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SMRT Home Study Educational Seminars

VOLUME 19 • Number 5

MRI Safety:

Incident Reporting, Suite Design & Safety Course



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MRI Safety: Incident Reporting, Suite Design & Safety Course July 2016

We are pleased to present the SMRT Educational Seminars, Volume 19, Number 5: "MRI Safety: Incident Reporting, Suite Design & Safety Course." This is the 75th accredited home study developed by the SMRT, exclusively for SMRT members. The accreditation is conducted by the SMRT acting as a RCEEM (Recognized Continuing Education Evaluation Mechanism) for the ARRT. Category A credits are assigned to each home study, which can be used to maintain one's ARRT advanced registry. SMRT Home Studies are also approved for AIR (Australian

Institute of Radiography), NZIMRT (New Zealand Institute of Radiation Technology) and CPD Now (The College of Radiographers, United Kingdom) continuing professional development (CPD) activities.

Three peer-reviewed, published articles appear in this home study issue. The authors of the first article review the rates of safety incident reporting in MRI at their academic medical center. "It is estimated that adverse events occur in ~10% of hospital admissions, with about 40-50% of these adverse events considered to be preventable." Often in MRI discussions of adverse events, we tend to focus on magnet related incidents but this article chooses instead to be more largescale including all happenings that negatively affect the patient.

The second article focuses on the planning and design of MR suites. "The most widely recognized and implemented practices and techniques to improve safety in the MR suite may create challenges for those facilities but does not alleviate the importance of renovation to ensure safety. Moreover, there is simply no excuse for facilities under current design not to seek out expert opinion from those knowledgeable in MR safety.

for MR was much different than other imaging modalities. Surely that

The third and final article describes the creation and implementation of a MR safety course for medical students. "An MRI safety course for medical students should be different from other MRI safety courses.

"The most widely recognized and implemented practices and techniques to improve safety in the MR suite are procedural in nature, such as standardized screening forms, staff education, and patient gowning procedures, to name a few. While these are essential to safe MR operations, they have not, in and of themselves, proven sufficient to reduce MRI adverse events. An oftenoverlooked element of MR safety, which may improve safety performance, is that of facility design."

Medical students do not necessarily have the same technical background as specialists in the field of medical imaging. Nevertheless, medical students will become the MRI-referring physicians of the future and would benefit from having a comprehensive MRI safety training included in their medical school curriculum." This is a fantastic idea. Anecdotal stories are widespread regarding incorrect, inappropriate orders for MR examinations by referring physicians who lack even the most basic MR knowledge. The correct answer is to be proactive, catch them early and provide the necessary training that will result in more efficient ordering of MR studies when they become staff primary care physicians and surgeons.

A special thank you to Vera Kimbrell, B.S., R.T. (R)(MR), FSMRT from Boston, Massachusetts, USA for acting as the Expert Reviewer.

Thanks also to Heidi Berns, M.S., R.T.(R)(MR),

are procedural in nature, such as standardized screening forms, staff education, and patient gowning procedures, to name a few. While these are essential to safe MR operations, they have not, in and of themselves, proven sufficient to reduce MRI adverse events. An often-overlooked element of MR safety, which may improve safety performance, is that of facility design." Unfortunately, many MR suites were designed in the early days of MR before it became apparent that layout and flow FSMRT, Chair of the SMRT RCEEM Ad-hoc committee from Coralville, lowa, USA and all those who participate on this committee by reviewing the home studies for accreditation. Finally, many thanks to Kerry Crockett, Associate Executive Director, Mary Keydash, Director of Marketing, Sally Moran, Director of IT and Web, Barbara Elliott, SMRT Coordinator, and the entire staff in the Concord, California, USA office of the ISMRM and SMRT for their insight and long hours spent supporting these educational symposia.

MRI Safety: Incident Reporting, Suite Design & Safety Course

SMRT Home Study Educational Seminars

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Educational Objectives

Rates of Safety Incident Reporting in MRI in a Large Academic Medical Center

- Review the research study components including human subject compliance, study site, incident report data collection, statistical analysis, and results;
- Provide a list of incident cases, definitions and examples;
- Discuss the descriptive statistics of incident reports related to MRI scan modality;
- Describe example cases for incident report categories;
- Explain example cases of different severity categories; and
- Provide diagrams to support the discussions.

Planning an MR Suite: What Can Be Done To Enhance Safety?

- Review MRI safety risks and the role of design and design standards;
- Discuss the design case study;
- Describe the safety design criteria;
- Explain the role of MR personnel; and
- Provide graphs, floor plans and diagrams to support the review.

Implementation of a Comprehensive MR Safety Course for Medical Students

- Review the proposed MRI safety modules for medical students;
- Discuss each module including specific information regarding magnetic fields, MRI zones, projectiles, thermal effects, peripheral nerve stimulation and acoustic noise;
- Describe MR screening procedures including implanted devices, foreign metal objects, and pregnancy;
- Explain concerns regarding the use of contrast media, claustrophobia, and the need for sedation/anesthesia;
- Review MRI operating modes, and emergency procedures in the MR suite;
- Describe the hands-on demonstrations to illustrate MRI safety concepts; and
- Explain the importance of conducting a comprehensive multiple-choice exam at the conclusion of the training.

Expert Reviewer



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NZIMRT APPROVED CPD ACTIVITY SMRT Home Studies, Online Electronic Studies & Online Video Studies Credits: 1.25 points per module Valid: 2016

Rates of Safety Incident Reporting in MRI in a Large Academic Medical Center

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Purpose: To describe our multiyear experience in incident reporting related to magnetic resonance imaging (MRI) in a large academic medical center.

Materials and Methods: This was an Institutional Review Board (IRB)-approved, Health Insurance Portability and Accountability Act (HIPAA)-compliant study. Incident report data were collected during the study period from April 2006 to September 2012. The incident reports filed during the study period were searched for all reports related to MRI. Incident reports were classified with regard to the patient type (inpatient vs. outpatient), primary reason for the incident report, and the severity of patient harm resulting from the incident.

Results: A total of 362,090 MRI exams were performed during the study period, resulting in 1290 MRI-related incident reports. The rate of incident reporting was 0.35% (1290/362,090). MRI-related incident reporting was significantly higher in inpatients compared to outpatients (0.74% [369/49,801] vs. 0.29% [921/312,288], P < 0.001). The most common reason for incident reporting was diagnostic test orders (31.5%, 406/1290), followed by adverse drug reactions (19.1%, 247/1290) and medication/IV safety (14.3%, 185/1290). Approximately 39.6% (509/1290) of reports were associated with no patient harm and did not affect the patient, followed by no patient harm but did affect the patient (35.8%, 460/1290), temporary or minor patient harm (23.9%, 307/1290), permanent or major patient harm (0.6%, 8/1290) and patient death (0.2%, 2/1290).

Conclusion: MRI-related incident reports are relatively infrequent, occur at significantly higher rates in inpatients, and usually do not result in patient harm. Diagnostic test orders, adverse drug reactions, and medication/IV safety were the most frequent safety incidents.

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t is estimated that adverse events occur in ~10% of hospital admissions, with about 40–50% of these adverse events considered to be preventable.¹ Nearly 35 million magnetic resonance imaging (MRI) studies were performed in the USA in 2014 alone, and this number continues to increase.² The sheer volume of MRI exams and the reality of human fallibility mean that errors are bound to occur. Incident reporting systems are tools that aid in identifying and addressing errors in healthcare processes.³ As such, incident reporting is considered to be a fundamental component of any healthcare quality and safety framework, including radiology.^{3,4}

The Radiology Event Register (RaER) is an example of a radiology incident reporting system used in Australia and New Zealand.⁵ RaER is intended to promote a safer healthcare environment by collecting and analyzing adverse events that occur during the delivery of diagnostic imaging services.⁵ In

2009, "clinical management" and "documentation" were the most common causes of incidents reported in RaER.⁶ More specifically, key problems included delay in detecting a problem, failure to act, and ordering tests for the wrong patient.⁶ Based on these findings, interventions were made to address the root causes of these adverse events.⁶ MRI-related incidents make up \sim 5% of radiology incidents reported in RaER.⁶

Contrast extravasations and adverse drug reactions have been well described in the literature as common safety incidents that occur in relation to MRI.^{7–12} However, there is a paucity of literature on other potential causes of safety incidents in MRI, including identification and labeling incidents, issues with lines and tubes, skin injuries and burns, missing or unavailability of equipment, incidents due to buildings and surroundings, and workplace violence. It is important to know how often these other causes of adverse

