MR Safety in Clinical Practice

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www.t2star.com/faulkner/MRSO_CourseMaterial

Which environment is safer?

1999: Institute of Medicine
up to 98,000 deaths annually
due to mistakes in hospitals

2010: Office of Inspector General (HHS)
180,000 patients in Medicare
alone in a given year
210,000 - 440,000 Annually

3rd leading cause of death

“Asked about the higher estimates, a spokesman for the American Hospital Association said the group has more confidence in the IOM’s estimate of 98,000 deaths”

Mitigating Risks

Is there any difference in expectations?

Reduce/Eliminate the Risks

Understanding the Risks
July 2001

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.

MRI adverse events

<table>
<thead>
<tr>
<th>Year</th>
<th>Reports</th>
<th>Accident % change from 2000</th>
<th>Procedure numbers</th>
<th>Utilization % change from 2000</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>31</td>
<td>0%</td>
<td>15.8</td>
<td>-</td>
</tr>
<tr>
<td>2001</td>
<td>40</td>
<td>29%</td>
<td>18</td>
<td>14%</td>
</tr>
<tr>
<td>2002</td>
<td>55</td>
<td>77%</td>
<td>21.9</td>
<td>39%</td>
</tr>
<tr>
<td>2003</td>
<td>46</td>
<td>48%</td>
<td>24.2</td>
<td>53%</td>
</tr>
<tr>
<td>2004</td>
<td>40</td>
<td>29%</td>
<td>24.7</td>
<td>56%</td>
</tr>
<tr>
<td>2005</td>
<td>80</td>
<td>158%</td>
<td>25.3</td>
<td>60%</td>
</tr>
<tr>
<td>2006</td>
<td>83</td>
<td>168%</td>
<td>26.6</td>
<td>68%</td>
</tr>
<tr>
<td>2007</td>
<td>116</td>
<td>274%</td>
<td>27.5</td>
<td>74%</td>
</tr>
<tr>
<td>2008</td>
<td>167</td>
<td>439%</td>
<td>28.4</td>
<td>80%</td>
</tr>
<tr>
<td>2009</td>
<td>164</td>
<td>836%</td>
<td>39.3</td>
<td>86%</td>
</tr>
<tr>
<td>2010</td>
<td>169</td>
<td>445%</td>
<td>30.2</td>
<td>91%</td>
</tr>
<tr>
<td>2011</td>
<td>186</td>
<td>500%</td>
<td>32</td>
<td>103%</td>
</tr>
<tr>
<td>2012</td>
<td>169</td>
<td>445%</td>
<td>32.9</td>
<td>108%</td>
</tr>
<tr>
<td>2013</td>
<td>182</td>
<td>487%</td>
<td>33.8</td>
<td>114%</td>
</tr>
</tbody>
</table>

| MAUDE data retrieved October 11, 2011 |
| MAUDE data retrieved October 8, 2014 |
| IMV Medical Information Division. Numbers in millions.

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
Founding Board Members

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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
Safety Incident at Your Facility

**Terminology**

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

**Zones and Access Restrictions**
Personnel Designation

Level 1

Those who have passed minimal safety educational efforts to ensure their own safety as they work within Zone III.

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.

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.

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.

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.

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

Level 1 MR personnel are not permitted to directly admit, or be designated responsible for, non-MR personnel in Zone IV.

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.
Secured Access

Non-MR personnel are not to be provided with independent Zone III access until such time as they undergo the proper education and training to become MR personnel themselves.

Training

- Level 1
- Level 2

Annual
Access tied to training

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