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Report of the 2021 Online Survey of MR Safety in AOSR countries

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Introduction

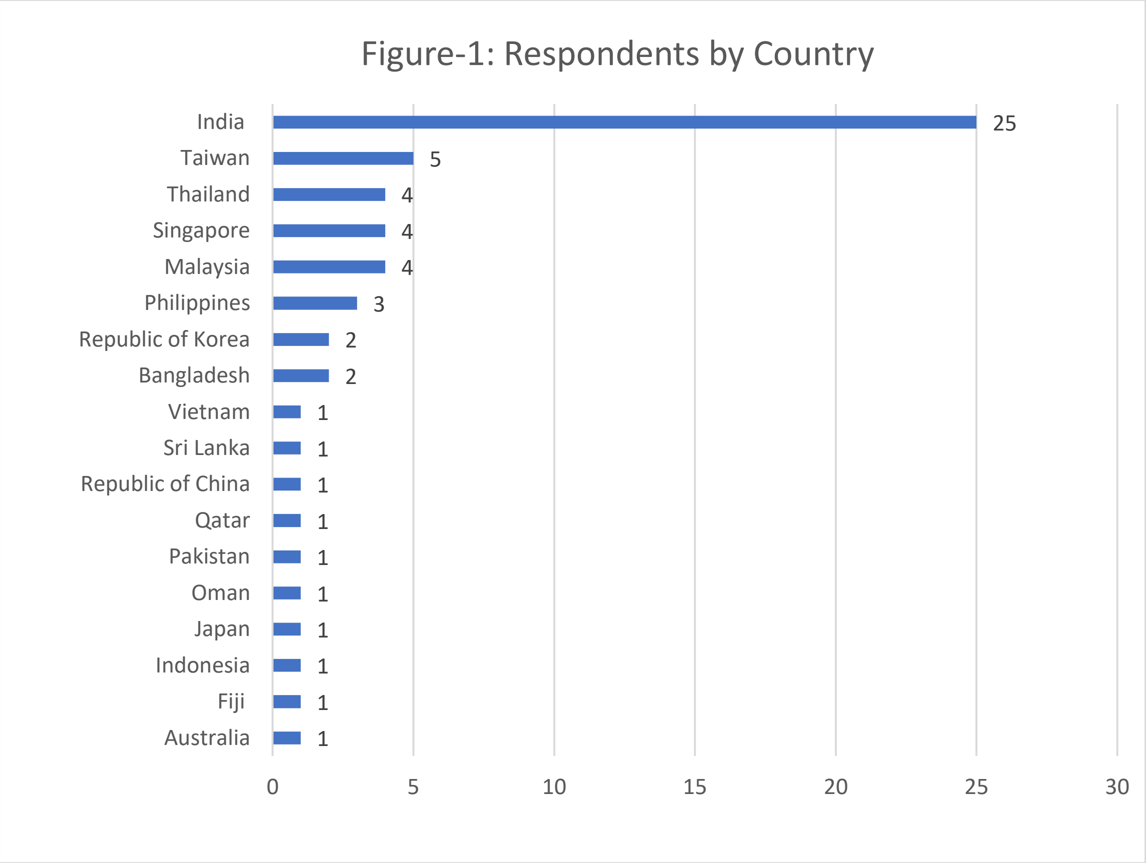
Magnetic Resonance Imaging (MRI), which provides opportunities for exceptional soft tissue contrast and non-ionizing radiation exposure, is increasingly used in healthcare diagnostics.[1] The advances in MR technology and the application of these technologies for different clinical conditions often lead to the identification of new safety issues. The three electromagnetic fields in MRI- the static magnetic field, the time-varying gradient magnetic field, and the radio-frequency field- can lead to different safety risks.[2-5] Adverse events associated with exposure to these electromagnetic fields may include vertigo, nausea, hazards caused by projectile forces, biomedical implant and device risk, translational forces on ferromagnetic objects, peripheral nerve stimulation, heat deposition and acoustic noise.[2,6-11] Safety-related incidents can increase as MR-based diagnostics becomes more prominent and more scanners with higher capabilities are installed.[4] Incident-reporting systems are essential to report and learn from incidents, understand their causes, and prompt action for prevention of similar incidents in the future, to minimize avoidable human suffering and save hospital and litigation costs.[4,12-15] However, several studies have reported that MR safety incidents are grossly underreported and that the system must become more robust.[16-19] It is important that MR technologists, radiographers and radiologists are aware of the rapidly evolving changes in MR safety to optimize safety practices. The Asia Oceania countries are diverse socioeconomically, culturally, and geographically, and an understanding of the local situation in each country is needed to promote and implement optimal safety practices. We designed an online AOSR-QSS survey focused on the status pertaining to MR safety regulations and practices in member countries of the AOSR. This survey aimed to give the Asia Oceania Society of Radiology (AOSR) and its Quality Safety Standards (QSS) Committee a baseline to further promote MRI safety awareness, educational videos or teaching materials in the Asia Oceania region. In this manuscript, we present the results of this AOSR-QSS Survey on MR Safety Practices.

