Generic implant safety procedures for assessing patients with implants prior to MRI scanning: results from a UK-wide survey

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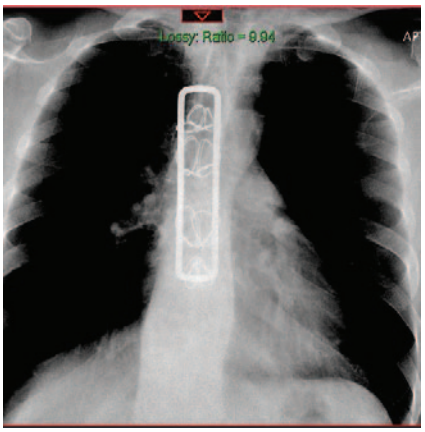

Figure 1
X-ray of a patient with a spinal implant being considered for MRI – how would you proceed? Is this approach defined in an institutionally approved procedure?

Introduction

While MRI is generally very safe, undergoing an MRI scan can present multiple risks to patients with certain implants. Given that between a quarter and a third of patients who present for their MRI scan will have an implant,[1] assessing patient suitability for MRI and managing this risk can pose a significant challenge.

Ideally the presence of any patient implant should be highlighted at the point of MRI referral, allowing sufficient time for the MRI safety of each implant to be checked. For this to happen, accurate implant information would need to be easily and quickly identified from the patient health record or from the patient themselves to allow the MRI safety labelling and MRI conditions to be established from the implant manufacturer.

In practice many of these steps can prove difficult, leading to delays and potential cancellations. However, for certain implant categories there is strong evidence that the risk of scanning the patient is very low. For instance, how would you approach deciding whether to proceed with an MRI scan where the patient who attends has an orthopaedic implant as shown in **figure 1**, but with no implant information available? Would your approach vary with the clinical urgency?

From presentations at national meetings[1,2] and from broader conversations among the MRI safety community in the UK, it became clear that many sites had independently started to define general workflows for how patients with certain categories of implants could be managed safely, without needing to explicitly identify the implant make and

