Safety in Magnetic Resonance Imaging

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Summary

SCoR and BAMRR issue this guidance and advice document on safety issues in MRI. This second edition updates the 2007 document and provides direction on where appropriate information can be found.

1. Rationale

1.1

This guidance and advice document overviews safety issues in Magnetic Resonance Imaging (MRI) and, while not claiming to be all-inclusive, it provides direction to where appropriate information can be found. All members of the workforce who are working or intending to work in the field are recommended to read the literature listed in this document to gain a more in depth appreciation of the issues involved.

1.2

The purpose of this document is to:

- increase awareness and reiterate safety issues which are uniquely associated with Magnetic Resonance Imaging (MRI)
- identify the professional responsibilities in ensuring safe practice in MRI
- offer practical advice for the development of MRI safety policies
- raise awareness of the potential impact of the European Union Physical Agents Directive concerning worker protection in Electro-magnetic fields (EUPAD) on working practices in MRI.

1.3

In this document considerations are given to areas relating to hazards, safety and responsibility of MRI staff, patients and referrers. It is not comprehensive as other documents are available, but is designed to be a useful reference guide and pointer in order for staff to be able to find and access information in busy MRI units. The Society and College of Radiographers (SCoR) and the British Association of Magnetic Resonance Radiographers (BAMRR) recommend that all departments have an up to date copy of The MHRA publication: Safety Guidelines for Magnetic Resonance Equipment in Clinical Use.

1.4
This guidance updates and replaces the previous guidance document produced by SCoR and BAMRR in 2007. SCoR is grateful to members of the SCOR Magnetic Resonance Advisory Group (MRAG) and BAMRR policy board who contributed to the writing of this document.

2. Defining the areas of safety and responsibility within the MRI department

For further details please refer to the publication Guidelines for Magnetic Resonance Equipment in Clinical Use.

2.1 Responsible Person

The MRI Responsible Person:

- has day to day responsibility for MRI safety in the MRI Centre;
- shall be required to have training in, and have good working knowledge of, MRI training and safety;
- shall be delegated as Responsible Person by Chief Executive or General Manager;
- may effectively be Clinical Director, Head of Department or Superintendent Radiographer in an MRI department;

NB. An MRI Responsible Person should not take on the role of an MRI Safety Advisor see 2.2.

Duties of an MRI Responsible Person:

- to ensure adequate written safety procedures, ethical approvals, work instructions and emergency procedures are issued to all concerned after consultation with the MRI Safety Advisors and Authorised Persons. See 2.2, 2.3.
- to maintain an appropriate record of MR training undertaken by Authorised Persons

2.2 MRI Safety Advisor

The MRI Safety Advisor:

- shall be conversant with MR Safety issues;
- shall be in contact with Safety Committees and relevant professional bodies.

Duties of an MRI Safety Advisor:

- to advise on safety aspects of clinical and scientific use of MRI scanners with reference to safety committees, local ethics committee, MRHA HPA (Radiation Protection Division) and other professional bodies;
- to advise on training materials, consent forms, questionnaires, safety record sheets and ensuring appropriate screening for persons entering the controlled area for approval by the MRI Responsible Person and the local ethics committee;
- to be competent to cover the scientific aspects of the department.

NB. The MRI Safety Advisor may be a physicist.

2.3 Authorised Person

The Authorised Person:

- shall be on a certified list to be given access to controlled area;
shall be one of the MRI Centre personnel, including the MR Operator. See 2.4;
must have read and understood the MRI Centre safety training materials, and have
completed and passed a screening questionnaire annually;
shall be one of certain external users with access to scanner rooms, such as engineers,
researchers, research assistants, cleaning and maintenance staff;
must have an appropriate record of their MR training which is kept by the Responsible
Person;
shall satisfy his/herself at all times that they conform to the requirements of the screening
process.

NB: the MRI safety screening questionnaires of all authorised personnel are to be kept by the
Responsible Person.

Additions to the authorised persons list can only be made by an MRI Advisor and/or the Responsible
Person, after appropriate training and screening processes have been completed.

Unauthorised persons, including carers escorting patients and the general public, must be
accompanied by an Authorised Person who is responsible for them while in the controlled area: they
must be screened, and have been authorised to enter the controlled area.

2.4 MRI Operator

The MRI Operator:

- is an authorised person deemed to have sufficient experience (knowledge and skills) and
appropriate training and is responsible for operating the scanner in a safe and appropriate
manner;
- Is also responsible for the safety of patients, volunteers and accompanying carers who are
undergoing MR Imaging at all times, and also for ensuring that any equipment taken into the
controlled area for the examination is MR compatible.

3. Static magnetic field (B0)

3.1 Definition

Static magnetic field (B0) is dependent on the field strength of the magnet.

The SI unit used for measuring magnetic field strength is the tesla; its symbol is T.

A magnetic field of one tesla (1T) is approximately 30,000 times as powerful as the Earth’s magnetic
field.

3.2 Controlled Areas

The static magnetic field and the shielding define the controlled areas. Typically, MR departments
will define two controlled areas the controlled area and the inner controlled area.

3.2.1 Controlled Area

The controlled area is where the static magnetic field, B0, may exceed 0.5 mT^2 (often referred to as
the 5 Gauss line: 5 Gauss = 0.5mT). The controlled area will incorporate the inner controlled area,
the control room and typically, preparation room, patient changing rooms and reporting rooms.
Ideally the limit of the 0.5mT line should be marked out on the floor as a safety guide for staff.
Access should be restricted to the controlled area by a permanently locked door, ideally with a keypad entry.

3.2.2 Inner Controlled Area
The inner controlled area is where the static magnetic field may exceed 3mT. This is typically the scan room itself and this area should be clearly marked and access controlled by means of a lockable door.

Due to the hazards of the static magnetic field described in this section, resuscitation of patients should take place outside the inner controlled area. Local rules should outline specific procedures to reflect this.

