MAGNETIC RESONANCE IMAGING ENVIRONMENTAL SAFETY IN ONTARIO

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INTRODUCTION

Magnetic resonance imaging (MRI) scanners are powerful diagnostic tools in modern medicine. In addition, there is no exposure to ionizing radiation, making this imaging modality highly attractive. As a result, the number of MRI installations is growing steadily, with 58 units in use in hospitals and private facilities in Ontario in 2005 [1]. However, MRI scanners have high static magnetic and radiofrequency electromagnetic fields, which can be extremely hazardous to patients and staff if they are not managed effectively. Recognizing this, the Ontario Health Technology Advisory Committee (OHTAC) instructed the Healthcare Human Factors Team at the Centre for Global eHealth Innovation to conduct a study of these environmental safety issues and make recommendations to optimize safety.

METHODOLOGY

A literature review was conducted, examining reported incidents, standards, safety guidelines and recommendations. This was complemented by a field study, to assess the level of safety at various MRI facilities throughout the province, including teaching hospitals, research facilities, community hospitals and private, provincially-insured facilities. A standard list of questions provided insight into the degree of variation between sites, and helped to guide recommendations on best practice.

LITERATURE REVIEW

Reported Incidents

The US Food and Drugs Administration's (FDA) Manufacturer and User Facility Device Experience (MAUDE) database provides valuable and comprehensive information on adverse events related to medical device technologies. In an audio conference on MRI safety in September, 2005, Jason Launders of ECRI presented an analysis of the contents of the MAUDE database on this topic from 1995 to May, 2005 [2]. He found a total of 389 reports, including nine reported deaths and 302 incidents attributable to MRI technology. Of the MRI injuries, 70% involved radiofrequency induced burns (coils, leads connected to monitoring equipment, or body loops), 10% involved other items (e.g., implants), 10% were caused by projectiles (ferrous materials drawn towards the scanner magnet), 4% were acoustic injury (e.g., temporary hearing loss), 4% were fire-related injuries, and 2% were caused by internal heating (implanted leads). In the opinion of Dr. Emanuel Kanal, a US-based MRI expert and Chair of the American College of Radiology Blue Ribbon Panel on MR Safety, the percentage of MRI incidents reported to the FDA is well below 10% [3], and so the actual number are far higher than these. Nevertheless, the MAUDE data give us a useful guide to the types of injuries and hazards in an MRI environment.

Standards

In 1997, the FDA defined two terms for categorizing risks that devices pose in an MRI environment [4]:

MR Safe - "The device, when used in the MR environment, has been demonstrated to present no additional risk to the patient, but may affect the quality of diagnostic information".

MR Compatible – "The device, when used in the MR environment, is MR safe and has been demonstrated to neither significantly affect the quality of the diagnostic information nor have its operations affected by the MR device".

While it was helpful to have definitions applied to MR safety, it was found that these terms were often used interchangeably or incorrectly, and so in 2005, the ASTM International issued a Standard Practice document [5] which defines the following three categories:

MR Safe – "An item that poses no known hazards in all MR environments" (e.g., a plastic Petri dish).

MR Conditional – "An item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Field conditions that define the specified MR environment include field strength, spatial gradient, dB/dt (time rate of change of the magnetic field), radiofrequency fields, and specific absorption rate. Additional conditions, including specific configurations of the item, may be required" (e.g., a patient monitor).

MR Unsafe – "An item that is known to pose hazards in all MR environments" (e.g., a floor buffer).

These terms have clarified the categorization of devices with regard to MR safety, and hopefully they will be adopted clinically.

Alerts, Guidelines and Recommendations

Health Canada has published safety alerts related to MRI systems through its Health Products and Food Branch, covering issues such as thermal burns with transdermal drug patches and the risks of conducting MR scans on patients with active implantable devices [6].

The American College of Radiology published White Papers on MR Safety under the chairmanship of Dr. Kanal in 2002 and 2004. At the time of writing, a further revision is anticipated. These recommendations have been widely adopted by a number of groups, including the Canadian Association of Radiologists, and form a very useful body of knowledge on this topic [7].

FIELD STUDY

Based on an analysis of the information contained in the literature, a field study questionnaire was designed, targeting key issues raised in the review. This questionnaire was completed by twelve facilities; eleven hospitals and one private MR clinic, representing approximately 25% of the facilities in Ontario that have MR scanners. The results of this field study are shown in the Table below.

Field Study Results

Inquiry	Yes	No	Explanation
Do sites have an MR Safety Officer?	0	12	No sites have appointed an MR Safety Officer
Do sites use the 1997 FDA MR equipment categorization?	12	0	All sites use MR compatible equipment
Do sites use the 2005 FDA/ASTM MR equipment categorization?	0	12	No sites had heard of this updated categorization
Do sites follow the 4-zone MR environment architecture	6	6	MR environment architecture was dependent on the configuration of the space allotted
Does the magnet room door (to Zone-4) swing outward?	0	12	All doors to Zone 4 swing inward
Do sites mark the 5 Gauss line on the floor of Zone 4?	8	4	Not all sites with 5 Gauss line have it marked permanently

Do sites have a location in Zone 4 for MR Conditional equipment?	3	9	Tables, poles and floor markings used to indicate the location for MR Conditional equipment
How many sites reported accidental projectiles in the MR suite?	2	10	Patient monitors, sand bag, ventilator
Do sites use MR safety labels on all MR equipment?	5	7	Different types of labels are used, depending on the site and the equipment
Do sites use multiple MR safety signs?	9	3	Different signs used depending on the MR site and the brand of scanner
Do sites require outpatients to change into gowns?	3	9	Patients are often scanned in their own clothing
How many sites reported patient burns while scanning?	2	10	Burns from conductive material in clothing, tattoos, body parts forming loops
Do sites use metal detectors?	0	12	Metal detectors cause too many false positives
Do sites use ferromagnetic detectors?	0	12	Ferromagnetic detectors are very new, untested technology, not widely available
Do sites offer safety training for staff?	12	0	All sites provide a one-time in-service

These results show some areas of consistency but other areas of divergent practice, and sometimes the area of consistency is out of step with current practice, e.g., the use of the 2005 ASTM MR equipment categories.

CONCLUSIONS & RECOMMENDATIONS

Following the analysis of the field study results, a report was prepared for OHTAC with a series of recommendations. Recognizing that this topic is constantly evolving as technologies such as high field strength magnets become available, and the use of interventional MRI increases, the primary recommendation was for the establishment of a provincial MRI Safety Committee, to maintain consistent up-to-date practices across the province. Specific recommendations for the Committee were as follows:

- Use the updated MRI categorization; MR Safe, Conditional and Unsafe
- Strictly control access to the MR environment
- Clearly indicate the 5G perimeter on the floor surrounding the scanner
- Assign a permanent location for equipment in the magnet room
- Use consistent MR labels on equipment used in the MR environment
- Use consistent MR signs that clearly indicate the hazards of the MR environment
- Require outpatients undergoing MR scans to change into hospital gowns without metal fasteners
- Provide annual training for personnel working in the MR environment

The full report was presented to OHTAC in June, 2006, and the committee accepted the report without modification. The report was then forwarded to the Ministry of Health and Long-Term Care, and was cleared for general release after 60 days. The full text of the report can be found at: www.ehealthinnovation.org/MOH-Publications

Following the release of this report and another report conducted by our team on CT radiation dose levels, the Ministry established a Diagnostic Imaging Safety Committee to consider both reports and make recommendations for follow-up back to the Minister. At the time of writing, this committee is finalizing its work and preparing to report. An update will be given at the conference presentation.

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