TABLE 1. Variables, Definitions, and Examples						
	Definition	Examples				
• Diagnostic test orders	• Any kind of medical test ordered to help in the diagnosis or detection of disease [13]	Test not ordered with contrastMRI was not planned at a correct timeRight side ordered which should be left				
 ID Documentation	 The process of identifying someone[13] Providing information or evidence that serves as a record [13] 	Wrong age enteredDate of birth was incorrectWrong medical record number				
SafetySecurityConduct	 Any situation that protects from or make unlikely to cause danger, risk, or injury [13] Being free from danger or threat [13] The manner in which someone behaves[13] 	 Security was called due to aggressive behavior of the patient Patient became aggressive in MRI Physician became verbally abusive 				
• Service Coordination	• The deliberate organization of patient care activities between two or more participants (including the patient) involved in a patient's care to facilitate the appropriate delivery of health care services [14]	 Critical patient was brought back to unit on monitor, without nurse or physician Transport was not arrived for a long time Patient was not transported on time 				
SurgeryProcedure	 The treatment of injuries or disorders by incision or manipulation [13] An action intended to achieve a result in the care of patient [13] 	Anesthetized patient did not regain consciousnessPatient coded during MRI				
LineTube	 An IV line that is inserted into vein for therapeutic or diagnostic purposes [13] A hollow cylindrical instrument used for insertion into bodily passages or hollow organs for removal or injection of materials [13] 	 Drain detached from bag, was leaking Patient removed central line Patient disconnected ventricular drain 				
MedicationIV Safety	 A drug used in health care [13] Any situation that makes intravenous injections safe and harmless [13] 	15 ml of fluid extravasatedIV infiltratedPatient felt dizzy after IV insertion				
• Employee General Incident	• Discrete occurrence in the course of work that may lead to physical or men- tal occupational injury [13]	 Patient's fluid splashed to face Pulled right shoulder after positioning patient Cabinet fell off hinge and hit my head. 				
EnvironmentEquipment	 Surroundings or conditions in which a person spends or operates at our institution [13] The necessary items for a special purpose [13] 	 The corner of handicap ramp was broken Smoke filled air MRI images were not sent into PACS 				
• Adverse Drug Reaction	• An appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future adminis- tration and warrants prevention or specific treatment, or alteration of the dosage regi- men, or withdrawal of the product [15]	 Patient developed hive on right shoulder Patient vomited after receiving 20ml of contrast. Facial hives occurred after IV gadolin- ium for MRI 				

TABLE 1: Continued

	Definition	Fromalas
	Demnuon	Examples
• Skin/Tissue	• The surface tissue forming the natural outer covering of the body of a person [13]	Patient bumped his head to a metal barPatient cut his faceTourniquet rubbed a layer of skin off
DiagnosisTreatment	 Identifying the nature of an illness by examination of the symptoms [13] The attempted remediation of a health problem, usually following a diagnosis [13] 	 Patient did not take medication Collar was not fixed in a patient who fell Insufficient contrast injection Wrong labeling of the sagittal images
• Fall	• Inadvertent change in a person's posi- tion from standing, sitting, or lying down to lying on the ground or other surface lower than their starting point [16]	 Patient was assisted to sit on the floor Patient fell onto the floor Patient slipped on wet area and fell on the ground
• Infection control	• A discipline that applies to the preven- tion or reduction in rates of nosocomial infections [17]	 Patient was on TB precautions but I was not informed that the patient was on TB precautions Needle stick while disposing needle During removal of tubing fluid splashed to the face

events occur in the setting of MRI to effectively design and focus quality initiatives. To this end, we aim to describe our multiyear experience with incident reporting related to MRI at a large academic medical center.

Materials and Methods

Human Subjects Compliance

This retrospective, Health Insurance Portability and Accountability Act (HIPAA)-compliant study was approved by our Institutional Review Board. The need for patient consent was waived.

Study Site

The study was performed in a radiology department at a 950-bed tertiary care academic center. The radiology department has over 100 staff radiologists, with over 500,000 diagnostic imaging studies performed and interpreted annually, including \sim 55,000 MRIs. Incident report data were collected during the study period from April 2006 to September 2012.

Incident Report Data Collection

The institution had an electronic system for incident reporting, which was readily accessible and available to all employees. Incident reporting data were prospectively recorded during the study period. The electronic incident reporting system was queried for all reports involving radiology during the study period. The incident reports returned by the query were reviewed by a single radiologist to determine if the report was related to MRI.

All incident reports determined to be related to MRI were classified by the radiologist with regard to the patient type (inpa-

tient vs. outpatient), primary reason for the incident report, and the severity of patient harm resulting from the incident. Primary reason categories included diagnostic test orders, ID/documentation, safety/security/conduct, service coordination, surgery/procedure, line/tube, fall, medication/IV safety, employee general incident, environment/equipment, adverse drug reaction, skin/tissue, and diagnosis/treatment. Definitions and examples for each category are listed in Table 1. Harm categories included: Level 0 (No Harm: did not affect the patient), Level 1 (No Harm: did affect the patient), Level 2 (Temporary or Minor Harm), Level 3 (Permanent or Major Harm), and Level 4 (Death).

Statistical Analysis

Descriptive statistical analyses were performed using Excel 2010 (Microsoft, Redmond, WA). The rate of MRI-related incident reporting in inpatients versus outpatients was compared with the chi-square test (Stata Statistical Software: Release 12, StataCorp 2011, College Station, TX).

Results

Incident Report Volume and Patient Population

There were 362,090 MRI exams during the study period, averaging 4642 exams/month. A total of 1290 MRI-related incidents were reported. This represents a ratio of 1 incident report for every 281 MRI exams, or a rate of 0.35% (1290/362,090). Overall, 28.6% (369/1290) of incident reports occurred in inpatients and 71.4% (921/1290) occurred in outpatients. The rate of incident reporting was significantly

TABLE 2. Inpatient vs. Outpatient Reporting Rates					
	Number of incident reports	Number of MRI exams	Number of incident reports ×100/number of MRI exams	Number of incident reports ×100/total incident reports (1,290)	
Inpatient	369	49,801	0.74	28.6	
Outpatient	921	312,288	0.29	71.4	

higher in inpatients than outpatients (0.74% [369/49,801] vs. 0.29% [921/312,288], P < 0.001) (Table 2).

Reason for Incident Reports

The most common reason for an MRI-related incident report was related to diagnostic test orders (31.5%, 406/1290), followed by adverse drug reactions (19.1%, 247/1290) and medication/IV safety (14.3%, 185/1290) (Fig. 1). Table 3 describes the reasons for the incident reports in greater detail and Table 4 provides an example for each category.

Patient Harm Associated With Reported Incidents

Less than one in four MRI-related incident reports were associated with patient harm (Fig. 2). Specifically, 39.6% (509/1290) were Level 0 (No Harm: did not affect patient), 35.8% (460/1290) were Level 1 (No Harm: did affect patient), 23.9% (307/1290) were Level 2 (Temporary or

Minor Harm), 0.6% (8/1290) were Level 3 (Permanent or Major Harm), and 0.2% (2/1290) were Level 4 (Death). Table 5 includes an example for each patient harm category. When compared to the total number of MRIs performed during the study period, incident reports identified patient harm in \sim 1 out of every 1100 MRIs, with permanent or major patient harm identified by incident reports in \sim 1 out of every 45,000 MRIs and death identified by incident reports in \sim 1 out of every 180,000 MRIs.

Discussion

Incident reporting data are fundamental to the surveillance and response functions of healthcare quality management and can be used to reduce patient harm. In the setting of radiology, MRI is a particularly concerning source for potential harm given the technological complexity of the



TABLE 3. Descriptive Statistics of Incident Reports Related to MRI Scan Modality							
Categories	Number of	Incident rate					
	mentent reports	# of incident reports ×100/total of MRI exams (362,090)	# of incident reports ×100/total of incident reports				
Diagnostic test orders	406	0.112	31.5				
• Wrong test	• 15	• 0.004	• 1.1				
• Requisition errors	• 30	• 0.008	• 2.3				
• Deviation from standard	• 80	• 0.022	• 6.2				
• Not ordered	• 63	• 0.017	• 4.8				
• Delays	• 29	• 0.008	• 2.2				
• Wrong patient	• 7	• 0.002	• 0.5				
• Others	• 182	• 0.050	• 14.1				
ID/Documentation	40	0.011	3.1				
Safety/Security/Conduct	63	0.017	4.9				
Service Coordination	125	0.035	9.7				
Surgery/Procedure	3	0.001	0.2				
Line/Tube	24	0.007	1.9				
Medication/IV Safety	185	0.051	14.3				
• Extravasation	• 161	• 0.044	• 12.4				
• Others	• 24	• 0.007	• 1.9				
Employee General Incident	55	0.015	4.3				
Environment/Equipment	27	0.007	2.1				
Adverse Drug Reaction	247	0.068	19.1				
Skin/Tissue	38	0.010	2.9				
Diagnosis/Treatment	28	0.008	2.2				
Fall	44	0.012	3.4				
Infection Control	5	0.001	0.4				
Total	1,290	0.356	100				

modality, the inherent danger of high magnetic fields, and the isolation of a patient during the imaging study. For instance, prior studies have found that MRI-related incident reports constituted 13% of all radiology department incident reports.¹⁸ Moreover, 21% of cardiac arrests occurring in a radiology department happen in MRI locations.¹⁹ To better understand factors contributing to adverse events in the MRI setting, our study evaluated MRI-related incident reports over a 6-year period and has several key findings that merit further discussion.

