The 2005 Australian MRI Safety Survey

Nicholas J. Ferris1,2
Helen Kavnoudias3
Christy Thiel3
Stephen Stuckey4

OBJECTIVE. The purpose of this study was to ascertain current MRI safety practices in Australia regarding permanent pacemakers, temporary pacing wires, cerebral aneurysm clips, implants of unknown MRI safety status, and use of metal detectors, with respect to adherence to published guidelines.

MATERIALS AND METHODS. A questionnaire was distributed to more than 100 MRI facilities in Australia.

RESULTS. Ninety-two responses, representing 102 MRI systems, were received. Respondents from approximately one in 15 sites were aware they had inadvertently imaged a patient who had a permanent pacemaker (eight patients). One of these episodes led to a death. Use of modified request forms, on which referring physicians are asked for MRI safety information, was incomplete (48/90 facilities). Four facilities deliberately imaged pacemaker patients. Seventy-seven of 89 facilities responded that they do not image patients with temporary pacing wires. Aneurysm clips were accepted by most sites (71/91), and only one site associated with a neurosurgical service refused such patients. Seventy of 71 facilities required written identification of the clip type. Most (77/90) of the sites reported delays due to the unknown MRI safety status of implants. Only four of 92 sites reported routine use of a metal detector. The guidelines of the American College of Radiology and of the Royal Australian and New Zealand College of Radiologists were equally influential (38% each). Only 10 of 90 respondents reported use of external audits of safety processes.

CONCLUSION. Ongoing vigilance is required for avoiding MRI of patients with pacemakers, particularly when information from the patient is unreliable or unobtainable. Requiring referring physicians to provide MRI safety information may help to minimize risk.

In 2000, a patient with a cardiac pacemaker died during an MRI examination at an Australian teaching hospital in the state of Victoria. The presence of the pacemaker was known to some of the treating medical staff but was not revealed to the MRI personnel by either the treating medical staff or the patient. This event, combined with similar events overseas and an American College of Radiology (ACR) white paper [1], prompted the Royal Australian and New Zealand College of Radiologists to issue more detailed safety guidelines for clinical MRI services [2]. After the release of these guidelines, a survey of Australian sites was conducted to assess response to the guidelines and opinions on contentious issues in MRI safety, to survey the safety procedures actually followed at sites throughout Australia, and to assess changes, if any, in practice as the result of published guidelines.

Materials and Methods
A three-page survey document (Appendix 1) was distributed by e-mail and conventional mail to all publicly identifiable clinical MRI services in Australia. There were believed to be 120–130 systems in clinical use. The document was addressed to the supervising radiologist at each site. Questions in the survey were generated by two experienced MRI radiologists. The wording and layout were reviewed and modified by investigators with extensive experience in conducting surveys. After initial distribution of the survey, sites that had not responded within 1 month were contacted by telephone, and a further round of telephone calls was made 8 weeks after initial distribution.

The survey sought basic information about MRI equipment (field strength, gradient performance), the relationship of the service to a neurosurgical service, and safety policy (19 yes-or-no questions). Respondents were given the option of an anonymous response. They also had the opportunity to provide detailed comments.
Positive responses to each dichotomous (yes or no) question were totalled and expressed as percentages of the total number (n) of responses to that question. The margin of error for these percentages was estimated to be 1 divided by the square root of n, expressed as a percentage. Stated margins were adjusted to avoid implication of negative percentages when the margin of error was larger than the estimated proportion of positive responses.

Results

Ninety-two responses were received, reporting policies at a total of 102 MRI facilities throughout Australia, for a response rate of approximately 80%. The response rate was higher (=90%, total number of systems not precisely known) in the state of Victoria, which contains one fourth of the Australian population, than in other states (70–80%). This difference in response rate may have been caused by greater awareness of MRI safety issues after the death, which occurred in Victoria, or better recognition of the survey team, which was based in Victoria. Most of the participating facilities had high-field systems with gradient slew rates greater than 50 T/m/s. Only four facilities had MRI systems with field strength less than 0.5 T.

