NHS Greater Glasgow and Clyde

ID: DR-GGC-RISK-018

Risk Assessment Form

Use this form for any detailed risk assessment unless a specific form is provided. Refer to your Summary of Hazards/Risks and complete forms as required, including those that are adequately controlled but could be serious in the absence of active management. The Action Plan and reply section is to help you pursue those requiring action.

Name of Initial Assessor/Reviewer	John McLean	**Post Held:**	MR Safety Expert
Department:	**Imaging**	**Date (Initial review):**	**30/10/17**

Subject of Assessment: E.g.: hazard, task, equipment, location, people

Scanning patients in MRI with cardiac stents when the MR conditional criteria for the static magnetic field gradient is exceeded

Hazards (Describe the harmful agent(s) and the adverse consequences they could cause)

There are a range of hazards the MRI scanner presents. The static magnetic field may affect ferrous metallic objects. RF fields can lead to heating of metallic objects. Many cardiac stents are made from metallic components, there has been some concern that the factors above may affect patients with a cardiac stent during MRI scans.

Of specific interest here is an aspect of the MRI conditional criteria which is often cited by the manufacturers as a condition for safe scanning of cardiac stents. The condition is the static magnetic field gradient, dB/dx, expressed in units of T/m or G/cm, (e.g. 560 G/cm is 5.6T/m). Put simply this is the rate at which the static magnetic field deteriorates as a function of the distance from the scanner's isocentre. This is cited as part of the conditional criteria as the static field gradient relates to the amount or torque or translational force that will be exerted on a ferromagnetic implant. There is a trend among newer scanners for the static magnetic field gradient to increase as to enable scanners to be placed within smaller MRI rooms and to better contain, the static magnetic field, which it could be argued, reduces the risk of missile incidents.

An important point to note regarding the T/m condition is that it is not a limit of safety. It is typically, simply, the highest T/m of the scanner a particular device was tested on. In this regard, the method by which implants are tested are in this sense, flawed to a degree as implants are not tested until failure. Thus, safety statements on implants often lag behind the MRI scanner technology as new generations of MRI magnets are developed and sold.

A further point that is worthy of note, may be considered another flawed aspect of the T/m values published by the scanner vendors. The maximum T/m values published by the scanner vendors are typically located within the covers of the magnet i.e. the maximum value cited is a not a value patient and their implant would come into contact with. To varying degrees, the scanners vendors provide some material to try and help the user extrapolate realistic values but these values are not wholly accurate or easy to interpret. However, what we do know is that the T/m value any patient is likely to be exposed to will be less than the maximum value cited. It is important to assess where the item is likely to be relative to the spatial gradient field map provided with the scanner.

The concern about an increasing T/m might be that the increasing gradient will have a greater impact on the forces exerted on a cardiac stent. However, there are few, if any cardiac stents which are ferromagnetic to such a degree as they would be affected. Moreover, there is no evidence or reported cases of incidents as a result of cardiac stents being displaced in the MRI environment. That said, we do continue to monitor this situation and remain abreast of the latest incidents and developments in this field such that we can adjust our advice rapidly if new evidence was to come to light.

Description of Risk
Describe the work that causes exposure to the hazard, and the relevant circumstances. Who is at risk? Highlight significant factors: what makes the risk more or less serious – e.g.: the time taken, how often the work is done, who does it, the work environment, anything else relevant.

The subjects of this risk assessment are patients with a cardiac stent or stents undergoing MRI scans where the static magnetic field gradient (T/m) aspect of the MRI conditional criteria is exceeded. This is often the case on the new generation of MRI systems. Significant factors here are the dB/dx and the material that cardiac stents are made from. The overwhelming majority of cardiac stents are made from non-ferrous materials, there may be some cardiac stents which are slightly ferromagnetic.
There is no evidence to date of incidents to patients with cardiac stents having been injured as a result of having an MRI scan or as is particularly the case here, the dB/dx condition having been exceeded. This situation continues to be monitored. Our local experience has been that many patients with cardiac stents have now been safely scanned on an MRI system where the dB/dx condition was exceeded. Had we adhered to the MRI conditional criteria in its literal form, these patients would not have benefited from the application of MRI technology and would likely have been exposed to more imaging technologies that use ionising radiation.

Existing Precautions	**Describe how they might fail to prevent adverse outcomes.**
Patients are taken through an extensive MRI safety checklist to identify any implants that they may have **The maximum static magnetic field for each MRI system is known and will recorded. An estimate of the actual maximum dB/dx that a patient will be exposed to will be estimated.** **MRI safety forums continue to be monitored by MRI Safety experts for any new evidence or incidents that may come to light in this area**	**A new stent may come onto the market which does not satisfy the MR safety conditions and if this device is strongly ferromagnetic, it may actually pose a risk. The likelihood of this happening seems highly unlikely. Moreover, by the time the stent reached release many patients would have had MRI scans and the safety status of the device would be known and any advice in this area would be adjusted accordingly. It would not be in any commercial organisations interest to develop a new implant that is not safe for MRI.**

Level of Risk - Is the control of this risk adequate?
Give more than one risk level if the assessment covers a range of circumstances. You can use the 'matrix' to show how 'likelihood' and 'consequences' combine to give a conclusion. Also, be critical of existing measures: if you can think how they might fail, or how they could be improved, these are indications of a red or orange risk.

Risk Matrix

Likelihood	**Impact/Consequences**				
	Negligible	**Minor**	**Moderate**	**Major**	**Extreme**
Almost Certain	Medium	High	High	V High	V High
Likely	Medium	Medium	High	High	V High
Possible	Low	Medium	Medium	High	High
Unlikely	Low	Medium	Medium	Medium	High
Rare	Low	**Low**	Low	Medium	Medium

Very High **High** **Medium** **Low**

Current risk level

Given the current precautions, and how effective and reliable they are, what is the current level of risk? **Green** is the target – you have thought it through critically and you have no serious worries. Devise ways of making the risk green wherever you can. **Yellow** is acceptable but with some reservations. You can achieve these levels by reducing the inherent risk and or by effective and reliable precautions.
High (Orange) or Very High (Red) risks are unacceptable and must be acted on: use the Action Plan section to summarise and communicate the problems and actions required.

Action Plan (if risk level is **High (Orange) or Very High (Red)**

Use this part of the form for risks that require action. Use it to communicate, with your Line Manager or Risk Coordinator or others if required. If using a copy of this form to notify others, they should reply on the form and return to you. Check that you do receive replies.

Describe the measures required to make the work safe. Include hardware – engineering controls, and procedures. Say what you intend to change. If proposed actions are out with your remit, identify them on the plan below but do not say who or by when; leave this to the manager with the authority to decide this and allocate the resources required.

Proposed actions to control the problem List the actions required. If action by others is required, you must send them a copy	**By Whom**	**Start date**	**Action due date**

Action by Others Required - Complete as appropriate: (please tick or enter YES, name and date where appropriate)

Report up management chain for action	
Report to Estates for action	
Contact advisers/specialists	
Alert your staff to problem, new working practice, interim solutions, etc	

Reply

If you receive this form as a manager from someone in your department, you must decide how the risk is to be managed. Update the action plan and reply with a copy to others who need to know. If appropriate, you should note additions to the Directorate / Service Risk Register.

If you receive this as an adviser or other specialist, reply to the sender and investigate further as required.

Date of last review:	As per QPulse record	**Next review date:**	As per QPulse record