First, our data suggest that MRI-related incident reports are relatively infrequent, occurring in ~ 1 in 280 MRIs. Based on the incident report filing data alone, the rate of adverse events related to MRI in our study would be 0.35%. Recognizing that this is likely lower than the actual rate due to underreporting, it is nonetheless an order of magnitude lower than hospital adverse event rates reported in the literature, which ranged from 4-17%.²⁰⁻²⁷

The higher rate of MRI-related incident reports in inpatients compared to outpatients in our study is of particular interest. Identifying the source of this differential was beyond the scope of the current study, and further studies are needed to better elucidate this finding. One possibility is that this differential reflects the greater complexity of inpatients (ie, higher acuity patients, more tubes and lines, etc.) and the greater number of inpatient care steps during which an adverse event could occur (ie, contact with the clinical team, transportation to the suite, stabilization during the

TABLE 4. Example Cases for Incident Report Categories					
Safety incident	Example case				
Diagnostic test orders	• Emergency patient, scheduled for an MRI. Screening requisition filled incorrectly: stat- ing no metallic foreign body in orbits. Initial MRI scan showed metallic artifact. Emer- gency neurology physician notified and the scan was aborted.				
ID/Documentation	• Patient came over to MRI and checked for ID band immediately. But ID band was not found. Pt's nurse was called over and nurse put ID band on patient's wrist.				
Safety/Security/Conduct	• During the MR exam technologist observed the patient trying to climb out of the scan- ner. The technologist ran to the room and began taking the table out of the bore. Before the technologist was able to completely take the table out the patient began yelling and swearing. The patient swung his fists at the technologist repeatedly. Security was called.				
Service Coordination	 Patient was put on call for MRI; he arrived in MRI; several calls were made to transport the patient. Patient had MRI, after several days she went to her doctor and there were no results. Patient very anxious about possible results. Exam was not finalized by radiologist. 				
Surgery/Procedure	• Patient was anesthetized for liver MRI due to claustrophobia. Immediately after comple- tion of exam, he was brought out of scan room to recover from anesthesia. Then he became restless and agitated. He did not seem to regain consciousness but remained agitated and seemed to be having difficulty breathing. Patient was then intubated and brought to ED approx 3pm for ongoing care.				
Line/Tube	 The technologist went into the room to assess a technical difficulty with the machine. It was noted then; the IV line was detached from the patient. The patient's IV line was disconnected during the procedure. Patient became agitated; disconnected external ventricular drain at sutured connection section of tubing. 				
Medication/IV Safety	 At end of injection 15.9ml saline extravasation. The technologist was informed patient at 3:40pm the patient received lower amount of contrast that the patient should have received. 				
Employee General Incident	 While moving a patient from the stretcher to the MRI table the technologist backed up and tore the skin on the brake/wheel of a table behind me. Leaving work at 11pm the nurse fell because the parking lot was sheer ice. There was no salt or sand in the lot at all. Strained neck while assisting patient from lying to a sitting position. 				
Environment/Equipment	• While setting up ventilator to put on patient, was showing good volumes with respirometer. After placing on patient, would not give volume. Attempted several changes with no success. Placed patient on other MRI ventilator and it worked without issues.				
Adverse Drug Reaction	 Patient developed hive on right shoulder and was treated with 25 mg benadril oral tablet. Patient had one hive on her back post gadolinium injection after she had been premedicated for the gadolinium. She had the same experience last time. 				

TABLE 4: Continued					
Safety incident	Example case				
Skin/Tissue	 Patient's head in elevated position on MRI table, hit a metal bar in rear of MRI bore. When the patient opened the room door, the bottom corner of the door injured the left big toe: resulted in skin and partial nail cuts. We cleaned and dressed the area. The patient didn't want to go to the emergency room. 				
Diagnosis/Treatment	• After several conversations with radiologists saying that patient would go immediately to MRI, patient still has not had stroke protocol MRI. This significantly delayed the diagnosis.				
Fall	• Visitor tripped on his own feet while walking to couch in waiting room striking his head on corner of couch. Ice bag given to visitor and visitor checked by radiologist.				
Infection Control	 Needle stick while disposing in needle box. The respiratory therapist detached the ventilator tubing from the patient and handed it to me; saliva and fluid splashed my face. The patient was on precautions for MRSA. 				

exam, etc.). For instance, safety incidents related to service coordination, patient transportation, and catheters are well recognized in healthcare,^{19,28–31} and one would expect that these reasons for incidents would disproportionately affect inpatients compared to outpatients. Incident reports related to service coordination and lines and tubes accounted for nearly 12% of the MRI-related incident reports in our study. Alternatively, the lower rate of incident reporting in outpatients could represent underreporting of events in the outpatient care setting compared to the inpatient setting,

recognizing that ambulatory care has traditionally been less of a focus of patient safety interventions than inpatient care.

Our study found that diagnostic test orders, adverse drug reactions, and medication/IV safety are the most common reasons for MRI-related incident reports, accounting for the majority of reports. This finding differs slightly from previously reported data, although this could reflect differences is classification schema.^{7,8} For instance, the Pennsylvania Patient Safety Authority (PPSA), a resource for the healthcare incident report data in the US, reported that the



FIGURE 2: Severity of incidents.

TABLE 5. Example Cases of Different Severity Categories					
Severity	Example case				
Severity Level 0- No Harm - did not affect patient	• Patient came down to have an MRI of his liver that was ordered. The nurse inter- viewed him for MRI safety. The patient told he had a cardiac pacemaker. The nurse felt his upper left shoulder and there was a device, probably a pacemaker. She explained to the patient that MRI could not be performed due to the pacemaker.				
Severity Level 1-No Harm - did affect patient	• After placing IV line, the patient felt faint. Patient was lower to floor. Legs were raised up, and after 2 minutes the patient felt fine. Blood pressure was stable and technologists continued to do the exam without incident.				
Severity Level 2- Temporary or Minor Harm/Damage	• Patient could not tolerate the first attempt at an MRI due to claustrophobia. Nurse was instructed to give the patient 0.5 mg of lorazepam, with a possible repeat for the next scheduled MRI. The nurse heard 5 mg and that's what the patient ended up taking. Despite specific instructions not to drive after the procedure, which the patient acknowledged both before and after the fact, tried to drive, got into an accident, and sustained a minor concussion.				
Severity Level 3- Permanent or Major Harm/Damage	• Patient came into the imaging center for a MRI of thoracic spine. The patient was given an IV prior to the MRI study. She was power injected with 30 cc of contrast. 40 seconds after injection, the patient screamed out in pain and warmth. The patient was removed from the MRI suite, the radiologist was alerted, and 9-1-1 was called. The patient subsequently developed difficulty breathing. Oral airway was placed and ambu bag ventilations were provided with supplemental oxygen. 1 mg of epinephrine IV was administered. Paramedics arrived and the patient was intubated. The patient was transported by ambulance to the hospital.				
Severity Level 4-Death	• Patient appeared to be in pain and the nurse was called to medicate patient to help tolerate MRI. The nurse was asked to assess the noise coming from tracheostomy and was deemed fine to continue with exam. The patient was checked multiple times throughout exam. The patient gave a gesture as to vomiting. The nurse was called to come assess patient. The patient then began to throw herself about in frustration. A code blue was called to assess patient. The patient died.				

most frequent incident type in MRI was wrong procedure (69%), followed by wrong patient (18%) and wrong side (13%) examinations.⁷ Another study found that wrong examination made up 26% of MRI-related incidents reports in radiology.⁸ In contrast, wrong-patient incidents represented only 0.5% of the MRI incident reports in our study, occurring at a rate of 0.002%. Defining an industry-wide classification scheme for incident reports in diagnostic imaging would allow for better interinstitutional comparisons and development of national performance benchmarks. These benchmarks could then be integrated into key performance indicators for radiology quality management systems.

