Magnetic resonance imaging (MRI) scanners have revolutionized patient care. However, these machines also pose significant threats to patient safety. Although the hazards of MRI scanners have been known and variously reported for some time, it was only recently, in the wake of a catastrophic incident, that MRI safety received national attention in both the lay press [1-3] and the medical community [4]. After this incident, the ACR convened a “blue-ribbon commission” to assess the state of the art in MRI safety and issue a policy statement on the subject. That statement was published as the ACR White Paper on MR Safety [5]. The white paper is a comprehensive description of overall safety concerns and sets out generic guidelines for safe practice in the MRI environment. The present report details the practical implementation of safe MRI practice guidelines, site design, and a comprehensive program of preemptive quality assurance that is in place at Montefiore Medical Center (MMC) in New York City, a large university hospital and regional health care network. This program has been in place for just over 3 years. Specifics of medical device safety are outside the scope of this report and will not be addressed in detail.

The entire MMC health care network operates under a single MRI safety program. The implementation, execution, and monitoring of safe MRI practice are unified across the entire health care enterprise under the auspices of the Department of Radiology. Magnetic resonance imaging facilities at MMC include four 1.5-T scanners, a 3.0-T scanner, and a 0.3-T open scanner. This equipment is sited across 2 inpatient hospitals and three outpatient imaging centers that are near, but physically separate from, the hospitals. A medical director for MRI services oversees MRI practice across the system, while designees at each site are responsible for the local execution of policies and follow-up. Physician staff members rotate between sites, but each site has its own technical, nursing, clerical, and administrative staffs. Quarterly meetings of all site MRI supervisors and the medical director are held to assess policy implementation, review policy issues and changes, and discuss incidents. The guidelines for safe MRI practice are codified in a written policy that is part of the Medical Center Policy and Procedure Manual and is available at all sites on the MMC Intranet. The written policy is updated as needed and also undergoes annual formal review.

Efforts to maintain a safe and efficient MRI practice are directed toward the following key areas: (1) restricted site access; (2) personnel training; (3) equipment restrictions; and (4) follow-up, monitoring, and quality assurance procedures. The safety policy is extensive and detailed. In addition, many physical modifications have been made to each MRI site to improve compliance with the policy. Ultimately, however, human beings form the
last and strongest defense against disaster. We continually emphasize that vigilance is the true cornerstone of our safe MRI practice, particularly the vigilance of the staff member in charge of an individual MRI site; the technologist on duty is vested with both the authority and responsibility for safe operation of the facility. His or her authority supersedes that of any non-MRI-trained individual and is vigorously supported by both departmental and medical center administration.

The implementation of this program involved the efforts of an array of individuals within the radiology department as well as key members of hospital administration, security, maintenance, and others. One administrative assistant was assigned to devote approximately 25% full-time equivalent to the MRI safety program. Significant direct costs were also incurred to modify the MRI sites. The approximate cost to secure a single MRI scanner suite (two access doors and one MRI scanner door lockbox) was $7,000. However, the centralized implementation of these security systems throughout MMC meant that the basic infrastructure and monitoring mechanisms were already in place. Clearly, the cost of implementing the security measures described below represents only a fraction of the potential human and legal costs of an MRI-related accident.

THE MRI FACILITY: ACCESS RESTRICTIONS

Each MRI facility is divided into 2 zones with restricted access:

- Zone I: areas with direct access to the doors of the MRI scanner room; and
- Zone II: the MRI scanner room itself.

As shown in Fig. 1, these designations are streamlined from those of the ACR’s White Paper to reduce complexity and closely parallel the personnel categories described below: Level I personnel and above are permitted in Zone I, but only Level II personnel are permitted in Zone II.

The MRI site is secured using automatically closing and locking doors at all points of entry to Zone I. All doors allowing entry to Zone I are equipped with electronic locking systems that are accessed using encoded cards at a card reader (Motorola, Inc., Schaumburg, Illinois) installed at each door. Because the shielded doors to the MRI scanner rooms (Zone II) cannot be fitted with electronic locks, the key to each door is kept within a lockbox mounted adjacent to the door. The key is secured to a retracting tether within the lockbox. Access to the lockboxes is also via encoded card readers and electronic locks. Magnetic resonance imaging personnel carry their own access cards, which are programmed to open only the doors they are cleared to access: Zone I doors for Level I personnel and Zone I and II doors for Level II personnel.

