MR Hazard Summary

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INTRODUCTION

Rationale: This magnetic resonance (MR) Hazard Primer is inspired by:

1. close calls formally and informally reported within VA medical centers,
2. MR events in the public press and FDA's Manufacturer and User Facility Device Experience (MAUDE) database,
3. the fact that MR hazards are complex and not obvious,
4. the increasing amount of procedures and even surgeries performed within MR suites, and
5. MR systems with more powerful magnets being marketed to facilities

Limitations: This MRI Hazard Primer only provides highlights and generalities and deals primarily with issues pertaining to use of medical devices in the MR environment; those persons directly involved in MR operations and MR safety should consider the References and Web Resources listed below for more comprehensive information.

FIVE TYPES OF MR HAZARDS

1. **Projectile effect** (also called missile effect; magnetic material pulled – often violently - toward the magnet bore)
   - While this phenomenon is generally associated with ferromagnetic materials, magnetic materials that are not ferromagnetic (e.g., diamagnetic and paramagnetic materials) can also be pulled into the magnet bore. The force on magnetic materials that are not ferromagnetic is just of smaller magnitude than the force on ferromagnetic materials.
   - Objects that have become projectiles in VA facilities: oxygen cylinder, IV pole, transport stretcher, traction weight, floor buffer, wheelchair, file cabinet, drill, and patient walker. Other items that have been reported to become projectiles in the MR environment include patient lifts, stethoscopes, infusion pumps, pulse oximeters, tools, laundry carts, scissors, pens, hair barrettes and more.
   - Paper clips and hairpins near a 1.5 Tesla (T) MR magnet can reach speeds of 40 mph.

- The projectile effect can be and has been fatal, can cause significant equipment damage and therefore can be costly, can cause a quench of the magnet (release of the magnet's cryogen), and can result in downtime for MR facilities.
- The average cost of a projectile incident in VA is $43,172. The financial and marketing costs of lawsuits must also be considered.

2. **Twisting** (also known as torque; magnetic objects aligning parallel with the MR system's magnetic field)
   - Magnetic cochlear implants and cerebral aneurysm clips can twist within the body causing damage. This can be fatal.
   - Magnetic components can rip loose from their foundation on equipment causing device failure or patient injury.

3. **Burns** (generally caused by heating of electrically conductive material inside the bore of the magnet)
   - Looped and unlooped electrocardiogram (ECG) leads, pulse oximeter cables, and MR accessories (e.g., radio frequency (RF) coil leads) in contact with a patient under sedation can cause full thickness burns, some requiring plastic surgery.
   - Skin burns have resulted at sites where pulse oximeter sensors and ECG electrodes have touched the patient's skin.
   - Patients have received skin burns from contact with the magnet's RF coils or the bore of the magnet.
   - Skin burns have resulted from conductive loops formed with the patient's body (e.g., patient's finger touched their thigh; patient's arms were crossed; patient's thighs were touching).
   - While rare in occurrence, tattoos or tattooed eye-liner containing iron oxide have heated to cause minor burns.

4. **Image artifacts** (changes to MRI images due to various factors)
   - RF emissions from equipment picked up by the MR RF receiver can result in image artifacts (e.g., decrease in contrast, stripes on image).
   - The presence of metals near the imaging site (e.g., mascara, metal biopsy needles) can produce image artifacts (e.g., signal voids, distortion of image). Signal voids, for instance, can mask pathology or be misinterpreted as pathology.

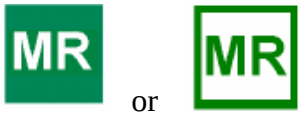
5. **Device malfunction** (electronics or mechanics of devices affected)
    - Devices with analog gauges, electric motors, transformers, relays, and switches can be adversely affected by the static magnetic field.
        - A patient-controlled analgesic (PCA) pump reversed flow, despite presenting normal displays to the user; a one-way valve stopped flow blood into the IV bag. A similar incident occurred with an insulin infusion pump.
        - A ventilator delivered inadequate inspiratory pressure.
    - Devices that use magnetization to attach to a patient (e.g., some dental devices) and some implants that are electrically, magnetically, or mechanically activated can be adversely affected by the static magnetic field.
    - Pacemakers can pace at the wrong point in the cycle and rapid pacing can occur due to RF field interactions.
    - ECG waveforms can be distorted (e.g., increased T-wave or ST segment) due to the static magnetic field interactions, and ECG signals can be misinterpreted (e.g., missed complexes) due to the gradient magnetic field interactions.

