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# MRI Safety: Professionals, Practice, Credentialing

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"The safe modality." That's what MRI is frequently referred to as. In a profession (and larger populace) focused on ionising radiation risks, MRI's exclusive use of non-ionising magnetic fields and radiofrequency energies makes it an appealing alternative to many x-ray based imaging modalities, particularly for young and repeating imaging patients. However, the absence of ionising radiation in MRI does not equate to an absence of risks to patients (or radiographers).

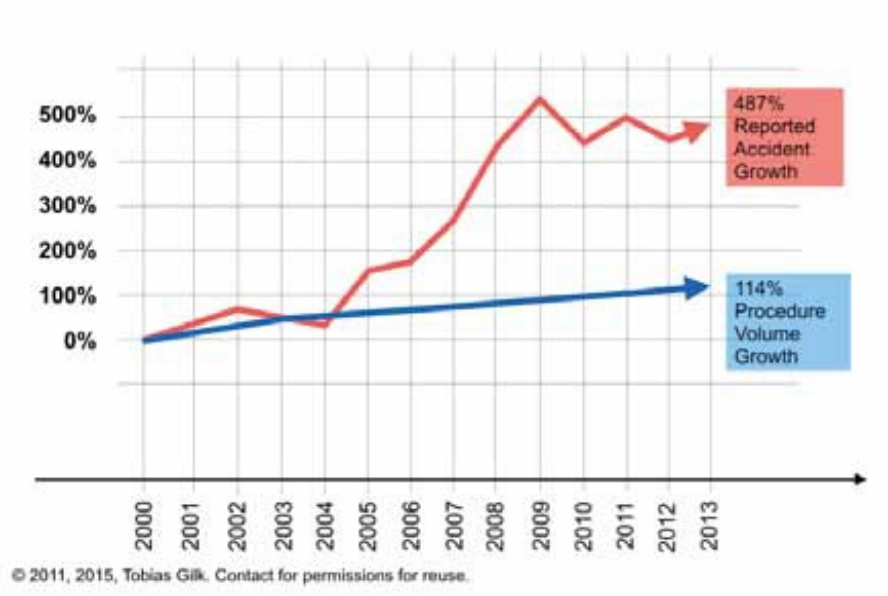
## MRI Adverse Events

As anyone who has worked in MRI for any length of time can tell you, there is no shortage of anecdotes about MRI accidents or injuries: from cryogens, magnetically-induced projectiles, or burns. There do appear to be a small number of touchstone anecdotes, such as the oxygen tank fatality of a young boy in the U.S. in 2001, or much more recently the four-hour entrapment of two hospital employees in India (again, involving another ferrous oxygen tank), but other accident accounts are often dismissed or diminished as oral tradition legends, embellished for the retelling. The lack of knowledge of the actual risks of MRI, and the diminution of the validity of retold accounts of accidents, stem from a lack of data about MRI accidents.

Regulatory accident reporting regimes are frequently based on the notion that approved radiological devices are only able to cause harm if the device malfunctions, or is improperly administered during the exam. For MRI, however, the risks of projectiles, burns, or hearing damage are inherent to the proper operation of the MR scanner equipment. Does a flying ferromagnetic projectile represent a malfunction when the MR scanner's magnetic field is designed to be 'always on'? Widely acknowledged to be profoundly under-representative of the actual number of MRI accidents and injuries, regulatory reporting remains our best resource for assessing the effectiveness of safe MR practices.

Perhaps the most accessible adverse event data for MRI comes from the U.S. Food and Drug Administration (FDA). TheFDA makes their reported approved-devicerelated incidents available online (**www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM**), and a year-overyear review of MRI accident data suggests that, over a 13-year period, MRI accident rates in the U.S. have

plateaued at a rate that has grown nearly five times the rate for overall utilisation from the year 2000 (see Figure, p. 100).




While generalised MRI accident growth should be a cause for alarm in the industry, it is the nature of the specific accidents that reveals the keys to prevention.

With regard to accident prevention, MRI accidents and injuries reported in the United States are exceedingly rarely attributable to the MRI equipment malfunctioning. Like any machine, MRI systems do experience errors, breakage, or malfunction that can cause harm, but when looked at in the context of the total number of adverse events, it is clear that other aspects of bolstering MR safety will have more substantive positive effects on reducing accidents.

