Magnetic Resonance Imaging (MRI) Safety Manual
For HA Hospitals

Quality Assurance Subcommittee
COC (Radiology)
Hospital Authority

Version 2.3
Updated Nov 2009

Prepared by
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## MRI Safety Manual for HA Hospitals

### Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disclaimer</td>
<td>4</td>
</tr>
<tr>
<td>(A) Introduction</td>
<td>5</td>
</tr>
<tr>
<td>(B) Administrative Policy of MRI Safety</td>
<td>6</td>
</tr>
<tr>
<td>(C) MRI Hazards and Safety Standards</td>
<td>8</td>
</tr>
<tr>
<td>(D) Static Magnetic Field Issues</td>
<td>10</td>
</tr>
<tr>
<td>(i) Concepts of Controlled Access Volume within MRI Suite</td>
<td>10</td>
</tr>
<tr>
<td>(ii) Screening of Patients and Other Personnel</td>
<td>11</td>
</tr>
<tr>
<td>(E) Time-varying Gradient Magnetic Field Issues</td>
<td>14</td>
</tr>
<tr>
<td>(F) Radiofrequency Magnetic Field Issues</td>
<td>16</td>
</tr>
<tr>
<td>(G) Cryogen-related Issues</td>
<td>18</td>
</tr>
<tr>
<td>(H) Medical Emergency During MRI Examination</td>
<td>20</td>
</tr>
<tr>
<td>(I) Pregnancy-related Issues</td>
<td>21</td>
</tr>
<tr>
<td>(i) Staff Pregnancies</td>
<td>21</td>
</tr>
<tr>
<td>(ii) Patient Pregnancies</td>
<td>21</td>
</tr>
<tr>
<td>(J) MRI Contrast Agent Safety</td>
<td>23</td>
</tr>
<tr>
<td>(i) Allergic Reaction of MRI Contrast Agent</td>
<td>23</td>
</tr>
<tr>
<td>(ii) Breast-feeding Women</td>
<td>23</td>
</tr>
<tr>
<td>(iii) Nephrogenic Systemic Fibrosis (NSF)</td>
<td>25</td>
</tr>
<tr>
<td>(K) Safety Concerns of High-field MR Imaging</td>
<td>32</td>
</tr>
</tbody>
</table>

QA Subcommittee, COC (Radiology)
Nov 2009
(L) Patient with Cardiac Pacemakers or implantable cardioverter Defibrillators ................................................................. 34

(M) Patient Monitoring ................................................................. 36

(N) General Anesthesia and Sedation within MR Environment 37

(O) Fire Safety within MRI Environment .............................................. 39

(P) Electric Safety ............................................................................. 40

(Q) References .................................................................................. 41

(R) Acknowledgements ...................................................................... 42

Appendix I - Short Summary Flyer
Appendix II – Check List Form
Appendix III- Choice of Gadolinium Agent
Appendix IV- Central Renal Committee’s GRF Calculation
Appendix V- Central Renal Committee’s Recommendation

QA Subcommittee, COC (Radiology)
Nov 2009
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(A) Introduction

Magnetic Resonance Imaging (MRI) has been utilized in the clinical setting for investigation of various disease entities in HA hospitals for approximately 15 years. During this time the technology has evolved continuously, yielding MRI systems with stronger static magnetic fields, faster and stronger gradient magnetic fields, and more powerful radiofrequency (RF) transmission coils. Most reported cases of MRI-related injuries that have occurred in worldwide were the apparent result of failure to adhere MRI safety guidelines or of the use of inappropriate or outdated information related to the safety aspects of biomedical implants and devices. Although MRI is a non-invasive diagnostic examination, there are potential risks in the MRI environment for the patients, accompanying family members, attending healthcare professionals, supporting staff and MRI staff. To guard against accidents in the MRI facilities of HA hospitals, the Quality Assurance Subcommittee of COC (Radiology) has developed the MRI safety manual for HA hospitals.

The following MRI safety manual document is intended to be used as a template for MR facilities of HA hospitals to follow in preventing or reducing hazards to patients and other personnel within the MRI environment. This document does not aim to exhaust the list of different types of hazards in the MRI environment, which may be referred from the recommended references or the internationally recognized MRI safety standards or guidelines. The principles behind the MRI safety manual for HA hospitals are specifically intended to provide a practical approach to identify potential safety pitfalls within MRI facilities and provide recommendations for reducing risks to patient and other personnel. All MRI sites of HA hospitals, irrespective of magnet format or field strength, should follow the guidelines of MRI safety manual. It is intended that these MR safe practice guidelines be reviewed and updated on a regular basis as the field of MR safety continues to evolve.
(B) Administrative Policies of MRI Safety

1. Precautions must be observed in the MRI facilities, particularly the magnet room with respect to the strong magnetic field and the presence of cryogen. These precautions apply 24 hours a day whether or not patients are being scanned.

2. Safety practices and policies must be documented, enforced and reviewed at least annually.

3. A safety policy must include:
   - exclusion of the general population outside the 5 Gauss line with appropriate warning signs;
   - procedures to screen patients and all other personnel entering the magnet room for intracranial aneurysm clips, cardiac pacemakers, intra-orbital foreign bodies and other contraindicated devices, e.g. cochlear implants.

4. All MRI safety related incidents should be formally reported for proper documentation and enhancement of staff awareness.

5. The MRI safety policy manual addresses the safety issues specific to the MRI facilities. Guidelines and procedures for other issues not in direct connection with MRI safety are referenced to the respective guidelines and policies of the Radiology Department.

Responsibilities

1. A designated staff should be appointed as a MRI Safety Officer. He/she should be responsible for overall supervision of the issues pertaining to the safe operation of the MRI system. The MRI Safety Officer shall have adequate experience and knowledge in MRI hazards and safety policy of the MRI facility.

2. MR Radiographer/technologist must exercise great care to:
   i. ascertain items purchased for use in or near MRI should have MR compatibility established for that particular MR environment \(^1\)

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\(^1\) As a general rule, err on the side of caution and assume materials are not safe or

QA Subcommittee, COC (Radiology)
Nov 2009
p. 6
This is especially important upon upgrading/replacing an MRI system: all items may need re-evaluation.

ii. prevent loose ferromagnetic objects from being brought into the MR suite

iii. screen patients for (i) implants and appliances that may be hazardous, and (ii) conditions that needs precaution, e.g., pregnancy, claustrophobia.

3. Attending clinician and MR radiologist should proactively plan for managing critically ill patients who require physiologic monitoring and continuous infusion of life sustaining drugs while in the MRI suite.

**Training**

1. Education programs of MRI safety shall be implemented, not only to MRI staff, but also to all other staff of the Hospital who would have an opportunity to enter the MRI environment.

2. All implicated personnel (including emergency, Transport, maintenance, housekeeping, and security) should undergo induction and refresher trainings on MRI safety annually.
(C) MRI Hazards and Safety Standards

1. Potential hazards within MRI environment
   - Static magnetic field
   - Time-varying gradient magnetic field
   - Radiofrequency electromagnetic field
   - Acoustic noise

2. Incidental hazards to patients, staff & other personnel within the magnet room:
   - Implanted objects might be displaced, malfunction or become attached to the magnet.
   - The patients, staff & other personnel could be trapped between the magnet and the projectile ferromagnetic objects if the latter are allowed to enter the magnet room.
   - If an object flies into the magnet, it should not be reached for until it has stopped moving. An object entering the bore of the magnet can fly through the magnet and hit someone on the other side, or even turn around and come back through the magnet like a boomerang.