Methods

The survey questions and response patterns were developed by members of the Quality and Safety Standards (QSS) Committee of AOSR based on the individual experience of committee members. The final questionnaire developed in English was converted to a Google Form document that enabled online administration of the questionnaire to eligible participants. The survey included questions on the availability of national legislative or society guidelines on MR safety, the availability, frequency and distribution of training and awareness programs on MR safety, current practices pertaining to MR safety including zoning, screening, and shields, and incident reporting systems. Respondents were asked to upload relevant legislative or societal guidelines either as a document or as a link to the digital version of the document. The link to the questionnaire with a brief description of the purpose of the survey was e-mailed to the national organizations of all AOSR member countries. The national organizations were requested to further disseminate the survey questionnaire to their members. The link to the survey and the details of the survey were also posted in the respective social media groups of radiologists including WhatsApp groups of the respective member countries of the AOSR. The responses to the online survey were anonymized and were further linked from the Google form to a Google spreadsheet for further analysis. The online survey was open from October 1, 2021, to November 1, 2021.

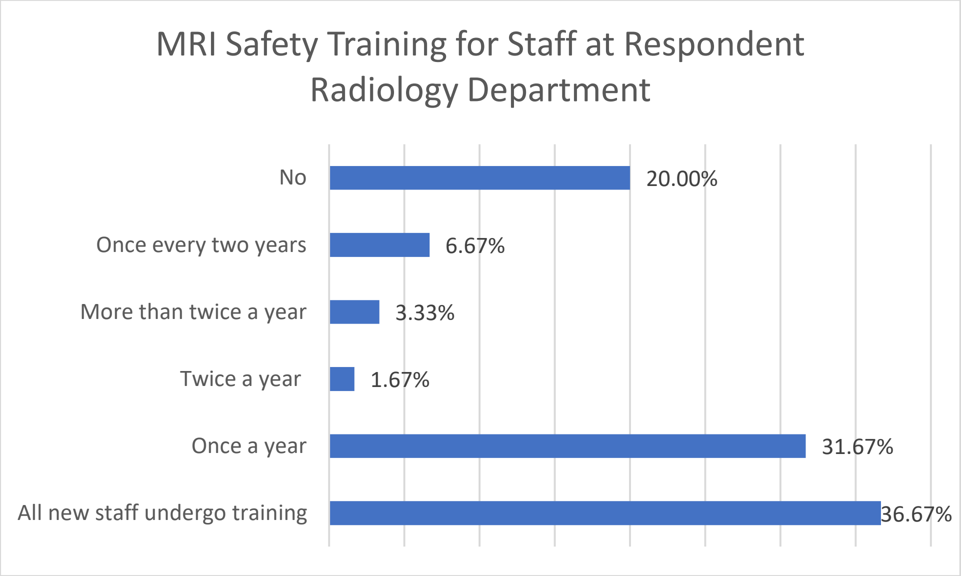