Inadvertent Imaging of Patients with Permanent Pacemakers

Seven responses showed that a total of at least eight patients with pacemakers had been inadvertently imaged, including the patient who died. No adverse event was identified in relation to the other seven inadvertent exposures. Therefore, at least one in 15 sites (7%; range, 0–18%) was aware that it had inadvertently imaged a patient who had a cardiac pacemaker.

In the case of the death, the presence of a pacemaker was known to two of the treating clinicians but was not communicated to the MRI staff. The patient denied having a pacemaker. The Victoria coroner recommended that referring physicians be required to complete safety questions on MRI referral forms (Appendix 2). Overall, 48 (53% ± 11%) of 90 facilities responded that they required referring physicians to provide safety screening information. In Victoria, where the death occurred, the proportion was 81% ± 20% (21/26); the proportion was 42% ± 13% among respondents outside Victoria. Only a minority of sites (22/53, 42% ± 14%) formally audited the completeness and accuracy of the safety information on the referral forms.

MRI Safety

Deliberate Imaging of Patients with Permanent Pacemakers

Eight responses indicated a willingness to image a patient with a pacemaker with appropriate (unspecified) precautions. Four of these facilities had actually imaged such a patient.

Temporary Pacing Wires

Seventy-seven (87% ± 11%) of 89 responses indicated that patients who had remnants of temporary pacing wires would not be accepted for imaging, but this percentage might have been an underestimate of the number of facilities that image these patients in practice. Temporary pacing wires and fragments of wires often are left in situ after cardiac surgery, and they may not be recognized before imaging. Of the sites accepting such patients, only four placed restrictions on the MRI sequences used.

Intracranial Aneurysm Clips

Twenty (22% ± 10%) of 91 responses stated that no patient with an intracranial aneurysm clip would be accepted for imaging, but only one of the 40 facilities associated with a neurosurgical service responded that they would refuse all such patients. Nearly all (70/71, 99%; range, 87–100%) facilities relied on written identification of the clip type. Only 10 (18% ± 13%) of 57 facilities required that the clip be in its original packaging at the time of surgery, and only four of 61 (7%; range, 0–20%) facilities tested clips on site. Similar proportions of facilities relied on clip manufacturer (43/66, 65% ± 12%) and third-party (47/65, 72% ± 12%) data on implant safety.

Other Implants

Most (77/90, 86% ± 11%) of the facilities reported delays due to difficulties in establishing the MRI safety and compatibility of implants. The frequency of these delays ranged from daily (three facilities) through weekly (27 facilities) to monthly (47 facilities).

Metal Detector Use

Only four (4%; range, 0–15%) of 92 responses indicated that a metal detector was used in routine screening. Anecdotal evidence from one of these sites showed that no significant implant had been identified with use of the metal detector alone. A ferromagnetic detection system (entry and prescreen system, Ferralert, Kopp Development) that has received publicity in North America is not available in Australia.

Use of Guidelines

Many sites reported changes in practice based on information in published materials. The American College of Radiology [1] (32/85, 38% ± 11%) and Royal Australian and New Zealand College of Radiologists [2] (34/89, 38% ± 11%) guidelines were similarly influential in affecting local practices.

Use of an External Audit Process

Ten (11% ± 11%) of 90 facilities responded that they had engaged an external consultant to review their safety procedures.

Discussion

The survey results showed that most Australian MRI facilities do not deliberately perform imaging on patients known to have implanted cardiac pacemaker devices. The death of a patient with a cardiac pacemaker during an MRI examination in Melbourne, Australia, in 2000 was a powerful reminder of the importance of MRI safety screening procedures, as was the death the following year of a child in New York struck by an oxygen cylinder missile while in an MRI unit.

The pacemaker incident also illustrated the dependence of MRI safety screening on accurate information from patients and their associates. The occurrence, acknowledged in our survey results, of at least seven (non-fatal) inadvertent exposures of pacemaker patients to MRI further emphasizes the potential for disaster.

This survey was addressed to the radiologist supervising each MRI facility. This person may not always have been the one who completed the questionnaire. We were not able to ensure that every member of an MRI staff was consulted, and it is possible that additional safety incidents involving pacemakers and other devices occurred but were not reported. Our survey results therefore represent only the lower limit of the frequency of such incidents.