3. The release of gaseous Helium into the magnet room in the event of magnet quench could displace oxygen rapidly within the magnet room and causes asphyxiation.

4. Food and Drug Administration (FDA) of USA deems MRI system significant risk when used under any of the operating conditions described below¹.

**Static Magnetic Field**

<table>
<thead>
<tr>
<th>Populations</th>
<th>Static magnetic field greater than (Tesla)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults, children and infants aged &gt; 1 month</td>
<td>8</td>
</tr>
<tr>
<td>Neonates i.e. infants aged 1 month or less</td>
<td>4</td>
</tr>
</tbody>
</table>
Specific Absorption Rate (SAR)

<table>
<thead>
<tr>
<th>Site</th>
<th>Dose</th>
<th>Time (min) equal to or greater than</th>
<th>SAR (W/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole body</td>
<td>Averaged over</td>
<td>15</td>
<td>4</td>
</tr>
<tr>
<td>Head</td>
<td>Averaged over</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>Head or Torso</td>
<td>Per gram of tissue</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Extremities</td>
<td>Per gram of tissue</td>
<td>5</td>
<td>12</td>
</tr>
</tbody>
</table>

Time-varying Gradient Magnetic Field

Any time rate of change of gradient fields (dB/dt) sufficient to produce severe discomfort or painful nerve stimulation.

Acoustic Noise

Peak unweighted sound pressure level greater than 140dB.
A-weighted root mean square (rms) sound pressure level greater than 99 dB with hearing protection in place.

(D) Static Magnetic Field Issues

(i) Concept of Controlled Access Volume within MRI Suite

1. Identify zones in the MRI suite where the magnetic field strength exceeds 5 gauss (G). Since magnetic fields are three-dimensional volumes, the 5G-zone may project through floors and ceilings of MRI suite, imposing magnetic field hazards on persons on floors other than that of the MRI scanner. Define the 5G-zone as controlled access volume. Only MRI staff should have free access to this volume. All other personnel must be screened and are only allowed to enter the controlled access volume under the authority and responsibility of MRI staff.

Site Access restriction and zoning (Recommendation by ACR guideline)

Restrict access to MRI suites by zones:

a. Zone I: This region includes all areas that are freely accessible to the general public. This area is typically outside the MR environment itself and is the area through which patients, health care personnel, and other employees of the MR site access the MR environment.

b. Zone II: This area is the interface between publicly accessible, uncontrolled Zone I and the strictly controlled Zone III and IV. Typically patients are greeted in Zone II and are not free to move throughout Zone II at will, but are rather under the supervision of MR personnel. It is in Zone II that the answers to MR screening questions, patient histories, etc.

c. Zone III: This area is the region in which free access by unscreened non-MR personnel or ferromagnetic objects or equipment can result in serious injury of death as a result of interactions between the individuals or equipment and the MR scanner’s particular
environment. All access to Zone III is to be strictly restricted, with access to regions within it under the supervision of MR personnel. It should be physically restricted from general public access.

d. **Zone IV**: This area is synonymous with the MR scanner magnet room itself, that is, the physical confines of the room within which the MR scanner is located. All MR installations should provide for direct visual observation by MR staff personnel to access pathways into Zone IV.

2. The MRI staff should be able to directly observe and control, via line of sight or via video monitors, the entrances or access corridors to the controlled access volume of MRI suite from their normal functional positions within the MRI control room.

3. All access of the controlled access volume should have warning signage indicating the present of strong magnetic field and the magnetic field is always on.

(ii) **Screening of Patients and Other Personnel**

1. Before the MRI staff allows anybody into the controlled access volume, they have to be properly screened for biomedical implants and ferromagnetic objects, and information must be given about potential hazards. Consistent screening to a high standard is the only way to avoid accidents.

2. A high standard of patient screening for MRI safety starts with the referring clinicians who should complete the safety checklist on the MRI request form regarding any biomedical implants of the patients. On arrival at the MRI department, a designated MRI staff should take patients through the safety checklist again to identify any safety issues.

3. A variety of biomedical implants may be encountered in safety screening of patients and other personnel entering the controlled access volume. Once positive identification has been made as to the type of implant or foreign object that is within a patient, best-effort assessments should be made to identify the MRI safety of the implant.
or object. Identification of MRI safety might include written records of the results of formal testing of the implant or object, product labeling regarding the implant or object, and review of peer-reviewed publications regarding MRI safety testing of the make, model and type of the object. The testing conditions should be matched with the specific MRI environment of your facility.

4. Patient information leaflet shall be available to alert patients about MRI safety issues.

5. Patients undergoing an MRI examination must remove all readily removable metallic personally belongings and devices. It is advisable to require that the patients change into hospital gown as far as possible to avoid bringing any ferromagnetic objects into the controlled access volume.

6. Screening unconscious patients is difficult and requires a clinical examination for biomedical implants and operation scars in addition to as much information as possible from family members and the referring clinician. The use of plain X-ray examinations may be required to identify or exclude biomedical implant or ferromagnetic foreign bodies within the patient before undergoing the MRI examination.

7. Other personnel such as accompanying family members, attending healthcare professionals, maintenance workers or other visitors required to enter the controlled access volume of MRI suite shall undergo screening process similar with that for the patients.

8. Metal detector can supplement the screening process of patients and other personnel for any metallic objects. In view of the variable sensitivity settings of metal detector and variable skills of the operators, it shall be reiterated that the use of metal detector is in no way meant to replace a thorough screening practice.

(iii) Device and Object Screening

1. Do not allow equipment and devices containing ferromagnetic components to enter the controlled access volume, unless they have been tested by the device manufacturer and have been labeled “MR
safe” for your specific MRI environment. Also, adhere to any restrictions provided by suppliers regarding the use of MR-safe equipment and devices in your environment.

2. All medical equipment or accessory items such as infusion pump, physiological monitor, anesthetic machine or ECG electrode used within the controlled access volume must be MRI safe.

3. Even if the equipment or devices are MRI safe, the function of the equipment or devices should be checked after leaving the controlled access volume to ensure proper function.

4. Test equipment or devices with a powerful handheld magnet (≥ 1000G) to determine their potential to be attracted by the MRI system before allowing them into the controlled access volume.

5. Bring non-ambulatory patients into the MR environment using a non-ferromagnetic wheelchair or stretcher. Ensure that no oxygen bottles, sandbags or any other ferromagnetic objects are concealed under blankets or stowed away on the transport equipment.

6. Ensure that IV poles accompanying the patient for the MRI examination are not ferromagnetic.

7. Reference materials to check compatibility:
   - Websites for MR safety / compatibility:
     - www.MRIsafety.com
       The international information resource for MRI safety, bioeffects, and patient management.
     - www.IMRSER.org
       The web site of the Institute for Magnetic Resonance Safety, Education, and Research (IMRSER)
(E) Time-varying Gradient Magnetic Field Issues

*Induced Voltages*

1. During MRI examinations, time-varying gradient magnetic fields may stimulate nerves or muscles by inducing electric fields in patients. At sufficient exposure levels, peripheral nerve stimulation is perceptible by patients as a tingling or tapping sensation. Current safety standards for gradient magnetic fields associated with present-day MRI systems appear to provide adequate protection from potential hazards or injuries in patients.