Results

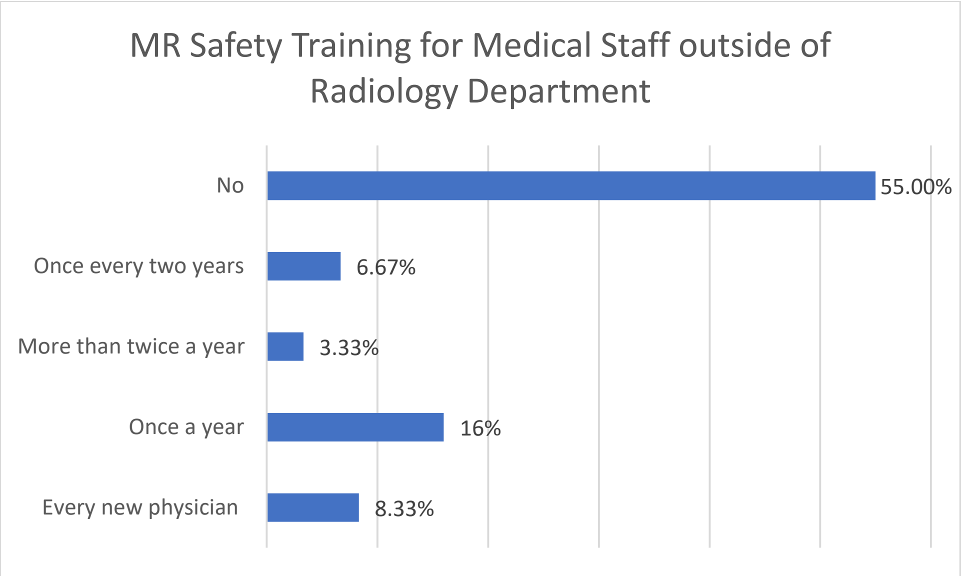
The survey elicited 59 responses from 18 countries and included responses from the national radiology societies and individual respondents from some countries. None of the respondent countries reported the presence of national legislation on MRI and MR Safety and most countries (90%) did not have documented national radiology society guidelines on MR safety. Forty-seven (79.66%) of the respondents reported that MR Safety guidelines were available at the institutional/hospital level and 93.22 % respondents reported the availability of MR safety guidelines at the radiology department level. Most Radiology departments (93.22 %) use a checklist or protocol for pre-MRI assessments.



Fifty (84.75%) of the 59 respondents reported that there was site restriction or zoning for their MR services. Forty-three (72.88 %) respondents reported the availability of a list of MRI safe items at the departmental level and the provision of this list to patients before MR imaging. Fifty-one (86.44 %) respondents reported that there was a regular screening of MR staff, however, screening of non-MRI personnel was reported by only 34 (57.62%)

respondents. Most (85.29%) of the 34 respondent units where screening of non-MRI personnel was done reported using ferromagnetic detectors for screening. Only 71.18% of respondents (n=42) reported that they screened the persons accompanying the patient for MRI and 75% of these 42 respondents reported using ferromagnetic detectors for the screening.