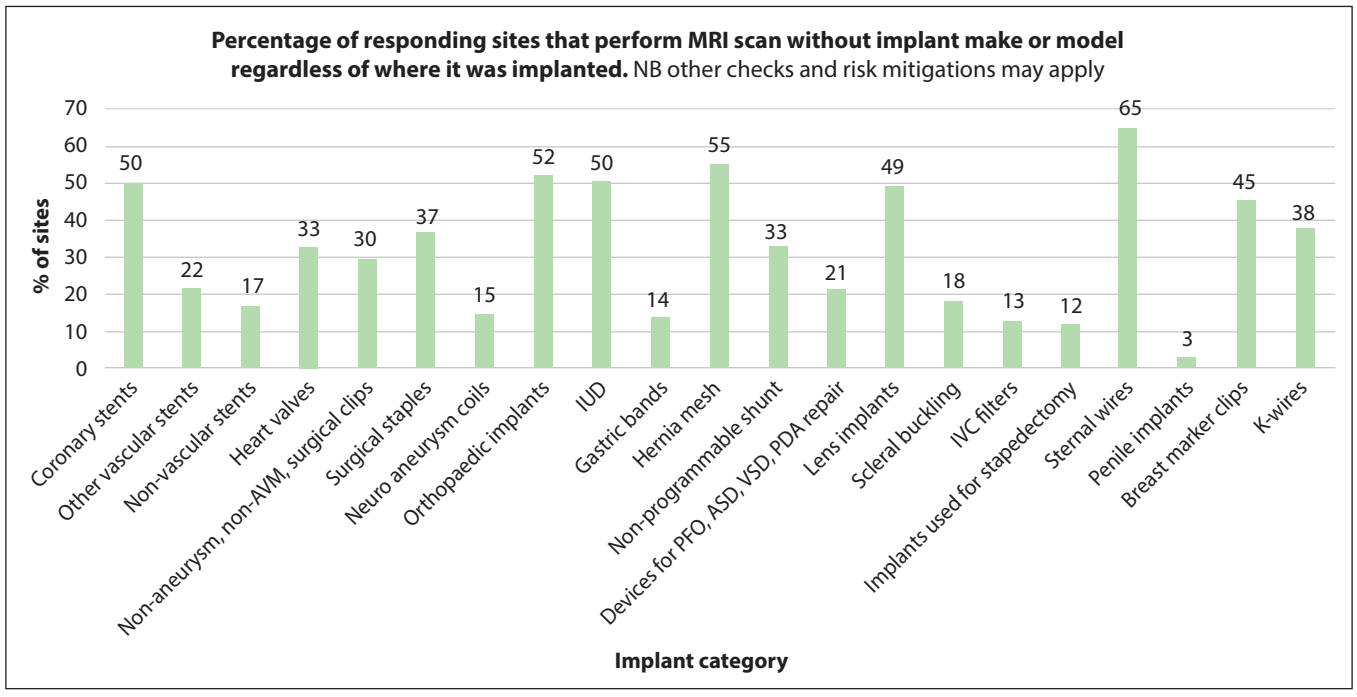

Figure 2
Survey results indicating whether respondents have a generalised approach to scanning various implant categories.

model. This approach typically includes a detailed review of available evidence sources, a risk assessment, a clear procedure statement and, where appropriate, a workflow. Under this approach, all patients with implants from a particular category will follow the same generic scanning workflow, we call these generic implant safety procedures (GISP). As well as the work going on in the UK, it is clear there is also increasing evidence internationally that such practices are becoming more acceptable.[3-6]

To establish how common this practice is in the UK, and with a view to capturing best practice, an Institute of Physics and Engineering in Medicine (IPEM) MR-SIG working party, in collaboration with colleagues from The Society of Radiographers, The British Institute of Radiology, The Royal College of Radiologists and the British Association of MRI Radiographers (BAMRR), developed a survey asking MRI units a range of questions regarding their approach to scanning patients with implants.

About the survey

IPEM's network of clinical scientists distributed an online survey to MRI superintendent/lead radiographers across the UK, with the aim of receiving a single response from each MRI unit in the UK. The survey link was also shared with MRI radiography staff at both the UK Imaging and Oncology (UKIO) conference and BAMRR educational events and the MRI Safety Matters MRI Safety Update and Innovations Day. Survey responses were received between June and September 2022. The survey, with site and personal identifiers removed, can be accessed here: www.ipem.ac.uk/media/2rmjoigu/implant-safety-for-mri.pdf.

The survey asked participating respondents 21 questions to determine:

- if the site currently has GISPs in place;
- what implant categories they currently have covered by GISPs;
- the governance procedures in place for their GISPs;
- what they believe the drawbacks are of not having a GISP and having to identify implant make and model;
- if they believe GISPs are an appropriate way to implement MRI safety practices;
- if following a GISP has ever contributed to an adverse event;
- what barriers were identified to implementing GISPs;
- what they see as the risks and benefits of GISPs;
- if they had dedicated staff to investigate implants.

Survey results

The survey received 86 responses. Of the 86 respondents, 80 (93%) were radiographers with 73% describing themselves as either the MRI superintendent or lead MRI radiographer. The remaining respondents were clinical scientists.

Eighty-seven per cent of sites responded that having to explicitly determine implant make and model (ie where a GISP was not present) caused delays in MRI scanning. This was the most common negative implication identified in the survey. The survey highlighted that GISPs are already in widespread use across the UK, with 89% of respondents reporting that they use them. **Figure 2** highlights the approach that sites take when scanning various implant categories. It should be noted that those respondents who did not identify the implant model often had restrictions and/or exclusions in place for scanning implants within a category. Examples include exclusions based on implant location and/or date, and restrictions based on field strength, implanting location and/or SAR. Therefore **figure 2** should not be taken to mean that every implant within an implant category can proceed to MRI without any consideration at all.

A number of barriers to creating and using GISPs were identified. Concerns over completeness of GISPs (58%), time to develop GISPs (53%) and difficulty in obtaining evidence (51%) were the three most commonly reported (**figure 3**).

Respondents highlighted that clinical scientists (58%) most commonly develop GISPs, followed by lead radiographers (36%). It was also found that 21% of respondents directly implemented a procedure that was provided by another site or information source, without further scrutiny.

Only 57% of sites have all their policies written down, with 2% having nothing written down. The majority of staff find out about policies during staff induction or during an initial training period (78% and 69% respectively), 37% of sites reported that staff would find out about policies as patients with implants present at the department.

The results indicating which aspect of local governance approved the use of the GISP is shown in **figure 4**.