3.3 Bio-effects
The interaction of the static magnetic field ($B_0$) with the body and its functions may result in the creation of electrical potentials, currents generated by body movements and the possible displacement of naturally generated currents within the body by $B_0$. Electrical potentials and related effects during physical movements within static magnetic field gradients may induce sensations of vertigo, nausea, phosphenes and a metallic taste in the mouth. The Health Protection Agency HPA offers the following advice regarding the movement of Patients and Volunteers in the static field:

“The Biological Effects most likely to occur are the production of vertigo-like sensations and these acute effects are associated with movement in the static field. The sensitivity to these effects varies considerably between individuals. Patients and volunteers should be moved slowly into the scanner, to avoid the possibility of vertigo and nausea.”

Further recommendations, guidance and exposure limits relating to Bio- effects of $B_0$ can be viewed in the following publications:

Health Protection Agency HPA Protection of Patients and Volunteers Undergoing MRI Procedures, 2008.


All the above are accessible on the SCoR website MRI Practice Page: https://www.sor.org/practice/cross-sectional-imaging/mri (accessed 27th February 2013)

3.4 Projectile and attractive forces
The potential hazard of the projectile effect of ferro-magnetic material in a strong magnetic field must be taken very seriously. The HPA reports that serious incidents have occurred including a patient fatality when items such as ferro-magnetic oxygen cylinders have inadvertently been brought into the scan room.
Extreme caution must be employed and strict screening protocols in place and adhered to, to ensure ferro-magnetic items do not enter the controlled area. Loose metallic objects can reach considerable velocities.

3.4.1 Ancillary Equipment
Caution should be exercised when assessing, purchasing and authorising equipment for patient support in the MR environment. Equipment must be assessed for MR compatibility and clearly labelled as indicated in section 3.5. Departments should ensure that an up to date inventory is kept of all equipment for use in the MR environment.

3.5 Labelling of Equipment
All equipment used or stored within the MR environment should be clearly labelled as one of the following:

- **MR safe**
- **MR conditional**
- **MR unsafe**

All staff should be conversant with the labelling system and understand the conditions for use. Further information on labelling of equipment can be viewed in the MHRA guidelines. Departments should take into account the different field strengths when labelling equipment. For example, if a department is equipped with two MR units of 1.5T and 3T only equipment which is safe in both units should be labelled as ‘MR Safe’. Clear guidance for use should be marked on equipment that is MR conditional.

3.6 Procurement
The MR Responsible Person and/or the MR Advisor must be involved in all procurement decisions relating to items for use in the controlled area.

4. Time-varying (gradient) magnetic fields (dB/dt)

4.1
Time-varying magnetic field gradients in MR systems provide position-dependent variation in magnetic field strength. The gradients are pulsed and the faster the sequence of imaging, the greater the gradient fields change rate. The main concerns associated with time-varying magnetic fields are biological effects and acoustic noise.

4.2 Biological effects

4.2.1
Subjecting the human body to time-varying electromagnetic fields leads to induced electric fields and circulating currents in connective tissues. At frequencies above 1MHz, a reactive element begins to be significant and at frequencies above 30 MHz, the wavelength begins to influence the electric field and current distribution. Induced electric currents can be sufficiently large to interfere with normal function of nerve cells and muscle fibres. An example of this is the sensation of flashes of light caused by induced currents stimulating the retina. A more serious response is that of ventricular fibrillation.
4.2.2 Peripheral nerve and muscle stimulation

At low frequencies, induced currents can produce stimulation of nerve and muscle cells. The body is most sensitive at up to about 5 kHz. Extreme cases can result in limb movement or ventricular fibrillation. Reference to exposure limits should be made and can be found in the MHRA guidelines.

4.3 Acoustic noise

Acoustic noise caused by the gradient coils switching on and off during the scan can reach unacceptable levels. In general, the higher the field strength, the higher the acoustic noise level, but this effect is not exponential and is also dependent on pulse sequence. The HPA reports that the threshold of instantaneous and permanent acoustic trauma normally associated with exposure to impulsive noise is 140dB in adults – children may have a lower threshold and maximum peak levels of 120dB are advised.

Departments should provide adequate hearing protection to ALL patients. The MHRA also advises that ear protection should be provided for others in the scan room if the levels reach 80dBA.

5. Radio-Frequency Radiation (B1)

5.1 Biological effects

Exposure to radio-frequency (RF) radiation results in increased oscillation of molecules and generation of heat. Dissipation of this heat occurs through the dilatation of blood vessels and increased blood flow. Avascular structures are therefore less efficient in removing this heat. RF exposure of patients is usually characterized by means of the ’specific energy absorption rate’ (SAR), which is defined as the average energy dissipated in the body per unit of mass and time.

ICNIRP summarises: For whole-body exposures, no adverse health effects are expected if the increase in body core temperature does not exceed 1°C. In the case of infants and persons with cardiocirculatory impairment, the temperature increase should not exceed 0.5°C. With regard to localised heating, it seems reasonable to assume that adverse effects will be avoided with a reasonable certainty if temperatures in localised regions of the head are less than 38°C, of the trunk less than 39°C, and in the limbs less than 40°C.

However, good practice should mean that RF deposition should be minimised in all patients. An accurate patient weight should be entered into the scanner and manufacturer software will alert scanner operators to high SAR sequences.

All patients should be weighed prior to scanning in accordance with manufacturers guidelines. Short bore magnets will also require the patient’s height to be recorded.

5.1.1 SAR Limits

SAR limits have been defined by the International Electrotechnical Commission (IEC) and ICNIRP. The MHRA recommends that departments make themselves familiar with the SAR limits used by their system from both the IEC standard and the manufacturer’s user manual. The use of different operating modes with regard to the varying SAR levels should be recorded within the local rules. Departments should also be aware that the IEC SAR limits are set assuming moderate environmental conditions of relative humidity and ambient temperature. There is a risk of overheating the patient if the SAR is not reduced in adverse conditions i.e. in high ambient temperatures and high relative humidity. The HPA recommends that departments follow the ICNIRP guidelines for RF fields for each
operating mode and additionally that an upper temperature limit be specified for the experimental operating mode.

