NHS Greater Glasgow and Clyde

ID: DR-GGC-RISK-210

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	J McLean/ P Hall Barrientos	**Post Held:**	MR Safety Expert
Department:	**Imaging**	**Date (Initial Review)**	**September 2023**

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

Scanning patients in MRI with coronary stent/s

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 coronary stents are made from metallic components, historically there has been concern that the factors above may affect patients with a coronary stent/s during MRI scans. The concern about an increasing T/m might be that the increasing gradient will have a greater impact on the forces exerted on a coronary stent. However, there are few, if any coronary stents which are ferromagnetic to such a degree as they would be affected. Patients may also have more than one or have overlapping stents

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.

Historically there has been some concern about components of the magnetic field, RF power and imaging gradients affecting patients with coronary stents (a type of cardiac stent) while in the MRI environment. However, this has not been borne out in practice and there have been no published cases of patients with a coronary stent having any adverse outcome or injury as a result of been scanned in MRI.

Many in the MRI community are wary of blanket statements of MRI safety for implants. One reason for this is a patient may give the wrong information when answering their MRI checklist. For example, a patient may report that they have a coronary stent when in fact they have a pacemaker. Given the multiple occasions that patients being referred for MRI are asked about such implants, the risk of this situation occurring is negligible.

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 5.6 T/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.

There is no evidence to date of incidents to patients with coronary 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 coronary 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 be 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.**	**The patient may fail to declare an implant that they have** **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