Mitigating Risks

Understanding the Risks → Reduce/Eliminate the Risks

July 2001

Roi, 8, died in MRI accident

By MELISSA KIRSCH AND OLIVIA TURCHIO

A boy who was killed in a hospital MRI accident in Queens County last July was a victim of equipment problems, not MRI's inherent risks.

The boy, Michael Israelovich, 8, of Wantagh, was about to undergo an MRI when a machine malfunctioned, causing the boy to be trapped between the machine's rotating parts. He died of head and neck injuries at Winthrop University Hospital in Mineola.

The hospital had conducted an internal investigation into the incident, but the results were never made public.

The hospital's reaction to the accident was slow and cautious, leading to a feeling among some that the hospital was trying to keep the incident under wraps.

The hospital's handling of the incident has drawn criticism from some, who say the hospital was slow to respond and did not do enough to prevent similar accidents in the future.

The hospital has since implemented new safety measures to prevent similar accidents from occurring again.

Health
It is estimated that less than 20% of incidents are reported. Between 2000 and 2013:
- MR utilization increased 114%.
- Reported incidents increased 487%.

“Show me another industry where the more we know about risks and the more we know about prevention, the worse we do in terms of protecting people from the known risks.”
- Emanuel Kanal, M.D.

ABMRS
American Board of Magnetic Resonance Safety

MR Safety Credentialing for:
- MR Medical Director (MRMD)
- MR Safety Officers (MRSO)
- MR Safety Experts (MRSE)

www.abmrs.org
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**Credentialing**

- The MRMD certification is designed for physicians, such as radiologists, who have responsibility for the safe administration of MR exams.
- The MRSO certification is designed for those with a supervisory MRI safety role at the point of care. While not exclusive to technologists, this role is most frequently filled by an MR technologist.
- The MRSE certification is designed for those in an expert, technical consulting role who may help determine the safety of complex conditions. While not exclusive to MR medical physicists, this role is most frequently filled by a medical physicist.

**Content**

- All three of the certifications share a common content syllabus, which can be found on the ABMRS website. Each of the three certifications will have different emphases for different topics, or knowledge domains, from that syllabus. At the current time, the ABMRS has not developed study materials beyond the content syllabus. The ABMRS does recommend familiarizing yourself with existing MR safety standards documents (e.g., the ACR Guidance Document on MR Safe Practices: 2013, and IEC 60601-2-33), and MR system manufacturer documentation.
- Other than best practice documents, regulatory structures, and MR system documentation, the ABMRS does not endorse any third party materials for exam preparation.
“Together with MR Site accreditation, the formation of the ABMRS now completes the logical extension of creating a system to certify not only the hardware, software, and siting of an MR scanner, but also the individuals who are formally organized for and charged with ensuring the safety of those who will be exposed to clinical and research magnetic resonance facilities.”

www.abmrs.org
What's the standard?
What's required?
Risk reduction strategies that allow maintenance and housekeeping personnel to enter the MRI suite

A recent study concludes that ferromagnetic detectors have 99 percent sensitivity. However, metal objects that are subject to heating, malfunction or failure during an MRI scan can cause false-positives and false-negatives.

The most common patient injuries in the MRI suite are burns. Burns are often caused by metal objects that are pulled into the MRI scanner at rapid velocity. "Missile effect" or "projectile" injuries can occur when ferromagnetic objects such as ink pens, metal clamps, and tattoo ink are drawn into the MRI scanner at high speed. More than 70 percent of the 389 reports were burns; 10 percent were projectile-related; another 10 percent were "other events, including implant disturbance; 4 percent were acoustic injuries; 4 percent were fire-related; and 2 percent were internal heating-related.

In 2005, Jason Launders, MSc, a medical physicist with the ECRI Institute, conducted an independent analysis of the FDA's MAUDE (Manufacturer and User Facility Device Experience Database) reporting database over a 10-year time span, which revealed 389 reports of MRI-related events, including nine deaths.