Mislabeled medical imaging has been reported to account for 7% of incidents relating to patient misidentification across medical practice.³² In our study, identification/ documentation errors accounted for 3% of MRI-related

incident reports and occurred at a rate of 0.011%. This rate is similar to previously reported data showing rates of identification and labeling errors in radiology of 0.017%.⁸ However, these radiology rates are lower than misidentification errors reported more generally in medicine, ranging from 0.05-1%.^{11,12,33,34}

Contrast reactions are an important source of morbidity and mortality in diagnostic imaging. Although adverse reactions to gadolinium-based MRI contrast agents occur at a lower frequency than iodinated computed tomography (CT)-based contrast agents, the adverse reaction rate after an injection of 0.1 or 0.2 mmol/kg of gadolinium chelate is nonetheless reported to be in the range of 0.07–2.4%.^{35–37} The majority of gadolinium-based contrast reactions are mild and include coldness at the site of injection, nausea, headache, warmth, pain, paresthesias, dizziness, and itching.³⁵ Adverse reactions to gadolinium-based MRI contrast agents represented nearly one-fifth of all the MRI-related incident reports filed in our study. The rate of adverse drug reactions to gadolinium-based MRI contrast agents in our study was 0.068%, consistent with previously reported rates.

Extravasation rates in MRI have been reported to be in the range of 0.06–0.9%.^{35,38} The extravasation rate in MRI is generally considered less common than CT due to the lower volumes of contrast medium given and the higher frequency of manual injections.³⁸ Females, age >60, inpatient status, and injection rate >3 mL/s have been associated with higher rates of MRI-related extravasations.³⁸ The rate of extravasation in our study was 0.044%, which accounted for 12.4% of incident reports.

Patient falls are an important source of healthcare liability for medical centers. The rates of falls in acute care have been reported to be in the range of 1.9-3%.^{39–41} In radiology, the incident rate has been reported to be 0.0046% and 0.0064%, accounting for ~6% of incident reports,^{16,19,42} with 28% of falls in radiology occur in CT or MRI locations.⁴² The rate of fall incidents in our study was 0.012%, which accounted for 3.4% of our incident reports.

The current study has a number of limitations. First, the retrospective nature of the study precludes findings of causation, particularly as it relates to the differential incident report rates in inpatients versus outpatients. Second, since the study was performed at a single urban medical center, the generalizability of the results to other healthcare settings is unclear. Third, the lack of an industry-wide classification scheme for diagnostic imaging incident reports could limit the comparisons made to previously published data due to different categorization of similar incidents. Lastly and most important, incident reporting is known to inherently suffer from a problem of underreporting. Thus, the incidence rates in our study, although comparable to previously published data for many of the categories, are nonetheless likely to underestimate the actual prevalence of MRI-related adverse events.

In conclusion, MRI-related incident reports are relatively infrequent, occurring in 0.35% of MRIs, an order of magnitude lower than hospital adverse event rates reported in the literature. Diagnostic test orders, adverse drug reactions, and medication/IV safety were the most common reasons for MRI-related incident reports and most reports were not associated with patient harm.

Conflict of Interest

The corresponding author is receiving book royalties. The other authors have no conflicts of interest.

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Planning an MR Suite: What Can Be Done To Enhance Safety?

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Upon completion of this educational activity, participants will be better able to:

- 1. Identify the constructive role that MRI facility design can play in MRI safety.
- 2. Recognize the importance of clinical and technical staff participation in MRI suite design efforts.

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This activity will be available for CME credit for twelve months following its publication date. At that time, it will be reviewed and potentially updated and extended for an additional period. Magnetic resonance imaging (MRI), frequently touted as the "the safe modality," suffers from significant, and growing, numbers of preventable adverse events. Improvements in MR safety can result from enhancements to expected operational elements: training, screening, and patient-management protocols. Less frequently considered is the safety benefits that may be realized through smart design of MR facilities. Through conscientious and thorough prospective site planning involving MR staff and radiologists in the design process for MR physical facilities, MR providers can have a positive impact on improving safety as well as efficiency for the benefit of their patients, for ancillary healthcare workers, and for themselves.

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MRI Safety Risks

With the heightened attention paid to the risks associated with ionizing radiation used in diagnosis and treatment (eg, Image Gently, Image Wisely), our industry often casually refers to magnetic resonance imaging (MRI) as "the safe modality" due to the absence of ionizing energy in the MRI process. And while it is true that most data suggests no associated known risk of carcinogenesis with MRI exposure, it is a fallacy to equate the absence of ionizing radiation with the absence of the potential for injury.

Analysis of accident reports from the Food and Drug Administration's (FDA) MAUDE database (Fig. 1) shows a 5-fold growth in reported MR adverse event rates over the 10-year period from 2000–2009.¹ This trend indicates that traditional means of assuring MR safety have been failing the industry, warranting a review of alternative means that may supplement or potentiate existing practice.



FIGURE 1: Graph showing percentage change in FDA-reported MRI adverse events (product code "LNH") from 2000.

The most widely recognized and implemented practices and techniques to improve safety in the MR suite are procedural in nature, such as standardized screening forms, staff education, and patient gowning procedures, to name a few. While these are essential to safe MR operations, they have not, in and of themselves, proven sufficient to reduce MRI adverse events. An often-overlooked element of MR safety, which may improve safety performance, is that of facility design.

MRI today is substantially different from what it had been 20 years ago. Ever-receding reimbursements generate pressures to further increase throughput and recapture lost revenues. Expanding clinical applications such as functional MRI have brought new patients, new devices, and new researchers into MRI environments. The increasing integration of MR services into emergency clinical care is bringing many new—and, as far as MR safety is concerned, uninitiated—healthcare providers as well as innumerable new foreign objects into MRI suites. The rapid growth in interventional MR procedures, both diagnostic as well as therapeutic, has also introduced new instruments and personnel into MR scan rooms that had not previously frequented these areas. For these and other related reasons, even for facilities designed years ago with MR safety in mind, it is appropriate to review what we know about the design of MR facilities and the degree to which those designs support contemporary safe practices.

The vast majority of reported MR injury accidents would be prevented through known best practices.² While facility design alone rarely mitigates MR injury risks, enhanced MR suite design can potentiate safer practices and outcomes. For example, convenient access to in-room storage for patient positioning aides and bore pads may help facilitate better operational practices to reduce RF burns. The design of suites that facilitate access restrictions and enhance situational awareness from the operator's console can help prevent unauthorized access within the MR suite. And the use of a ferromagnetic detection system can help alert technologists to the presence of potential projectile threats before they are brought into the MR scanner room.

These MR safety facility design tools are not novel to this work; many of these have been detailed in existing design guidance documents for a decade or more. Chief among these MR safety standards of practice for physical design is the American College of Radiology's Guidance Document on MR Safe Practices (2013), which includes substantial guidance on facility design to enhance and support safety in and around the MRI environment.³

Role of Design and Design Standards

In addition to all four iterations of the ACR MR Safety Guidance Document (2002, 2004, 2007, and most recently, 2013), other documents seek to codify some of the basic elements of physical MR safety through facility design. These include the US Department of Veteran Affairs' MRI Design Guide (2008),⁴ Facilities Guidelines Institute's hospital "building code" document, Guidelines for Design and Construction of Hospitals and Outpatient Facilities (2014),⁵ the American Society of Healthcare Engineering's monograph publication, "Designing and Engineering MRI Safety" (2008),⁶ the Joint Commission's Sentinel Event Alert #38 "Preventing Accidents and Injuries in the MRI Suite" (2008),⁷ and soon, the Joint Commission's own standards revision for Diagnostic Imaging services.⁸

The ACR Guidance Documents, VA MRI Design Guide, and the ASHE monograph are, at the time of this writing, only recommendations and not required standards promoted by their respective organizations. Others, such as the "Guidelines" building code are only applicable to newly built MR suites, and then only for qualifying projects undertaken in those states that have adopted this model code as their own. In other words, the overwhelming majority of existing MR scanners and suites are exempt from any of the safety design requirements. With design standards existing solely as recommendations for most MR installations in the USA, MR safety may be improved through a more consistent application of these design best practices.

The Joint Commission, the largest healthcare accreditation body in the USA, released new Diagnostic Imaging standards in January of 2015, including a few MR safety provisions, which are to become effective in July of 2015. These new standards will become requirements for all Joint Commission-accredited MR providers. (Note: Joint Commission standards are distinct and independent from those of its sister agency, Joint Commission International, which provides healthcare accreditation services throughout the world beyond the USA.) This will represent the first time that any physical design safety requirements will be imposed on existing MRI providers in the USA, though they are modest in scope.