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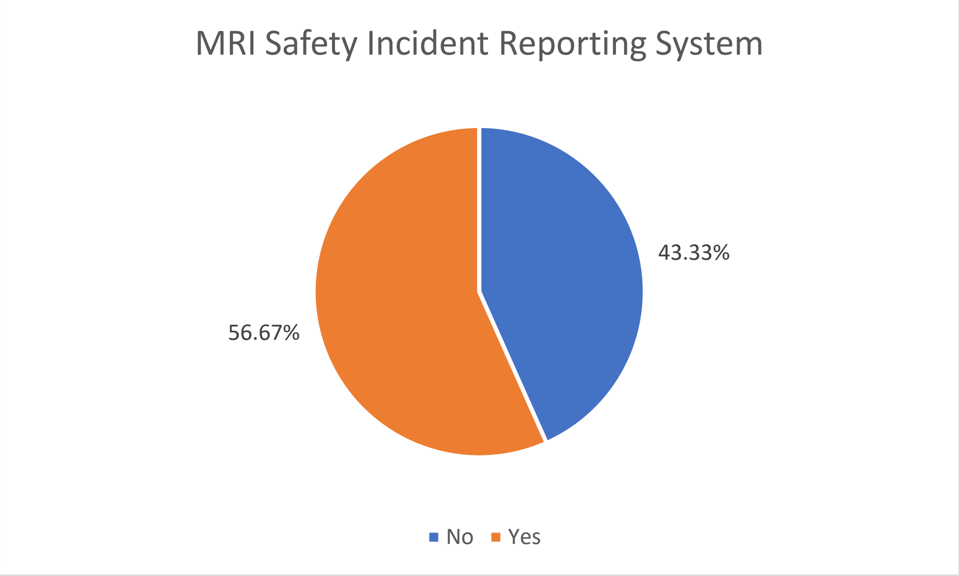

Discussion

Patient safety is an important priority that involves all aspects of preventive, diagnostic, therapeutic and interventional healthcare. Patient safety, within the specific context of MR imaging, involves interactions between human factors (patients, attendants or family members, personnel involved with the imaging), the instrumentation and technology used for the imaging including the magnetic fields, the external environment and the robustness of the systems used to identify and report critical incidents. The results of our survey highlight the need to improve several aspects of MR safety in the AOSR countries including the need to develop specific guidelines and protocols for MR safety, increased awareness and regular training for radiologists, radiographers and MR technologists, and utilization of critical incident reporting systems.

Adverse events associated with static magnetic fields include interactions with human tissue and equipment (projectiles, implant malfunction or movement, malfunction or movement of monitoring devices).[4] The risks associated with radiofrequency fields include specific absorption rate (SAR) issues, tissue heating, burns, implant heating and implant interference effects.[4,20] Major risks with time-varying gradients are peripheral nerve stimulation and acoustic noise, including potential interference with implants or monitoring devices.[4,20]

Clinical MR scanners utilize a superconducting magnet and a static magnetic field is always present. An estimated 10 to 20% of patients that undergo an MRI have implanted medical devices.[21] These implants and devices including ferromagnetic objects are subjected to translational and rotational forces in the static magnetic field that can cause a projectile effect.[7] An understanding of the composition of these objects and their behaviour in the magnetic field environment of MRI can help to improve patient safety. The American Society of Testing and Materials (ASTM) International Committee has identified three MRI safety categories: MR Safe, MR Conditional and MR Unsafe, and labels each with an associated icon.[22] MRI system vendors provide spatial gradient magnetic field (SGMF) maps for each scanner. The SGMF plots the change of the static magnetic field over distance and demonstrates the point of the maximum spatial gradient. The SGMF maps will differ between scanners and the MRI technologist must interpret different SGMF map formats as appropriate to determine implant safety with respect to any defined spatial gradient limitations prior to imaging patients with medical devices.[22,23] A rotational force or torque that forces the realignment of objects with the direction of the main magnetic field can occur on ferromagnetic objects when patients are brought into the scanning room.[24] The combination of translational and rotational forces may lead to implant dislodgement, mechanical failure in active implants, or movement of metallic devices or foreign bodies with organ damage or even death.[25] The MRI technologist must obtain the most relevant information regarding the health of the patient including the presence and safety labels of any device or implants. Interpretation of any MR conditions and the ability to apply these conditions to a specific scanner in the workplace by understanding the vendor SGMF maps is a necessary skill for the MR technologist or radiographer.[25] Acute sensory effects, including a metallic taste, nausea and vertigo, associated with moving through the static magnetic field are related to the induced voltages created by movement (due to Faraday's law of induction), and are of particular concern as 7T systems are introduced into the clinical setting.[11,26,27]