Notwithstanding that a number of patients with pacemakers have safely undergone imaging with appropriate precautions, a large number of patients with potentially unsafe devices continue to undergo imaging [3]. Unremitting vigilance is required, and any suspicion that a patient may not be an accurate informant (e.g., because of dementia or an acute confusional state) should prompt further assessment by clinical examination, consultation with caregivers and referring physicians, review of previous images, and, if necessary, acquisition of appropriate conventional radiographs.
In response to the fatal incident, the Victoria coroner, who is empowered to investigate and make recommendations about unexpected deaths, recommended that referring physicians be required to complete safety screening information as part of the MRI referral process. This recommendation was prompted in part by the peculiar feature of the case in question, that the treating physicians were aware of the presence of the pacemaker, but did not realize that MRI would be hazardous to such a patient and did not communicate their knowledge to the MRI staff. The survey results show that this recommendation has been widely but not universally influential in Victoria, but is followed less than 50% of the time in other states. Even in Victoria, it is well recognized that some referring physicians will not complete the screening information accurately or at all and that the information cannot and should not be relied on. Ongoing audit of the completeness of such information apparently is uncommon. For there to be any chance of accurate referral information, such audits are clearly needed.

Referral safety questionnaires produce an additional layer of precautionary screening and raise the awareness of referring physicians about the issue. They have not, however, been shown to reduce the number of MRI safety incidents or to save lives. Evidence supporting such an outcome would be difficult to obtain.

We found that most Australian sites require written evidence of the type of aneurysm clip known to have been inserted in a patient and require third-party information on the MRI compatibility of the clip type in assessing the safety of MRI of patients with such clips. Variations in practice with regard to aneurysm clips have prompted discussions with the Neurosurgical Society of Australia that are aimed at standardizing clip handling and documentation in operating suites. Documentation of the MRI safety of other implants continues to be difficult, particularly because most of these devices are manufactured outside Australia. This issue is being discussed with the Therapeutic Goods Administration, the Australian organization responsible for the regulation of such devices.

Stage 3 of the Royal Australian and New Zealand College of Radiologists accreditation program for radiology practices includes on-site inspection of MRI systems, including safety procedures, but this inspection is not as comprehensive as a dedicated external safety audit. There may be greater scope for the use of MRI safety advisors, as recommended by the UK Medicines and Healthcare Products Regulatory Agency [4].

In conclusion, ongoing vigilance is required to minimize pacemaker-related MRI incidents. At least one in 15 Australian MRI facilities is aware that it has inadvertently performed imaging on a patient with a pacemaker. Particular care is needed when the patient may not be able to respond accurately to MRI safety questions. Consideration should be given to requiring referring physicians to supply safety information at the time of referral to give an additional level of hazard recognition.

Acknowledgments
We thank Professor Ken Thomson for allowing us to work with his research team.

References

Appendixes begin on next page
# MRI Safety Screening Survey

**MRI SAFETY SCREENING SURVEY**

**Site Address:** ____________________________

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**Site parameters** (please circle as appropriate)

- **Field Strength:**
  - <0.5T
  - 0.5–1.5T
  - >1.5T

- **Maximum gradient slew rate:**
  - <50T/s
  - 50–100T/m/s
  - >100T/m/s

- Co-located with neurosurgery service? 
  - Y
  - N

## A. Intracranial aneurysm clips

1. Does your site **EVER** perform MRI examinations on patients known to have an intracranial aneurysm clip? 
   - Y
   - N

2. If the answer to the above question is **YES,** what steps do you take to establish clip safety **(circle as many as apply):**

   - Only scan clips tested by your site prior to implantation 
     - Y
     - N

   **If YES,** please describe testing performed ____________________________

   - Require written evidence of clip type
     - Y
     - N

   (signed operation notes, etc)

   - Require clip to have been removed from original packaging at time of surgery (and not before) 
     - Y
     - N

   - Require manufacturer’s statement of clip safety 
     - Y
     - N

   - Accept third party statement of clip safety 
     - Y
     - N

   **If YES,** any particular third parties accepted? ____________________________

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Comments ____________________________
APPENDIX 1: MRI Safety Screening Survey (continued)