Among the standard's new requirements is the following section, which speaks specifically to facility layout and construction:

"The hospital manages safety risks by doing the following:

- Restricting access of everyone not trained in MRI safety or screened by staff trained in MRI safety from the scanner room and the area that immediately precedes the entrance to the MRI scanner room.
- Making sure that these restricted areas are controlled by and under the direct supervision of staff trained in MRI safety.
- Posting signage at the entrance to the MRI scanner room that conveys that potentially dangerous magnetic fields are present in the room. Signage should also indicate that the magnet is always on except in cases where the MRI system by its design, can have its magnetic field routinely turned on and off by the operator." ⁹

In addition to these explicit design expectations, the new accreditation standards also identify risks that can be mitigated through facility design or operational means, including acoustic damage and ferromagnetic projectile risks, although these other risks are not similarly provided with explicit accidentpreventing performance criteria in the Joint Commission's standard.

With respect to the role that MR safety design could play, historically it has been left to individual providers to determine what they wished to do, either adhering to or ignoring recommended best practice design standards.

Design Case Study

For the purpose of MR facility design and implementation, it is often useful to review exemplars of what not to do. The following MRI suite floor plan (Fig. 2) represents the site of an infamous MR-related fatality in which a young boy died from injuries sustained while in the MR scanner when a portable steel oxygen tank was brought into the MR scanner room and was forcefully magnetically drawn into the bore of the scanner while the patient was within the scanner bore. Despite the lessons learned from that accident, contemporary MR facilities continue to be designed and built that share alarming similarities with failings of this layout.

Design failings of this MR suite included the fact that 1) the technologist, seated at the console, had no view of the magnet room door (or the area around it); 2) the door did not have adequate warning signage; 3) the oxygen supply to the MR scanner room was provided via noncodecompliant oxygen tanks/cylinders in the adjacent MR equipment room; 4) there was no effective physical site access restriction to prevent untrained/unscreened persons from entering the suite; and 5) ferromagnetic portable oxygen cylinders were stored in the induction alcove immediately across from the entrance to the MR scanner room.

These design/operating conditions allowed a failure of the oxygen flow to an anesthetized patient in the bore, which prompted the technologists to leave a position of partial situational awareness (1), to a position of zero awareness (3), allowed a non-MR safety trained nurse to admit herself into what ought to have been a controlled access portion of the suite (4), and retrieve (5) and hand a ferromagnetic cylinder to the anesthesiologist (2).

Facility design elements that could short-circuit the causal path for this infamous accident include the use of a "Zone III" controlled access vestibule, the use of nonferromagnetic support equipment within the controlled access areas, ensuring that no non-MR personnel were left unattended in Zones III or IV and were under the direct supervision of MR personnel at all times, and the use of ferromagnetic detection systems. Had the above MR safety design shortcomings been addressed prior to this event, the likelihood of such an event transpiring would have been reduced so severely as to have been practically nullified.

The site discussed above was designed and built prior to the compilation of the body of MR safety knowledge



FIGURE 2: Floor plan of the MR suite at the time of the fatal accident.

that we currently have available, and thus predates the publication of even the first iteration of the ACR MR Safe Practice Guidelines. The authors' intention is not to excoriate the design of the MR suite that serves as our illustration (designed prior to available guidance), but rather to draw your attention to specific design failings, of which there are numerous contemporary examples of in hospitals and imaging centers around the world.

Safety Design Criteria

Despite minor variations in wording or presentation, common to all the contemporary design and construction MR safety guidance is the concept of the 4-zone layout initially defined by the ACR Guidance Document for MR Safe Practices, 2002. The basic principle is similar to managing unintended exposure risks with radiopharmaceuticals, namely, that proximity to the potential hazard (the MR scanner in our case) requires increasing levels of staff qualification or, in the case of patients or visitors, direct supervision. Simply put, there must be physical restriction to prevent accidental exposure of the uninitiated (eg, patients or family members or non-MRI personnel) to potentially hazardous energies used in the MRI environment. Physical site access restrictions to accidental exposure are achieved by locked doors that separate areas with functionally zero hazard from areas of either potential appreciable hazard or with direct unrestricted access to the MR scanner room itself.

Zone I: Areas with no MRI-related hazard, and no immediate MRI function (the world beyond the MRI suite).

Zone II: Areas with no MRI-related hazard, but with MRI function (typically waiting, reception, screening, changing rooms).

Zone III: Areas with potential MRI-related hazard, with access controls (frequently control rooms, or other areas in which the static magnetic field may exceed 5 gauss / 0.5 mT).

Zone IV: Area with the greatest MRI-related hazards. This is exclusively the MR scanner room.

Optimal MR safety design contributions are achieved with physical restrictions around the MR scan room in the form of the 4-zone concept combined with appropriate screening and supervisory practices by trained MR personnel of the site (Fig. 3).

Role of MR Personnel

At this point it might be reasonable for the reader to inquire: If MR safety design is outlined in new accreditation standards and building codes, why is it important for clinicians, technologists, physicists, and radiology administrators to be educated about MR safety and facility design?

To help ensure that safety is an integral element of an MR site's design process, it is the authors' belief that technical and clinical MR personnel should be directly involved in the formulation of a capital project's design and objectives. To achieve optimal safety and efficiency in design requires an understanding of site's operational objectives, the manner in which exams are executed, the potential problems likely to be encountered by patients and healthcare personnel in



MRI Functional Diagram

FIGURE 3: MRI suite safety functional diagram.

that modality, and practice patterns that have been shown to be effective and efficient in these settings.

Whereas MR clinicians and staff should undergo at least two levels of safety training (Level 1, where they are trained to a point where they can safely conduct their own activities within the controlled access portions of the MRI suite, and Level 2, where they are trained to a point where they can safely oversee and direct the activities of persons with less safety training), many architects and equipment planners may have a very limited understanding of the operational consequences of MR site and safety designs. Will the site be accommodating ambulatory as well as nonambulatory patients? Will sedation and/or anesthesia be available to patients at that site-with its accompanying requirements for locations and equipment and site preparation for induction and recovery? How will emergencies be handled at the site? If the site design is intended to accommodate full cardiac arrests, where is the prospectively designated area, with the necessary gases, suction, equipment, etc., where such interventions will take place? These are clinical/operational conditions frequently contemplated by MR safety trained individuals, but not by their design professionals. To help prevent conflicts among equipment requirements, operational efficiency, and safety practices, there are tremendous benefits that can result from recruiting direct involvement from "endusers" from the beginning of the site design effort.

In conclusion, operational practices play an indispensable role in achieving and maintaining a safe clinical MR environment, but the success of these operational steps can be augmented by appropriate prospective physical design of the facility—or opposed by the lack thereof. While an MR suite's architect must have a command of the MR-specific construction methodologies, building codes, and state licensure standards, s/he does not necessarily understand the nuances behind a safe and efficiently operated MR facility. Therefore, it is essential that persons with clinical and operational MR experience lend their expertise in the early stages of any capital equipment project that may involve the upgrade, replacement, addition, or integration of a new MR system.

Just as the radiology report guides clinical intervention for a patient, the early involvement, feedback, and assistance of MR radiologists, MR technologists, and operational staff in the planning of an MR facility can provide critical design performance objectives to the architects, engineers, and equipment planners implementing the site's construction or expansion. While it might come as a surprise to some, clinical/operational MR personnel clearly understand the workings of MR facilities far better than does the average MR suite planner or architect. When technologists, radiologists, nurses, medical physicists, and department managers become involved in the planning of MR facilities, safety issues can be more effectively, efficiently, and almost always more inexpensively resolved by the designer.

The authors specifically recommend that every new MRI installation, renovation, or building addition design include the following prompts and reviews from MR departmental staff:

- Is the area laid out with a clear 4-zone sequence?
- Are there effective access controls, both for patients/visitors, and for hospital staff?
- Are ferromagnetic detectors appropriately deployed in a manner that integrates with screening protocols?
- Does the facility have induction/recovery/resuscitation areas and infrastructure appropriate to the patient population and clinical usage?
- Are there clear lines-of-sight from the operator's console to both the patient inside the MRI scanner, but also directly to the MR scanner room access door?
- Are the accessories and support equipment appropriate to the MRI environment?
- Has secured storage been provided for the inevitable unsafe medical equipment brought to the MRI suite with a patient?

- Does the MR scanner room have appropriate, convenient storage for consumables and reusable materials?
- Is the MR scanner room design appropriate to the level of interventional care (eg, procedure lighting, hand-washing, scrubable surfaces)?