MR operators should ensure that a good airflow is passing through the MR scanner while patients are in situ.

MR Operators should be aware of the acceptable limits of humidity and ambient temperature for each scanner.

**NB:** this information should be provided within the manufacturer’s literature.

MR operators should be aware of the different operating modes available on systems, and their importance in ensuring that SAR levels remain as low as reasonably possible. Local rules should provide clear guidance on the use of such operating modes.

### 5.2 Induced current burns

#### 5.2.1
Burns will occur when patients are positioned in such a way to create a conductive loop pathway, for example, where thighs meet or when hands are clasped. Poor positioning of the patient and associated leads and sensors are the cause of many burns.

#### 5.2.2
Care should be taken to ensure that cables should be correctly positioned and to avoid them touching patients. The cables should not be crossed, looped or allowed to lie diagonally across patients. Ideally, cables should lie parallel and as close to the centre of the bore as possible, and should not touch the bore of the magnet at any point.

#### 5.2.3
Patient’s skin should be insulated from the bore of the magnet and staff should ensure that there is no skin to skin contact.

#### 5.2.4
Staff should visually inspect patients after imaging to look for any areas of skin redness that may develop into a burn.

#### 5.2.5
All incidents of induced current burns should be reported as outlined in Section 17.3 of this document. It is good practice to provide all patients with an after-care leaflet as it is often the case that a burn will develop after the patient has left the department.

Careful positioning technique is essential in order to avoid any skin to skin contact.
Burns from poor patient and cable positioning are entirely avoidable with good MR practice.

6. Cryogen hazards

Cryogens should only be handled by authorised and trained cryogen suppliers.

6.1 Venting in superconducting magnets

Superconducting magnets offer a potential cryogen hazard. Adequate attention should be paid to the provision of the venting of the cryogens, including ensuring that the external vent pipes are of the correct dimensions and in the case of a quench, able to withstand pressures above that recommended by the manufacturers as outlined in the MHRA guidelines. External vent pipes should also be designed and fitted so that there is no ingress of rain, or other detritus and they should have a regular maintenance and inspection schedule.

MRI scanner manufacturers are not usually responsible for the maintenance of quench pipes and do not routinely check them during planned preventive maintenance.

6.2 Quench hazards in superconducting magnets

There should be no hazards from cryogens for MR scanning staff, visitors and patients, provided adequate attention has been paid to the provision of venting directly to the air outside the unit. In the event of a quench, low temperature liquefied gases, designed to keep the magnet close to absolute zero (-273°C) expand and boil off to the outside. In order to detect any unplanned leakage of helium into the scanner room, suitable low oxygen warning alarms should be placed in the MR room and be regularly checked and maintained. If, for any reason, the gases should enter the room, instead of exiting to the outside, there will be the hazard of asphyxiation owing to the displacement of oxygen, hypothermia and frostbite. There may also be over pressurisation in the room owing to the rapid expansion of the liquid gas and this may make it difficult to enter the MR room.

If the low oxygen monitor alarm sounds or a quench should occur, the MR room should be evacuated immediately. Appropriate local emergency procedures should be in place and included in the training programme for all authorised personnel. See also section 13.

Departments should adhere to the manufacturers’ recommendations regarding maintenance programmes and checking of equipment.

Departments must also ensure that a system is in place for handover of responsibility to and from engineers during maintenance checks and system repairs.

7. MRI phantoms

MRI phantoms are utilised in performance testing of the MR system; they are generally filled with aqueous paramagnetic solutions.

7.1 Storage and handling of phantoms
MR departments should follow the manufacturers’ guidance on the storage and handling of MR phantoms. A record should be kept detailing the contents of each phantom; this record should be passed to fire departments in the event of a fire in the MR scanner. Protocols for general use and the process for dealing with phantom spillages should be documented within the local rules.

8. Implantable medical and non-medical objects

The use of MRI continues to expand in the UK, alongside advances in device technology. In order to ensure good patient management and patient safety, departments should implement robust procedures to ensure the MRI safety status of any implanted device. The SCoR and BAMRR recommend that departments obtain a copy of the annually updated publication by Shellock,F Reference Manual for Magnetic Resonance Safety, Implants and Devices.10 This contains safety advice and guidance and a comprehensive list of implants alongside the field strength under which they have been tested. The list can also be viewed on the website hosted by Shellock F: http://www.mrisafety.com/ 11 (accessed 27th February 2013)

However, as these are both American hosted publications, they may not always contain information on a particular device. In this instance, contact should be made directly to the device manufacturer to ascertain its MRI safety status.

Departments should be aware that the MR compliancy listing of an implant may be changed and should ensure that their information is kept up to date.

All visitors and patients should be adequately screened by means of a safety questionnaire prior to entering the controlled area and no-one should be allowed to enter within the area if there is any doubt regarding the compliancy of any implants. Please also see section 17.1

An example safety questionnaire can be viewed on the BAMRR Website at the following link: http://www.bamrr.org/mri-safety (accessed 27th February 2013)

Departments should have a mechanism for recording and storing details obtained regarding an implant’s MR compliancy.

For MR conditional devices, departments should liaise with their MR safety advisor and equipment manufacturer to ensure that the conditions can safely be met.

Departments should proceed with caution. The SCoR and BAMRR recommend that written evidence regarding an implant’s compliancy be obtained prior to scanning. If a department is unable to obtain the required information, then scanning should not take place.

NB. Manufacturers of implants and devices have a duty to supply safety information. If you are unable to obtain such information, please report it to the MHRA.