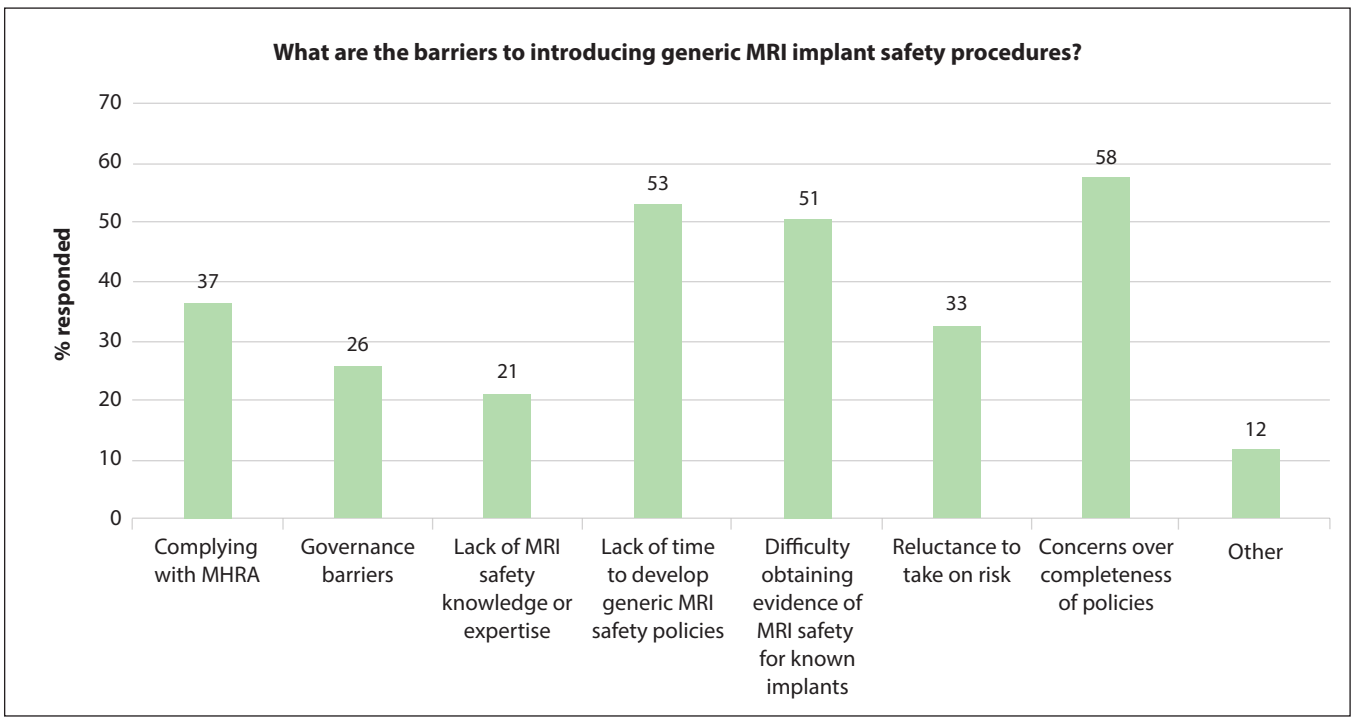

Figure 3
Survey results indicating what respondents reported as barriers to creating a GISP.