MR can live up to its moniker of "the safe modality," but to do so requires a more concerted effort than recent history has shown. Through conscientious and thorough prospective site planning involving all the key players in the design process for MR physical facilities, MR staff and radiologists can have a meaningful impact on improving safety as well as efficiency.

One tool to assure the relevant safety knowledge of MR professionals is individual MR safety certification by the American Board of Magnetic Resonance Safety (ABMRS). The ABMRS certification process is a tool with which MR providers can assure essential knowledge for not only stakeholder input for the purpose of improving safety through intelligent site design, but by ensuring that all ongoing MR safety practices are organized under credentialed Magnetic Resonance Medical Directors (MRMD), Magnetic Resonance Safety Officers (MRSO), and available Magnetic Resonance Safety Experts (MRSE) that are certified by the newly formed ABMRS.

In the end, the goal is not simply a better designed MR suite, but rather a reduction in MR-related accidents and injuries. MR safety credentials, increased involvement of credentialed clinical and technical staff in the design of MR facilities, and an effective integration between physical facilities and ongoing operations will all contribute to safer MR environments and practice, benefiting patients as well as MR providers.

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Implementation of a Comprehensive MR Safety Course for Medical Students

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This review article proposes the design of an educational magnetic resonance (MR) safety course for instructing medical students about basic MR and patient-related safety. The MR safety course material can be implemented as a traditional didactic or interactive lecture in combination with hands-on safety demonstrations. The goal of the course is to ensure that medical students receive a basic understanding of MR principles and safety considerations. This course will prepare medical students for patient screening and safety consultations when ordering MR studies. A multiplechoice exam can be used to document the proficiency in MR safety of the medical students. The course can be used by various medical school programs and may help to ensure consistent quality of teaching materials and MR safety standards.

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Magnetic resonance imaging (MRI) is a cross-sectional imaging technique with superior soft-tissue contrast compared to other imaging modalities, e.g., ultrasound, positron emission tomography (PET), computed tomography (CT), and other imaging devices that use x-rays. MRI has lead to new insights in anatomical, physiological, and functional imaging. The continued growth of MRI in the last decades has led to more than 25,000 MRI scanners that were sold worldwide, millions of MRI exams performed, and thousands of healthcare professionals that were educated in MRI safety to protect patients and other healthcare workers from the hazards associated with MRI.¹

The purpose of this article is to describe a comprehensive approach to educate medical students who will be the physicians of the future in the safety aspects of MRI. There are multiple commercial MRI safety courses available that are offered online.^{2–6} The expected audiences of these courses are participants in the field of medical imaging including MR technologists, radiologists, and medical physicists. The content of most of these courses follow the ACR guidance document on MR safe practices but none of these courses focus specifically on medical students.⁷ An MRI safety course for medical students should be different from other MRI safety courses. Medical students do not necessarily have the same technical background as specialists in the field of medical imaging. Nevertheless, medical students will become the MRI-referring physicians of the future and would benefit from having a comprehensive MRI safety training included in their medical school curriculum. The course proposed here will focus on medical students because as physicians they will refer patients for MRI exams and will often have to evaluate MRI safety and compatibility of new medical devices and implants. They will also often be the first healthcare professionals who will talk to their patients about the MRI exam, potential risks, and MRI safety.⁸ Referring physicians who understand the principles of MRI safety can help contribute to MRI safety screening since they know the patient's medical history better than the radiologists or technologists who will only meet a patient very briefly during screening and preparation for an exam. A pre-screening of patients before their MRI exam by a referring physician offers an additional safety check which can streamline procedures directly before the exam in a radiological imaging facility and can improve MRI results.9 This article proposes a comprehensive MRI safety course for medical students that includes the basics of bio-effects and risks of the magnetic fields that interact with patients and healthcare professionals in an MRI suite.¹⁰

Sammet and Sammet: MR Safety Course for Medical Students

Proposed MRI Safety Modules for Medical Students

The following $4^{1}/_{2}$ -hour, seven-module course about basic MR and patient-related safety is proposed for inclusion in medical school curricula.^{10,11} The duration for each component of the course is suggested, although this could be altered to suit the institution's or instructor's preference and audience's skill level.

- 1. "Importance of MR Safety for Non-radiologist Physicians" (30 minutes)
- 2. "MR Principles and Magnetic Fields" (30 minutes)
 - i. Magnetic fields in MRI
 - a. Static magnetic fields (B_0)
 - b. Radiofrequency field (B₁)
 - c. Gradient fields (Gx, Gy, Gz)
 - ii. MRI zones
- 3. "Effects of Magnetic Fields in an MR Suite" (30 minutes)
 - i. Attractive/projectile forces on ferromagnetic objects
 - ii. Thermal effects
 - iii. Peripheral nerve stimulation
 - iv. Acoustic noise
- 4. "MR Screening Procedures" (1 hour)
 - i. Implanted devices
 - a. Definition of MR Safe
 - b. Definition of MR Conditional
 - c. Definition of MR Unsafe
 - ii. Foreign metal objects
 - iii. Pregnancy
 - iv. MR contrast agent reactions and renal insufficiency
 - v. Claustrophobia in MRI
 - vi. Evaluating the need for sedation/anesthesia
- 5. "MRI Operating Modes and the Implications" (30 minutes)
- 6. "Emergency Procedures in the MR Suite" (30 minutes)
- 7. "Hands-on Demonstrations to Illustrate MRI Safety Concepts" (1 hour)

Module 1: "Importance of MR Safety for Nonradiologist Physicians"

Radiologists are well trained in the area of MRI safety during their residency programs and subsequent professional appointments. However, radiologists often have little or no contact with patients before their MRI exam. Although they are more knowledgeable about MRI appropriateness criteria, they often require assistance from referring physicians to determine the risks vs. benefits of MRI procedures of high-

risk patients.¹² This is particularly relevant in circumstances where new implants have not yet been tested for MRI compatibility.^{13,14} Alternatively, situations do occur where, despite the fact that an implant is known not to be MRIcompatible, there are circumstances where the MRI risk is clinically acceptable. For example, many cochlear implants are fixed with ferromagnetic materials and are prone to displacement even when scanning other parts of the body with MRI.¹⁵ The increasing frequency of cochlear implants requires a team of physicians to evaluate the patient's risk of implant displacement (and subsequent need for surgical revision) with the medical necessity of the MRI for whatever serious, unrelated condition the patient may have. A critical decision must be made depending on the area being scanned, particulars about the implant, and the patient's likelihood to tolerate revision (meaning, how stable they are for surgery if the implant is displaced while in the MRI). A team of providers needs to decide whether or not to go forward with the MRI scan by balancing medical necessity vs. risk. These teams are composed of physicians from several different disciplines involved in the patient's care. A radiologist often cannot individually determine the medical appropriateness of MRI in such a high-risk patient without input from the ordering physician, and in this particular case, also the audiology and neurosurgical team. Thus, a wide range of physicians may require a basic understanding of MRI safety including but not limited to anesthesiologists, cardiologists, audiologists, orthopedic surgeons, neurosurgeons, and general practitioners. A comprehensive MRI safety course for medical students should include a module that explains the need for nonradiologist physicians to be competent in basic MRI safety.

Module 2: "MR Principles and Magnetic Fields"

The content of this course module should cover the following material.

Magnetic Fields in MRI

In an MRI unit there are three major magnetic fields that can pose a hazard 16,17 :

- 1. Static magnetic field $B_0,$ which is in clinical scanners in the range of 0.2T to 3T. 18,19
- 2. Radiofrequency (RF) field B_1 , which is on the order of $\mu T.^{20}$
- 3. Gradient fields which are in the order of 100 mT/m with slew rates up to 200 T/m/s.²¹

These three magnetic fields have different potential interactions with the patient.

1. The static magnetic field B_0 of superconducting magnets is more than 10^4 times stronger than the magnetic field of the earth and it can attract ferromagnetic objects and accelerate them in the direction of the opening of the bore of an MRI scanner. It can also interfere with implanted devices such as pumps and pacemakers.^{1,14,17–20,22–40}

- 2. The radiofrequency (RF) field B_1 is produced by the integrated system antenna or by local transmit receive RF-coils. Transmitted RF leads to energy deposition that can cause heating in tissue, especially when implants are present.^{12,16,19,23,39,41-60}
- 3. The gradient field is used for the spatial encoding of the MRI signal and can cause peripheral nerve stimulation, implant heating, and is responsible for the noise in MRI suites that can reach levels of 100 dB or more and potentially cause hearing damage.^{19–21,28,30,33,39,47,61–67}

MRI Zones

The ACR guidance document on MR safe practices from 2013 suggest different zones for an MRI facility.^{68,69} It is important to discuss the purpose of the different zones with medical students and make them specifically familiar with the MRI zones of the MRI units in the hospital where they are training.^{13,70} MRI facilities and hospitals restrict access to the MR suite by establishing four zones around the MRI scanner. The boundary of each zone in this four-zone safety system is defined by its purpose and distance from the MRI scanner.²⁰ Since the magnetic field extends in three dimensions, some zones may extend into other areas or floors of the facility.⁷¹

Zone I consists of all areas freely accessible to the general public. Zone I includes the entrance to the MR facility and the magnet poses no hazards in these areas.