8.1 Active devices
Safety in Magnetic Resonance Imaging
Published on Society of Radiographers (https://www.sor.org)

Mechanically, electrically and magnetically operated devices may malfunction in the presence of a strong magnetic field. This malfunction may not be obvious at the time of examination but may subsequently have serious consequences. Examples include:

- cardiac pacemakers
- cochlear implants
- programmable hydrocephalus shunts
- implanted neurostimulation systems
- implanted drug infusion pumps

NB: this is not an exhaustive list of examples.

Departments should ensure that their local rules contain information about active device implants which are contraindicated. For those which are MR conditional, a process for scanning patients with such implants should be clearly documented.

Most cardiac pacemakers are contra-indicated in MRI. Field strengths as low as 1mT may be sufficient to cause deflection, programming changes or to close reed switches. Such patients should not enter the MR controlled area. Departments should also be aware of patients who have had a pacemaker removed and should check for any remaining pacemaker wires which can act as antennae and cause induced currents. However, there are now a number of manufacturers in the UK that have developed MR conditional pacemakers and leads, see 8.2.

The field strengths and other relevant operating parameters at which specific implants have been tested should be noted when assessing the safety of implants. Safety at one field strength may change at another.

It should be noted that many implants and devices have NOT been assessed at field strengths of 3T and above.

8.2 MR Conditional Pacemakers

Certain manufacturers have now developed MR Conditional pacemakers, allowing for patients with these to undergo MRI scanning under certain stated conditions for safe operation.

Current examples include:


MEDTRONIC Sure Scan- Advisa MRI Pacemaker and Ensura MRI Pacemaker systems. Further information available at: http://www.medtronic.com/surescan/index.html\(^{13}\) (accessed 28\(^{th}\) February 2013)

The MHRA states ‘Exceptionally, a person fitted with an MR conditional pacemaker may enter the MR controlled area for scanning only if the MR operator has confirmed that all of the manufacturer’s stated conditions for safe operation are met’. ²

In addition to complying with the manufacturers’ conditions for safe operation, the SCoR advises that departments formulate a local policy to be included within the local rules. Such a policy should include: a patient pathway; clearly defined roles and responsibilities of the radiology department, radiographic staff and the cardiology department; a list of any contraindications, potential adverse events and emergency procedures; the manufacturers’ specific operating instructions and any local specific instructions.

- Departments must ensure a robust process for checking that both the pacemaker and the leads are MR conditional.

- Departments should ensure that they obtain the manufacturers’ guidelines relevant to the United Kingdom.

8.3 Non-active devices

There is a risk that implanted ferro-magnetic devices will undergo attractive forces such that they can dislodge, causing serious injury or discomfort to the person concerned. Such devices will be labelled as MR unsafe, MR conditional or MR safe.

Departments should ensure that their local rules contain information about non-active device implants which are MR unsafe. For those which are MR conditional a process for scanning patients with such implants should be clearly documented.

Examples include:

- Coils, stents and filters
- Aneurysm clips
- Heart valves
- Orthopaedic implants

NB: this is not an exhaustive list of examples.

8.3.1 Aneurysm clips

Numerous aneurysm clips are contraindicated, namely those made of certain stainless steels.¹⁰

The majority are listed as either MR conditional or MR safe.¹⁰

If your department has a policy to scan MR conditional and MR safe aneurysm clips, a clearly defined process for ensuring accurate MR compliancy details of the clip and the process for scanning these clips should be documented within the local rules.

8.3.2 Management of Post Operative Patients

Great care must be taken with regard to recently implanted MR safe or MR conditional ferro-magnetic implants or clips which are not anchored into bone, before they become embedded with fibrous tissue. Local rules should specify the time which should elapse prior to scanning, but it should be not be less than six weeks. Those objects, such as bone screws or joint replacements
which are firmly anchored, may safely be scanned but should be monitored carefully because the object may be subject to temperature rise: scanning should be discontinued if discomfort occurs. Image quality around the site will, in any case, be seriously degraded and the examination may not be of diagnostic quality.

8.4 Intra Orbital Foreign Bodies

8.4.1 Patients

Intra orbital foreign bodies (IOFB) are of particular concern and any patient presenting with a history of an IOFB should be treated with caution. SCoR and BAMRR recommend that departments initiate a clinical screening process. This should be documented within the local rules and must comply with IR(ME)R Schedule 1. The MR operator may be a named IR(ME)R Referrer who is also a registered healthcare professional and is entitled by the IR(ME)R Employer to refer for plain film radiography of orbits.

Departments should also investigate the existence of any previous orbital imaging prior to the patient undergoing an X-ray to exclude an IOFB.

8.4.2 Staff or carers accompanying a patient

Staff or carers accompanying a patient should not enter the MR controlled area, nor should they undergo an X-Ray if they have a history of an IOFB. In such an instance the department should make alternative arrangements if the patient requires a carer within the scan-room.

8.4.3 Volunteers

Volunteers who present with a history of an IOFB should not generally be scanned (although they should be advised that this would not necessarily preclude them for a clinical scan if they were to require one in future). However, if there has been provision made within the ethical approval for exposure to ionising radiation then the volunteer may proceed and undergo the clinical screening procedure for IOFB as outlined in 8.4.1.

NB. All volunteers participating in experimental trials should be screened before exposure and should have given informed consent. The scanning of volunteers requires approval from local ethics committees. It is recommended that all examinations are reported and suitable processes be in place for onward referral for those found to have abnormal scans.

8.5 Non-medical objects

8.5.1 Bullets and Shrapnel

Metallic objects in the body (such as shrapnel or a bullet) become fibrosed in tissue within six weeks. Beyond that time it may be safe for scanning. However, consideration must be given to the likelihood of heating effects and also the potential for larger, ferro-magnetic objects to experience significant forces while being positioned within the bore of the magnet.

Any large (>1 cm$^3$) metallic fragments should be assessed on a case by case basis. Such objects are of greater concern if they are located near significant soft tissue or vascular structures. Therefore, obtaining current and previous imaging is essential in the assessment of risk versus benefit required before the MR scan may proceed. Involvement of the patient, the referring clinician and a radiologist or consultant radiographer who can review and comment on related imaging is recommended in such cases.