2. MRI Safety guidelines for peripheral nerve stimulation will include:
   - Inform the patients that peripheral nerve stimulation may occur during MRI examinations and describe the nature of sensation to the patients.
   - Instruct patients not to clasp their hands during MRI examinations since this may create a conductive loop which will increase the possibility of peripheral nerve stimulation.
   - Maintain constant contact with the patients during MRI examinations.
   - Instruct patients to alert the operator if they experience painful stimulation during MRI examinations.
   - Terminate the examination immediately at the patients' requests.

3. Patient with implanted or retained wires in anatomically or functionally sensitive areas such as myocardium, epicardium or implanted electrodes in the brain should be considered to be at higher risk, especially from faster MRI pulse sequences e.g. echo planar imaging.

*Auditory Considerations*

1. Activation of gradient magnetic field is the primary source of acoustic noise during MRI examinations. Acoustic noise will be manifested as loud tapping, knocking or chirping sounds. It is advisable to provide
hearing protection to all patients, accompanying family members and attending healthcare professionals during MRI examinations.
Radiofrequency Magnetic Field Issues

Thermal Considerations & Burns

1. Electrical voltages and currents can be induced by radiofrequency magnetic field in electrically conductive materials that are within the magnet bore during MRI examinations. This might result in the heating of this conductive material by resistive losses and result in thermal injury of human tissue.

2. All unnecessary or unused electrically conductive materials should be removed from the magnet bore before MRI examination.

3. The cables of radiofrequency coils, gating leads and monitoring wires shall be checked by MRI staff and service engineers at regular intervals to ensure the integrity of the thermal and electrical insulation.

4. When electrically conductive materials are required to be within the magnet bore with the patient during MRI examination, care should be taken to place thermal insulation (e.g. soft pads) between the patient and the electrically conductive material. It is also appropriate to try to position the leads or wires as far as possible from the inner walls of magnet bore if the body coil is being used for radiofrequency transmission.

5. Care is needed to ensure that the patient’s tissue do not directly come into contact with the inner walls of magnet bore during MRI examination.

6. It is also important to ensure the patient’s tissues do not form large conductive loops and thus not to cross their arms or legs during MRI examination.

7. Patients should be warned about the heating effect of radiofrequency magnetic field, particularly when there are risk factors such as the presence of implants or tattoos.
High Fields Considerations

1. Another important consideration is that as a direct result of the above thermal considerations, it has already been demonstrated in vitro that heating of certain implants or wires may be clinically insignificant at, e.g. 1.5 Tesla but quite significant at 3.0 Tesla.

2. On the other hand, it has been demonstrated that specific implants might show no significant thermal issues or heating at 3.0 Tesla, but may heat to clinically significant or very significant levels in seconds at, e.g. 1.5 Tesla.

3. MR scanning at either stronger and/or weaker magnetic field strength than those tested may result in significant heating where none had been observed at the tested field strength(s).

4. Therefore, at no time should a label of ‘MR conditionally safe for thermal issues at a given field strength’ be applied to any field strength, higher or lower, other than the specific one at which safety was demonstrated.

5. It is important to follow established product MR safety guidelines carefully and precisely, applying them to, and only to, the static magnetic field strengths at which they had been tested.
(G) **Cryogen-related Issues**

1. For super-conducting MRI systems, if the magnet quenches, the escaping cryogenic gases are ducted outside the building to an unoccupied discharge area. However, there have been documented failures of cryogen vent pipe assemblies, which have led to considerable quantities of cryogenic gases being inadvertently discharged into the magnet room. This produces several potential safety concerns including:
   - Asphyxiation due to displacement of oxygenated air by cryogenic gases within the magnet room.
   - Frostbite or cryoburn caused by the exceedingly low temperatures of the cryogenic gases.
   - Hyperbaric pressure considerations within magnet room due to escape of cryogenic gases into the magnet room.

2. In the event of magnet quenching, it is imperative that all personnel and patients shall be evacuated from the magnet room as quickly as safely feasible. The site access shall be immediately restricted to all individuals until the arrival of service engineers of the MRI system.

3. Oxygen sensor and alarm for low oxygen level shall be available at the magnet room to alert the MRI staff for low oxygen level during magnet quenching.

4. A separate emergency exhaust pathway shall be installed at the magnet room to draw the cryogenic gases away from the magnet room while there is failure of the cryogen vent pipe in the unlikely event of quench breach. An additional form of passive pressure relief / pressure equalization shall be available to minimize the risks of positive-pressure entrapment. Such additional installations can provide a degree of redundancy to minimize the risk of cryogens. Detailed specifications of the installation shall be referred to installation guides of the equipment vendor.

5. The practice of breaking a control window should not be advocated as a primary means of relieving and equalizing pressure of magnet room in a quench situation. The current construction of many radiofrequency-
shielded observation windows is such that breaking the window would be very difficult, further diminishing that as a viable means of pressure relief.

6. Contingency plan of magnet quenching shall be available at each MRI facility to ensure safety of patients and other personnel.

7. To ensure proper operation of the cryogen vent pipe assemblies, service engineers shall inspect the cryogen vent system annually. A thorough inspection of the cryogen vent system is also necessary following any quench of a super-conducting magnet.
(H) Medical Emergency During MRI Examination

1. In case of cardiac or respiratory arrest or other medical emergency within the magnet room for which emergent medical intervention or resuscitation is required, appropriately trained MRI staff should immediately initiate basic life support as required by the situation while the patient is being emergently removed from the magnet room to a predetermined, magnetically safe location.

2. Quenching the magnet of super-conducting MRI system is not routinely advised for medical emergency since quenching the magnet and having the magnetic field dissipate could take more than one minute. Moreover, quenching the magnet intentionally can theoretically be hazardous, all personnel and patients shall be evacuated from the magnet room as quickly as safely feasible. One should rather initiate life support measures while removing the patient from the magnet room to a location where the strength of the magnetic field is insufficient to be a medical concern.

3. Defibrillators and emergency carts must not be taken into the magnet room.

4. Contingency plan of medical emergency during MRI examination shall be available at each MRI facility to ensure efficiency and MRI safety during management of patients requiring emergent medical intervention.

5. Emergency equipment/cart should be available and regularly checked. The emergency cart must contain equipment to provide the necessary age-appropriate drugs and equipment to resuscitate an unconscious and apneic patient.
(I) Pregnancy-related Issues

(i) Staff Pregnancies

Upon the agreement of pregnant staff, they are permitted to work in and around the MRI environment throughout all stages of their pregnancy. Although permitted to work in and around the MRI environment, pregnant staff are requested not to remain within the magnet room during actual data acquisition or scanning.

(ii) Patient Pregnancies

1. At present, there is no documented data regarding any deleterious effect of MRI on the developing fetus.

2. According to ACR guideline 2007\(^1\), no special consideration is recommended for the first, versus any other trimester in pregnancy. However, it is prudent to screen women of child-bearing age for pregnancy prior to proceed with MRI examination. 28-day rule shall be applied for screening of pregnancy if indicated.

3. If pregnancy is established, it is necessary to reassess the potential risks versus benefits of the pending study in determining whether performance of the requested MRI examination could safely wait until the end of the pregnancy. The risk-benefit assessment shall be based on the following considerations:
   – The information requested from the MRI examination cannot be acquired via other imaging modalities without ionizing radiation.
   – The acquired data will potentially affect the care of the patient or fetus during the pregnancy.

4. Pregnant patients can be accepted to undergo MRI examinations at any stage of pregnancy if the risk-benefit ratio to the patient warrants that the MRI study be performed. The written informed consent should be available to document that the pregnant patients understand the potential risks and benefits of the MRI examination to be performed. The aforesaid guidelines apply to MRI systems operating up to and including 3 Tesla.

5. MRI contrast agents should not be routinely administered to pregnant patients. The risk to the fetus with administration of MRI contrast agents remains unknown and may be harmful. The decision of administration of MRI contrast agent must be made on a case-by-case basis by assessing the risk-benefit ratio for individual patient.
(J) MRI Contrast Agent Safety

(i) Allergic Reaction of MRI Contrast Agent

1. According to ACR Manual on contrast media, and with reference to peer-reviewed publications on safety of MRI contrast agents, adverse events after intravenous injection of gadolinium-based contrast agent seem to be more common in patients who had previous reactions to an MRI contrast agent. Patients with asthma or allergies also seemed to be at increased risk. Patients who have had adverse reactions to iodinated contrast media are more than twice as likely to have an adverse reaction to gadolinium.

2. At present, there are no well-defined policies for patients who are considered to be at increased risk for having an adverse reaction to MRI contrast agents. However, patients who have previously reacted to one MRI contrast agent can be injected with another brand of contrast agent if they are restudied. For at-risk patients, may consider giving pre-medication with corticosteroids or antihistamines depending on individual hospital and clinician.

3. All patients with asthma, allergies, prior iodinated or gadolinium-based contrast reactions etc. should be monitored more closely after contrast administration as they are at a demonstrably higher risk of adverse reaction.

(ii) Breast-feeding Women

1. Gadolinium-based MRI contrast agents have a biological half-life of approximately 2 hours and are almost completely cleared from the blood pool within 24 hours. With reference to the respective publications, less than 0.04% of administered dose of gadolinium-based MRI contrast agent will be excreted into the breast milk in the

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1 American College of Radiology Committee on Drugs and Contrast Media. Manual on contrast media, 4.1 ed. Restong VA; American College of Radiology, 1998. p. 23

QA Subcommittee, COC (Radiology) Nov 2009
first 24 hours. Since less than 1% of the contrast medium ingested by the infant is absorbed from its gastrointestinal tract, the expected dose absorbed by the infant from the breast milk is less than 0.0004% of the administered dose. The dose of gadolinium absorbed from the gastrointestinal tract of a breast-feeding infant will be much less than the permitted intravenous dose for neonates. According to the available data, it is safe for the mother and infant to continue breast-feeding after receiving gadolinium-based MRI contrast agent.

2. If the breast-feeding woman remains concerned about any potential adverse effects of the contrast agent, a precautionary 24-hour suspension of breast-feeding following the administration of a gadolinium-based contrast agent can be considered. It is also advised to have active expression and discarding of breast milk from both breasts during that period. The breast-feeding woman may be required to use a breast pump to obtain milk before contrast MRI examination to feed the infant during the 24-hour suspension of breast-feeding.
(iii) **Nephrogenic Systemic Fibrosis (NSF) or Nephrogenic Fibrosing Dermopathy (NFD)**

1. Nephrogenic Systemic Fibrosis (NSF) is a severe delayed fibrotic reaction of the body tissue linked with exposure to some gadolinium-based MRI contrast agents. With reference to the available data, the following categories of patients will have higher risk of development of NSF:
   i. Patients with moderate to end-stage renal disease – Glomerular Filtration Rate (GFR) < 60mL/min/1.73m².
   ii. Patients on dialysis
   iii. Patients with reduced renal function who have had or are awaiting liver transplantation – hepatorenal syndrome.
   iv. Children under 1 year old because of their immature renal function.

2. There are differences in the incidence of NSF with different gadolinium-based contrast agents, which appear to be related to differences in physico-chemical properties and stability. At present, it is thought to be appropriate to assume for now that a potential association might exist for all gadolinium-based MRI contrast agents until there are more definitive data to suspect otherwise.

**Current Views on the use of Haemodialysis (HD):**

1. Up to now, there is no proven benefit of hemodialysis for prevention and treatment of NSF. The use of haemodialysis was not agreed by all radiologists and clinicians.

2. Recommendations by European Society of Urogenital Radiology¹,²: (by Dr Tim Leiner Kanal @ ISMRM 2008, NSF Seminar)
   - In patients at risk, not yet on HD:
     - Only inject macrocyclic Gd-based contrast agent in lowest possible dose if no other alternative imaging modality is deemed satisfactory.
◆ Do NOT initiate HD for sole purpose of elimination of Gd-based contrast agent.

➢ In patients already on HD:
  ◆ Schedule HD within 3 hrs after injection
  ◆ At least 9hrs of HD (3x3hrs) is needed to remove Gd

3. ACR guideline\(^3\) consider dialysis when eGFR <60mL/min/m\(^2\)

➢ "In light of the near-total apparent ineffectiveness of peritoneal dialysis at clearing the gadolinium from the body, it may well be worth considering immediate initiation of hemodialysis in peritoneal dialysis patient who receive even a low dose of a GBMCA, or no administering the agent if clinically feasible." - by Dr E Kanal @ ISMRM 2008, MR Safety Forum.

**Current Trend on NSF Treatment:**
1. Up to now, there is no proven benefit of hemodialysis of prevention of NSF.

2. There are no effect on the use of topical and oral immunosuppressants, plasmapheresis and IV-gammaglobulin.

3. There are some anecdotal reports on the improvement in symptoms after extracorporeal photopheresis\(^4,5\), after imatinib mesylate (Gleevec\(^\circledR\)) use\(^6\), and after IV-sodium thiosulfate (chelator) use\(^7\).

4. In very severe cases, may consider renal transplantation.

**Determination of renal function:**
1. Accurate determination of GFR is not easy. Serum creatinine may not reflect the true GFR accurately.

➢ Up to 25% elderly may does not exclude acute renal failure\(^7\)

➢ Single GFR determination does not exclude acute renal failure\(^8,9\)

2. Some useful web-sites to determine GFR:

➢ *Codkroft-Gault\(^10\)*
i. Based on [plasma creatinine]m weight, gender & age
ii. http://www.nephron.com/cgi-bin/CGSI.cgi
  ➢ MDRD11
iii. Based on [plasma creatinine], gender, age & race
iv. http://nephron.org/cgi-bin/MDRD GFR/cgi

3. The Central Renal Committee in HK has come up with a recommendation for your reference according to the eGFR formula (modified from the abbreviated MDRD equation) recently published [J Am Soc Nephrol 17: 2937-2944, 2006] by the Beijing group. (Appendix IV)

Use in Paediatric and Pregnant Patients2,12
The principles of the guidelines on reducing the risk of NSF in adult patients are also applicable for paediatric cases.

Particularly in patients with a increased risk for NSF, also including infants, only macrocyclic Gd compounds should be used, as they are more stable and presently are considered to bear a lower risk of inducing NSF.

Some Gd-contrast media preparations are not licensed for paediatric use. Off-label use of contrast media should be clinically justified, supported by published data in scientific journals and on a named patient basis under local protocol arrangements.

All this should not be exaggerated, and thus should not deny any child a well indicated MR study that offers therapeutically or prognostically essential information.

If the use of a Gd-contrast media is essential, whatever the maternal renal function, choose the most stable Gd-contrast media in the lowest possible dose to protect the fetus. (Appendix III)

Current views on the use of MR Contrast in high risk patients:
1. There are still many unanswered questions about exact pathophysiology of NSF and its treatment. It is anticipated that...
there will be much further study of this issue, and that more information will be forthcoming that will hopefully shed more light on this important issue.

2. NSF concerns should not lead to denial of necessary and justified MRI examination. The risk of inducing NSF must always be weighed against the benefit of the contrast-enhanced MRI examination for those high-risk patients.

3. When risk-benefit assessments warrant administration of gadolinium-based contrast agents to patients with high risk factors, consideration should be given to administration of the lowest dose that would achieve an adequate diagnostic examination.

4. Radiologists should try to assess other imaging possibilities such as US, CT, Intravascular DSA. However, one should bare in mind that the risk of iodinated contrast induced nephropathy greatly exceeds NSF risk\textsuperscript{13,14}.

5. MR staff should try to consider the use of non-enhanced techniques, such as TOF sequence, PC-MRA (mainly for brain).

6. Radiologists should try to coordinate with Gd- contrast agent administration in high risk patients if MR contrast is considered necessary to be given. (Appendix III)

7. Use simple measures to prevent NSF:
   - Know your patients renal status
   - Try to use low dose to lowest possible level in patients at risk
   - When in doubt, use a macrocyclic agent

8. For administration of gadolinium-based MRI contrast agents to patients on haemodialysis, patients shall be scheduled to have dialysis session shortly after the contrast-enhanced MRI examination. At least 9 hours of haemodialysis (3 sessions) is required to remove a Gd-contrast media. The efficacy of haemodialysis can be variable and depends on many factors. However, this is optional and should not cause delays in obtaining important diagnostic information.
9. Initiating haemodialysis for the sole purpose of removing gadolinium-based contrast media should be considered carefully since the haemodialysis itself can be associated with significant morbidity, which is higher than the risk of inducing NSF with gadolinium-based contrast agents.

10. For administration of gadolinium-based MRI contrast agents to patients on peritoneal dialysis, several rapid exchanges of dialysis fluid are recommended to facilitate clearing the gadolinium from the body.

11. The Central Renal Committee in HK has come up with a recommendation. (Appendix V)

**Current views on gadolinium-containing contrast agents**


2. For **high-risk** gadolinium-containing contrast agents (Optimark, Omniscan, Magnevist, Magnegita and Gado-MRT ratiopharm) the Committee recommended contraindications in patients with severe kidney problems, in patients who are scheduled for or have recently received a liver transplant and in newborn babies up to four weeks of age. To minimise the risk of using these high-risk agents in patients with unknown kidney problems, the Committee for Medicinal Products for Human Use (CHMP) advised that patients should always be screened for kidney problems using laboratory tests before use. The CHMP also recommended that women should discontinue breastfeeding for at least 24 hours after a scan.

3. For **medium-** (Vasovist, Primovist and MultiHance) and **low-risk** agents (Dotarem, ProHance and Gadovist), the CHMP recommended adding new warnings in the prescribing information concerning their use in patients with severe kidney
problems and patients receiving a liver transplant. The CHMP advised that screening patients for kidney problems using laboratory test is generally recommended before administration of these gadolinium-containing contrast agents and that the decision to continue or suspend breastfeeding for at least 24 hours after a scan should be taken by the doctor and the mother.

4. The CHMP recommended that the prescribing information of all gadolinium-containing contrast agents should include:

- a warning that the elderly may be at particular risk of NSF due to impaired ability of their kidneys to clear gadolinium from the body;
- a statement that there is no evidence to support the initiation of haemodialysis to prevent or treat NSF in patients not already undergoing haemodialysis.
- a statement that the type and dose of contrast agent used should be recorded.

5. Based on currently available data, and with these risk minimization measures in place, the CHMP considers that the balance of benefits and risks of these agents is acceptable.

6. Finally, the CHMP recommended that further studies should be carried out on the long-term retention of gadolinium in human tissues.

7. European Commission decisions on this option will be issued in due course.

2 Gadolinium-based contrast media and nephrogenic systemic fibrosis. The Royal College of Radiologists November 2007.
7 Yerram et al. Nephrogenic systemic fibrosis: a mysterious disease in patients with renal

QA Subcommittee, COC (Radiology)
Nov 2009
8 Thomsen et al. In which patients should serum creatinine be measured before iodinated contrast medium administration? Eur Radiol 2005; 15:749-54
15 The CHMP recognised that within the high risk group the risk of NSF with Omniscan and OptiMARK appears higher than with Magnevist base on physicochemical properties, studies in animals and the number of cases of NSF reported worldwide. However, as the risk with Magnevist remains substantially higher than the NSF risk with the medium an low risk contrast agents, the CHMP recommended that Magnevist should be retained in the high risk group and be subject to the same risk minimisation measures.
16 More information is available in a question-and-answer document.
17 The procedure was carried out under Article 31 of Directive 2001/83/EC as amended, for nationally authorised gadolinium-containing agents, and under Article 20 of Regulation (EC) No 726/2004 for centrally authorised agents. This type of procedure may be initiated in specific cases where the interest of the Community is involved. The expression ‘Community interest’ has a broad meaning but it refers particularly to the interests of the public health in the Community, for example following concerns related to the quality, efficacy and/or safety of a medicinal product or new pharmacovigilance information.
18 Gadolinium-containing contrast agents are: gadoversetamide (OptiMARK), gadodiamide (Omniscan), gadofosveset (Vasovist), gadoxetic acid (Primovist), gadobenic acid (MultiHance), gadopentetic acid (Magnevit, Magnevist and Gado-MRT-ratiopharm), gadobutrol (Gadovist), gadoteric acid (Dotarem), gadoteridol (ProHance). Most of gadolinium-containing medicines are authorised nationally. OptiMARK and Vasovist are authorised centrally.
19 A public statement on the association between gadolinium-containing contrast agents and the NSF was published in February 2007:
20 This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency website: www.emea.europa.eu
Safety Concerns of High-field MR Imaging

1. In line with the escalating clinical utilization of 3-Tesla MRI system, specific MRI safety issues of high-field MR imaging shall be considered. Most of the previous investigations regarding MRI safety of biomedical implants and devices are based on MRI systems with static field strength of 1.5 Tesla or less. It is necessary to acquire information on ex vivo testing at 3 Tesla or higher to characterize MRI safety of those biomedical implants and devices before proceeding with high-field MR imaging, especially with regard to magnetic field interactions including MRI-related heating and displacement of the biomedical implants. Importantly, a biomedical implant that displayed weakly ferromagnetic qualities in association with a 1.5-Tesla MRI system may exhibit substantial magnetic field interactions during exposure to a 3-Tesla MRI system. The MRI safety of the biomedical implant at high field strength should be fully characterized before proceeding with the related MRI examinations. Identification of MRI safety might include written records of the results of formal testing of the implant or object, product labeling regarding the implant or object, and review of peer-reviewed publications regarding MRI safety testing of the make, model and type of the object. The testing conditions should be matched with the specific MRI environment of your facility.

2. Sound pressure levels (SPL) of gradient noise increase with static field strength. The noise levels at 3 Tesla approach twice that of 1.5 Tesla and can be in excess of 130dB. It is advisable to provide hearing protection to all patients, accompanying family members and attending healthcare professionals during MRI examinations.

3. Specific absorption rate (SAR) is a measure of energy deposited by radiofrequency field in a given mass of tissue. Dissipation of radiofrequency energy in the body can result in tissue heating. SAR is proportional to the square of static field strength, the square of flip angle and duty cycle.
The doubling of field strength from 1.5 Tesla to 3 Tesla leads to a quadrupling of SAR. Patients undergoing MRI examinations at high field strength will be more susceptible to tissue heating. Cooling delays between data acquisitions may be required in order to comply with SAR limitations. Real-time monitoring of SAR by MRI system during imaging examinations at 3-Tesla or higher field strength is recommended.
(L) Patient with Cardiac Pacemakers or implantable cardioverter Defibrillators (ICD)

1. It is recommended that the presence of implanted cardiac pacemakers or implantable cardioverter defibrillators be considered as a relative contraindication for MRI. MR imaging of those patients is not routine.

2. Should an MRI be considered, it should be done on a case-by-case and site-by-site basis, and only if the site is staffed with individuals with the appropriate radiology and cardiology knowledge and expertise on hand.

3. As of this writing, no cardiac pacing and/or defibrillating devices are labeled safe or conditionally safe for MRI scanning. Pacemaker and/or implantable cardioverter defibrillators leads may also present a hazard in the absence of any implant connected to them.

4. Unexpected programming changes, inhibition of pacemaker output, failure to pace, transient asynchronous pacing, rapid cardiac pacing, the induction of ventricular fibrillation, heating of the tissue adjacent to the pacing or ICD system, early battery depletion, and outright device failure requiring replacement may all occur during MRI of patients with pacemakers or ICDs.

5. Should any MRI examination be done, a risk-benefit ratio for the patient has to be established. The non-emergent patient should be apprised of the risk associated with the procedure and should provide prospective written informed consent prior to the initiation of MRI. While the risk may be low, device patients who are considered for MRI should be advised that life-threatening arrhythmias might occur during MRI and serious device malfunction might occur.

6. Should any MRI examination be contemplated for a patient with an implanted pacemaker or ICD, it is recommended that radiology and cardiology personnel and a fully stocked crash cart be readily available throughout the procedure in case a significant arrhythmia develops during the examination that does not terminate with the cessation of the MR study.
7. All such patients should be actively monitored for cardiac and respiratory function throughout the examination. At a minimum, ECG and pulse oximetry should be used. At the conclusion of the examination, the cardiologist should examine the device to confirm the function is consistent with its pre-examination state. Follow-up should include a check of the patient’s device at a time remote (1-6 weeks) after the scan to confirm appropriate function.

8. Other consideration is the substantial magnetic field interactions, causing these implants to move or be uncomfortable for the patients in 1.5 to 3-Tesla MR systems. In addition, the magnetic field-related translational attraction are substantially different comparing the long-bore and short-bore MR systems. Therefore, regardless of the fact that magnetic field interactions may not present a risk for these patients, potentially hazardous mechanisms should be considered carefully for these devices.

9. MR healthcare professionals are advised to contact the respective manufacturer in order to obtain the latest safety information to ensure patient safety relative to the use of an MR procedure.
(M) Patient Monitoring

1. In view of the enclosed environment of magnet bore, all patients undergoing MRI examinations shall be visually and/or verbally monitored.

2. Intercom and patient alert system shall be available with the MRI system to facilitate patient monitoring during MRI examination.

3. Any patients, who are sedated, anaesthetized, clinically ill or unable to response or alert MRI staff for whatever reasons should be physiologically monitored (e.g. oxygen saturation, pulse rate, Blood pressure and ECG etc.).

4. The physiological monitoring equipment and accessories shall be MRI safe. Satellite display of the physiological data at MRI control room will facilitate patient monitoring.
(N) General Anesthesia and Sedation within MR Environment

1. Children form the largest group requiring sedation or general anesthesia for MRI.

2. The other groups of patient are patients who are at high risk for severe distress in the MR environment, such as claustrophobia, anxiety or panic attacks in response to MR procedure. They can be identified as such by their referring clinician or by the scheduling MR staff.

3. Sedation protocols may vary from hospitals to hospitals according to the procedures performed, the method of sedation and the qualifications of the sedation providers.

4. Sedation providers must comply with protocols established by the individual hospital. A protocol for access to back-up emergency services should be clearly identified in case immediate help is needed. The use of sedation or general anesthesia requires special preparation and requirement. The followings are recommended:
   - Pre-procedural medical history and examination for each patient
   - Fasting guidelines appropriate for age
   - Qualified sedation providers
   - Intra-procedural and post-procedural monitors with adaptors appropriately sized for children and compatible with the magnetic field
   - Constant patient observation (window, camera)
   - Resuscitation equipment, including oxygen delivery and suction
   - Record keeping and charting for the continuous assessment and recording of vital signs
   - Location and protocol for recovery and discharge

5. For neonatal and young pediatric population, special attention is needed in monitoring body temperature for hypo- and hyperthermia in addition to vital signs.

6. Equipments must be suitable for children of all ages and size being treated.

7. Equipment for non-invasive blood pressure monitoring and oxygen saturation monitoring must be available.
8. Appropriate suction catheters must be immediately available both in the Magnet Room and in the preparation Room. Airway management and breathing equipment must be checked to make sure they are functioning properly prior to any sedation.

9. An emergency cart must be immediately accessible, The cart must contain equipment to provide the necessary age-appropriate drugs and equipment to resuscitate an unconscious and apneic patient.
(O) Fire Safety within MRI Environment

1. Fire prevention system (e.g. fire sprinklers) should be available at each MRI facility. Only non-ferromagnetic fire extinguishers are allowed to use within the magnet room. Fire hoses with metal nozzles must not be taken into the magnet room.

2. Contingency plan for fire at different areas of the MRI facility shall be available to ensure safety of patients and MRI staff.

3. Press “Emergency Stop” button to terminate power supply to the MRI system in case of fire.

4. Evacuate patients from magnet room.

5. Escort all patients within the MRI facility to a safe location.

6. Activate Fire Alarm within the MRI facility.

7. Quenching of super-conducting magnet may be required during emergency situations when fireman equipped with non-MRI-safe devices are required to enter into the magnet room.

8. If fire outbreaks with no MRI staff on site, the MRI safety officer or his/her delegate shall be contacted to instruct the fire fighting officer and/or security staff as to the means of entry and to the proper means of quenching the magnet if necessary.
(P) Electrical Safety

1. Service engineers shall evaluate the MRI system regularly for electrical safety.

2. All electrical installations of MRI system shall comply with the local rules of electrical safety.
References

- Section For Magnetic Resonance Technologists (SMRT). Safety Aspects in MRI. SMRT Educational Seminars. Volume 4 Number 1
- ESUR Guideline: Gadolinium based contrast media and nephrogenic systemic fibrosis 2007. (www.esur.org)
- Gadolinium-based contrast media and nephrogenic systemic fibrosis. The Royal College of Radiologists November 2007.
- Websites for MR safety / compatibility:
  - www.MRIsafety.com
    *The international information resource for MRI safety, bioeffects, and patient management.*
  - www.IMRSER.org
    *The web site of the Institute for Magnetic Resonance Safety, Education, and Research (IMRSER)*
(R) Acknowledgements

I would like to thank for the help and contributions from the followings:

Mr Lawrance Yip
Dr KS Tai
Dr HW Liu

Contribution of MR safety manuals from different hospitals:
PYNEH
PWH
QEH
QMH
UCH
Appendix I: Short Summary Flyer

1. **Purpose**
   Ensure safety and prevent accidents and injuries in MR suites.

2. **Scope**
   This document deals with MR specific environmental hazards, such as:
   a) Burns, due to presence of electrically conductive material inside the bore.
   b) MR system generates a powerful magnetic field, which attracts iron-containing (ferromagnetic) objects:
      - "Missile effect", e.g., scissors, watches, ink pens, hairpins, hearing aids, stethoscopes, nail clippers, wheelchairs, medical gas canisters.
      - Dislodge implant, e.g., aneurysm clips, pins in joints
      - Malfunctioning of equipment/device, e.g., battery-powered devices, programmable infusion pumps, external hearing aid, pacemakers and implantable defibrillators.\(^1\)
   c) Acoustic injury.
   d) Accidents related to cryogen handling, storage, or inadvertent release.

3. **Responsibilities**
   a) A designated staff should be appointed to oversee and enforce safe practices in the MR environment.
   b) MR radiographert/radiologist must exercise great care to
      - ascertain items purchased for use in or near MRI should have MR compatibility established for that particular MR environment.\(^2\) This is especially important upon upgrading/replacing an MRI system: all items may need re-evaluation.
      - prevent loose ferromagnetic objects from being brought into the MR suite
      - screen patients for (i) implants and appliances that may be hazardous, and (ii) conditions that needs precaution, e.g., pregnancy, claustrophobia.
   c) Attending clinician and MR radiologist should proactively plan for managing critically ill patients who require physiologic monitoring and continuous infusion of life sustaining drugs while in the MRI suite.

4. **Risk Reduction Strategies**

   4.1 a) Restrict access to MRI suites by zones\(^3\), for example,
      - Zone I: General public
      - Zone II: Unscrenne patients
      - Zone III: Screened patients and authorized personnel
      - Zone IV: Screened patients under constant direct supervision of trained MR personnel
   b) Post an eye-catching notice to warn people that MR is at "on" state all the time.

4.2 Screen patients for MR procedures and individuals for the MR environment (watch out for housekeeping and maintenance personnel) before permitting entrance to the MR suite.

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1 The American College of Radiology recommends implanted cardiac pacemakers and implantable cardioverter/defibrillators be considered as a relative contraindication for MRI.
2 As a general rule, err on the side of caution and assume materials are not safe or compatible until proven otherwise, e.g., some sand bags may contain iron. Whenever applicable, use manufacturer-approved fiberoptic, carbon or graphite leads instead of conductive leads on medical devices.
a) Use standardized checklists to ensure comprehensive evaluation (Appendix II)
b) If a patient is unconscious or unable to answer questions, question the patient’s family member or surrogate decision maker.
c) If the person is unsure, use other means to determine if the patient has implants or other devices that could be negatively affected by the MRI scan, e.g., review past history, look for scars and deformities, use plain-XR, metal and/or ferromagnetic detectors\(^4\) to assist in the screening process, etc.

5. Special Precautions

5.1 Thermal Considerations & Burns
a) The most common patient injuries in the MRI suite are burns and the most common objects to undergo significant heating are wires and leads. Other objects include pulse oximeter sensors and cables, cardiorespiratory monitor cables, safety pins, metal clamps, drug delivery patches (which may contain metallic foil), and tattoos (which may contain iron oxide pigment), or from the patient’s body touching the inside walls (the bore) of the MRI scanner.
b) Ensure that no items (such as leads) are formed into a loop, since magnetic induction can occur and cause burns, e.g., don’t loop conductive leads or cables; don’t allow cables to cross over one another; don’t let cables touch the magnet bore and if possible, don’t let cables touch the patient (other than where they have to); don’t inadvertently make the patient’s tissue a loop (e.g., patient’s hand touches the thigh).
c) Place a cold compress or ice pack on ECG leads, surgical staples, and tattoos that will be exposed to radiofrequency irradiation during the MR procedure.
d) If the patient’s body touches the bore of the MRI scanner, use non-conductive foam padding to insulate the patient’s skin and tissues.

5.2 Implanted Devices
a) All implants identified must be evaluated individually for safety.\(^5\)
b) If you are unsure if a device or implant is safe or compatible for your specific MRI machine, check the technical information about the device or implant (if available), consult the vendor/manufacturer of the device/implant and MRI machine, and/or refer to other up-to-date resource on MR safety / compatibility.

- Reference Manual for Magnetic Resonance Safety, Implants, and Devices by Frank G. Shellock, Biomedical Research Publication Group
- Websites:
  - www.MRIsadety.com
    The international information resource for MRI safety, bioeffects, and patient management.
  - www.IMRSER.org
    The website of the Institute for Magnetic Resonance Safety, Education, and Research (IMRSER)

c) If a contraindicated device is revealed in the middle of an MRI procedure, stop it immediately and notify workplace supervisor/clinician and report via AIRS.

5.3 Warning Signs
Post a warning notice to remind “Never run a cardio-pulmonary arrest code or resuscitation inside the MR suite.”

\(^4\) Ferromagnetic detectors are more sensitive than metal detectors.

\(^5\) Risk of dislodgement, induction of currents, excessive heating, changes in the operational aspects, and the presence of artifacts.
5.4 Calculation of GFR in Renal Failure Patients:

- Codkroft-Gault\(^6\)
  Based on [plasma creatinine]m weight, gender & age
  [www.nephron.com/cgi-bin/CGSI.cgi](http://www.nephron.com/cgi-bin/CGSI.cgi)

- MDRD\(^7\)
  Based on [plasma creatinine], gender, age & race
  [http://nephron.org/cgi-bin/MDRD GFR/cgi](http://nephron.org/cgi-bin/MDRD GFR/cgi)

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\(^6\) Cockroft et al, Nephron 1976; 16:31-41

\(^7\) Levey et al, J Am Soc Nephrol 2000; 11:155A
Appendix II

MRI Checklist

This can be seen on GCR request form.
9) Neurostimulator:  
10) Bone growth / fusion stimulator:  
11) Aneurysm clip(s), please specify location, make & model, if any:  
12) Cochlear, otologic, or other ear implant:  
13) Hearing aid:  
14) Ocular implants:  
15) Eyelid spring or wire:  
16) Metal worker:  
17) Intracranial metallic foreign body:  
18) Dentures, partial plate or brace:  
19) Metallic stent, filter or coil, please specify, if any:  
20) Implanted infusion pump (e.g. insulin pump):  
21) Electronic / magnetically-activated implant, please specify, if any:  
22) Vascular access port and/or catheter:  
23) Conventional shunt (spinal or intraventricular):  
24) Programmable shunt (spinal or intraventricular):  
25) Joint replacement / prosthesis limb:  
26) Shrapnel / metallic fragment, please specify location, if any:  
27) Surgical staples, clips, or metallic sutures, please specify location, if any:  
28) Radiation seeds or implants, please specify location, if any:  
29) Penile prosthesis:  

[Options: Yes, No]
Appendix III: Choice of Gadolinium Agent

There are differences in the incidence of NSF with the different Gd-CM, which appear to be related to differences in physico-chemical properties and stability. Macrocyclic gadolinium chelates, which are pre-organised rigid rings of almost optimal size to cage the gadolinium ion, have much higher stability in comparison to linear chelates. Current knowledge about the properties of the different agents and the incidence of NSF when they are used in at-risk patients are summarised below. Products are presented in alphabetical orders according to their generic names.

**Gadobenate dimeglumine (Multihance®)**
*Ligand:* Ionic linear chelate (BOPTA)
*Incidence for NSF:* No unconfounded cases have been reported.
*Special feature:* Similar diagnostic results can be achieved with lower doses because of its 2-3% protein binding.
*S-creatinine (eGFR) measurement:* Not mandatory.

**Gadobutrol (Gadovist®)**
*Ligand:* Non-ionic cyclic chelate (BT-DO3A)
*Incidence of NSF:* No unconfounded cases have been reported.
*S-creatinine (eGFR) measurement:* Not mandatory.

**Gadodiamide (Omniscan®)**
*Ligand:* Non-ionic linear chelate (DTPA-BMA)
*Incidence of NSF:* 3-7% in at-risk subjects.
*S-creatinine (eGFR) measurement:* Mandatory.
*Haemodialysis:* Gadodiamide is contraindicated in patients on dialysis.
CONTRAINDICATED in
- Patients with CKD 4 and 5 (GFR<30 ml/min/1.73m²), including those on dialysis.
- Patients with reduced renal function who have had or are awaiting liver transplantation.
USE WITH CAUTION in
- Patient with CKD 3 (GFR 30-60 ml/min/1.73m²).
- Children less than 1 year old.

**Gadofosveset trisodium (Vasovist®)**
*Ligand:* Non-ionic cyclic chelate (DTPA-DPCP)
*Incidence of NSF:* No unconfounded cases reported, but experience is limited.
*Special feature:* It is a blood pool agent with affinity to albumin. Diagnostic results can be achieved with 50% lower doses than extracellular Gd-CM. Biological half-life is 12 times longer than for extracellular agents (18 hours compared to 1½ hours, respectively).
S-creatinine (eGFR) measurement: Not mandatory.

Gadopentetate dimeglumine (Magnevist®)
Ligand: Ionic cyclic chelate (DTPA)
Incidence of NSF: Estimated to be 0.1 to 1% in at risk subjects.
S-creatinine (eGFR) measurement: Mandatory.
Haemodialysis: Gadopentetate dimeglumine is contraindicated in patients on dialysis.
CONTRAINDICATED in
• Patients with CKD 4 and 5 (GFR<30 ml/min/1.73m²), including those on dialysis.
• Patients with reduced renal function who have had or are awaiting liver transplantation.
USE WITH CAUTION in
• Patient with CKD 3 (GFR 30-60 ml/min/1.73m²).
• Children less than 1 year old.

Gadoterate meglumine (Dotarem®)
Ligand: Ionic cyclic chelate (DOTA)
Incidence of NSF: No unconfounded cases have been reported.
S-creatinine (eGFR) measurement: Not mandatory.

Gadoteridol (Prohance®)
Ligand: Non-ionic cyclic chelate (HP-DO3A)
Incidence of NSF: One case of mild localised NSF in a patient with severe renal impairment.
S-creatinine (eGFR) measurement: Not mandatory.

Gadoversetamide (OptiMARK®)
This agent is not approved for use in Europe
Ligand: Non-ionic linear chelate (DTPA-BMEA)
Incidence of NSF: Unknown, but unconfounded cases have been reported.
S-creatinine (eGFR) measurement: Mandatory.
CONTRAINDICATED in
• Patients with CKD 4 and 5 (GFR<30 ml/min/1.73m²), including those on dialysis.
• Patients with reduced renal function who have had or are awaiting liver transplantation.
USE WITH CAUTION in
• Patient with CKD 3 (GFR 30-60 ml/min/1.73m²).
Children less than 1 year old.

Gadoxetate disodium (Primovist®)
Ligand: Ionic linear chelate (EOB-DTPA)
Incidence of NSF: No unconfounded cases have been reported but experience is limited.
Special feature: Organ specific gadolinium contrast agent with 10% protein binding and 50% excretion by hepatocytes. Diagnostic results can be achieved with lower doses than extracellular Gd-CM. S-creatinine (eGFR) measurement: Not mandatory.

Definitions

Unconfounded: In ‘unconfounded’ cases only one Gd-contrast media had been given before NSF developed.

Confounded: If two different Gd-contrast media had been given within eight weeks of each other (may be longer), it is impossible to determine with certainty which agent triggered the development of NSF and the situation is described as ‘confounded’. However, the agent that is most likely responsible is the one which has triggered NSF in other unconfounded situations.

Triggering Agent: To be described as an NSF triggering agent, there must be at least 5-10 NSF cases, validated by adequate documentation including deep skin biopsy, following exposure to a Gd-contrast agent.

1 Abstract from ‘Gadolinium-based contrast media and nephrogenic systemic fibrosis.’ The Royal College of Radiologists November 2007.
Appendix IV

MRI Contrast in Renal Failure Patient

The Central Renal Committee has come up with the following recommendation for your reference:

According to the eGFR formula (modified from the abbreviated MDRD equation) recently published [J Am Soc Nephrol 17: 2937-2944, 2006] by the Beijing group:

1. In patients with end-stage kidney disease (GFR<15mL/min/1.73m²) who need an imaging study, unenhanced MR procedure or an alternative imaging modality should be considered.

   - serum creatinine 470 umol/L corresponds to an estimated GFR of 15 ml/min/1.73m² (for male)
   - serum creatinine 380 umol/L corresponds to an estimated GFR of 15 ml/min/1.73m² (for female)

2. In patients with moderate kidney disease (GFR<60mL/min/1.73m²), gadolinium enhanced imaging should be used only if clinically essential and preferably at low doses.

   - serum creatinine 142 umol/L corresponds to an estimated GFR of 60 ml/min/1.73m² (for male)
   - serum creatinine 110 umol/L corresponds to an estimated GFR of 60 ml/min/1.73m² (for female)

assumptions: age=50 ethnicity=Chinese

{P.S. For moderate kidney disease (GFR < 60ml/1.73m²) is based on Canadian recommendation whereas US (FDA) is using < 30ml/min/1.732m²}
Appendix V

GCRS workflow for MRI contrast request

Note:
1) Renal failure patients receiving gadolinium contrast are associated with nephrogenic systemic fibrosis and deaths have been reported.
2) In patients with end-stage kidney disease (GFR<15mL/min/1.73m²) who need an imaging study, unenhanced MR procedure or an alternative imaging modality should be considered (Serum creatinin 470 (male), 380 (female) umol/L corresponds to an estimated GFR of 15 mL/min/1.73m²).
3) In patients with moderate kidney disease (GFR<60mL/min/1.73m²), gadolinium enhanced imaging should be used only if clinically essential (Serum creatinin 142 (male), 110 (female) umol/L corresponds to an estimated GFR of 60 mL/min/1.73m²).