When evaluating two years of FDA MRI device injury accident reports, it was discovered t hat m ore t han 8 5% o fall reported injuries stemmed from RF burns, ferromagnetic projectiles, and hearing damage (**youtube.com/watch?v=ciMRYXhlzg** - recorded research presentation to 2012 RSNA Annual Meeting, entitled "MRI Accidents & Adverse Events: Empirical Analysis of Frequency, Type, Severity, Trends, and Preventions"). In the overwhelming majority of cases of injury studied from that two-year period, existing best practice standards guiding operations and patient care would have prevented the injury, had they only been followed. In short, the phenomenon of MRI injury accidents is one of "pilot error," and not equipment malfunction, that is responsible for the overwhelming majority of injuries in the MRI setting.

## Regulatory Background

Disturbingly, while there are established best practice guidance standards available for MRI that have provisions that can be shown to reduce accidents and injuries when followed, these standards have failed to be incorporated in many regulatory, licensure, or accreditation programmes for healthcare providers. In this instance, the moniker of "the safe modality" may have led governing boards and bodies to believe that requirements haven't been necessary to prevent MRI injury. After all, how could "the safe modality" possibly produce injuries?

Those regulations that do exist largely don't appear to be specifically shaped by the occurrence of injury accidents that continue to happen. Take, as an illustration, the single most substantial piece of MRI safety regulation to have been proposed anywhere in the world in the past decade, the EU's Physical Agents (EMF) Directive.

## EU Physical Agents (EMF) Directive

The Physical Agents (EMF) Directive, while not targeted specifically towards MRI, purported to be safety legislation intended to diminish occupational exposure to non-ionising radiation. The effects of the EMF Directive on MRI, as originally proposed, would have been to substantially curtail the allowable working hours of MR radiographers, radically shifting the cost structure of providing MR services.

It was later revealed that the EMF portions of the Directive were not based on acute health risks, as

originally stated, but rather were intended to be precautionary, based on small studies that weren't immediately relevant to the conditions found in clinical MRI. During the effort to postpone (and ultimately obtain an exemption for MRI from) the implementation of the EMF Directive, nearly a decade passed where the only regulatory effort of the EU purportedly on behalf of MR safety required the concerted effort of medical physicists, trade organisations, and healthcare providers themselves, to beat back serviceimpairing regulation. In short, fighting the EMF Directive stole nearly a decade of resources that might otherwise have been directed at the actual sources of MRI injury.

## Accreditation

Accreditation regimes promote themselves as being overseers of both quality and safety, but the "safety" half of this promise is often not met for MRI. In the U.S., where accrediting agencies compete for healthcare providers' business, there are inherent disincentives to enacting new unilateral requirements (and thereby making competing accreditation organisations appear 'less onerous'). This is further complicated when an accreditation organisation simultaneously serves as a professional society for radiologists who have ownership interests in imaging facilities, equipment, and practices. The standards of practice described in the four-times published American College of Radiology's guidance Document on MR Safe Practices (Expert Panel on MR Safety 2013) are not (as of the date of this publication) requirements of the ACR's own MR accreditation programme.

## Prevention, Professionals and Credentialing

So, if one were to specifically target the source(s) of contemporary MRI accidents and injuries in order to better prevent them, where would one focus their efforts? Western MRI equipment is already profoundly reliable, and existing means of oversight of a healthcare enterprise or the image quality of a piece of MRI equipment neither seem effective nor practical routes towards enhancing safety, given the inherent conflicts of interest. If MR accidents and injuries could be prevented with existing best practices, and are - nearly universally - the result of lapses at the point of care, perhaps the focus on reducing MRI accidents should be directed to the MR professionals directly responsible for patient care.

Individually, and in groups, organisations within the MRI industry have begun by seeking to standardise definitions of the specific MR safety duties and knowledge attributed to radiologists, researchers, radiographers, and medical physicists responsible for the safety of patients or research subjects. The Medicines and Healthcare Products Regulatory Agency (MHRA), the Society of Radiographers (SOR), the British Association of MR Radiographers (BAMRR), and the Institute of Physics and Engineering in Medicine (IPEM) individually sought to codify these roles and responsibilities, with some agreement, but also significant conflicts, among their preliminary standards.