8.5.2 Make up, piercings, tattoos

Non-medical objects such as piercings and make-up which has a high iron oxide content may cause burning and, wherever possible, should be removed both for patient safety and diagnostic image quality. Some tattoos also have a high ferrous content and patients should be counselled regarding
the possibility of local burns and asked to report any discomfort immediately and scanning stopped. Consideration should also be given to patients who have hair extensions as there are certain types that are bonded or tied to the hair using metal components.

8.5.3 Transdermal Patches
Some transdermal patches contain metal within the backing which could potentially become conductive, leading to skin burns.

Transdermal patches should be removed prior to the patient entering the scan room if they contain, or may possibly contain, metal within the backing.

9. Pregnancy

9.1 MRI of the pregnant patient
For MR procedures on pregnant women, the safety of both the mother and the developing fetus needs to be carefully considered. Departments should proceed with caution and scanning should only take place following consideration of the risks and benefits of using MRI including assessing the suitability of alternative imaging modalities.

There are numerous sources of current guidance; please refer to the documents listed in 9.2 for further information.

Departments should have in place a clear process for consenting and scanning pregnant patients recorded within the local rules.

Once the decision to scan has been made:

MR operators should ensure that, wherever possible, scanning is within the normal operating modes. Scan parameters should be recorded on the RIS system, in particular scan duration and accumulated SAR.

9.2 Current Guidance
Please refer to the following publications for further information on potential risks and guidance and exposure limits:

International Commission on Non-Ionising Radiation (ICNIRP) Guidelines on Limits of Exposure to Static Magnetic Fields, 2009 3

Amendment to the ICNIRP Statement on Medical Magnetic Resonance (MR) procedures Protection of Patients 2009 6

Health Protection Agency (HPA) Protection of Patients and volunteers undergoing MRI procedures 2008 4

MHRA Guidelines for Magnetic Resonance Equipment in Clinical Use 4
9.3 Decision to scan pregnant patients

The MHRA recommends that a decision to scan should be made at the time between the referring clinician, an MRI radiologist and the patient, regarding the risks weighed against the clinical benefit to the patient. This decision should be recorded in the patient’s notes and on any Hospital Information System (HIS) or Radiology Information System (RIS) used.

Although it is likely that an initial discussion as to whether MRI is the appropriate modality would take place between a referring clinician and radiologist, there are many MRI units operating as standalone/satellite units often without access to radiologists. It is within the scope of practice for a suitably trained and experienced MR radiographer to advise patients and referring clinicians on the risks and benefits associated with MRI and to offer advice on the most appropriate imaging exam.

9.3.1 Factors to consider prior to deciding to scan pregnant patients

If your opinion is requested regarding the suitability of MRI on a pregnant patient, consider the following:

- can the examination be deferred until after delivery? Discuss with the referring clinician their proposed course of treatment/action.
- can the clinical question be answered using a different method/modality, in particular consider ultrasound.
- consider the risks associated with other modalities eg CT. Consider radiation dose.

9.3.2 Consenting the pregnant patient

Departments should have in place a clear process for consenting pregnant patients. This should include a consent form signed by the patient, the referring clinician and the MR radiologist and/or MR radiographer.

Please also refer to section 17.2 Consent.

9.4 Pulse sequence selection and parameter manipulation

Manufacturers often provide general guidance in their user manual with more specific advice available from applications support teams. If required, seek advice from your MR safety advisor regarding pulse sequence selection and discuss with a radiologist or a suitably qualified radiographer the possibility of utilising a reduced protocol examination. MR operators should utilise low SAR and quiet pulse sequences wherever possible.

9.4.1 Reducing heating effects

Gradient echo sequences are generally less RF intensive resulting in less heating effects. Where possible, select low SAR pulse sequences.

It is essential to ensure patient weight is accurately obtained.

9.4.2 Reducing acoustic noise levels

Where possible, switch gradients into reduced acoustic noise mode, such as whisper or soft tone. Longer TRs, lower resolution, increased slice width, larger Field of Views will all reduce the dB/dt and, thus, the acoustic noise generated. Echo Planar Imaging and other fast acquisition techniques will produce high acoustic noise levels and these should be carefully considered before use.

9.5 Use of gadolinium based contrast agents - pregnant patients
The MHRA\textsuperscript{15} has issued advice to healthcare professionals regarding the use of gadolinium based contrast agents (GBCA): use of any GBCA during pregnancy is not recommended unless absolutely necessary.

9.6 Pregnant staff

Under the Management of Health and Safety at Work Regulations (Regulation 16)\textsuperscript{16} employers are obliged to undertake a risk assessment for expectant mothers relating to hazards caused by physical agents. Further information is available within the SCoR\textsuperscript{17} publication, available online: https://www.sor.org/learning/document-library/health-safety-and-pregnancy-clinical-imaging-and-radiotherapy-departments-guide-pregnant-women (accessed 28\textsuperscript{th} February 2013)

Risk assessments should be conducted for each MR scanner.

9.6.1 Current guidance

Please refer to the documents listed in 9.2 for further information.

Employers should ensure that they comply with the advice issued in Safety Guidelines for Magnetic Resonance Equipment in Clinical Use, MHRA\textsuperscript{2}, as updated, superseded and replaced from time to time. Currently the MHRA recommends that

‘each site should undertake a risk assessment analysing staff movement and location in relation to the levels of the magnetic fields and the total length of time that they will be exposed. In general, it is expected that the level of the time-varying electromagnetic fields, dB/dt, and the radio frequency will be relatively low except in the immediate vicinity of the scanning aperture. This may be of concern in the interventional situation. The level of the static magnetic field exposure is dependent on the field strength and shielding incorporated into the design of the magnet.’

The MHRA recommends that throughout their pregnancy it is advisable that staff do not remain in the scan room while scanning is underway.

10. Considerations for high field strength scanners (3T and above)

The use of higher field strength units in a clinical setting is increasing. The increased SNR gained offers many advantages in clinical scanning. However, there are also further safety considerations and employers and staff need to be fully conversant with these. Staff will require further training in order to ensure patient safety. Employers should conduct a comprehensive risk assessment prior to the use of a new high field strength installation and there should be an independent set of local rules created.

10.1 Implantable medical and non-medical objects

There must be no assumption made that because a device or implant is safe at 1.5T it will still be safe at field strengths of 3T and above. Departments should proceed with caution and if they are unable to obtain the required information then scanning should not take place.

Departments should ensure that the implant or device has been tested up to the required field
strength. For those listed as conditional at field strengths of 3T, departments should be fully aware of the conditions under which the device or implant can be safely scanned in liaison with the MR safety advisor and manufacturer. A record of all implants and their MR safety status should be included within the local rules alongside processes for scanning patients with MR conditional implants.

10.2 Projectile and attractive forces

The attractive force on a ferro-magnetic object is proportional to the spatial gradient of the magnetic field. This is normally steeper at higher fields particularly since active shielding is used to reduce the extent of the stray fields around the scanner. Therefore, objects including implants that have been found to be safe to use in the presence of 1.5T systems may not be so with 3T systems.  

Department will need to reassess all equipment for use in 3T units that has been proved to be safe in 1.5T units. In particular, any equipment that is found to be conditionally safe at 3T must be carefully assessed, as the distance that an object can be safely kept from the magnet will alter at the higher field strength.

Equipment should be clearly labelled as detailed in section 3.5

10.3 Specific Absorption Rate (SAR)

SAR is the measurement of energy deposited by an RF field in a given mass of tissue. SAR increases quadratically with field strengths. When using RF-intensive pulse sequences such as FSE, EPI and FLAIR then SAR limits can quickly be reached. Extra precautions should therefore be taken to ensure patient safety. Manufacturers have developed many SAR reducing sequences and staff should be fully conversant with their use. See also section 5.1.1.

10.4 Peripheral Nerve Stimulation (PNS)

This effect is increased at 3T and the radiographer should be aware of methods to reduce this, both by means of patient positioning, sequence selection and parameter manipulation if required.

10.5 Acoustic Noise

The noise levels generated in a 3T system approaches twice those generated by a 1.5T system and can be in excess of 130 dBA. Higher gradient performance at 3T scanning also causes higher sound pressure levels.

10.6 Pregnancy

Please also refer to section 9.

10.6.1 Scanning of pregnant patients at 3T

Departments need to carefully assess the risks and benefits prior to making the decision to scan at the higher field strength; they should consider whether scanning at a lower field strength such as 1.5T would adequately answer the clinical question. The decision to scan a pregnant patient at 3T should be clearly documented and the risks and benefits discussed with the patient.

10.6.2 Pregnant staff in high field strength units

Please refer to section 9.6. Employers must conduct a risk assessment as detailed in section 9.6.1. This should include detailed field plots to fully assess the static field exposure.
10.7 Design and planning of a high field strength unit

Where a department has several MRI scanners of different field strengths then the design and the layout of the unit should reflect the caution needed when imaging a patient who has an implant or device that is safe to scan only at the lower field strength, in order to avoid the possibility of the patient entering the higher field strength unit. Accurate and clear labelling of distinct areas should be employed and local rules should reflect the need for a strict pattern of working that avoids patients being inadvertently scanned on the higher field strength scanner.

11. Contrast agents and other drugs

A variety of contrast agents and other drugs are used in the MR environment. Examples include gadolinium based contrast agents (GBCA), liver specific contrast agents, iron oxides, diazepam, antispasmodic agents such as buscopan and glucagon and diuretics such as furosemide.

11.1 Contrast agent injections should only be undertaken if clinically indicated and at the request of the supervising MRI radiologist or radiographer who is appropriately trained and is authorised by the Clinical Director or Lead Radiologist. This authorisation should be documented in the local rules. Radiographers are permitted, under law, to supply and administer prescription only medicines (including contrast media) under patient group directions (PGDs) and, therefore, MRI departments should have PGDs in place. If the drugs being administered are not prescription-only medicines, then PGDs are not required in law although they are considered good practice. If an intravenous (IV) injection is to be given by a radiographer, that radiographer should be trained and competent in IV administration. A register of contrast administration should be kept.

11.2 Patient consent should be sought in line with departmental protocols and all staff should be conversant with local emergency procedures.

11.3 Up-to-date information on supply, administration and prescribing of medicines, including example PGDs, can be accessed from the members section of the website: https://www.sor.org/practice/other-groups/prescribing (accessed February 28th 2013)

11.4 Gadolinium containing agents are the most common contrast agents used in MR imaging. They are linked in varying degrees to a risk of nephrogenic systemic fibrosis (NSF). The European Medicines Agency and its Committee for Medicinal Products for Human Use (CHMP) reviewed the risk of nephrogenic systemic fibrosis (NSF) with gadolinium containing contrast agents and classified them according to risk as follows:

- **High risk** - Omniscan (gadodiamide), OptiMARK (gadoversetamide), Magnevist (gadopentetic acid)
- **Medium risk** - MultiHance (gadobenic acid), Primovist (gadoxetic acid), Vasovist (gadofosveset)
- **Low risk** - Gadovist (gadobutrol), ProHance (gadoteridol), Dotarem (gadotericacid)

11.5 Risk minimisation methods

The MHRA has issued guidance regarding minimising the risk of NSF: this can be viewed on their
Departments should have within the local rules clear written procedures in place regarding the use of GBCAs in order to minimise the risk of NSF.

12. Manual handling in MRI

Manual handling within an MR unit frequently involves the moving and positioning of cumbersome coils, heavy phantoms, other equipment and patients.

It is advisable for departments to ensure that there are storage units for coils at a corresponding height to the MR table top to avoid staff frequently lifting coils from floor to table top. If this is not feasible, for example on a mobile unit, appropriate measures should be put in place to minimise risks. This may include altering the bookings to minimise coil changes throughout the day.

The SCoR is currently working on a guidance document on manual handling due to be published in 2013. Further information is available on the SCoR website: https://www.sor.org/trade-union-support/health-safety

13. Fire and emergency safety and training

The static magnetic field means that extra considerations are required in the case of an emergency or fire within an MR unit. MR staff should be conversant with all safety procedures and practiced in the safe removal of patients in an emergency situation. We recommend that this is practiced as a minimum 4 times per annum and on induction to the unit for new staff. Staff should be aware of the location of the fire extinguishers, quench buttons, oxygen monitors and departmental crash trolley.

13.1

In the case of a patient emergency within the scan room such as cardiac arrest, the patient should be removed from the scan room prior to the arrival of the resuscitation team and their equipment.

13.2

Clear fire procedures should be kept with the local rules. Staff should be aware of these and in particular under what scenario a quench would be required during a fire in the MR unit.

13.3

Staff should be aware of the circumstances under which they should quench a magnet and understand the implications of a magnet quench.


14.1 Background
The Electro-Magnetic Fields (EMF) Directive was first adopted in 2004 with an original implementation date of April 2008. The Directive required that worker exposures to EMFs were kept to below agreed limits; these limits were set from recommendations published by the ICNIRP.

The Directive had a significant impact on MRI whereby certain types of scanning would have resulted in worker exposures above the ICNIRP limits; this would be prohibited under the Directive. Following widespread concerns raised by the medical imaging and MR research communities, an amended Directive was adopted in 2008 that delayed implementation of the original directive until 2012. This delay was to allow the European commission to consult stakeholders from across Europe on the future of the directive and allow time for scientific studies to analyse the impact of the directive on the use of MRI.

The study ordered by the commission demonstrated that compulsory compliance with the exposure limit values of the directive would indeed hamper the further use of MRI. A new draft directive which included updated ICNIRP values was then proposed. This draft allowed for a conditional derogation for MRI from the numerical exposure value limits although not from the directive as a whole.

14.2 Current Status

The European Parliament’s Committee on Employment and Social Affairs (EMPL) has approved a draft directive which will form the basis of negotiations with the European Council and will potentially be voted on by the European Parliament in 2013.

For further information and forthcoming updates please see SoR webpage:


NB. Once the directive has been adopted full, details of the directive and its implications for the MR community will be published as an addendum to this document.

15. Staffing of MRI units

The SCoR receives many enquiries regarding the staffing of MR units, primarily relating to the suitable skill mix and minimum staffing levels. Generally, the SCoR tends not to be prescriptive about staffing levels as configurations will very much vary to meet local circumstances and service delivery model; rather we would suggest an approach that considers certain principles in order to provide a quality, safe and effective service for patients and staff. Under the Health and Safety at Work Act, employers have a general duty to ensure the health, safety and welfare at work of all employees. Employers are also obliged to carry out risk assessments into all aspects of working including systems and patterns of work. When considering the staffing requirements of an MR unit, managers should take into account the following:

15.1 Safety of patients and staff

Patient safety is paramount, particularly regarding the hazards associated with the strong magnetic fields utilised in clinical MRI. Staffing levels and competences should be such that there are no compromises to patient safety.

The MHRA advises that staff should not work alone, especially out of hours. Where it is considered essential that staff do work alone, the Lone Worker Policy of the Trust should be considered.

15.1.1 MR safety knowledge

The high static magnetic field strengths used in clinical magnetic resonance imaging pose additional
It is recommended that all staff working in MR units should have as a minimum:

- knowledge and understanding of the threats posed by the static magnetic field;
- understanding of the environment and controlled area;
- awareness of MR authorised personnel;
- understanding of the screening process and access rights;
- knowledge and understanding of emergency procedures within the scan room;
- understanding of the nature of a magnet quench and when a system may need to be quenched by the operator;
- understanding of the labelling system for MR equipment;
- understanding of the requirement for hearing protection and correct positioning;
- understanding of the correct use and positioning of the coils and cables and ancillary equipment.

Radiographers require further post registration knowledge and understanding in the following areas:

- Bio effects of the static magnetic field
- Projectile and attractive forces
- Bio effects of time varying gradient magnetic fields
- Bio effects of RF radiation
- Recommended exposure value limits
- Sequence selection and parameter manipulation to minimise all of the above
- Conditional implants and devices
- Contrast agents and other drugs

15.1.2
All staff should have adequate training in departmental emergency procedures.

15.1.3
When considering staffing using a radiographer working alongside a non- clinically trained helper then provision must be made for adequate rest periods for the radiographer.

15.2 Equitable service provision
Managers should consider if the service being offered is of the same quality and safety for the patients and staff throughout the whole day i.e. will there be any difference in the service delivered to a patient attending at 9am than one attending at 9pm?

15.3 Skills, experience and knowledge of staff
When considering staffing using radiographers working with either a non-clinical helper or an assistant practitioner grade then the radiographer should be appropriately experienced with:

- post registration skills and knowledge in MR
- skills in clinical decision making eg taking appropriate action for incidental findings
- taking responsibility for the episode of care, particularly in the absence of other staff trained in MRI.

15.4 Assistant Practitioners in MR Units
The role of an assistant practitioner in magnetic resonance imaging (MRI) is related to providing support for other registered healthcare practitioners eg radiographers and radiologists, and for
aspects of patient care.\textsuperscript{22}

16. Design and planning of units

16.1
It is essential that a radiographer is, from the outset, part of the project team for the design and planning of a new or additional MR unit along with an MRI physicist, NHS estates or private company estates person, vendor’s project manager and architect etc. It is also useful to include a member from the hospital’s infection control team, nursing team, medical physics, manual handling and risk assessment departments to gain their input to the project as any equipment will need to be tested/certified and furniture/fittings should be ergonomically designed and comply with current standards.

16.2
It is important to obtain a copy of the pre-installation guidelines document from the magnet vendor as soon as possible, as that will give the specifics/particular requirements for the system.

16.3
There are many safety considerations related to site selection, site location, site access, quench pipe design considerations, location of scan rooms, control rooms, preparation rooms, storage of equipment, emergency equipment etc.

For further information please refer to the MHRA Guidelines.\textsuperscript{2}

17. Professional responsibilities of the radiographer

17.1 MRI safety screening questionnaires

17.1.1
Risk/benefit decisions must be taken by the MRI team in consultation with the patient or their guardian. Before the patient is allowed to enter the controlled area, the authorised person (usually the MR operator/radiographer) is responsible for ensuring that the risks are made clear and that the evidence provided is based on the most current and up to date literature.

17.1.2
Written documentation, normally in the form of a questionnaire, regarding the risk assessment for each patient should be completed by the patient and checked through with them by the authorised person. Any discrepancies or queries should be discussed with the patient and the decision to scan should be made in conjunction with the local rules and employing authority policies.

17.1.3
The questionnaire should be signed and dated by the patient and countersigned as checked by the MR operator.

17.1.4
There may be occasions when it is not possible for the patient to be able to answer the safety questionnaire directly, for instance, in the case of the unconscious patient, or clients who do not speak English.
17.1.5
In the case of the unconscious patient, close reference should be made to the patient notes and, ideally, the next of kin may be asked to complete the questionnaire. Reference should be made to employing authority policy on consent and this should be reflected in the local rules. Please also refer to 17.2.1. Any doubt about patient status with regard to MRI safety should be rigorously pursued; this may involve, for example, plain radiography to establish metallic intra-orbital foreign body (IOFB).

17.1.6
Patients who do not speak English as their first language should be accorded the same information and confidentiality as any other patient. Ideally, an employing authority translation service, using an approved translator, should be utilised. This should ensure that the questions put to the patient, and the answers received, are accurate and not changed. A translator may be booked in advance, or a phone translation service, approved by the employing authority should be utilised. If the translator is present they should sign the form to confirm that they asked the patient all the questions listed and that the answers noted are a true record of those received. If the translator is not present, a note of their name or identification code should be made on the form. The safety of the patient, however, is the responsibility of the authorised person, usually the scanning radiographer. It should not be common practice to use a relative for translation purposes and it is inappropriate for minors to perform this function.

17.2 Consent

17.2.1 Duties
Under your duties as a registrant with the HCPC, you must obtain informed consent to provide care or service. This involves explaining the service you are planning to provide any risks involved and any other possible options. 23

Radiographers undertaking a clinical imaging diagnostic exam have a duty of care to ensure that patients are fully aware of the procedure and have consented to it. The health professional carrying out the procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done: it is they who will be held responsible in law if this is challenged later. 24

17.2.2 Consent and adults with impaired capacity
The HCPC acknowledges that in some situations such as emergencies or where a person lacks a decision making capacity, it may not be possible for you to explain what you propose, get consent or pass on information.23 The SCoR 24 advises that all reasonable steps must be taken to support a patient to make a decision. This involves taking extra time with the patient and using language appropriate to the level of understanding.

The patient’s carers may be able to help in this regard but they cannot give valid consent on behalf of the patient, including the patient who lacks capacity. Acting in the best interests of the patient may involve the radiographer delaying or postponing the procedure if, in their opinion, more time needs to be taken to obtain consent. The referrer should be informed and discussions may include possible alternative procedures, if relevant.

If the employing authority has policies regarding consent which have been developed locally these policies should be followed. If, after taking every practical step to achieve consent from the patient, consent is not achievable, the radiographer needs to be clear that by providing imaging and/or treatment they are acting in the best interests of the patient.

Radiographers must record decisions taken along with a brief explanation of why the decisions were taken.

17.2.3 Consent and the child
Consent for MRI scanning in the case of minors should reflect employing authority policy.

17.2.4
For further information and advice on Consent, please view the following SCoR publications:

Consent to Imaging and Radiotherapy Treatment Examinations

Patient Identification, Confidentiality and Consent: Further Guidance


17.3 Reporting of incidents and near misses

All incidents and near misses related to patient or staff safety within the MRI unit should be reported in accordance with your local employers’ rules. Also, incidents and near misses involving MR diagnostic equipment should be reported to the MHRA. Incident forms are available on their website and you can report an incident online:


There are also links for the reporting of incidents in Scotland, Wales and Northern Ireland.

If you are unsure please contact the Adverse Incident Centre: aic@mhra.gsi.gov.uk

17.4 Knowledge, skills and competency

The science of MR and technological developments in equipment and device implant evolves rapidly and radiographers must ensure that their knowledge skills and competencies keep pace with these advances in order to ensure a quality and safe service.

It is a requirement as a registered professional to ensure that you keep your knowledge and skills up to date and that you act within the limits of your knowledge skills and experience.

17.4.1 Scope of Practice

In identifying and communicating their individual scope of practice, radiographers must consider the roles and the environments in which they work and ensure that they are educated and competent to operate in their specific roles. Further information is available in the SCoR publication ‘The Scope of Practice’.

18. Further Resources

The Society and College of Radiographers MRI web pages
https://www.sor.org/practice/cross-sectional-imaging/mri

The Society and College of Radiographers Magnetic Resonance Advisory Group
https://www.sor.org/practice/cross-sectional-imaging/mr-advisory-group

The British Association of MR Radiographers - BAMRR
http://www.bamrr.org/home

The Institute of Physics and Engineering in Medicine - IPEM
http://www.ipem.ac.uk
19. References


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**Source URL:** https://www.sor.org/learning/document-library/safety-magnetic-resonance-imaging-0