A unique advantage of the card reader system over keys is that it allows the centralized monitoring and control of all access points at one time. Each card is uniquely encoded so that when a door is accessed, a log is created permitting the identification of the individual opening the door at the time of an incident. Hospital security officers monitor door and lockbox status from a central location 24 hours a day, 365 days a year. They receive
alarms if doors are forced or propped or stuck open and respond to these occurrences. Absolutely no physical keys are distributed; access for each individual can be turned on, changed, or turned off at any time without a need to recapture previously issued keys. The unauthorized copying of keys is completely eliminated. In addition to training level, access is granted on the basis of work schedule; staff members working only during day hours do not have night access. Those working variable shifts or others, such as physician staff members, who may need access at any time are granted 24-hour access.

Emergency egress from within the MRI facility is enabled at all doors without the need for an access card. The doors are opened using motion sensors installed above the doors or clearly labeled release buttons. During a power failure, a failsafe system allows egress. In the event that emergent entry to the MRI facility is required from the outside, emergency release buttons are provided, clearly marked and under break-glass enclosures. This mechanism provides access for such emergency personnel as the hospital’s cardiac arrest team. Providing access cards to these personnel, who constantly rotate on and off service, would result in an excessive number of hospital staff members with access to the restricted MRI site. Emergency release buttons are provided at entry doors to Zone I as well as at the lockboxes for the Zone II doors. As a final safeguard, hospital security responds to the MRI facility in person whenever one of the emergency release buttons is used, and the release buttons are clearly marked for emergency use only.

PERSONNEL SCREENING AND TRAINING

Personnel are classified by the level of MRI safety training that they have completed. Individuals from various departments are trained according to the demands of their function within the MRI suite. Access to the MRI facility is limited accordingly. We have adopted a variation of the white paper classification of personnel as follows:

- Level 0: non-MRI personnel;
- Level I: low-level MRI safety training;
- Level II: high-level MRI safety training; and
- Level III: specially trained physicians empowered to make safety judgments not clearly addressed by the written MRI safety policy.

All MRI personnel undergo safety screening at the time of employment using the same instrument employed in patient screening. This is to determine if it is safe for a staff member to enter the magnetic field. Documentation of this time-of-employment screening is kept in each staff member’s personnel file, and staff members are instructed to inform their supervisors of any changes in health, injuries, or surgery that could alter...
dresses static magnetic

ion of the examination questions. Level I training ad-

zone II.

nel (Level 0) are screened every time they need to enter

enter the MRI site. Patients and other non-MRI person-

work in MRI no longer require screening each time they

their status. After screening, personnel found safe for

work in MRI no longer require screening each time they

enter the MRI site. Patients and other non-MRI person-

nel (Level 0) are screened every time they need to enter

Zone II.

Training involves a live or videotaped presentation

followed by a written examination and follow-up discus-

sion of the examination questions. Level I training ad-

resses static magnetic field hazards, particularly projec-

tile hazards, as well as patient screening and site access

restrictions. Level II training also addresses gradient and

radio-frequency magnetic field hazards, particularly burns, potentially hazardous devices, contrast agents, and

quench procedures. An updated training presentation is

prepared each year. The training incorporates any new

information and, each year, both reviews all safety issues

and focuses on a specific area in depth. The in-depth

training is varied from year to year to reinforce as many

issues as possible in depth. All personnel must attend a

training session and pass a new examination annually. A

sticker is affixed to the identification badge of staff mem-

bers when they successfully complete their training, al-

lowing the immediate differentiation of trained and un-

trained personnel. The stickers are dated and must be

replaced annually. Each year, access to the MRI site is

reassessed; only the access cards of personnel who have

renewed their training remain active.

Level 0 includes all individuals who do not require

access to MRI to perform their duties. This category

includes patients, visitors, and medical staff accompan-

ying patients. These individuals are never allowed access to

any restricted MRI area without chaperones with Level I

or higher training. They may not be left unsupervised

within restricted areas.

