NHS Greater Glasgow and Clyde

ID: DR-GGC-RISK-039

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:	John McLean	**Post Held:**	MR Safety Expert
Department:	**Imaging**	**Date:**	**08/01/2018**

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

MRI scanning of pregnant patients where Gadolinium Based Contrasts Agents (GBCA) has been requested

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

Some GBCA's agents used in MRI have been known to cause Nephrogenic systemic fibrosis (NSF). This occurs in patients with poor renal function. In the case of a pregnant patient, the GBCA can cross the placental barrier, the GBCA is not excreted as it would be in a patient who is not pregnant. Thus there is a theoretical risk that the Gadolinium may dissociate from it chelate and cause damage to the fetus.

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.

Patients are screened using a MRI safety checklist to determine whether they are pregnant or not.

If interrogation for the safety checklist reveals the patient to be pregnant then contrast should not be administered, unless explicitly sanctioned by an Authorised MR Radiologist following a full risk/benefit analysis and consent must be obtained and documented. The MHRA guidelines for safe use of MRI in a clinical setting (2021) state that the use of GBCA in pregnant patients is not recommended. Therefore, GBCA's in pregnant patient should only be used if absolutely necessary.

In 2016 Ray et al reported that GBCA exposure during any point in pregnancy was associated with an increased risk of a broad set of rheumatological, inflammatory or infiltrative skin conditions and for still birth or neonatal death. The risk was higher when the exposure was during the first trimester.

1. Jabehdar Maralani, Pejman, et al. "Canadian Association of Radiologists Recommendations for the Safe Use of MRI During Pregnancy." *Canadian Association of Radiologists Journal* (2021): 08465371211015657.
2. Ray, Joel G., et al. "Association between MRI exposure during pregnancy and fetal and childhood outcomes." *Jama* 316.9 (2016): 952-961.

Existing Precautions	Describe how they might fail to prevent adverse outcomes.
In keeping with the MHRA Safety guidelines for MRI in clinical use, 2021; the use of GBCA's during MRI scans on pregnant patient is not recommended. **GBCA's in pregnant patients should only be used where absolutely necessary following the consideration of the risks and benefits**	**Patient does not declare that they are pregnant or knows that they are pregnant at the time of scan and administration of contrast.**

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	08/12/2021	**Next review date:**	As per QPulse record