MRI Safety: Prepare for New Guidance

Tobias Gilk, MRSO (MRSC™), MRSE (MRSC™)

For more than two decades, the American College of Radiology (ACR) has offered a collection of guidance documents outlining a number of best practices to maximize safety in hospital-based and freestanding MRI facilities.

These documents are poised to receive significant expansion under an effort to update the ACR's 2020 "Manual on MR Safety."[1] Public comment on the proposed changes is now closed, but if implemented in its entirety, the 135-page document will include a wide range of additions.[1] These include:

- An introduction to the risks of MRI;
- Expanded information on MRI safety management policies and procedures;
- Recommendations of minimum training criteria for Level 1 and Level 2 safety training;
- An initial safety framework particular to remote-scanning environments;
- Significantly expanded content on risk identification, assessment, and mitigation;
- Guidance for physiologic monitoring of patients;
- Guidance on emergency response practices;
- Discussion of "alternative MRI environments," including PET/MR, MR-guided Linac devices, and point-of-care systems; and,
- New appendices with checklists for site policies, spatial field gradient data, and conducting risk assessments of implanted devices.

Additionally, the draft document has been organized into chapters to allow for easier navigation, and a number of figures and illustrations have been added to provide examples of risks, harms, and best practices.

One of the most important improvements to the document lies in explaining the 'why' of MRI risks and not just enumerating the tasks that prevent them. This expansion of scope consists of a description of risks throughout the document, including the new appendix dedicated to conducting MRI risk assessments. These changes alone represent a shift in the ACR's intent to transform the document from an "instruction manual" to more of a "teaching tool."

Since implementing its original MRI safety guidance in 2002, the ACR has long advocated for two distinct levels of training but had not—prior to this draft publication—provided any specific guidance on what each of those levels should contain. Until now, the details of training content and implementation has been determined by the supervising radiologist.

The proposed draft also addresses remote scanning, which is perhaps the most contentious of MRI safety issues. Virtually all contemporary MRI safety guidance (including the ACR's) is predicated on the notion that the technologist performing the exam is physically present at the point-of-care. Increasingly, however, and similar to how radiologists have had the ability to read electronic studies remotely, new software options from many of the leading MRI manufacturers now allow the operating MRI technologist to be in an entirely different location from where the images are being acquired. With the MRI technologist located remotely (sometimes controlling two or more remote MRI scanners simultaneously), standards of point-of-care workflow and responsibilities have not yet been clearly defined.

The new section on remote scanning seeks to lay out an alternative path for remote scanning safety without entirely rewriting guidance for point-of-care scanning. One of the challenges, however, is the multiplicity of ways that remote scanning can be deployed (eg, technical, teaching, expert model, and full operation). At last year's RSNA meeting Siemens provided several presentations in their booth about how Advent Health, an integrated healthcare system headquartered in Florida, was deploying remote scanning.

Advent Health's use of remote scanning includes remote updating of scanner protocols and pulse sequences, "over-the-shoulder" training of remote technologists by senior MR technologists, remote expert scans (eg, a remote cardiac MR expert executing a specialty scan at a remote community hospital or imaging center), and full-shift coverage of remote MR facilities

Affiliation: Founder, Gilk Radiology Consultants, Overland Park, Kansas.

operation during unplanned technologist absences.

The sections of the proposed draft that cover remote scanning are largely dedicated to a discussion of staffing location, with comparatively little discussion devoted to how workflows, decision making, and communications would be required to change under remote scanning.

Owing to the shifting nature of MRI scanning hardware, the draft Manual also features a section on "alternative MR environments." From portable devices like the Hyperfine Swoop, to dedicated neonatal systems like the Aspect Embrace, to MR-Linacs designed to be retrofitted into existing radiation therapy bunkers, MRI scanners are now found throughout many areas of the hospital besides the radiology department. This necessitates alternative sets of standards as well as careful integration of MRI safety practices within the area(s) where the MRI scanner is operating.

As of this writing the ACR has not offered an anticipated release date for the final document; it is expected to take quite some time for the ACR to consider and decide what additions and/or deletions to make prior to publication. Ultimately, however, the next edition of the ACR Manual on MR Safety can likely be expected to continue defining the standard of care with respect to MR imaging performance and safety.