Level I includes staff members whose work requires

them to enter restricted areas but not to be directly in-

volved in patient scanning. This group is allowed unsu-

ervised access to Zone I only. Level I staff members

include clerical personnel, housekeeping, patient trans-

port, maintenance, and engineering staff members.

Level II includes all staff members directly involved in

patient scanning: physicians, technologists, nurses, and

MRI service personnel. This group is allowed access to

both Zones I and II. At MMC, a large number of young

children are imaged under sedation and general anesthe-

sia administered by anesthesiology physicians and staff.

To allow these anesthesiology staff members to work in

the MRI facility, including within the scanner room,

they undergo the same training as Level II MRI person-

nel. As a result, they do not require direct and constant

supervision when performing their work in the MRI

scanner suite.

The final class of MRI personnel, Level III, differs not

in their access to the MRI facility but in authority. Level

I and II personnel are expected to know and follow the

written MRI safety policy and, when it is unclear whether

a specific situation is safe, to escalate decision making to

a higher level. Level III is composed of a subset of the

attending radiologist staff trained and experienced to

make proper judgments in ambiguous situations. The

training of several staff members at this level ensures that

a Level III physician will always be available when such

an unclear case arises.

In the event of a spontaneous quench or if there is

cause to ramp down or quench the magnetic field, Level

III personnel are consulted whenever time permits; in

almost all cases, controlled ramp-down can be under-

taken. The deliberate quench of the magnet should be

undertaken only if a patient or other person is trapped by

an object against the scanner or in the event of a fire in the

scanner room and only when these situations cannot be

handled safely in a more conservative manner. All Level

II personnel (who must be present whenever the scanner

is in use) are trained to handle a spontaneous quench and
to initiate a deliberate quench.

THE MRI FACILITY: EQUIPMENT

The MRI safety policy excludes all ferromagnetic or

otherwise unsafe equipment from Zone II, but equipment

that is unsafe in Zone II is used within Zone I. Equipment

testing and labeling (Fig. 3) is used to prevent the

inadvertent transfer of unsafe equipment from Zone I to

Zone II. All equipment within Zone I must be labeled as

safe or unsafe. Equipment brought into Zone I first un-
dergoes in-house testing using a strong hand magnet

(http://www.mrimagnet.com). The hand magnet is

tested in house to ensure that it is at least 1000 gauss (0.1

T) in strength. Any object demonstrating even the slight-
est attraction to the test magnet is deemed unsafe and

labeled as such. Equipment with no attraction is labeled

as safe. Labels placed on unsafe equipment such as chairs,
crash carts, and defibrillators are made as large as possi-

ble, typically 8 by 10 inches. Multiple labels are applied
to each item so that it is clearly identifiable from all

directions. When standard laminated adhesive labels are

not appropriate or effective, rigid laminated signs or tags

are suspended from items (e.g., scissors or fabric covered

chairs) using heavy duty plastic cable ties. Monthly in-

spections are conducted at each site to identify any unla-

beled equipment and either test and label or remove it

from Zone I.

Additional precautions have been introduced to ex-

clude potentially hazardous equipment. Medical gases

are provided via direct plumbing. This includes oxygen

and vacuum and, at sites where general anesthesia is

provided, nitrous oxide and medical air. In general, gas

cylinders are prohibited in Zone I. If a cylinder is re-
quired, only MRI-safe gas cylinders are permitted within Zone I and are labeled MRI safe. Fire extinguishers within the MRI sites are all MRI safe. Magnetic resonance imaging safe models of basic medical equipment including stethoscope, sphygmomanometer, scissors, and flashlight, and at sites at which general anesthesia is provided, laryngoscope are provided to minimize the chance that unsafe equipment (even though it is clearly labeled as such) will be inadvertently brought into Zone II.

The MRI safety policy clearly indicates that in any medical emergency, a patient is removed from the MRI suite using the MRI-safe stretchers that are always at the ready and clearly labeled. No emergency equipment is brought in. Extensive signage in the MRI suite and on the crash cart and other emergency equipment reinforces this key policy. During an emergency, the technologist on duty is in charge of and dedicated to ensuring safety.