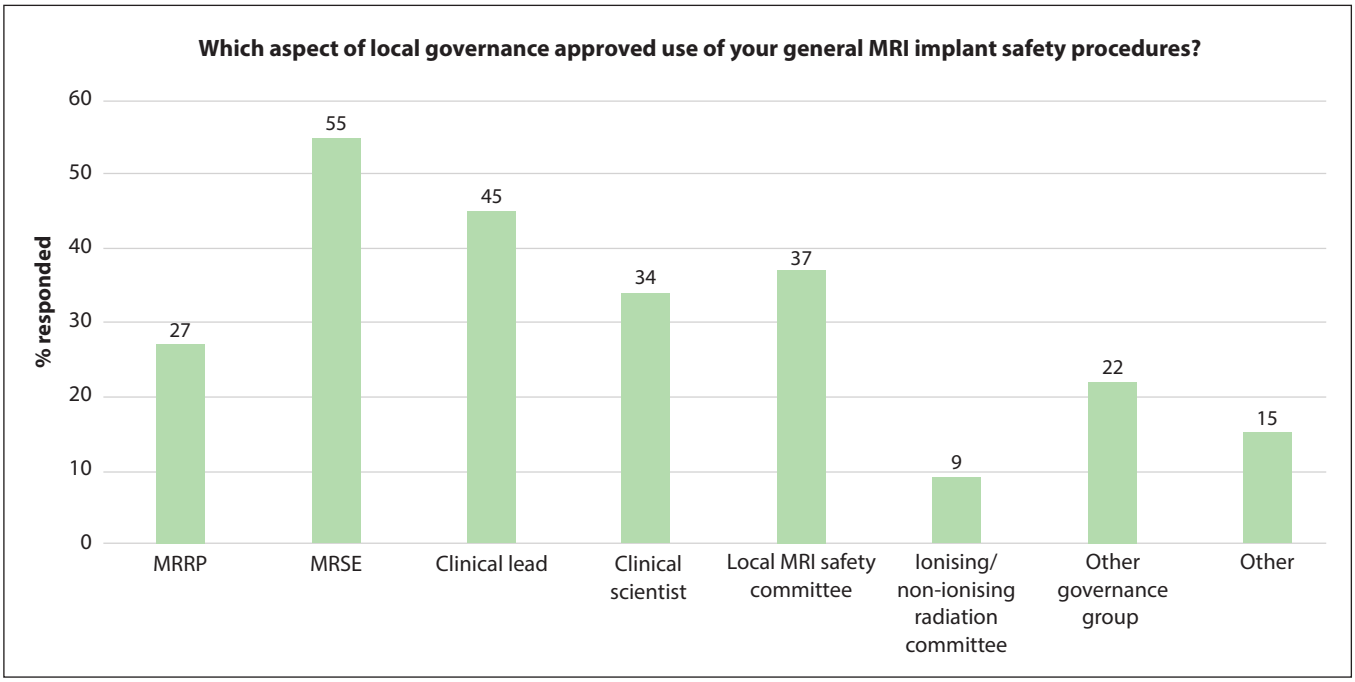

Figure 4
Survey results indicating which aspect of local governance approved the use of the GISP.

Very few adverse incidents associated with GISPs were reported; 95% of respondents stated no adverse events had occurred. Of the remaining respondents, three skipped the question, two preferred not to answer, leaving two respondents reporting an adverse event.

Of these events one highlighted a heating event that they believe was the result of an MR conditional hip replacement and femur plate implanted close together. The patient experienced some warmth during scanning and a significant degree of pain and discomfort after the scan had finished. All scans were conducted in normal operating mode.

Upon analysis of the case, the site felt the incident was a result of heating of the implants from either the RF or imaging gradients. As the implants involved in this case were determined to be MR conditional, we do not believe a GISP was used, although we note sites that do operate a GISP for orthopaedic implants may well have cleared this patient for MRI without checking the MR conditions. This serves to highlight two important points, firstly that GISPs are not without risk but also that adverse events for patients with orthopaedic implants are exceptionally rare.

The second event reported a near-miss as a result of a vagus nerve stimulation device not being scanned under the correct conditions. There was no adverse outcome and our assessment of this event is that it was not a result of a failure of a GISP.

Discussion

Overall, the survey highlights that GISPs are already prevalent within the UK MRI community, with a variety of approaches to their implementation between sites. The next steps for the working party are to publish a peer reviewed article that will outline good practice for developing GISPs. Beyond that, there is debate in the community as to the future of GISPs. Each site developing their own set of GISPs would lead to a significant amount of duplication; therefore, it would be desirable if a central resource of these procedures was available to all in the UK MRI community. This is something that we hope to discuss at the forthcoming IPEM MR Safety Update in November. Previous feedback from radiographers highlights that there is a desire for a publicly available set of procedures that are endorsed by the relevant professional bodies.

While we are clearly proponents of a generic approach, there are a number of risks of implementing GISPS as outlined below:

- Newly developed or previously unrecognised unsafe implant (or MR conditional where the GISP does not follow the conditions);
- Updated MR safety information that changes the safety status of an implant such that it is no longer safely scanned under a GISP;
- When following a GISP, implants not disclosed by the patient at screening might not be discovered, whereas identifying implant specifics in patient notes can highlight inaccuracies in the patient's account of their own medical history;
- Confusion regarding exactly what implants or patient groups a GISP covers. When make and model are identified this ambiguity is removed (eg an active orthopaedic implant mistakenly categorised as a passive orthopaedic implant).

Those who are less in favour might also cite challenges with scanning implants off-label when a GISP is in use (eg scanning at 3.0T when a device has only been tested and labelled at 1.5T) and to what extent the patient is required to consent to this off-label use. These are useful points to raise and discuss. However, we believe adoption of a GISP ultimately comes down to variations in attitudes to risk and what different sites feel is appropriate. What is clear is that this practice is already widespread and that being the case, we believe that trying to provide guidance on how this might be best implemented will be of value to the MR community.

References

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