Reference

1) Watson R, Altman D, Dillman J, et al. Draft ACR Manual on MR Safety. American College of Radiology. 2023.

Commentary: Safety Guidance Requires Minimum Standards

Tobias Gilk, MRSO (MRSC™), MRSE (MRSC™)

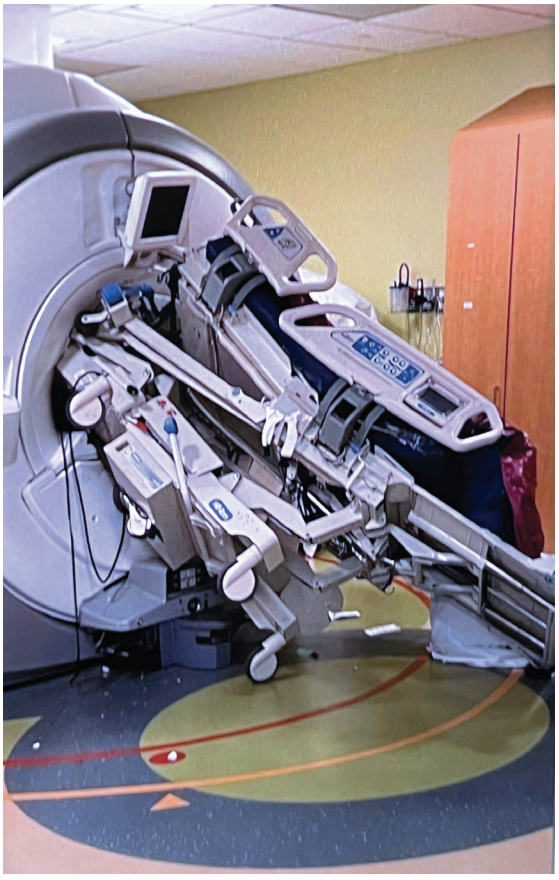


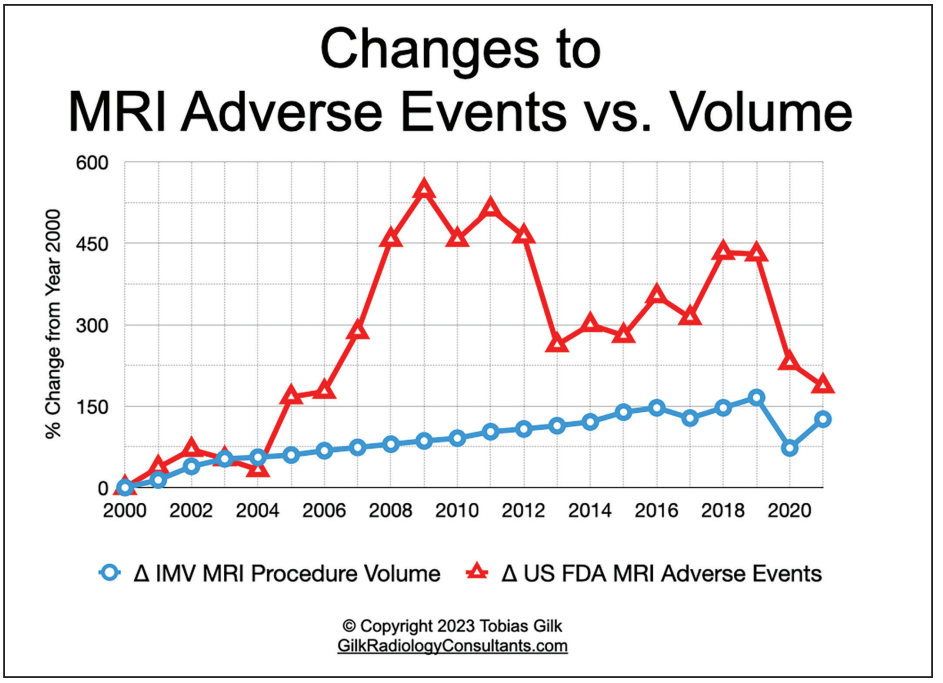
Figure. A nurse at Redwood City Hospital in Redwood City, California, became trapped and seriously injured when an ICU bed was accidentally wheeled into the facility's MRI suite. The ICU patient on the bed at the time was unharmed. *Photo appears in the State of California Department of Industrial Relations Citation and Notification of Penalty Inspection Report (#1654644).*

Earlier this year, a nurse at Redwood City Hospital in Redwood City, California, was seriously injured after becoming pinned between an MRI scanner and a hospital bed that had been wheeled into the MRI scanner room (Figure).