Five MRI-related cases in the Joint Commission's Sentinel Event database resulted in four deaths and affected four adults and one child. One case was caused by a projectile; three were cardiac events, and one was a misread MRI scan that resulted in delayed treatment.

While the capabilities of the MRI scanner are well-recognized, its inherent dangers may not be as well known. Adverse events related to the administration of MRI contrast agents can occur, including allergic reactions, anaphylaxis, and anaphylactic shock. Acoustic injury from the loud knocking noise that the MRI scanner makes can be another risk.

Injury or complication due to failure to attend to patient support systems during the MRI is especially true for patient sedation or anesthesia in MRI arenas. For example, oxygen canisters or infusion pumps run out and staff must either leave the MRI area to retrieve a replacement or move the patient to an area where a replacement can be found.
### Joint Commission Checklist

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<td>47</td>
<td>Data is collected on incidents where patient motion or other complications occurred, including the presence of foreign objects in the MRI scanner.</td>
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Terminology

- Safety Zones
- Personnel
  - MR Personnel
    - Level 1
    - Level 2
  - MR Medical Director
  - MR Safety Officer
- Non-MR Personnel

Zones and Access Restrictions

MRI Functional Diagram
Personnel Designation

Level 1

Those who have passed minimal safety educational efforts to ensure their own safety as they work within Zone III
Level 1 MR personnel are not permitted to directly admit, or be designated responsible for, non-MR personnel in Zone IV.

Personnel Designation

Level 2

Those who have been more extensively trained and educated in the broader aspects of MR safety issues, including, for example, issues related to the potential for thermal loading or burns and direct neuromuscular excitation from rapidly changing gradients.

Personnel Designation

Level 2

It is the responsibility of the MR medical director not only to identify the necessary training, but also to identify those individuals who qualify as level 2 MR personnel.
Personnel Designation

Level 2: MR Medical Director

It is understood that the medical director will have the necessary education and experience in MR safety to qualify as level 2 MR personnel.

Personnel Designation

Non-MR Personnel

Non-MR personnel will be the terminology used to refer to any individual or group who has not within the previous 12 months undergone the designated formal training in MR safety issues defined by the MR safety director of that installation.

Secured Access

Zone III regions should be physically restricted from general public access by, for example, key locks, passkey locking systems, or any other reliable, physically restricting method that can differentiate between MR personnel and non-MR personnel.
Secured Access

Only MR personnel shall be provided free access, such as the access keys or passkeys, to Zone III.

There should be **no exceptions** to this guideline. Specifically, this includes hospital or site administration, physician, security, and other non-MR personnel.

Secured Access

Non-MR personnel should be accompanied by, or under the immediate supervision of, and in visual or verbal contact with, one specifically identified level 2 MR person for the entirety of their duration within Zone III or IV restricted regions.
A respiratory therapist was wheeling around a ventilator to the 'backside' of a magnet. It was known that the vent was supposed to stay a minimum distance away from the magnet, but as the respiratory tech was looking for an outlet to plug the vent in, their focus was not on where the vent was rolling around within the room.

This was not a small hospital. This was not a hospital that doesn't have a serious focus on MR safety issues. This was a hospital where the restrictions (conditions) of use for a device were not followed, which could be any site, really.

**Controlled Access**
- Surgery
- Intensive Care Units
- Hot Lab
- MRI

**Why?**

**Controlled Access**
- Surgery
- Intensive Care Units
- Hot Lab
- MRI

**Why Not?**
Who is responsible for the safe execution of an MRI procedure?

It HAS been well defined in court

It’s the radiologist / MR Medical Director

"Captain-of-the-Ship"

Captain-of-the-Ship Doctrine is a principle of medical-malpractice law, holding a surgeon liable for the actions of assistants who are under the surgeon's control but who are employees of the hospital, not the surgeon. The surgeon as "the captain of the ship," is directly responsible for an alleged error or act of alleged negligence because he or she controls and directs the actions of those in assistance.
Who is the captain of this ship?

The Radiologist