Burns are an important adverse event, and 59% of the FDA's MAUDE MRI adverse event database was related to thermal injury.[28] Burns are mostly caused by the introduction of electrically conductive materials into the scanner, direct contact with RF coils, proximity burns due to contact with the scanner bore or electrical loops formed by the patient's body.[28] Newer MRI burn hazards occur with technological advances in other industries, as in clothing manufactured with invisible silver-embedded microfibres that can produce electromagnetic eddy currents and highlighting the importance of changing all patients into facility-provided gowns.[29] An MRI face mask burn was reported in 2020 and reinforces the need to remain aware and vigilant during the patient screening and preparation processes especially as face masks are mandated during the COVID-19 pandemic.[30] Transdermal patches such as those used to administer pain relief and nicotine patches may have a metallic backing and the United Kingdom (UK) Medicines and Healthcare Products Regulatory Agency (MHRA) recommends the removal of medicinal patches that may contain metal if removal will not compromise patient treatment.[31] MRI technologists must adhere to best practice by changing the patient out of street clothes, using pads to avoid skin-to-skin and skin-to-bore contact, checking the position of the limbs of the patient, ensuring the patient's skin is not in contact with leads or monitors and use a heat sink over tattoos situated within the RF coil. [25] The technologist must consider the patient's age, thermoregulatory system and underlying health conditions that may compromise the ability of the patient to disperse or tolerate heat change. MRI technologists must alter environmental and scanning parameters to minimize patient heating and understand why specific scanner field strengths, RF coils, SAR limitations and lead positions are defined for various MR Conditional implants and devices and the potentially adverse impact of not adhering to these conditions.[25] The MRI technologist must correctly fit earplugs and check that the patient does this, and ensure that appropriate hearing protection is provided to, and worn by, anyone remaining in the scanner room during the examination.[25]

The reporting of critical incidents is important from the perspective of magnitude and provides a good learning opportunity to further improve or refine safety standards and processes. Critical incident reporting systems exist but are grossly underutilized.[16-19] Kihlberg, et al, reported that only 38% of critical incidents were reported and that several of the unreported incidents could have turned catastrophic.[17] They also reported a negative correlation between the number of annual incidents (per scanner) and staff MR knowledge and the number of MR physicists per scanner.[17] A major finding from their study was that only half of the study sites had implemented the EU directives on MR safety.[17] Hansson et al, observed that 16% of MR safety incidents had the highest severity or worst case scenario score, that severe adverse events still exist despite safety protocols, critical incidents are poorly shared within the team and are preventable.[32] Hansson et al reported that the confidence in internal communication or local reporting systems might be much greater than the true usefulness of such routines and there is a need for careful design of critical incident reporting systems to facilitate the use and sharing of information.[32] These issues and challenges were described by Jones et al in their paper that explored the challenges to establish national critical incident reporting systems.[33] Blankholm and Hansson have also reported a high rate of underreporting of MR safety incidents with 53% of MR professionals reporting involvement in an MR-related incident that was reported, and 25% reporting involvement in an incident that was not reported.[19]

Several specific and interlinked actions targeted at specific groups are necessary to improve MR safety. These include, but are not limited to, the identification and demarcation of specific risk zones, design of specific educational programs dedicated to every category of professionals that work in or might visit MR sites at regular intervals, and development of state clear MR safety procedures including screening forms and protocols and rigorous but easily manageable incident-reporting systems with a focus on prevention and learning from mistakes.[19]

The results of this survey highlight the potential actions that the QSS committee and AOSR can initiate to further improve MR safety standards in the AOSR countries. The survey provides a benchmark to monitor and evaluate the progress of these initiatives. The varied distribution of responses from member countries may be considered a limitation as most of the responses were from national societies and not from individual respondents. However, this limitation is a pragmatic reality in reaching individual practitioners in some of these countries.

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