



MRI-related FDA adverse event reports: A 10-yr review

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(Received 6 May 2019; revised 11 July 2019; accepted for publication 6 August 2019; published 8 October 2019)

Purpose: To provide an overview of the types of adverse events reported to the US Food and Drug Administration (US FDA) for magnetic resonance (MR) systems over a 10-yr period.

Methods: Two reviewers independently reviewed adverse events reported to FDA for MR systems from 1 January 2008 to 31 December 2017 and manually categorized events into eight event types. Thermal events were further subcategorized by probable cause. Objects that became projectiles were also categorized.

Results: FDA received 1568 adverse event reports for MR systems between 1 January 2008 and 31 December 2017. This analysis included 1548 reports. Thermal events were the most commonly reported serious injury (59% of analyzed reports). Mechanical events — defined as slips, falls, crush injuries, broken bones, and cuts; musculoskeletal injuries from lifting or movement of the device — (11%), projectile events (9%), and acoustic events (6%) were also observed.

Conclusions: Adverse events related to MR systems consistent with the known hazards of the MR environment continue to be reported to FDA. Increased awareness of the types of adverse events occurring for MR imaging systems is important for prevention. *Published 2019. This article is a U.S. Government work and is in the public domain in the USA.* [<https://doi.org/10.1002/mp.13768>]

Key words: burns, FDA MAUDE database, MRI adverse events, MRI safety, MRI thermal injuries

1. INTRODUCTION

Magnetic resonance imaging (MRI) has been an available clinical imaging tool for approximately 35 yr. While MRI began as a purely diagnostic imaging modality, in recent years, MR technology has expanded into additional areas, such as guiding interventional procedures and planning and gating radiation therapy. Because MRI does not use ionizing radiation, it can be perceived as a completely safe imaging modality by those unfamiliar with the hazards of the MR environment.¹ Known hazards in the MR environment include a strong static magnetic field, pulsed gradient magnetic fields, and radiofrequency energy.^{2–4} The strong, static magnetic field attracts magnetic objects that may become projectiles. Pulsed gradient magnetic fields may induce peripheral muscle or nerve stimulation and their on/off pulsing creates loud knocking noises that can lead to acoustic injuries. The radiofrequency energy used during the MRI scan can lead to heating of the body and any other conductive objects that enter the bore of the MR system. Moving parts of patient tables may create pinch points. Potential harms in the MR environment include injury to patients, medical professionals, or laypeople due to projectile events or unexpected device motion due to the static magnetic field, tinnitus, or hearing loss (temporary or permanent) due to acoustic noise, peripheral nerve stimulation, heating and/or patient burns from the radiofrequency energy, and crush and pinch injuries from moving parts and falls.^{1,2,5} Misdiagnosis

or delayed treatment from distorted or incorrect images is also possible.⁵

The purpose of this article was to provide an overview of 10 yr (2008–2017) of FDA adverse event reports for MR systems. While previous studies have looked at adverse events in specific patient populations, particularly those with implanted medical devices (e.g., cochlear implants,^{6,7} pacemakers or defibrillators,⁸ breast tissue expanders,⁹ magnetically controlled growing rods¹⁰) or specific imaging studies (e.g., fMRI¹¹), our goal was to provide a broad characterization of the types of adverse events that occur in the MR environment. Unlike previous studies, we did not limit our analysis to only thermal¹² or auditory¹³ injuries. Our goal was to use this information to increase awareness of the unique safety challenges that are inherent in the MR environment. As the clinical applications of MR imaging change and grow, it is especially important that all of those involved in patient care, including MR technologists, medical physicists, and physicians, are aware of the unique safety challenges associated with the MR environment.

2. MATERIALS AND METHODS

2.A. FDA adverse event reporting requirements

Adverse event reporting requirements for medical device manufacturers and user facilities are outlined in Title 21 of

the Code of Federal Regulations (CFR), Part 803 — Medical Device Reporting. Medical device manufacturers must submit an adverse event report to FDA within 30 calendar days of becoming aware that the device they market may have caused or contributed to a death or serious injury, or when the device has malfunctioned, and this device or a similar device that the manufacturer also markets would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.¹⁴ User facilities must submit an adverse event report within 10 working days of becoming aware that a device has caused or may have contributed to the death or serious injury of a patient at the facility.¹⁵ FDA accepts voluntary reports from anyone who wishes to alert the FDA to a problem with a medical device. Forms for reporting to FDA can be found on FDA's website.¹⁶

2.B. FDA's adverse event databases

FDA receives adverse event reports from a variety of sources (e.g., device manufacturers, user facilities, patients, and medical professionals) through a program called MedWatch.¹⁷ FDA also has a program called MedSun (Medical Product Safety Network), an adverse event reporting program launched in 2002 that is a partnership between clinical sites and FDA.¹⁸ In addition to the reporting requirements from statute, MedSun participants are also encouraged to report "close calls," potential for harm, and other safety concerns. FDA's Alternative Summary Reporting Program was in effect from 1997 through June 2019.¹⁹ FDA had allowed alternative summary reports (ASRs) for specific well-known and well-characterized events associated with specific devices. Data in ASRs are based on the same threshold for reporting as MedWatch but differ in format.

Within FDA, all device adverse event reports are archived in a database called the System for Uniform Surveillance (SUS). Data in SUS are not redacted, but the complete data are available only to FDA staff.

Users outside FDA can access MedWatch reports through an adverse event database,²⁰ while MedSun reports are archived separately in the MedSun database.²¹ Identifying information is redacted from publicly facing databases before records are made public. The MAUDE web search feature²⁰ only makes accessible the 10 most recent years of data. MAUDE is updated monthly, and the search page reflects the date of the most recent update. Older MAUDE reports are available as zipped files for download; some older reports are also available in the MDR database.²² ASRs were not made publicly available because they were not submitted in a format compatible with the public database. The FDA recognized the public interest in this information and modified the conditions of the ASR Program in 2017 to require submission of a companion report on the official mandatory reporting form.¹⁹ Companion reports included the total number of events being summarized in the quarterly report through the ASR Program and are available publicly.²⁰

2.C. Adverse event analysis

For this analysis, SUS was queried to retrieve all adverse event reports received by FDA between 1 January 2008 and 31 December 2017, inclusive, for MR imaging systems (FDA product code LNH), MR specialty coils (FDA product code MOS), NMR spectroscopy (FDA product code LNI), and PET/MR systems (FDA product code OUO). A device product code is a unique three letter identifier assigned by FDA for a specific device type. The name and product code identify the generic category of a device for FDA. The product code assigned to a device is based upon the medical device product classification designated under 21 CFR Parts 862–892.²³ SUS contains both MedWatch and MedSun adverse event reports. ASRs for the analyzed timeframe were also queried and verified to not include any MRI system data.

Reports were exported into Excel. Reports of adverse reactions to MR contrast agents and miscoded events were identified and removed from further analysis. Miscoded events were those reporting problems with a device other than an MR system or accessory (for example, a spectroscopic blood analyzer).

Death reports were reviewed and all available information, including the results of any FDA follow-up investigations, scrutinized to determine whether the cause of death was directly attributable to the MR device. Since deaths are serious, infrequent events for MR devices, and in most cases multiple reports are submitted for the same event (e.g., by manufacturers, user facilities, others), for death reports only we attempted to separate the number of reports from the number of events based on event information including date, location, and patient information (i.e., to determine whether multiple reports were submitted for the same event).

All events (deaths, injuries, and malfunctions) were classified into one of the mutually exclusive event categories in Table I. The categories in Table I were defined based on known and common hazards within the MR environment and expected adverse event types.^{4,24–26}

Each report was reviewed independently by two FDA adverse event analysts (JGD, 17 yr of MRI experience, including 7 yr as an FDA adverse event analyst and DMK, 16 yr of MRI experience, including 6 yr as an FDA adverse event analyst). Following independent review of each event by the two analysts, the classification results of the two reviewers were compared. Discrepancies in event categorization were flagged and discussed with the aim of reaching agreement on the appropriate categorization of a flagged event. If no agreement was reached, the event was referred to a third individual (SAF, diagnostic radiologist with 22 yr of clinical experience and 4 yr as an FDA adverse event analyst) for adjudication. The third individual selected one of the two categories previously assigned by the initial two reviewers, and that category was the final classification for the event. Therefore, all events were placed into one of the above mutually exclusive categories based on agreement of two out of three reviewers.

TABLE I. Mutually exclusive event type categories.

| Category | Description |
|------------------------------|---|
| Thermal | Skin reddening, blisters, burns, warming, heating sensation, fires, and smoke |
| Acoustic | Hearing loss and/or tinnitus (temporary or permanent) |
| Image quality | Lost, misoriented, inadequate, or mislabeled images. These include items such as image artifact, image flipping, and images attributed to the incorrect patient. An error anywhere along the image acquisition chain may fall into this category |
| Projectile | Events in which objects were pulled into or attracted to the main static magnetic field |
| Mechanical | Slips, falls, crush injuries, broken bones, and cuts; musculoskeletal injuries from lifting or movement of the device were considered mechanical events |
| Peripheral nerve stimulation | Nerve or muscle stimulation or patients experiencing “tingling,” “twitching” or involuntary movements. When tingling was reported in conjunction with heating or blistering, the event was classified as a thermal injury |
| Miscellaneous | Adverse event reports for which a sufficient narrative was provided to describe the event, but the event did not fit into the above categories. (These are events that are clearly linked/attributed to or caused by the MR system.) |
| Unclear | Insufficient information was available to draw any conclusions, or the event description and/or conclusion are inconclusive or contradictory. Events describing symptoms or a clinical narrative for which the connection to the MRI exam is unclear were placed into this category |

TABLE II. Thermal injury root cause categories.

| Category | Description |
|----------------------|--|
| | The thermal injury was attributed to contact with another object. Anything present within the bore of the MR system was considered an object (e.g., accessory coils, ECG leads, patient headphones, patient implants, patient clothing). For attribution to an object as the root cause, the location of the thermal injury needed to match the location of the object |
| Skin-to-skin contact | A thermal injury attributed to skin-to-skin contact at two anatomic locations, or a report describing thermal injuries in two anatomical locations that are likely to have been in direct contact (e.g., inner thighs, left and right calf, thumb, and ipsilateral hip) leading to a possible current loop |
| Bore contact | Thermal injury occurring at an anatomic site in contact with (or near) the bore of the MR system |
| Not RF-related | Thermal events that are clearly not RF-related, for example, fires and cryogen burns |
| Unclear | The root cause of the event was unknown or the event description includes insufficient detail to draw any conclusions. Reports for which multiple causes were possible were also placed in this category |

Projectile and thermal events were further analyzed. For projectile events, the object that became a projectile was recorded. Thermal events were subcategorized into a single

TABLE III. Breakdown of MRI adverse events.

| MRI adverse event category | Number (%) ^a |
|------------------------------|-------------------------|
| Thermal | 906 (59) |
| Mechanical | 170 (11) |
| Projectile | 133 (9) |
| Miscellaneous | 109 (7) |
| Image quality | 89 (6) |
| Acoustic | 86 (6) |
| Unclear | 55 (4) |
| Peripheral nerve stimulation | 0 (0) |
| Total | 1548 |

^aTotal percentage may not be 100 due to rounding.

category (Table II) based on the likely cause of the thermal injury.

The categories in Table II are mutually exclusive. For thermal events whose root cause was attributed to contact with another object, the involved object was recorded. As with the event categorization, thermal root cause classification was conducted independently by each of the two readers and discrepant classification results were resolved in the same manner.

3. RESULTS

Our search retrieved 1568 adverse event reports. Twenty reports were removed from further analysis because they were either miscoded (14 reports) or adverse reactions to contrast agents (six reports).

The analyzed dataset contained 12 death reports that described ten unique events. For three events (two involving field service engineers and one involving a patient), the cause of death was attributed directly to the MRI system. These events described a patient death attributed to malfunction of an implantable pain pump after exposure to the static field of the MR system, a field service engineer crushed by a blower panel that became a projectile, and a field service engineer who went into cardiac arrest while under anesthesia for follow-up treatment of a cryogen burn. For the remaining nine reports that describe seven unique events, the cause of death was not attributed to the MRI system. These included a screening failure for a patient with an aneurysm clip; however, the cause of death was ultimately not attributed to movement or alteration of the aneurysm clip (three separate reports were submitted for this one event), and six reports where the cause of death was unrelated to the MRI examination (e.g., cardiac arrest during or immediately following the MRI exam).

The 1548 analyzed reports, which included deaths, injuries, and device malfunctions, were classified into the event type categories described in Table I. The two initial reviewers disagreed on the classification of 166 of 1548 reports (11%). The appropriate classification for 155 of 166 (93%) of these reports was resolved through discussion. Fifteen events were

TABLE IV. Thermal event root cause.

| Thermal injury root cause | Number (%) ^a |
|---------------------------|-------------------------|
| Unclear | 348 (39) |
| Contact with an object | 257 (28) |
| Skin-to-skin contact | 147 (16) |
| Bore Contact | 97 (10) |
| Not RF-related | 57 (6) |
| Total | 906 |

^aTotal percentage may not be 100 due to rounding.

referred to the third reader for adjudication. The final categorical breakdown of the 1548 events is given in Table III.

Thermal events accounted for 906 of 1548 (59%) of the adverse events reported to FDA for MR systems and coils. The two reviewers independently agreed on a likely root cause for 732 of 906 (81%) events; after discussion, the reviewers reached agreement on a likely root cause for 904 of the 906 events. The remaining two reports were sent to the third reader for adjudication. The final root cause categorization of the thermal injuries is given in Table IV. For the 257 thermal reports where the root cause was attributed to contact with another object, the objects involved are presented in Table V.

The majority of the 170/1548 mechanical injuries (11% of analyzed reports) we encountered in our analysis — finger pinch events related to a moving patient table, falls, and injuries to a technologist from moving heavy items — is not specific to MR systems. One injury type specific to MR systems is broken ribs in patients undergoing breast exams (22 reports). The hazard is specific to breast exams, as breast coils are elevated from the patient table, increasing the risk of patient collision with the bore of the magnet.

One hundred thirty-three (133) of the 1548 reports (9% of analyzed reports) were categorized as projectile events. Items involved in reported projectile events are listed in Table VI.

Eighty-six of 1548 reports (6% of analyzed reports) were categorized as acoustic events. These reports included patients who developed tinnitus, hearing loss, or both, on either a transient or permanent basis. These reports included both patients who were not provided hearing protection and patients for whom hearing protection was provided. At least one report of hearing loss involved a field service engineer.

We did not observe any reports attributable solely to peripheral nerve stimulation (PNS). We categorized reports in which patients complained of tingling or shocking during or after an MRI exam coupled with heating sensations or blistering as thermal events.

To help readers understand our report classifications, we provide example excerpts from report narratives included in our study. The number in parentheses after each excerpt is the associated MDR Report number. Vendor-specific and patient-identifying information has been removed from these sample report narratives. As stated previously, readers should be aware that MAUDE is updated monthly and the MAUDE

TABLE V. Objects involved in thermal events with a root cause of contact with an object.

| Object | Number (%) ^a |
|--|-------------------------|
| MR coils | 138 (54) |
| ECG electrodes or leads | 39 (15) |
| Patient clothing | 12 (5) |
| Stereotaxic head frames | 11 (4) |
| Blankets | 9 (4) |
| Orthopedic implants | 8 (3) |
| Pulse oximeters | 7 (3) |
| Tattoos/permanent makeup | 6 (2) |
| Headphones | 3 (1) |
| Dermal patches | 3 (1) |
| Jewelry | 3 (1) |
| Miscellaneous (e.g., urine bags, wet pantyliners, orthopedic splints, other medical devices) | 18 (7) |
| Total | 257 |

^aTotal percentage may not be 100 due to rounding.

TABLE VI. Objects involved in projectile events.

| Object | Number (%) ^a |
|--|-------------------------|
| Patient transport and mobility equipment, including walkers and wheelchairs (21 reports), stretchers (8 reports), and chairs (6 reports) | 35 (26) |
| Gas cylinders | 13 (10) |
| Magnet components exposed during service | 13 (10) |
| Tools, including both general tools such as scissors and specialized tools involved in magnet servicing | 10 (8) |
| Patient monitoring equipment | 9 (7) |
| Carts | 8 (6) |
| IV poles | 8 (6) |
| Surgical tools | 7 (5) |
| Firearms | 5 (4) |
| Floor polishers | 3 (2) |
| Firefighting equipment | 3 (2) |
| Miscellaneous | 19 (14) |
| Total | 133 |

^aTotal percentage may not be 100 due to rounding.

web search feature²⁰ provides access to only the most recent 10 yr of data. Therefore, some referenced reports may not be accessible via the web-based MAUDE search portal. User facility reports can be found in the MedSun database,²¹ not in MAUDE.

