bloemfontein; the central region of the Free State. These hospitals (hospital A and B) are used as public referral centers for patients who need radiological services such as MRI.8 To determine the overall safety risks within the MRI units, 21-questions MRI safety interviews were conducted based on safety practices in the MRI suites. The questions were classified into three themes; operational safety in the MRI units, availability of departmental safety policy manuals, and safety training programs for MRI staff. These questions 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.<sup>5</sup> Four clinical imaging staff: two radiologists, a medical physicist, and a radiographer were interviewed separately in the English language. One radiologist was stationed in hospital A, while the medical physicist, one radiologist, and a radiographer were stationed in hospital B. Inclusion of these participants was considered the feasible and best way to obtain reliable, detailed, and comprehensive information about MRI safety risks. The four interviews were

electronically recorded, transcribed and questions were grouped into themes for further thematic analysis. Furthermore, participants were also asked to describe their number of years in the MRI units, scanner worked on, shift duration, how tiring is their workweek and the level of their workload.

Before the commencement of the study, ethical clearance was obtained as well as permission from the relevant health department. Signed consent was also obtained from all the participants. Before 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 30 minutes. The interview responses were recorded on a voice-recording device, transferred to a computer, and coded for safe storage.

## Results

The large national survey on the safety of MR scanners has been developed and is under consideration somewhere else, and the results presented here, are of the pilot study of the same research project. The descriptive data for study participants who were interviewed is provided in Table 1 below. It must be noted that these are only participants who agreed to be part of this pilot study, and felt comfortable to disclose the safety compliance status of their MRI units.

The interview consisted of sections A, B, and C. Each question in the MRI safety interview questionnaire required a "Yes" or "No" option (Table 2), followed by comments that the interviewee could make concerning the specific question asked. There were questions to which the interviewees responded differently and this may be related to the different post levels of participants, for example, the radiographer's point of view differed from a radiologist's point of view.

### Comparison of comments

Operational safety at MRI unit. According to the responses of interviewees, it does not seem that medical devices 
 Table 2. Closed-ended interview responses.

Questions	Chief radiographer (B)	Medical physicist (B)	Radiologist (B)	Radiologist (A)
Section A: Operational safety at MRI unit				
I. Have all medical devices brought into Zone III and Zone IV in the MRI units undergone standardized evaluations and labeling 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 color 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
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
II. Are all MR and non-MR personnel aware of the hazardous cryogenic gas during an emergency magnet quench?	Yes	Yes	Yes	Yes
Section B: Availability of departmental policy manual				
I. Are there updated MR Safety policies and procedures	No	No	No	No
<ul><li>in place?</li><li>2. When introducing any changes in the safety parameters of MRI units (e.g. hardware or software upgrade), do</li></ul>	No	No	No	Yes
<ul> <li>you update your safety policies or procedures?</li> <li>3. Is there a written procedure to report the occurrence of all MR-related adverse events, safety incidents, or "near incidents"?</li> </ul>	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
6. Is there a policy for the MRI emergency quench?	Yes	Yes	Yes	Yes
Section C: Training programs for MRI				
I. 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 program for MRI staff?	No	No	No	No
4. Are all MR and non-MR staff trained on the safety risks of MRI cryogenic fluids (liquid helium/ nitrogen)?	No	Yes	No	No

brought into Zone III and IV in the MRI units undergo standardized 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. Labeling 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 labeling 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 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 standardized evaluation and be labeled 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 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.

Although the ACR Committee on MR Safety et al.<sup>6</sup> suggest that all equipment used in the MRI units must be color coded, the equipment used in the MRI units of both hospitals have no color codes to identify ferrous material and MRI-safe material. According to the medical physicist and radiographer, staff assigned to work in the MRI units are regarded as specialized 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 color-coded.

The question on whether routine maintenance of the MRI scanners is done according to manufacturers' requirements, the radiographer indicated 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 MRI 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 standardized 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 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 time; therefore, it is "not necessary" for screening to take place. The second reason was that all MRI 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 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-MRI personnel (e.g. a nurse) brings a patient from, for instance, casualty to the MRI. "Normally, the MRI nurse will take over from the other nurse and if she needs help, she will be assisted by the other two MRI 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 environment does not pose any harm to non-MRI 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 MRI 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 radiographer and medical physicist emphasized 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 radiographer, the access door to Zone IV is kept locked when the scanner is not 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 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. The medical physicist, two radiologists and a radiographer indicated that all MR and non-MR personnel are aware of the hazardous cryogenic gas during an emergency magnet quench. All of the radiologists and a radiographer suggested that they have seen a safety sign "cold burn hazardcryogenic liquid" in their respective MRI units, and the medical physicist indicated that hazard awareness for liquid and nitrogen gases used in the MR systems was part of their training syllabus.