B. Temporary cardiac pacing wires

1. Does your site accept patients with:
   * Temporary epicardial pacing wires in situ?  Y  N
   * Remnants of temporary epicardial pacing wires, after the external portions of the wires have been removed?  Y  N

2. If YES to either of the above, do you place any restriction on the pulse sequences that may be used?
   Details__________________________________________
   ____________________________________________
   ____________________________________________

C. Pacemakers

1. Are you, or any of your staff, aware that you have ever inadvertently scanned a patient with a permanent pacemaker?  Y  N
   If YES, could you please provide details below (eg. No. of occasions (estimate), pacemaker type/model/date, side-effects encountered)
   ____________________________________________
   ____________________________________________
   ____________________________________________

2. Would your site ever deliberately perform MRI examinations on a patient with a pacemaker?  Y  N

3. Have you deliberately scanned a patient knowing they had a pacemaker?  Y  N
   If YES, please describe the indication and number of occasions:
   ____________________________________________
Survey No. _____

**D. Screening procedures**

1. Does your site use a handheld metal detector routinely prior to the patient entering the 5 gauss zone?  
   - Y  
   - N

2. Does your site request form have a mandatory safety questionnaire to be completed by referring doctors?  
   - Y  
   - N

   If YES: Is this enforced?  
   - Y  
   - N

   Is this audited?  
   - Y  
   - N

3. How often are exams delayed by inability to establish implant compatibility?  
   (please circle)  
   - Daily  
   - Weekly  
   - Monthly

**E. External audit**

1. Has your site ever undergone an audit of the unit’s safety procedures by an external consultant/monitor?  
   - Y  
   - N

**F. Practice Guidelines**

1. Has your site changed practice because of:
   - ACR safe practice guidelines  
     - Y  
     - N
   - RANZCR MRI safety guidelines  
     - Y  
     - N

**Thank you for your participation!**
**APPENDIX 2: Sample Information Sheet Used by Referring Physicians**

*If the information requested on this form is not complete the MRI examination will not be performed.*

### Screening Questions

<table>
<thead>
<tr>
<th>Question</th>
<th>Y / N</th>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the patient require an interpreter?</td>
<td>Y / N</td>
<td>If Yes, language</td>
</tr>
<tr>
<td>Has the patient had surgery in the last 6 weeks?</td>
<td>Y / N</td>
<td>If Yes, what?</td>
</tr>
<tr>
<td>Is the patient claustrophobic?</td>
<td>Y / N</td>
<td></td>
</tr>
<tr>
<td>Are there any contra-indications to sedation? (e.g., cardiac disease)</td>
<td>Y / N</td>
<td>If Yes, what?</td>
</tr>
<tr>
<td>Does the patient have an aortic aneurysm clip?</td>
<td>Y / N</td>
<td>If Yes, MRI contra-indicated</td>
</tr>
<tr>
<td>Steerable marker</td>
<td>Y / N</td>
<td>If Yes, MRI potentially contra-indicated</td>
</tr>
</tbody>
</table>

**Objects and conditions requiring further assessment:**
- Retained shrapnel / bullet / pellet: History of *metal in the eye* not removed by a doctor
- Heart valves, pacing wires, vascular stents, filters, coils, clips
- Internal or external, infusion pumps
- Brain shunt, tube (especially if programmable); Penile implant
- Joint prosthesis, metallic fixation devices (especially if in region of interest)
- Possible or known pregnancy, lactation

*Please advise details; MRI staff will assess.*

### Examination

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Episode No.</td>
<td></td>
</tr>
<tr>
<td>Series No.</td>
<td></td>
</tr>
<tr>
<td>MIT</td>
<td></td>
</tr>
<tr>
<td>No. Films</td>
<td></td>
</tr>
<tr>
<td>Radiologist</td>
<td></td>
</tr>
</tbody>
</table>

**Clinical Notes**

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
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</thead>
<tbody>
<tr>
<td>Referring Dr.</td>
<td></td>
</tr>
<tr>
<td>Address</td>
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</tr>
<tr>
<td>Signed</td>
<td></td>
</tr>
<tr>
<td>Provider No.</td>
<td></td>
</tr>
</tbody>
</table>

**Date**

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