The CMS-2567 "Statement of Deficiencies/ Plan of Corrections"[1] and the Cal/OSHA inspection report have already uncovered a number of gaps between site practice and best practice guidance.[2] These include:

- Indications of an apparent misunderstanding of which radiologist(s) were serving as the site's medical director for MRI safety at the time;
- The designated MR Safety Officer was a radiologist and, given standard workload models for radiologists, that person may not have been capable of ensuring application of site policy at the point of care;
- The intensive care unit nurse was said to be Level 2 MRI safety trained (equivalent to the training level of an MRI technologist), despite having been to the MRI suite only once prior to the accident;
- The site used the same materials for Level 1 and Level 2 MRI safety training; ie, there was no difference in content between the two;
- The MRI suite layout did not comply with the ACR 4-zone criteria although it apparently did meet the criteria for the hospital's Joint Commission accreditation; and,
- The department's contracted medical physicist completed the ACR MRI Safety Program Assessment Checklist and gave the site "perfect marks" for safety, even though the hospital did not maintain ACR MRI accreditation.

Table. Percentage change in US MRI procedure volume (in blue) shown with percentage change in US FDA MRI-classified adverse events (in red). Statistical analysis shows MRI adverse events growing at nearly 3x the rate of MRI procedure volume growth.



All of which raises the question: Why do serious but preventable MRI accidents continue to occur, even as our collective wisdom about MRI safety has grown over the past 20 years?

Institutional accreditation organizations are expected to assure the public of the quality and safety of healthcare delivery from any given accredited facility. It is that dual promise that is the central point of nearly all accreditation marketing to both healthcare organizations and the public that they serve. However, are accreditation organizations' promises of safety met with corresponding minimum standards to prevent MRI injuries?

In a word, no.

The number of MRI accidents reported to the US Food and Drug Administration over the past two decades has been growing nearly three times as fast as MRI procedure volume (Table). Paradoxically, the more safety guidance that becomes available, the less safe that MRI procedures seem to grow.

An analysis presented at the 2012 RSNA meeting[3] looked at injury prevention best practices for burns, projectiles, and hearing damage. Accident report narratives were tested against each best practice. The analysis indicated that three existing best practices for burn prevention could have prevented 97% of MRI-related burns; three measures for safety from projectiles could have prevented 94% of projectile-related injuries; and one best practice for hearing protection could have prevented 29% of the hearing-related injuries. In aggregate, the study found that these seven practices could likely have prevented 84% of the MRI injury incidents.

Today, more than a decade since that analysis, these best practices remain nearly entirely absent from licensure or accreditation standards for MRI providers. As a result, MRI providers are free to act as they see fit in ensuring the safety of their staff and patients. To be sure, many MRI providers do adhere to accepted best practices, such as those put forth by the ACR. However, there remains no "gold seal" to inform patients whether a given site is among them.

Given this current state of affairs, expecting meaningful reductions in the rates of adverse events in MRI suites may be unrealistic. If, as the saying goes, the "chain is only as strong as its weakest link," the proliferation of safety guidance will have minimal impact on the prevention of MRI-related accidents unless it is accompanied by the establishment, and enforcement, of minimum practice standards.

References

1) CMS-2567 Statement of Deficiencies Plan of Correction Survey Report. US Department of Health and Human Services Centers for Medicare & Medicaid Services. completion date: March 17, 2023.

2) Cal/OSHA Inspection Report #027-23. Aug.7, 2023.

3) Gilk T, Kanal E. MRI accidents and adverse events: empirical analysis of frequency, type, severity, trends and preventions. Presented at The Radiological Society of North America Scientific Exhibition and Annual Meeting, Chicago, Illinois. Nov. 27, 2012.