3.A. Thermal — skin-to-skin contact

- Patient had an MR procedure. Patient was scanned on an...1.5 T MR system with no additional RF coil attached. Immediately after the examination, second to third degree burns appeared on the inside of his calves (3003768277-2009-00083).

- Patient was having an MRI of his shoulder. Patient complained of a burning sensation on his right thumb and right thigh which were in contact with each other. When patient was removed from MRI machine, MRI tech observed a 1/2" blister on his right thumb and right thigh. Doctor was notified. Patient was treated for burn (MW5012499).
- The patient had a MR exam. He was scanned with the ... body coil which was positioned at the upper legs. Sometime after the examination, a 2nd to 3rd degree burn that was approximately 2 cm was found on the inside of both calves. No separating material was used between the legs and the calves which means these body parts had been in contact during the exam (3003768277-2010-00250).

3.B. Thermal — bore contact

- A large patient sustained burns on the elbows during a MR exam. The patient's elbows were touching the bore of the magnet (2183553-2008-00010).
- A patient sustained redness on both arms and a burn above the right elbow, approx. two inches by two inches in size. Padding was not used during the scan (2183553-2008-00013).
- A sedated patient sustained a second degree burn on their upper right arm after the MRI exams. ... according to the site, the patient was not padded and was touching the side of the bore (2183553-2008-00030).
- A patient ... underwent a scan of the elbow... the patient was placed in the magnet bore asymmetrically in order to bring the elbow iso centre [sic] with the patient's left flank in direct contact with the bore wall. Immediately following the exam, a blister approximately 4 inches in diameter was noticed on the patient's side... (2240869-2017-64568).

3.C. Thermal — contact with another object

- The patient was scanned with the ... coil with the head first into the magnet. No padding was used between the coil cable and the patient which resulted in the cables touching the patient's skin. During the examination, the patient was burned on the left thigh. A second degree burn with a 5 cm blister appeared immediately after the scan (1217116-2008-00040).
- The patient had a MR procedure. The patient was scanned with the ... head coil with the cable on the right side of the patient's humerus. Patient was dressed with long sleeve shirt with a sheet placed between the cable and arm. After the examination, a second degree RF burn appeared on the lower third of the right humerus (217116-2008-00091).
- The patient had a MR procedure. The patient was scanned with the ... body coil. Immediately after the scan, a second degree burn with a 2–3 cm blister was

observed at the place there [sic] the coil cable was touching the patient. . . (3003768277-2009-00059).

- A patient was being scanned with a stereotactic frame attached to his head. The patient sustained a burn at the point where the stereotactic frame screws were inserted into his skull. . . (2183553-2008-00051).
- Patient had a MR exam. He was under anesthetic and scanned with ... spine coil with a third-party ECG-leads and pads connected to him. Immediately after the exam, third degree burns were observed under the ECG pads. Also, the clips of the pads were melted (3003768277-2010-00057).

3.D. Thermal — not RF-related

- It was reported that while scanning a patient, the MR scanner stopped. The technologist went into the MR scan room and smelled and noticed smoke. The patient was removed from the room. The technologist then noticed an orange glow coming from a gap between the doors of the magnet room closet. It was determined that the gradient cables were arcing in the closet causing a small flame (2183553-2017-00012).
- During a service action at the magnet, a trained ... engineer sustained serious cryogenic burns on his hand (3003768277-2015-00097).
- It was reported that a third-party field engineer was installing a power monitor into the main power distribution panel when there was an apparent short that led to the engineer being burned. It was reported that the engineer sustained serious burns on both arms (2183553-2015-00015).

3.E. Thermal — unclear

- It was reported ... that a patient underwent a brain diffusion examination on the ... system. The examination was conducted with no incident and the patient was released. The following day, the patient returned to the hospital with a second degree burn approximately 10 cm in diameter on the left hip (2240869-2015-06489).
- The patient got a skin burn on the calves during the examination of the thighs. No further info is available. . . (3003768277-2011-00485).
- A patient noticed a second degree burn several days after an examination with an ... MR system. No additional information is available at this moment... (3003768277-2011-00338).
- A patient undergoing an MRI of the breasts sustained a 3–4 cm burn to the left side of her abdomen. The patient was positioned probe [sic], feet first, with their arms/hand placed above their head. The patient was padded to isolate contact of their arms to the side of the

magnet and padded between their legs. The patient was reported to not have any skin to skin contact and was not in contact with any cable or conductive material during the scan. The burn sustained by the patient was described to be red with a central black area that later developed ulceration (2183553-2014-00019).

- A patient received a burn on the left elbow during an MRI exam of the lumbar spine that was described as a blister with pink around the edges. The burn was approximately 1.5 inches in diameter. The hospital reported that there was adequate padding placed between the patient's elbow and the bore of the magnet (2183553-2014-00016).
- The patient was scanned with the . . . spine coil in the head first position. Immediately after the scan, a second degree burn with a blister, size of approximately 3 cm × 6 cm, was found on patient's back (right side). Also, another second degree burn with a blister, size of approximately 2 cm × 3 cm, was found on the right leg (3003768277-2009-00148).