WHAT MAKES THE MR ENVIRONMENT SUCH A RISKY SPACE?

1. Large invisible magnetic fields that extend in 3 dimensions
2. MR system magnets are powerful, similar in strength to those used to lift cars in junkyards.
3. It is impossible to tell by looking at an MR system whether it is "ON" or not. (Most MR systems are on 24 hours a day, 7 days a week.)
4. If you need to emergently shut off the MR system (quench the magnet), there are potential risks (e.g., asphyxiation, frostbite, fire hazards) and costs ranging from $20,000-$500,000.
5. A combination of complacency (i.e., acceptance of the risks as “normal”), workarounds for speed, and diffuse responsibility
6. People and equipment who are "new" to MRI suites (more interventions and surgeries being conducted under MR guidance)
7. Equipment and consumables that are safe to use in other areas of the facility can be potentially fatal near MR systems.
8. Some objects don't appear to contain ferromagnetic (or otherwise dangerous) materials)
    - Some sandbags contain iron pellets even though one would not think so.
    - Some pillows contain metal springs.

9. Terminology used to describe whether a device is suitable for the MR environment has changed and can cause confusion. New terminology (**MR Safe**, **MR Conditional**, and **MR Unsafe**, as defined in the American Society of Testing and Materials (ASTM) Standard F2503-05) has replaced old MR terminology (MR safe and MR compatible, as defined in the 1997 FDA's MRI Working Group report on medical device interactions with MR systems). (See References for both of these documents.)

   - The new MR Safe and the old MR safe terms have **very** different meanings. MR Safe (the new labeling, as defined in ASTM F2503-05) indicates that the device is safe - period; it poses no risks in any MR environment. MR safe (the old labeling) meant that the device was safe for use in a particular MR environment. Bringing a device with an old marking of MR safe into the MR environment and expecting it to be MR Safe (according to ASTM F2503-05) could have catastrophic results. Hence, ensure devices and equipment are labeled according to the new terminology laid out by ASTM F2503-05. Devices with icons (as laid out in ASTM F2503-05 and shown below) indicate new terminology is being used.
   - The term MR Unsafe (according to ASTM F2503-05) indicates the device would be unsafe in any MR environment.
   - The term MR Conditional (according to ASTM F2503-05) indicates that the device poses no known hazards in a specified MR environment (specific field strength, spatial gradient, RF pulse limitations, and specific absorption rate). In other words, the safety of the device is conditional upon a specific MR environment; MR Conditional devices may not be MR Conditional with more powerful or upgraded MR systems.
   - MR Conditional data is not easily extrapolated. Just because a device is MR Conditional for a 1.5 T system doesn't mean it will be MR Conditional for a 3 T system, and vice-versa.

MR Safe	 or
MR Conditional	
MR Unsafe	

NOTE: Symbols may also appear in black and white.

10. It is difficult and inaccurate to make "simple" lists of unsafe materials.
    - In general, ferromagnetic materials (e.g., high carbon steel alloys, pure iron) can become projectiles or twist in the bore, and all metals are conductors so they all can become hot or interfere with imaging in the bore. However, you run more risks by compiling “simple” lists than diligently identifying and labeling items appropriate to enter the MR scan room and the bore.
11. New 3 Tesla systems have been introduced.
    - Devices previously labeled MR Conditional (according to ASTM F2503-05) may no longer be MR Conditional with these newer, more powerful systems since many claims for MR Conditional were established with 1.5 T systems. Further, even upgrades to the same system could render a previously MR Conditional device unsafe in the upgraded environment.
    - Projectile incidents are more likely to occur and ferromagnetic implanted objects are more likely to move or rotate with these stronger magnets. Close calls that you may have had in the past with 1.5 T MR systems could translate into major incidents with 3 T MR systems.
13. Benefits of costly interventions might be difficult to envision because there are only scattered and relatively infrequent reports of death or serious injury; however, incident data is under-reported. Many near misses that don’t cause injury to the patient or staff go unreported.