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 fetus." The radiographer and two radiologists indicated that they had never seen the policy.

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 radiographer, there has never been any upgrade because their MR machine (1.5 T) is new. 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 radiographer indicated that a procedure did exist; however, it is not MRI specific, and it is a standardized 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 results. 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 cognizance of infection control, the 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. The medical physicist indicated that a standard operating procedure exists, but it is mostly applicable to nursing staff. The two radiologists, on the other hand, indicated that there was no standardized 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 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 to assist with emergency situations. The two radiologists said no, there were no policies and procedures for emergency management in the MRI facilities. All the participants indicated that there is a policy available on the MR emergency quench, and it is posted in the MR zone IV (magnet room).

Training programs for MRI. When asked about it, the 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 MRI 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 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, 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 MRI staff took place. The 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. All participants indicated that MR and non-MR personnel have not received training on the safety risks of MRI cryogenic fluids, except for the medical physicist. The medical physicist suggested that training on safety risks of MRI cryogenic fluids is part medical physics syllabus, and additional refresher training is provided by the MR service provider.

## Discussion

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.<sup>5</sup> Opuku et al.<sup>5</sup> 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<sup>7</sup> regard safety policies in the workplace as a cornerstone for efficient safety practices. It is essential for all MRI staff to realize safety aims, objectives, and targets for all safety issues in the MRI units.9 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 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 standardized evaluation and classification of equipment by labeling 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<sup>6</sup> indicates that all equipment prior to being brought into the MRI units must undergo standardized evaluation and labeling 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,<sup>9</sup> 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-MRI staff members are allowed to enter zone III or IV without undergoing safety screening, consequently putting them at risk of exposure to magnetic fields. A similar observation was made among nurses, anesthetics and medical doctors in Opoku et al.'s<sup>5</sup> study 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<sup>10</sup> suggest

detector in hospital A. Shellock and Spinazzi<sup>10</sup> suggest that a standardized 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. All participants suggested to be aware of the potential safety risks of cryogeinic fluids and availability of the MR emergency quench policy. However, training on the safety risks seem to be lacking among radiologists and a radiographer. According to Kanal et al.,<sup>15</sup> the properties of cryogenic liquids present significant safety hazards such as asphyxiation, frostbite, abnormal pressure, and fire threats. Therefore, safety training on the MR cryogenic fluids is essential, to safegurad the health and safety of both MR and non-MR personnel.

It was noted that infection control does exist in the MRI units of both hospitals in a form of cleaning MRI units. However, the 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.<sup>11</sup> The MRI radiographers and radiologists are required to undergo annual advanced MRI safety training<sup>12</sup> and non-MR staff who are constantly in the MRI units must have basic annual training.<sup>11</sup> The MRI staff members who sometimes work in the MRI units must undergo a quick screening conducted by an MRI radiographer or radiologist.

Though the maintenance schedule for hospital B was missing (according to the 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,<sup>13</sup> 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<sup>14</sup> suggests that the four MRI safety zones should be clearly demarcated as this will ensure strict adherence to MRI safety.<sup>15</sup> 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.<sup>16,17</sup> Kanal et al.<sup>15</sup> recommend emergency preparedness plans to be part of the organizational safety culture, and that healthcare professionals should be equipped with the required knowledge and skills in order to deal with emergency situations.<sup>18</sup>

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.<sup>10</sup> The use of hearing protective devices, such as earmuffs and earplugs, is mandatory when entering zone IV.<sup>16</sup> 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 MRI staff, that static magnetic fields cannot pose any harm to the health and safety of MRI staff.

## Conclusions

This study revealed existing safety challenges in the 1.5 and 3.0 T MRI units. When benchmarking with the latest ACR MR safety guidelines, it is noted that the few major shortfalls could be addressed by establishing the following: (i) MRI-specific safety policies should be updated when there are any changes that need to be effected to MRI scanners; (ii) MR safety training to be given to all MRI staff, including the development of guidelines on how to report MRI-related incidents; (iii) the installation of properly working 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 MRI staff on the use of PPE in zone IV, and MRI-related health effects. These could be attained by introducing a comprehensive occupational health and safety program with commitment from hospital managers.

#### **Declaration of conflicting interests**

The author declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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# Research involving human participants and/or animals

Ethical clearance was obtained from University of the Free State Health Sciences Ethics Committee (UFS-HSD2018/0438/3107) and permission was granted by the Free State Department of Health (FS201805 020).

#### Informed consent

Informed consent was obtained from all subjects involved in the study.

#### Availability of data and materials

N/A.

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