3.F. Acoustic events

- It was reported that a patient had hearing loss after an MRI of the brain. It was reported the patient was provided hearing protection for this exam. The patient underwent a hearing exam, which showed hearing loss in the left ear and some loss in the right ear compared to a prior audiogram (2183553-2015-00022).
- Report from a customer related to hearing loss of a patient examined with an . . . 1.5 T system. The patient was scanned for a brain examination without hearing protection (3003768277-2017-00005).
- Patient who underwent a magnetic resonance cholangiopancreatography (MRCP) was not provided hearing protection. At the end of the exam, the patient did not state any issues with her hearing. At a later date, the patient reported back to the customer that she has a buzzing sound in her ears. The patient was seen by her physician and found to have a small amount of hearing loss (2183553-2017-00023).
- A field service engineer reported that they had been experiencing ringing in their ears due to exposure to loud noises from an MR unit during installation. The FE was evaluated by an ENT physician who confirmed they have new hearing impairment (2183553-2015-00017).

3.G. Image quality

- The customer reported finding images with incorrect left/right annotations after the system was serviced. The x-axis gradient cable had been incorrectly connected to the gradient coil. . . (2183553-2008-00047).

- It was reported that the site was experiencing image quality issues. The Field Engineer performed an investigation at the site and found burned capacitors on the RF body coil. . . (2183553-2008-00032).
- The site reported that an artifact seen on 3d TOF SPGR maximum intensity pixel images of an area of the brain (Circle of Willis) led to a surgeon to diagnose stenosis of the middle cerebral artery. Initial report from the site stated that the diagnosis was performed on scans of four patients. . . the site confirmed that only two patients were involved. Both affected patients reportedly underwent x-ray cerebral angiogram procedure, the results of which disproved the stenosis observed on the MR images (9612283-2009-00002).

3.H. Projectile events

- A service engineer from the hospital got injured during a service action. The shim filter was attracted to the magnet when the service engineer tried to remove it from the examination room. The engineer sustained a severe cut on one of his fingers, that required stitches, a cut in his thumb and bruising on his stomach (3003768277-2017-00075).
- A 3rd party contractor brought a box of tools into the scan room during servicing. The contractor had been trained on MR safety, however did not check to see if the tools were MRI safe. The box had ferrous tools which became attracted to the magnet. When this occurred, the contractor received an injury to the right hand. The right middle finger was fractured and received sutures, the index finger received a suture and the thumb sustained only a flesh wound (2183553-2017-00027).
- Customer brought in a magnetic drip stick which was attracted to the magnet. While attempting to remove the drip stick, the technician was pinned between the drip stick and the magnet. The technician suffered a laceration to the right index finger requiring 10 sutures (3002808157-2017-10156).
- A ventilator was attracted to the magnet when a hospital technologist was moving it within the MR scan room. The technologist twisted her back and received physical therapy and epidural injections. There was no patient present in the room at the time of the incident (2183553-2008-00007).
- Site brought patient into scan room on a ferromagnetic gurney. The patient was thrown into the magnet with the gurney. The technician immediately quenched the magnet in order to release the patient as well as the gurney from the magnet. The patient sustained fractures to the foot, ankle and leg (2240869-2009-00002).
- MR technologist was assisting a patient into the scan room when all of sudden, while positioning the patient, the son entered the room to try and help. The son

(military policeman) had a gun at his waist along with a cell phone. The gun went off and struck the cell phone and then the son in his leg. The gun then became attracted to the magnet. The son was initially treated at the imaging center and then sent to a different hospital where the bullet was removed from his leg (2183553-2017-00005).

- Fireman entered the MRI room with a metal pole which was attracted to the magnet hitting the fireman's head. This fireman got a laceration on the head and was treated with stitches (3003768277-2015-00082).

3.I. Mechanical events

- During an MRI exam, a sedated patient sustained a cut finger from an open space between the bridge and the magnet cover near the front opening. The cut required sutures (2183553-2017-00025).
- A patient received an injury to her finger during the MRI scan. The technologist put a coil on the patient and told the patient to stay still and keep arms at her side. As the table advanced with the patient into the bore, the patient's finger got stuck in the table. The exam was stopped; the technologist applied pressure to the wound on the fifth digit of the patient's right hand and wrapped it with gauze. The patient's finger was lacerated and required stitches (3002808157-2017-98018).
- While lowering the table, a patient who had just completed a lumbar spine MRI exam, grazed their head on the cradle hook. Due to the amount of bleeding from the scalp injury, the patient was sent to urgent care where a staple was placed to stop the bleeding (2183553-2017-00020).
- A patient's finger had to be amputated after a finger pinch event (3003768277-2017-00072).
- A patient sustained fractures of the 10th and 11th anterior ribs while being positioned for a MR examination of the breast. . . (2183553-2016-00028).
- A patient's finger got injured while being moved into the bore of the MR system. The finger of the patient was pinched between the table top and the magnet bore cover, resulting into [sic] a fracture of the finger (3003768277-2016-00106).
- It was reported that the technologist dropped the patients' [sic] earplug to the floor under the patient table. The technologist reached under the table to pick up the earplugs and was bringing his hand back out when he injured his left hand on the underside of the table side cover edge. The technologist [sic] left thumb and forefinger skin peeled back about 2.3 cm. Since the range of the injury was wide and deep, plastic surgery was consulted who stitched the wounds. The technologist has recovered but retains a scar on his fingers (2183553-2014-00003).

3.J. Miscellaneous events

- This patient had a MR procedure. Operator scanned a 69 yr old male with a pacemaker. Patient had selected "yes" on patient safety screening form for pacemaker. This was not noticed until scout image was completed. Patient was immediately removed from magnet. Patient was not injured (1217116-2008-00034).
- It was reported to the . . . customer service engineer that a patient with a shunt having a ferromagnetic dial was scanned. During the procedure, the dial rotated/moved. This was documented with x-rays that are routinely taken on this patient before the MR study and after the MR study (2020563-2009-00001).
- A patient urinated on the table top during an MRI scan, the urine leaked down into the electronics inside the table which eventually caused the electronics to malfunction. . . (MW5034652).
- Spontaneous quench of MRI system for the third time in 3 yr (MW5043110).

4. DISCUSSION

MRI is generally perceived as a safe imaging modality, but it is not risk free. The MR environment involves a large static magnetic field, pulsed gradient magnetic fields, and radiofrequency (RF) fields, all of which interact with body tissues and devices present within the imaging field and may create translational and torqueing forces, heating of tissues and devices, stimulation of muscles and nerves, and hearing damage. Both injuries (which can at times be serious) and deaths continue to occur during MRI exams.

It is not the intent of this manuscript to provide a comprehensive review of the existing MRI safety literature; for that, the reader is directed elsewhere.^{4,27-31} Instead, our intention is to examine the adverse event reports submitted to FDA and to characterize the types of adverse events being reported.

In our analyzed dataset, thermal injuries occurring during MRI exams were the most commonly reported adverse event (59% of analyzed reports), a finding consistent with prior reports.³² Previous publications have examined in detail the physics and causes of thermal injuries during MRI exams^{28,29,33} as well as best practices for prevention,^{25,30,31} and it is not our intention here to provide a comprehensive review. Rather, we used existing knowledge to define three broad categories of situations that may increase the likelihood of thermal injuries during MRI, into which we binned our adverse event data: (a) formation of RF loops within the body due to skin-to-skin contact, (b) contact with the bore of the MR system, and (c) the presence of conductive objects within the bore of the MR system. Reports for which a clear cause could not be determined were the largest subcategory of thermal injuries in our dataset (39% of analyzed reports), followed by contact with a conductive object within the bore (16% of analyzed reports), skin-to-skin contact (16%), and

contact with the bore wall (10%). Thermal injuries from conductive objects were observed for both medical (e.g., coil cables, implanted devices, ECG leads or cables) and nonmedical (e.g., jewelry, silver-impregnated clothing, tattoos) devices. It is important to remember that devices which have been shown to be safe within a defined set of use conditions (i.e., MR Conditional devices) can heat and lead to patient injury under other conditions.²⁵ Skin-to-skin contact RF loop burns were observed between the thumb and the buttocks or hip area, between the patient's inner thighs, between the calves, and between the hands of patients positioned with crossing arms. We observed bore contact injuries resulting from proximity to the high electric fields near the capacitors of the RF transmit body coil in large patients who cannot fit within the bore of the magnet without touching the sides, and in examinations that require off-center positioning of the patient (e.g., shoulder or breast exam). Injuries attributable to bore contact were most common in the arms, elbows, forearms, shoulder regions, and the abdomen (if the patient is large and the anterior abdominal wall is touching the bore of the magnet).

A surprising finding of our analysis was that the MRI coils used in the examination were often cited as the likely cause of burn injuries, such as when coils were routed directly over the patient, patients were in contact with coil cables or baluns, or when only sheets or blankets were used to separate coil cables from the patient. It was not possible in our analysis to differentiate between receive-only RF coils and transmit/receive accessory coils. The MRI vendor community has been made aware of the coil heating hazard and is developing a standardized test method to evaluate heating of MRI accessory coils. In parallel, the international MR standards community is exploring whether modifications to the RF safety specifications of MR systems are needed to help in reducing burn injuries. FDA has also partnered with the Society of Magnetic Resonance Technologists (SMRT) to develop educational materials to help develop awareness of this hazard. The FDA/SMRT MRI Burn Prevention Poster is available for free download on FDA's webpage³⁴ in English and on SMRT's webpage³⁵ in English and multiple additional languages. The FDA webpage also includes two additional posters that address safety issues that arise when medical devices are used in the MR environment: one poster gives tips for scanning patients with implants, and the other poster provides information about how to interpret MRI safety labeling. We hope these additional resources raise awareness and increase patient safety by bringing attention to good practices.

Exposure to acoustic noise is an often-overlooked MRI hazard. Injury prevention is a responsibility shared between manufacturers and clinical facilities. MRI system manufacturers must specify the necessary level of hearing protection to be provided to patients when sound pressure levels exceed 99 dBA.²⁴ Efficacy of hearing protection is highly dependent on fit; correct application of hearing protection is the responsibility of the facility. Reports of tinnitus and hearing loss imply that hearing protection is not always used or

properly applied. These reports may be limited to a subset of the population that is more acoustically sensitive than the general population, but identification of these patients beforehand is difficult. Therefore, we recommend that hearing protection be provided and used correctly during all MR examinations.

The harm from inadequate image quality is misdiagnosis, which may be difficult to attribute to a single set of images. FDA recently issued a warning to healthcare providers that images from magnetic resonance angiography performed on patients with neurovascular embolization coils containing 304 V stainless steel may contain larger than expected MR artifacts and result in inaccurate diagnosis of occlusion status.³⁶ The most commonly reported image quality concern we noted was image flipping. Image flipping can be difficult to detect in brain and extremity exams and can have major clinical consequences; these types of events are also among the least likely to be reported. A delay in the delivery of necessary care is another potential health consequence of inadequate or unavailable images. This is likely a more significant problem for emergent and critical care patients. The frequency and impact is impossible to quantify based on our data and analysis.

Projectile events are an example of a "never event," a medical error that should never occur.³⁷ However, despite being a well-known and well-understood hazard of the MR environment, projectile events continue to occur. This highlights the importance of keeping MR Safe and/or MR Conditional items on hand near the MR environment and ensuring that all involved in patient care are aware that these special items are the only ones that should enter the MR environment. We were surprised to discover multiple projectile events involving magnet service tools or MR system components exposed only during service; this highlights the need for continued training of service personnel. Events involving firefighting equipment and firearms underscore the need for education of first responders and other nonclinical individuals (e.g., janitorial staff) and lay individuals who may find themselves within the MR environment. Well-placed signage may be useful in some situations to alert emergency personnel to the presence of high magnetic fields. The American College of Radiology provides specific recommendations for prospective education of firefighters and other emergency responders.²⁵ We note that the individual responsible for introducing the projectile into the MR environment was typically someone other than the patient (e.g., service personnel, transporters, patient's relatives); that is, few projectile events could be attributed to patient screening failures. Unfortunately, most projectile events are attributable to human error, so continued vigilance and education remain the only mitigations.

Given current safety limits related to imaging gradient switching,²⁴ avoidance of peripheral nerve stimulation is generally a patient comfort issue rather than a safety concern; this may be one explanation for why we did not observe any reports of only nerve stimulation. There may be instances, such as examinations on anesthetized patients, where it may

be appropriate to increase the gradient switching limits to enable greater imaging performance.

The majority of mechanical injuries we encountered in our analysis — finger pinch events from the patient table, falls, and injuries to technologist from moving heavy items — was not specific to MR systems. We encourage and support continued improvement in general safety standards to address the causes of mechanical injuries. Facilities should be aware of the potential for rib fractures in patients undergoing breast MRI, and should take care when introducing patients, especially larger patients, into the magnet bore for these types of exams.

The number of reports we reviewed without sufficient information to permit categorization underscores the importance of complete, detailed reports. FDA and device manufacturers are only able to identify trends and initiate meaningful follow-up when sufficient information is provided to allow meaningful conclusions to be drawn.

4.A. Limitations

A major limitation of this retrospective study is that the adverse event reports are derived from a passive reporting system¹⁷ that relies on information provided by users of the devices and other sources, and therefore some information about certain events may be missing, inaccurate, or unverified. Although manufacturers of involved devices are responsible for following up to obtain missing information, it is not always possible to obtain all details of an adverse event. Therefore, some fields in adverse event reports may be blank.

Data in FDA adverse event reports cannot be used to determine rates of adverse events. Underreporting of events is a known problem, and the absence of information about frequency of device use is a known limitation of this database. The number of reported events may fluctuate over time for a variety of reasons that do not reflect a change in the actual rate of the events, such as changes in technology that impact rate of use in clinical practice, changes in a firm's reporting processes, and following a public communication or media reports about a technology. The presence of an adverse event report — or even multiple adverse event reports — does not necessarily mean there is a problem with a device; often additional investigation and data collection (which may not be publicly available) are necessary to make that determination.

Adverse events are reported, archived, and searched based on device product codes. A device product code is a unique three letter identifier assigned by FDA²³ and referenced when the adverse event is reported. If more than one device is involved in a given incident, the reporter of the incident should include the product codes for all involved devices in the adverse event report. This does not always happen, so it can be challenging to get a full picture of the conditions for adverse events involving more than one device. For example, if one were searching for infusion pump malfunctions that occurred within the MR environment, it is likely that a different set of adverse events would be retrieved when searching for infusion pumps within the MRI product code versus searching for MRI within the infusion pump product code.

Additionally, variations in trade, product, and company names affect search results.

Duplicate counting of events is sometimes seen, such as when both an initial and a follow-up report are filed for the same event, or when the same event is reported to FDA by the manufacturer, the user facility, and the patient. Conversely, some reports pool information about more than one event, so a single report cannot be assumed to contain information about a single event.

We based our search on the date the adverse event report was received by FDA. This is a consistent and reliable search metric but is not an indication of the date when an event occurred. The “event date” in the report is not always an accurate indicator of when an event occurred.

Given the above limitations, our data cannot be used to establish rates of events, evaluate a change in event rates over time, or compare event rates between devices. Due to these limitations, our data cannot provide information about incident rates or trends.

5. CONCLUSIONS

Adverse events consistent with the known hazards of the MR environment continue to occur and to be reported to FDA. The majority of these events have known causes and are thus preventable. Reducing the occurrence of these preventable events is a shared responsibility among all those working within the field of MR. As the clinical applications of MR imaging move out of the diagnostic radiology suite to include interventional and radiation oncology applications, it is especially important that all of those involved in patient care, including MR technologists, medical physicists, and physicians, are aware of the unique safety challenges associated with the MR environment. Our shared safety goal should be to bring the preventable adverse event rate to zero.

CONFLICT OF INTEREST

All four authors are U.S. government employees and have no conflict of interest to report.

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REFERENCES

1. Gilk T, Kanal E. Planning an MR suite: what can be done to enhance safety? *J Magn Reson Imaging*. 2015;42:566–571.
2. Woods TO. *Encyclopedia of Biomedical Engineering*. Hoboken, NJ: John Wiley & Sons; 2006.
3. Stecco A, Saponaro A, Carriero A. Patient safety issues in magnetic resonance imaging: state of the art. *Radiol Med*. 2007;112:491–508.
4. Kim SJ, Kim KA. Safety issues and updates under MR environments. *Eur J Radiol*. 2017;89:7–13.
5. The Joint Commission. Preventing accidents and injuries in the MRI suite. *Sentinel Event Alert*. 2008;38:1–2.
6. Kim BG, Kim JW, Park JJ, Kim SH, Kim HN, Choi JY. Adverse events and discomfort during magnetic resonance imaging in cochlear implant recipients. *JAMA Otolaryngol Head Neck Surg*. 2015;141:45–52.