Zone II is a buffer between Zone I and the more restrictive Zone III. Patients are under the general supervision of MR personnel in Zone II. This zone often includes the reception area, dressing room, and MRI screening room.

Zone III is an access-restricted zone, which is achieved by physical barriers such as doors with coded access. Only approved MR personnel and patients that have undergone MRI screening are allowed inside Zone III. The MR control room is located in Zone III.

Zone IV is the magnet room. Access into the magnet room should only be possible by passing through Zone III.

Access between each zone is controlled via locked doors and key cards, including the Zone I–II, Zone II–III, and Zone III–IV interfaces. It should not be possible to skip MRI safety zones by an alternative entrance (even for staff members). Zone III and Zone IV are often referred to as the MR suite. The MRI suite should be designed in a way that the walls of Zone IV—the magnet room—includes the 5 Gauss line (or 0.5 mT line) of the fringe field of the magnet. The 5 Gauss line defines a border to an area in which the magnetic field could affect implanted devices such as pacemakers.¹⁴ If the 5 Gauss line extends outside the magnet room, which can happen with ultrahigh field magnets in research facilities, then additional physical boundaries are established to limit access to avoid interference of the magnetic field with implanted devices.⁷² Hospital and MR facility personnel that work near the MRI scanner must be made aware with warning signs about the powerful magnetic field and its associated hazards. These warning signs must be clear to lay people (including patients/volunteers and non-medical staff) that they are in a hazardous area and that they should not try to gain access to restricted MRI zones. An MR safety program should be established for each individual facility to train employees about the hazards associate with the magnetic field.⁷³

Module 3: "Effects of Magnetic Fields in an MR Suite"

This course module should focus on the following topics.

Attractive/Projectile Forces on Ferromagnetic Objects

The static magnetic field B₀ of an MRI machine will attract ferromagnetic objects and accelerate them toward the bore of the MRI scanner. Common ferromagnetic objects such as coins, hairpins, or scissors can be torqued or displaced by the large static magnetic field.^{12,16} Larger ferromagnetic objects, such as steel oxygen tanks, can become dangerous projectiles.³² There is often a misconception that larger objects will resist attraction to the field and so this education course should emphasize the relationship between object size, material components, and projectile risk. Even well-established hospitals continue to have problems with medical equipment (such as anesthesia or ventilator systems) becoming lodged in the bore of the magnet due to insufficient MRI safety training of ancillary medical personnel.^{31,32} The static magnetic field can also influence the endolymph in the inner ear, which is responsible for maintaining balance. Medical students should be instructed that patients undergoing MRI scans may experience dizziness when moving into a high magnetic field gradient (such as in the fringe field at the entrance to the bore).

Thermal Effects

Another important aspect that medical students should be aware of are bioeffects of RF fields.⁵⁰ RF fields can cause heat in the human body.^{51,56} The amount of RF energy that is absorbed by the human body and transformed into heat is described by the specific absorption rate (SAR).⁷⁴ SAR is the mass normalized rate at which RF power is coupled to biological tissue with units of watts per kilogram (W/kg).⁴¹ Future physicians should be aware that infants, children, and patients with thermoregulatory disorders might experience increased body core temperatures due to RF-induced heating during MRI exams,^{42,59,74,75} and that obese patients may be exposed to larger RF energy deposition. It is also important to discuss the effect of examination duration with respect to the risk of thermal injury and to advise against excessively long examination times. In order to better counsel their patients before MRI exams, the medical students should be instructed that each patient can expect to feel a warming sensation during scanning. In some cases, prolonged exposure can lead to perspiration, which can become a further hazard for contact burns. If a patient feels particularly localized heating then they should alert the operator by pressing the patient alarm and the technologist should act accordingly. It is important to explain this process to conscious patients prior to the MRI and to closely monitor anesthetized or sedated patients.

Medical students should be informed that additional important steps in preparing patients for MR scans are necessary to avoid burns and/or thermoregulation problems even for patients without implants^{13,14,76}:

- 1. Removal of unnecessary metallic objects contacting the patient's skin (e.g., drug delivery patches with metallic components, jewelry).
- 2. Use of insulation material of a minimum recommended thickness of 1 cm to prevent skin-to-skin contact points and the formation of closed-loops from touching body parts.
- 3. Use of only electrically conductive devices, equipment, accessories (e.g., ECG leads, electrodes), and materials that have been thoroughly tested and determined to be MRI-safe.
- 4. Avoidance of excessively long duration scans.
- 5. Avoidance of practices that limit the ability of the patient to cool down (for example, wrapping the patient tightly in a blanket).
- 6. Use of extra diligence when scanning obese patients since they may have comparatively high local heat deposition and awareness that an obese patient is less likely to tolerate exams that deposit very high RF energy.
- 7. Registration of the correct patient details into the system (particularly weight/mass) since some MRI systems adjust the transmitted energy based on these demographics.

Further details can be found in the Guidelines to Prevent Excessive Heating and Burns Associated with Magnetic Resonance Procedures.⁷⁷

Peripheral Nerve Stimulation

During MRI exams the time-varying gradient magnetic fields may stimulate nerves or muscles in patients by inducing electrical fields.⁶² Gradient magnetic field interactions with biological tissues depend on the frequency of the gradient field, the maximum and average flux densities, the presence of harmonic frequencies, the waveform characteristics of the signal, the polarity of the signal, the current distribution in the body, the electrical properties, and the sensitivity of the cell membrane.^{21,28,30,61,62,65,67} Physicians should be aware of this bioeffect so they can explain this to their patients before referring them for an MRI exam.

Acoustic Noise

The quickly switching gradients are also responsible for the high acoustic noise during an MRI exam.^{21,62} Hearing protection such as head phones and earplugs are essential to avoid hearing damage in patients and any person in the MRI suite during scanning.³⁰ This should be clearly conveyed in the educational module for medical students and also included in the hands-on presentation proposed below.

Module 4: "MR Screening Procedures"

This course module should cover the following important material about MR screening procedures.

Medical students should be made aware of the fact that MRI screening is essential before any MRI exam since the relative risk of injury is dependent on the magnetic properties of the foreign body, the geometry and dimensions of the object, and the strength of the static magnetic field B_0 of the MRI system.^{12,16,19,23,32,78,79} It is therefore essential to require that patients and accompanying persons remove all objects from their pockets and hair before they enter the MRI suite.^{31–33} Patients should also be asked to wear MRI gowns before the scan to avoid that their clothing items have metallic fasteners, loose metallic components, or metallic threads.⁸⁰

Implanted Devices

Medical students should know where they can look up the MRI safety and compatibility of medical implants and devices as future referring physicians.^{13,14,76} Several books and a searchable online catalog list MRI-safe devices and implants with their field strengths and gradient limitations (http://www.mrisafety.com/TheList_search.asp).^{12,16,33–35,51–58}

In patients with implants it is important to know that the potential for injury is related to the proximity of the implant to vital vascular, neural, or soft-tissue structures.³³ Orthopedic implants, materials, and devices that were implanted in the last three decades in the US and Europe are made from nonferromagnetic materials and are usually labeled MR-safe or MR-conditional (according to specific instructions for scanning patients with the implants).⁵¹ Other older implants may be contraindicated and deemed MRI-unsafe. The interaction and torque of ferromagnetic implants should be explained, including how the forces on these objects change as they move through the fringe field of the main magnetic field (B₀). Magnetic field interactions of these implanted devices can cause severe artifacts and

heating.¹⁴ However, it is important to instruct the students that even non-ferromagnetic implants are subject to heating due to eddy currents that propagate in metals exposed to oscillating magnetic fields.^{53,54} MRI-related heating may specifically be a problem for some orthopedic implants such as external fixation systems.^{12–14,16,54,58,76,78,81} There are additionally some devices that will malfunction once exposed to such a powerful magnetic field because the forces cause permanent and irreparable damage. Finally, there are new implants that have not been tested or labeled yet for MRI compatibility.¹⁵ This can pose a unique challenge requiring close collaboration between the radiology team, the ordering physician, and the physician who placed the implant. Therefore, any MRI safety module for medical students should contain a thorough description of implant safety.

Foreign Metal Objects

Unknown metallic objects inside the body need to be included in the MR screening procedures. A variety of professions and life experiences can leave metal particles, slivers, or objects in the body. Some examples include a history of professional or amateur operation of metal cutting machines, which may unknowingly deposit metal slivers inside the body (of particular concern is the sensitive tissue around the eyes). Veterans and active military members may have shrapnel or bullet fragments in their tissue (either known or unknown). The MRI safety screening should be carefully designed to assess the likelihood of foreign metal bodies. Questions such as "Do you have any foreign metal bodies?" are seldom effective. An alternative, effective line of questioning is "Have you ever served in the military, and if so, were you ever wounded?" Careful attention should be paid to interviewing subjects with diminished memory capacity in order to ascertain the likelihood of the presence of a foreign metal object.

Pregnancy

Medical students should also be aware of the following ACR-SPR practice guideline⁸²: "Present data have not conclusively documented any deleterious effects of MRI at 1.5 T on the developing fetus".⁸³ Therefore, no special consideration is recommended by the ACR and the SPR for any trimester in pregnancy.⁸² Pregnant patients can be accepted to undergo MR scans at any stage of pregnancy if, in the determination of a level 2 MR personnel-designated attending radiologist, the risk–benefit ratio to the patient warrants that the study be performed.^{73,82} The radiologist should confer with the referring physician and document the following in the radiology report or the patients' medical record⁸²:

1. The information requested from the MRI study cannot be acquired by ultrasonography.

- 2. The data are needed to potentially affect the care of the patient or fetus during the pregnancy.
- 3. The referring physician does not feel it is prudent to wait until the patient is no longer pregnant to obtain these data.

MRI contrast agents should not be routinely administered to pregnant patients according to the ACR Manual on Contrast Media.⁶⁸ Gadolinium is a pregnancy class C drug, meaning that the safety in humans has not been proven.^{7,84}

MR Contrast Agents

Medical students should be informed about adverse effects of MRI contrast agents.

MRI contrast agents that are approved by the FDA are gadolinium chelates with differences in stability, viscosity, and osmolality. 85

Gadolinium-based contrast agents are well tolerated and acute adverse reactions are encountered infrequently.⁸⁶ Acute adverse events after injection of 0.1 or 0.2 mmol/kg of gadolinium contrast media are reported to occur in 0.07% to 2.4%^{85,87} of administrations. Side effects of gadolinium chelates are a cold or warm feeling upon injection; nausea, dizziness, or headache; and pain, numbness, or itching at the injection site.^{85–95}

Severe allergic reactions including rash hives, urticaria, and bronchospasm range from 0.004% to 0.7%.⁸⁹ Life-threatening reactions to gadolinium-based contrast agents are very rare (0.001% to 0.01%).^{89–91,95} It is reported that, "In an accumulated series of 687,000 doses there were only 5 severe reactions" and that "fatal reactions to gadolinium chelate agents occur but are extremely rare".^{85,86,89}

Gadolinium chelates administered to patients with acute renal failure or severe chronic kidney disease can result in a syndrome of nephrogenic systemic fibrosis (NSF).⁸⁸ There are no reports of NSF in patients with normal kidney function, therefore; the U.S. Food and Drug Administration (FDA) has asked manufacturers to include a new boxed warning on the product labeling of all gadolinium-based contrast agents that patients with severe kidney insufficiency who receive gadolinium-based agents are at risk for developing NSF.^{86,89}

Claustrophobia in MRI

Medical students should be aware that if their patients are not well advised about the MRI scanning procedure they may become claustrophobic and refuse to complete the exam.^{96,97} Students should be informed about alternatives to traditional MRI that reduce claustrophobia including larger bore sizes and "Open MRI". Referring/ordering physicians can significantly reduce claustrophobia events by discussing the details of the MRI procedure with the patients before their exam.⁹⁸ Radiologists can also act to shorten protocols appreciably.

Evaluating the Need for Sedation/Anesthesia

Due to the long procedure times and sensitivity to motion, non-compliant patients such as children and claustrophobic adults may require sedation or anesthesia during MRI.⁹⁹ Pain management may also be necessary for patients to remain motionless during the MRI. MRI safety education for medical students should include specific risks and benefits of using sedation, anesthesia, and pain management in these patient populations.¹⁰⁰

Module 5: "MRI Operating Modes and the Implications"

Medical students should be aware that there are different operating modes for MRI systems. The International Electrotechnical Commission (IEC) defines the following three operating modes for MR systems (IEC 60601-2-33:2010):

1. Normal operating mode:

The normal operating mode of the MRI system is the one in which none of the outputs have a value that may cause physiological stress to patients.

The default SAR limit is 2.0 W/kg in normal operating mode for whole body scans but might vary in different countries depending on the scanned anatomy. The body core temperature increase is limited to 0.5° C and the gradients are limited to 80% of the peripheral nerve stimulation threshold.

2. First level (Level I) controlled operating mode:

The first level (Level 1) mode of operation of the MRI system is the one in which one or more outputs reach a value that may cause physiological stress to patients, which needs to be controlled by medical supervision.

The default SAR limit is 4.0 W/kg in first level controlled operating mode for whole body scans but might vary in different countries depending on the scanned anatomy. The body core temperature increase is limited to 1°C and the gradients are limited to 100% of the peripheral nerve stimulation threshold.

3. Second level (Level II) controlled operating mode:

The second level (Level II) mode of operation of the MRI system is the one in which one or more outputs reach a value that may produce significant risk for patients, for which explicit approval by an Institutional Review Board is required.

In most countries standard MRI systems are limited to a maximum SAR of 4 W/kg, so most scanning in Level II is not possible.

Medical students should be aware of the safety risks and implications of the different operating modes of an MRI system and that patients need to be informed before the system is used in any other mode than the normal operating mode.

Module 6: "Emergency Procedures in the MR Suite"

Increasingly, non-radiologist physicians participate in MRI scanning, often entering the MRI room to evaluate the patient and administer medications or interventions. Therefore, medical students need to be aware of emergency procedures in an MRI suite.⁷² It is often necessary to remove the patient from the MRI magnet room to resuscitate or treat the patient in emergency cases.⁷⁸ It also critical for all physicians to be trained about which objects can be brought into the MRI zones in order to prevent fatal injuries and medical equipment failure.

Module 7: "Hands-on Demonstrations to Illustrate MRI Safety Concepts"

A comprehensive MRI safety module for medical students should include, in addition to the presentation of the technical and medical background of MRI safety, hands-on demonstrations of¹⁰:

- 1. Screening of patients with a questionnaire for ferromagnetic objects, implants, devices, body piercing, allergies to MRI contrast agents, kidney disease, pregnancy, and breast feeding.
- 2. Screening of patients that have a history of being injured by a metallic foreign body such as bullets, shrapnel, or other type of metallic fragments.
- 3. Missile effects of ferromagnetic objects (e.g., small ferromagnetic objects of different shapes and sizes securely fastened to a strong rope can be used to demonstrate the attractive force and torque on the object in response to the magnetic field and the varying strength of the fringe field).
- 4. Noise of the gradient system during an MRI scan and the use of earplugs and headphones to avoid potential hearing damage.
- 5. Videos from a quenching magnet, offered for example from the Institute for Magnetic Resonance Safety, Education, and Research (http://www.imrser.org/genpg. asp?pgname=VideoList).
- 6. Situations in which patient positioning can lead to RF burns when limbs or other body parts are in direct contact with transmit RF coils of the MR systems or how skin-to-skin contact points can be responsible for these injuries. This demonstration can be supplemented by images of RF burns that have occurred in patients.

Comprehensive Multiple-Choice Exam

A standardized multiple-choice exam, either written or accessible through the Internet, should be administered at the end of the course to evaluate the medical students proficiency in MRI safety material. The multiple-choice questions should include content from all modules in order to assess the medical students competency in each area of MRI safety. There are several preexisting online proficiency exams from non-profit and full-profit organizations that have been evaluated by content experts before inclusion in the exam. This offers an excellent opportunity to objectively evaluate the effectiveness of an MRI safety education program.

In conclusion, the proposed MR safety course contains seven modules that cover all critical areas of MRI safety for the general physician. These modules can be implemented as traditional didactic lectures, interactive sessions, or selfadministered online.⁸ The goal of the course is to ensure that medical students receive a basic understanding of MR principles and safety considerations. It prepares the medical students for optimal ordering of MR studies while emphasizing patient screening and safety. The course will help to ensure consistent quality of teaching materials and MR safety standards.¹⁰

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