RECOMMENDATIONS

NOTE: Most personnel dealing with an MR-related event and MR safety experts agree that safety issues need to be dealt with as **systems issues.** That is, simply addressing only one component of hazard reduction (e.g., training) is an ineffective or a short-term fix.

REDESIGN :

a. identify and physically mark the 5 Gauss line that identifies the MR environment, and do not allow any equipment past this line, unless it is proven to be suitable for your particular MR environment
b. hang posters reminding patients and providers of the hazards in the MR environment in plain English. Ensure that items used to hang the posters are suitable for the MR environment.
c. design MR suites for safety
    - consider installing ferromagnetic detectors. Note however, that the detectors should only supplement screening patients; they should never take the place of screening. And, while they will detect a ferromagnetic oxygen cylinder, they

will not detect metallic, nonferromagnetic materials that could cause burns to patients if in contact with their body inside the bore of the magnet.

- consider installation of piped-in oxygen systems to reduce the risk that oxygen cylinders will be brought in the MR scan room
- control access to the MR environment (see section B.1 - "Static Magnetic Field Issues: Site Access Restriction, Zoning" - of the American College of Radiology (ACR) Guidance Document for Safe MR Practices: 2007 as a guide; see References below.)
- provide a designated quarantine area where unsafe equipment (e.g., patient arrives to MR suite in a ferrous wheelchair or with a ferrous walker) can be deposited and locked away during the patient's MR scan
- finishes (floors, counter surfaces, etc) should be designed to facilitate cleaning for infection control. Consider also a sink/hand-washing station.

TRAINING :

a. initial and annual refresher training on MRI safety considerations for all personnel related to MRI, including, but not limited to, MR technicians, nurses and MDs who may need to enter the MR environment, emergency, transport, maintenance, housekeeping, and security. There is at least one report in the FDA's MAUDE database regarding a firefighter with a respirator who was drawn into the magnet bore.

b. add conceptual and some practical training to radiology residents and fellows training

c. conduct drills (e.g., patient code, fire) to aid personnel in responding under emergent conditions

PROCEDURAL :

a. assign MR safety officer duties to an appropriate staff member to assure that MR policies are in effect and personnel are trained appropriately. A good guidance document for an MR safety program is the ACR Guidance Document for Safe MR Practices: 2007 (see References).

b. always assume the MR magnet is "on" even if it appears idle

c. empower MR technicians to have control over access to the MR environment

d. carefully screen all personnel entering the MR environment for magnetic or conductive objects in, on, or attached to their bodies. Conduct the screening process in an area that is private for the patient to encourage them to disclose information that my otherwise be embarrassing in front of others (e.g., possessing a penile implant).

e. check the patient's medical records for implants and other devices that are contraindicated for MR scans

f. have patients don hospital-provided gowns, acceptable for the MR environment, and provide them with lockers for their belongings

g. use a hand-held magnet to screen objects on or accompanying patients and other items that need to be brought into the MR environment. Note that this has limited effectiveness; for example, ferromagnetic springs within a pillow have gone undetected with a hand-held magnet.