7. Bawazeer N, Vuong H, Riehm S, Veillon F, Charpiot A. Magnetic resonance imaging after cochlear implants. *J Otol*. 2019;14:22–25.
8. Russo RJ, Costa HS, Silva PD, et al. Assessing the risks associated with MRI in patients with a pacemaker or defibrillator. *N Engl J Med*. 2017;376:755–764.
9. Dibbs R, Culo B, Tandon R, Hilaire HS, Shellock FG, Lau FH Reconsidering the "MR Unsafe" breast tissue expander with magnetic infusion port: a case report and literature review. *Arch Plast Surg*. 2019;46:375–380.
10. Woon RP, Andras LM, Noordeen H, et al. surgeon survey shows no adverse events with MRI in patients with magnetically controlled growing rods (MCGRs). *Spine Deform*. 2018;6:299–302.
11. Hawkinson JE, Ross AJ, Parthasarathy S, et al. Quantification of adverse events associated with functional MRI scanning and with real-time fMRI-based training. *Int J Behav Med*. 2011;19:372–381.
12. Hardy PT 2nd, Weil KM. A review of thermal MR injuries. *Radiol Technol*. 2010;81:606–609.
13. Bongers S, Slottje P, Kromhout H. Hearing loss associated with repeated MRI acquisition procedure-related acoustic noise exposure: an occupational cohort study. *Occup Environ Med*. 2017;74:776–784.
14. Code of Federal Regulations - 21 CFR 803.52. In: Office of the Federal Register; 2018.
15. Code of Federal Regulations - 21 CFR 803.32. In: Office of the Federal Register; 2018.
16. US Food and Drug Administration. MedWatch Forms for Reporting to FDA <https://www.fda.gov/safety/medwatch/howtoreport/downloadforms/default.htm>. Accessed July 2, 2019.
17. US Food and Drug Administration. Reporting Serious Problems to FDA. <https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda>. Accessed July 2, 2019.
18. US Food and Drug Administration. MedSun: Medical Product Safety Network. <https://www.fda.gov/medical-devices/medical-device-safety/medsun-medical-product-safety-network>. Accessed July 2, 2019.
19. US Food and Drug Administration. MDR Data Files <https://www.fda.gov/medical-devices/medical-device-reporting-mdr-how-report-medical-device-problems/mdr-data-files>. Accessed July 2, 2019.
20. US Food and Drug Administration. MAUDE - Search Tool. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>. Accessed July 2, 2019.
21. US Food and Drug Administration. Medical Product Safety Network (MedSun) Database. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/Medsun/searchReportText.cfm>. Accessed July 2, 2019.
22. US Food and Drug Administration. MDR Database Search. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMDR/Search.cfm>. Accessed July 2, 2019.
23. US Food and Drug Administration. Medical Device Product Classification Database. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>. Accessed July 2, 2019.
24. International Electrotechnical Commission. Medical Equipment. Part 2–33. Particular Requirements for the Basic Safety and Essential Performance of Magnetic Resonance Equipment for Medical Diagnosis. International Electrotechnical Commission. Edition:3.2; 2015.
25. Kanal E, Barkovich AJ, Bell C, et al. ACR guidance document on MR safe practices: 2013. *J Magn Reson Imaging*. 2013;37:501–530.
26. Shellock FG, Cruess JV. MR procedures: biologic effects, safety, and patient care. *Radiology*. 2004;232:635–652.
27. Tsai LL, Grant AK, Mortelet KJ, Kung JW, Smith MP. A practical guide to MR imaging safety: what radiologists need to know. *Radiographics*. 2015;35:1722–1737.
28. Panych LP, Madore B. The physics of MRI safety. *J Magn Reson Imaging*. 2018;47:28–43.
29. Dempsey MF, Condon B. Thermal injuries associated with MRI. *Clin Radiol*. 2001;56:457–465.
30. Chandra T, Chavhan GB, Sze RW, et al. Practical considerations for establishing and maintaining a magnetic resonance imaging safety program in a pediatric practice. *Pediatr Radiol*. 2019;49:458–468.
31. Weidman EK, Dean KE, Rivera W, Loftus ML, Stokes TW, Min RJ. MRI safety: a report of current practice and advancements in patient preparation and screening. *Clin Imaging*. 2015;39:935–937.
32. Dewilde J, Grainger D, Price D, Renaud C. Magnetic resonance imaging safety issues including an analysis of recorded incidents within the UK. *Prog Nucl Magn Reson Spectrosc*. 2007;51:37–48.
33. Dempsey MF, Condon B, Hadley DM. Investigation of the factors responsible for burns during MRI. *J Magn Reson Imaging*. 2001;13:627–631.
34. US Food and Drug Administration, MRI Safety Posters. <https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MRI/ucm482788.htm>. Accessed July 2, 2019.
35. International Society for Magnetic Resonance in Medicine, Society for Magnetic Resonance Technologists. MRI Burn Prevention Poster. <https://www.ismrm.org/mr-safety-links/mri-burn-prevention-poster/>. Accessed April 10, 2019.
36. US Food and Drug Administration. Neurovascular Embolization Coils: Healthcare Provider Letter - Potential for Increased Image Artifact When Using Magnetic Resonance Angiography For Follow-Up. <https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm600565.htm>. Accessed July 2, 2019.
37. Flug JA, Ponce LM, Osborn HH, Jakerst CE. Never Events in Radiology and Strategies to Reduce Preventable Serious Adverse Events. *Radiographics*. 2018;38:1823–1832.