While international efforts are presently afoot to reconcile the different nomenclature and standards defining MR safety roles, the recently formed nonprofit American Board of Magnetic Resonance Safety (ABMRS), which was formed for the specific purpose of credentialing MR professionals in matters of safety, is both participating in the international effort, and already looking beyond it to what can be done with standardised MR safety roles.

While standardised definitions and roles will go a long way to shaping the future structure of MRI safety, unified terminology itself won't improve safety at the point of care. ABMRS seeks to turn these shared positions into actionable standards. Within a few months, ABMRS intends to begin a credentialing process, certifying MR safety professionals.

The ABMRS MR Safety Certified™ (MRSC™) credential will demonstrate a diplomate's competency within a range of MR safety topics, and to levels commensurate with his/her role in responsibility for safety at the point of care. The organisation has published a syllabus/outline of the subject areas that will be subject to examination (**http://abmrs.org/Syllabus.php**). The exams are slated to present a mixture of didactic and scenario-based questions, intended to test a candidate's mastery of the science underpinning MR safety considerations, as well as their ability to translate scientific information into practical application.

This year, ABMRS will offer MR Safety Certified™ credentialing for three positions: MR Medical Director/Physician (MRMD), MR Safety Officer (MRSO) and MR Safety Expert (MRSE).

The MR Medical Director will be the only position with a prior credential requirement. Candidates for the MRMD exam must have, at the time of examination, either an MD or DO. This is due to the particular fiduciary and legal obligations specific to the physician's duty to the MR patient.

The MRSO and MRSE credentials will have no prior credential requirement. The MRSO examination will focus more on the specific application of MR safety knowledge in a direct patient care setting, and will be closely aligned with the responsibilities of an MR radiographer. The MRSE credential will weigh more heavily on the scientific aspects of MR safety, such as the physics of RF heating, and will be more aligned with the responsibilities of a consulting MR physicist.

ABMRS is planning to administer the exam twice this year, both times in the U.S., but the organisation's Board is already discussing the establishment of an international body. Dr. Emanuel Kanal, President of ABMRS, asked the nearly 300 attendees at a recent MR safety seminar in Sydney, Australia, about their personal interest in accreditation, and nearly every attendee indicated that they would seek it out, if available. Even should the formation of an international version of ABMRS take time to establish, discussions are already underway about offering the ABMRS credentialing exams outside the U.S.

It is the stated goal of the new organisation that every MR patient's exam should have the benefit of an MRSO overseeing the unit's delivery of care, an MRMD setting the policies and standards for clinical MR safety, and an MRSE to serve as a reference to both the MRSO and MRMD.

It is expected that providers of MRI services will begin to train and credential radiologists, lead researchers, radiographers, and medical physicists to help assure the appropriate knowledge assets are applied to enhancing safety in the MRI environment.

Based on what we know of the causes and preventions of MRI accidents, MRI is certainly capable of living up to its moniker of "the safe modality." We know that it is entirely possible to prevent the overwhelming majority of MRI injury accidents with existing best practice knowledge. The twin efforts of developing an international consensus on MRI safety roles and responsibilities, and credentialing those who fill those roles, offer the promise of even safer MR imaging in the years ahead.

**Further Information**

American Board of Magnetic Resonance Safety **http://abmrs.org**

**Key Points**

- While generalised MRI accident growth should be a cause for alarm in the industry, it is the nature of the specific accidents that reveals the keys to prevention.
- More than 85% of all reported injuries stemmed from RF burns, ferromagnetic projectiles, and hearing damage. the phenomenon of MRI injury accidents is one of "pilot error" and not equipment malfunction.
- Established best practice guidance standards for MRI have provisions that are shown to reduce accidents and injuries when followed, but these standards have failed to be incorporated in many regulatory, licensure, or accreditation programmes for healthcare providers.
- the recently formed nonprofit American Board of Magnetic Resonance Safety (ABMRS) has been formed for the specific purpose of credentialing MR professionals in matters of safety.

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