FOLLOW-UP AND MONITORING PROCEDURES

Even the best designed safety program is effective only if it is actually adhered to in practice. In addition to extensive training, we have implemented a comprehensive and proactive program of quality assurance and improvement. Staff members and supervisors are instructed to report any deviations from the MRI safety policy or untoward events that they are involved in or witness. Reporting is not limited to “adverse events” but also captures deviations from the policy that do not lead to personal injury or property damage. For example, doors found open, screening forms found incomplete, and patients referred for MRI who have pacemakers—even though identified during screening—are all included. The demographics of each occurrence, including patient information, MRI staff members involved, and referring clinicians, are reported along with details of the occurrence. Occurrences are classified into one of eight categories (Table 1) and entered into an electronic database.

Surveillance information is used in two ways to improve safety. First, serious breaches that could lead to the imminent compromise of patient safety are addressed immediately by counseling the staff members involved and making any policy modifications necessary. When patients with pacemakers are referred for MRI—detected during the screening process—immediate follow-up with the referring clinician is warranted to make them aware of the safety issue and ensure that they do not refer such patients in the future. In addition, training sessions are held for MRI staff members to reemphasize the need to screen thoroughly and not rely on information from referring clinicians. Second, occurrences that do not demand immediate action are tracked over time using monthly queries of the database. Queries are performed on the basis of event type as well as for each individual staff member. This facilitates the targeted education of staff members who are repeatedly out of compliance with the policy as well as the identification of gaps or problems in the safety policy. Improvements in the response time of security personnel to “door-open” alarms and more thorough patient screening were initiated on the basis of these monthly queries of database surveillance information. The acquisition of plastic stethoscopes resulted when surveillance indicated that the MRI-safe stethoscopes that had been in use in fact showed attraction to the magnetic field. Additional surveillance data are extracted from the electronic door locking system. Because the entire hosp-

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**Table 1. Classification of adverse events that may present safety concerns**

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<th>Event Category</th>
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<tr>
<td>Unauthorized personnel</td>
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<td>Unsafe implant</td>
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<td>Pacemaker</td>
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tal-wide card access system is centrally monitored and electronically logged, security personnel are able to generate monthly reports of door access activity. Data collected include the number of times each door is accessed, the number of forced entries, the number of times doors were propped open, and the number of emergency entries using the emergency release devices. Each data type is graphed over time for each MRI site. When evidence of high rates of improper usage and access are detected, the data for the site involved are then sorted by time of day (shift). This allows targeted education and intervention to minimize breaches in the security of the MRI perimeter. The specific individuals who accessed the MRI site at the time of an incident can also be determined.

Finally, a monthly MRI quality assurance report is reviewed by the department’s Quality Improvement Committee. This report includes information on incidents, door access, monthly inspections, and MRI system uptime quality assurance testing and performance.

CONCLUSIONS

The role of MRI in diagnostic imaging will continue to dramatically increase for the foreseeable future as advances in technology continue at an astonishing rate. The expansion of MRI capabilities can surely advance patient care. However, patients and staff members may be at higher risk for injury as a result of improvements such as higher field strength and gradient duty cycles. Prevention through proactive safety policies and procedures is the only way to minimize these safety risks and avoid disaster. This report has outlined the “nuts and bolts” of MRI safety policy implementation at a large university health system. Although the scope of some of these procedures could be scaled according to the size and specifics of a different MRI practice, the essential components remain the same:

- Physical restrictions on access to an MRI site are necessary, preferably two layers of restricted access:
  - the management of keys is essential to minimize entry of unauthorized personnel, and
  - centralized electronic access control systems are an ideal solution.

The exclusion of all personnel from the MRI facility who do not have training and expertise in MRI safety is necessary:

- any untrained personnel (patients or others) must be directly supervised at all times, and
- site access (keys, key cards, etc.) is issued only to those with current safety training.

The effective management of potentially unsafe equipment that must be kept in the MRI suite is necessary:

- clearly label any unsafe equipment; and
- conduct periodic inspections to remove, test, or label potentially unsafe items.

Proactive surveillance for policy compliance and minor incidents is necessary, because it is the detection of and response to “minor” policy violations that is most likely to avert “major” incidents and their “major” consequences:

- strictly monitor site access, and
- track minor policy transgressions even if they do not lead to injury or property damage.

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REFERENCES