h. maintain a database of MR Safe and MR Conditional equipment (according to ASTM F2503-05) and label devices appropriately

i. if you buy a new MRI or upgrade an existing system, make sure the label of MR Conditional still applies

j. do not make assumptions about implants, devices, or equipment (e.g., sand bags that actually contain iron). **Err on the side of caution, assuming materials are not suitable for the MR environment unless they are proven to be so.** If you do not know if your implants, devices or equipment are MR Conditional, MR Safe, or MR Unsafe, you can take three steps:

    a. Read the technical information about the device or implant

    b. Call the manufacturer of the device or implant and obtain information regarding the suitability of the device in the MR environment in writing

    c. Call the manufacturer of the MR system

k. assume that blankets and clothes are hiding something missed during screening (e.g., oxygen cylinder, sandbag)

l. don't loop conductive leads or cables, don't allow cables to cross over one another, don't let cables touch the magnet bore and if possible, don't let cables touch the patient (other than where they have to)

m. place sensors and cables as far away as possible from RF coils and the magnet bore

n. remove all unnecessary conductors from inside the magnet bore

o. do not let the patient contact the magnet bore; provide insulation between the two if needed

p. periodically check sensor sites on unconscious patients for heating

q. don't inadvertently make the patient's tissue a loop (e.g., don't position the patient's hand so that a finger touches their thigh)

r. periodically check sedated patients for heating at sensor sites

s. conduct codes outside the MR environment (i.e., move the patient out of the MR scan room)

t. report not only serous incidents but also close calls to NCPS. Report serious incidents to FDA as well.

u. ensure cryogen vent systems are adequately designed, as minimum design requirements have been revised by some MR system suppliers, and inspect the cryogen vents at least annually

PURCHASING :

a. all items purchased for use in or near the MR environment should be suitable for your particular MR environment
b. use manufacturer-approved fiber optic, carbon fiber or graphite leads instead of conductive leads on medical devices
c. use manufacturer-approved large surface area, low impedance ECG electrodes
d. purchase sand bags that really contain sand and pillows without magnetic springs for use within or near the MR system
e. consider providing the patient with an alarm device suitable for the MR environment to alert staff

THE BOTTOM LINE

The MR environment presents many challenges for safety. Responsibility for hazard reduction and patient/provider protection is shared among FDA, manufacturer, radiology management, MRI technicians, nurses, transport personnel, patients, family members, and more. While it is impossible to eliminate risk in the MR environment, addressing the various components of hazard reduction - redesign, procedural, purchasing, and training - will work toward mitigation of the risks. Considering the actual costs of incidents, along with the financial and marketing costs of lawsuits, it relatively easy to make a case for MR safety.

REFERENCES

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2. ECRI Institute. What's new in MR safety. *Health Devices* 2005 Oct; 34(10):333-349.
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WEB RESOURCES

Flying Objects

Vivid examples of what can happen when you bring magnetic objects into the MR environment. Site provides several interesting pictures of chairs and oxygen cylinders that have been attracted to and pulled into MR systems.

MR Safety

The American College of Radiology's MR Safety web-page.

Preventing accidents and injuries in the MRI suite

The Joint Commission's Sentinel Event Alert on preventing accidents and injuries in the MRI suite (2008).

ACR Guidance Document for Safe MR Practices: 2007

The American College of Radiology's Guidance Document for MR Safe Practices (2007). Contains guidance on establishing and maintaining an MR safety program.

ECRI Institute

ECRI Guidance Article What's New in MR Safety" (2005) and "The Safe Use of Equipment in the Magnetic Resonance Environment" (2001). (Both articles require ECRI membership.)

Metal detector promises increased safety in MR suites

Diagnostic Imaging Online news article: Metal detector promises increased safety in MR suites (2004).

Patient Safety Alert – Magnetic Resonance Imaging Systems

National Center for Patient Safety's Patient Safety Alert discussing sandbags becoming projectiles in the MR environment (2001).

Patient Death Illustrates the importance of Adhering to Safety Precautions in Magnetic Resonance Environments

ECRI Institute free (no subscription required) Hazard article, "Patient Death Illustrates the Importance of Adhering to Safety Precautions in Magnetic Resonance Environments" outlining recommendations for preventing the projectile effect. (2001)

MRI Safety: Everyone's Job

Good example of RCA activities based upon an MR close call at a facility outside of VHA (2001).

A Primer on Medical Device Interations with Magnetic Resonance Imaging Systems

FDA's CDRH Magnetic Resonance Working Group report (1997): A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems