Oxford University Hospitals NHS
NHS Foundation Trust

Procedure for exceptional magnetic resonance scanning in patients with standard (non-MR-conditional) pacemakers

Category:	Standard Operating Procedure
Summary:	This procedure outlines the process for assessing the safety and suitability of, and for performing, magnetic resonance imaging (MRI) in patients with non-safe (standard) implanted cardiac pacemakers under rare circumstances where an MRI scan is critical to clinical management
Equality Impact Assessment undertaken:	May 2014
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Approval Date/ Via:	Magnetic Resonance Safety Group (21st December 2015) Clinical Policy Group
Distribution:	Trust-wide
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Further Information:	See references

Lead Director: Medical Director

Issue Date:

Oxford University Hospitals NHS
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AT A GLANCE

Trust-Wide Procedure for Exceptional MRI Scanning in Patients with Standard (non-MR-conditional) pacemakers.

What is the Procedure?

- This SOP outlines a framework for very rare MRI scanning for patients with standard cardiac pacemakers
    - Historically, standard pacemakers have been a contraindication to MRI scanning due to known significant risks
    - There are occasional patients however for whom the MRI scan is critical for patient management and where the benefits may outweigh the moderate risks
- The SOP outlines the circumstances in which these scans may take place, and the procedures to be followed, including a risk assessment, communication with the patient regarding risks, and the on-the-day procedures to be followed to minimise the risks

Who does this apply to?

- This applies to all patients who have implanted standard cardiac pacemakers (and/or pacing leads) in whom a magnetic resonance (MR) scan is considered critical for their clinical care, and the staff involved with their clinical care.
- It does not apply to the newer MR-conditional pacemakers (which are safe to undergo MRI scans under certain conditions) – there is an existing SOP for these pacemakers.
- This procedure only applies for magnetic resonance scanners with a static field strength ≤1.5Tesla. Higher field strengths should not be used in patients with pacemakers.

Where can I find more information?

- For a summary flow chart of the process please see Appendix 1

Contents

Introduction

1. Pacemakers have traditionally been regarded as absolute contraindications to MR scanning. 'MRI conditional' pacemakers now exist however (i.e. safe under certain conditions) which are significantly more resistant to MRI, and their use is covered in the separate OUH SOP for scanning patients with MR-conditional pacemakers. For standard (i.e. non-MR-conditional) pacemakers, the contraindications to MR scanning still exist, but there may be exceptional circumstances where the MRI scan is critical to patient management and when the benefits may outweigh the risks. This approach has also been endorsed by the British Heart Rhythm Society (see references). However, these patients need careful individual assessment of the risks and benefits from MR scanning, and a specialised approach is required if MRI is to be undertaken in the safest possible environment. A structure is required for providing a service in these exceptional circumstances, and this document addresses the relevant processes to be followed.

Policy Statement

2. It is the policy of the Trust that all patients with standard (non-MR-conditional) cardiac pacemakers who potentially require magnetic resonance scanning for compelling clinical reasons undergo appropriate risk assessment, and are managed as outlined in this document

3. This procedure only applies for magnetic resonance scanners with a static field strength ≤1.5Tesla. Higher field strengths should not be used in patients with pacemakers.

Aim of this SOP

3. The purpose of this Standard Operating Procedure (SOP) is to provide guidance on the process involved for assessing the safety and suitability of magnetic resonance imaging (MRI) in patients with standard (non-MR-conditional) implanted cardiac pacemakers who may potentially require an MRI scan for clinical management, under exceptional circumstances.

Scope

4. This document applies to all patients who have implanted standard cardiac pacemakers (and/or pacing leads) in whom a magnetic resonance (MR) scan is considered critical for their clinical care, and the staff involved with their clinical care.

5. Primarily, this will involve staff in radiology and cardiology departments, but applies to all areas of the Trust, and all employees of the Trust, including individuals employed by a third party, by external contractors, as voluntary workers, as students, as locums or as agency staff.

6. The document applies to patients with standard (non-MR-conditional) pacemakers, but not newer 'MR-conditional' pacemakers (i.e. safe only under certain conditions), for which the SOP for scanning patients with MR-conditional pacemakers should apply.

7. Implanted cardioverter-defibrillators

   The document does not apply to patients with implanted cardioverter-defibrillators (ICDs). There are additional risks involved for these patients, who currently are not considered safe for MR scanning.

8. Retained epicardial pacing wires (from previous cardiac surgery)

   The document does not apply to patients with *short* (<10cm) segments of retained epicardial pacing wires (usually from previous cardiac surgery). These are generally considered at low risk (i.e. safe) for MRI, and the assessment of the suitability for MRI (including the length of wire) is made by the appropriate radiologist (or cardiologist for cardiac MRI scans). Longer lengths of retained epicardial pacing wires (>10cm) and

coiled sections of wire need greater consideration and may need to be considered within the scope of this document.

Definitions

9. The terms in use in this document are defined as follows:

   9.1. **Cardiac pacemaker** – implanted electronic pacemaker and/or pacing leads used for cardiac electrical pacing. This includes single-chamber, dual-chamber and biventricular pacemakers ('cardiac resynchronisation therapy' devices) *without* defibrillation capability. This also includes retained permanent pacing leads where the pacing generator has been removed, but does not include short segments of retained epicardial pacing wires, as outlined in paragraph 8.

   9.2. **Magnetic resonance imaging/scanning** – entering the restricted area (>5G) of an MRI department, irrespective of whether the patient lies in the scanner bore or any imaging is actually undertaken

   9.3. **Referring consultant** – the consultant with clinical responsibility for the patient's care in the appropriate specialty, who has identified a clinical need for an MRI scan and refers the patient.

   9.4. **Imaging radiologist/cardiologist** – a radiology or cardiology consultant responsible for delivering the MRI scans in the relevant body area

   9.5. **Cardiologist with specific MRI and pacing knowledge** – a cardiologist with specific knowledge +/- experience of the specific risks of MR scanning in patients with pacemakers.

10. Abbreviations :

   10.1. MR – Magnetic resonance

   10.2. MRI – Magnetic resonance imaging

   10.3. ICD - implantable cardioverter-defibrillator

   10.4. CRM – Cardiac Rhythm Management (a team within the cardiac physiology department)

   10.5. OCMR – University of Oxford Centre for Clinical Magnetic Resonance Research, where the clinical cardiac MRI scans take place

Responsibilities

11. The **clinical directors** for the cardiothoracic and radiology directorates have overall responsibility for ensuring an appropriate framework is in place for this procedure to be followed

12. The **referring consultant** is responsible for discussing the need for a scan with the patient, and the presence of potential problems with the pacemaker, necessitating a risk assessment. S/he is responsible for sending the request to the relevant imaging radiologist (or cardiologist if cardiac MRI scan required) for consideration of an MRI scan. The information must include details of the clinical importance of the scan to the patient. S/he is also responsible for reviewing the risk assessment from cardiology and to take a decision on the clinical appropriateness of the scan, jointly with the cardiologist, taking into account the risks and benefits

13. The **imaging radiologist/cardiologist** is responsible for assessing the appropriateness of the request and i) whether equivalent information could be obtained from other imaging modalities in preference to the MRI, ii) if not, the ability of MRI to deliver the relevant clinical information. S/he is also responsible for sending appropriate requests to specific cardiology consultants (see appendix 5) for assessment of the cardiac risk. Details of the patient should also be sent to the cardiac rhythm management (CRM) office to gather the device information.

14. The **MR Radiographer** is responsible for-
    i) Ensuring the pacemaker checklist has been completed and is satisfactory
    ii) Completing the standard patient safety questionnaire
    iii) Ensuring the scan acquisition remains within the specific parameters outlined in this SOP

15. The **cardiologist with specific MRI and pacing knowledge** is responsible for forwarding details of the patient to the CRM team (if not already sent), to enable the acquisition of details on the pacing device(s) and leads for the patient. The cardiologist's main role is to assess the cardiac risk, taking into account the nature of the pacemaker and importance of the pacemaker to maintaining cardiac output for the individual patient. See appendix 2 for risk assessment guide. S/he is responsible for making a recommendation on the balance of risks in each case, with feedback to the relevant imaging consultant and the referring consultant. S/he is also responsible for discussing the risks with patient, and takes responsibility for the clinical cardiac care of the patient.

16. The ultimate decision on the appropriateness of a scan is taken by the imaging consultant (radiologist/cardiologist), in conjunction with advice from the referring consultant ±cardiologist as appropriate. The imaging consultant best understands the value of the scan, and knows the capabilities of alternative imaging techniques, while the cardiologist with specific MRI and pacing knowledge understands the risks and takes responsibility for these.

17. The **cardiac rhythm management (CRM) team** are responsible for obtaining details of the pacemaker and leads from the relevant pacing department and providing these to the cardiologist for risk assessment. Once the scan is approved, the team are responsible for liaising with the relevant imaging department (either radiology, or OCMR for cardiac MRI scans) and organising an appointment for a pacing check before and after the MRI scan. A cardiac physiologist from the CRM team is responsible for attending the scan and monitoring the cardiac rhythm during the scan.

Procedure to be followed for each case (see also flow chart in appendix 1)

18. For all patients:

18.1. **Referral**
A referral is made to the appropriate imaging department by the referring consultant, having discussed with the patient the possibility of an MRI scan and the need for a risk assessment beforehand.

18.2. The imaging radiologist/cardiologist confirms that the scan can provide the information required at a field strength ≤1.5T, is critical for the clinical management of the patient, and cannot be provided adequately by alternative imaging techniques.

18.3. **CRM team**
The CRM team are informed either by letter (or copy of initial referral) or phone (extn 20981).

18.4. Information on the medical and pacing history, and type of pacemaker will be obtained by the CRM team (target: within 1 week from contact). The pacing system should also have been implanted at least 4-6 weeks before the scan.

Information will also be sought on the default settings of the pacemaker in a magnetic field and what settings can be programmed in the pacemaker, specifically whether VOO or DOO (asynchronous pacing) mode is available, and whether a noise recognition mode exists and what the pacemaker settings are for this.

Information on pacing leads may be obtained from recent chest x-rays, but in some cases additional x-ray imaging may be required if uncertainties remain.

The CRM team will also ascertain the total number of pacing leads remaining in the patient and if there are any old and/or broken leads

18.5. This information is passed to a consultant cardiologist knowledgeable in this area

18.6. **Assessment of risk** (see also appendix 2)
An assessment of the cardiac/pacing risk is made by the cardiologist, in conjunction with the cardiac physiologist/clinical nurse specialist and the radiologist. It is acknowledged that some risks are difficult/impossible to quantify accurately for individual patients

18.7. A decision on the appropriateness of the scan is taken jointly by the cardiologist, radiologist and referring physician considering the risks and benefits involved. The team approach is important to weigh up the cardiac risk (the major safety concern), with the importance and appropriateness of the scan

18.8. The scan should only take place if the information from the MR scan is critical to the clinical management of the patient, and where the benefits clearly outweigh the estimated risks. For pacemaker-dependant patients, there should be highly compelling circumstances, and the greater risk of death should be outlined to the patient.

18.9. **Patient discussion / consent and documentation**
A discussion with the patient should take place outlining the risks and benefits of the scan and an explanation of why the scan is felt to be appropriate. The exchange of information should ideally include a letter to the patient outlining this, though an opportunity should be made for the patient to discuss the scan with one of the consultants involved (cardiologist, radiologist or referring consultant), either by telephone or in person. A template letter outlining the general risks of MR scanning in patients with pacemakers is included as appendix 4. At least a verbal agreement to the scan is required from the patient at this time.

18.10. A scan appointment is then created for a time when the relevant staff are available (imaging radiologist/cardiologist and CRM team) – liaison between the radiology and CRM team administrative departments is required.

18.11. All information to be documented in the patients notes

18.12. Formal consent is obtained from the patient by either the cardiologist or the clinician who knows the patient best (usually the referring clinician), ideally with the patient signing any information letter provided to indicate their understanding of the risks and benefits discussed, in addition to any hospital consent form. Formal consent may take place on the day of the scan.

18.13. **Location of the scan**
All scans in patients with standard pacemakers should take place in the neuro-radiology department, with the exception of cardiac MRI scans which take place in OCMR, and where additional cardiac and MRI expertise is available. The majority of patients with standard pacemakers in whom MR scanning would be considered acceptable are likely to be for neuro-radiology indications, and this also helps to concentrate the limited experience of these infrequent patients. Appropriate facilities for patent resuscitation also exist in both these locations.

18.14. **Tariff applied to the scan**
The tariff for the scan should reflect the additional time, expertise and monitoring involved, and a suggested amount which is easy to code is 2 x the usual tariff for the scan (i.e. a double slot), plus 2 x pacing checks (one before and one after the scan)

19. On the day of the scan:

19.1. The checklist outlined in appendix 4 is used

19.2. Informed consent is obtained, if not already taken.

19.3. A pacemaker check is carried out to determine current lead threshold, battery life and pacemaker settings.

- Wherever possible, the pacemaker should be programmed into either a sensing only mode, asynchronous pacing (e.g. VOO) mode, or off completely, depending on the clinical and device circumstances. (MR scanning may introduce electrical currents or noise in the pacing leads, which could be misinterpreted by the pacemaker as cardiac activity, and inappropriate inhibition could occur).
- Lead polarity should be programmed to bipolar if possible.

19.4. A cardiac physiologist/clinical nurse specialist from the CRM team should be present in the relevant radiology dept/OCMR during the scan for monitoring of the cardiac rhythm and external pacing/defibrillation if required. The pre-scan pacemaker interrogation/programming, and post-scan pacemaker check/reprogramming may be performed in the imaging department.

19.5. A nursing or medical staff member from radiology/OCMR (familiar with the department) should be in attendance

19.6. A resuscitation area should be available in the scanning department. No resuscitation should take place in the magnet room – all patients must be removed first, for both staff and patient safety, and the department should have a documented emergency evacuation procedure. A pacing-capable defibrillator for temporary external pacing should be immediately available in the resuscitation area.

19.7. The patient should have cardiac monitoring with ECG and/or pulse oximetry during the whole time they are in the magnetic field of the scanner (within the 5 Gauss line)

19.8. MR-conditional ECG, pulse oximetry and blood pressure monitoring should be performed throughout the scan. NB the equipment should be able to provide an adequate signal during scan sequences.

19.9. For pacing-dependent patients, a cardiologist should be in attendance

19.10. **Scan protocol**
The MR scan should use the minimum number of images required to obtain the clinical information, and the minimum energy delivery from the scanner, with the standard absorption rate (SAR) kept <2 W/kg and a scan time <15-20 minutes. If it is difficult to keep the SAR low, the sequence may have to be adjusted (e.g. by increasing the repetition time, or field of view, or reducing the flip angle or the acquisition bandwidth) - a physicist should be consulted if this is the case.

19.11. Communication with the patient should be maintained throughout the scan.

19.12. After the scan, the pacemaker should be checked and any changes from the pre-scan check noted. If significant changes have occurred (e.g. increase in pacing threshold), this may require a change in the pacemaker settings, and/or a change in the follow up arrangements. Communication with the usual pacemaker clinic may be required. The pacemaker may need to be re-programmed to its original settings

19.13. The scan will be reported by the radiologist (cardiologist in OCMR) and communicated to the referring clinician.

19.14. **Follow-up checks**
A pacing check should occur 1 month after the scan, to ensure that any late scarring that may affect pacing parameters is detected and acted upon.

20. Adverse events

20.1. If the patient becomes haemodynamically unstable, or a dangerous cardiac rhythm is detected (e.g. VT, severe bradycardia, asystole), the patient should be removed from the scanning room immediately and taken to the clinical resuscitation area where appropriate measures should be taken to treat the patient. Resuscitation procedures must not take place within the scanning room due to the high risk to staff and patient safety from the high magnetic field.

20.2. If temporary trans-venous pacing is required, this should take place in the Heart Centre cardiac angiography suite, as per the Cardiac Medicine directorate's standard procedure, with external pacing performed in the interim as required.

20.3. Any adverse occurrence should be recorded in the notes and via the Trust incident reporting system. This should be shared with the Cardiology and referring clinician's directorate for learning and audit of this new procedure

21. Emergency MR scanning

21.1. Rarely, patients may present with an urgent reason for MRI within hours/days (e.g. to investigate spinal cord compression)

21.2. In principle, the same process should be followed but expedited, and some compromises may be necessary due to the clinical urgency.

21.3. A discussion is required between the referring consultant, the radiologist/cardiologist potentially performing the scan and a cardiologist with knowledge of the risks of MR scanning in patents with pacemakers. The same risk-benefit assessment should be performed as for elective patients, though it is accepted that some details on pacemaker implantation and device type may not be readily available. There may however be emergency cases where the benefit to the patient was high enough to justify the scan (e.g. acute spinal cord compression), and some information on the device and pacing dependency of the patient could be obtained through device interrogation by the physiologist/nurse specialist.

21.4. A discussion with the patient is required explaining the urgent nature of the scan and the risks involved.

21.5. The procedure during the scan should ideally be the same as for elective patients. Either a cardiologist or cardiac physiologist with skills in pacemaker programming is required for the pre-scan assessment and programming, as well as monitoring of the patient during the scan and post-scan pacemaker re-programming. Knowledge of the appropriate action in the event of a problem during MR scanning is also required.

Training

22. There is no mandatory training associated with this policy. Ad hoc training based on an individual's training needs will be defined within their annual appraisal or job plan

Monitoring Compliance

23. Compliance with the document will be monitored in the following ways.

Aspect of compliance or effectiveness being monitored	Monitoring method	Responsibility for monitoring (job title)	Frequency of monitoring	Group or Committee that will review the findings and monitor completion of any resulting action plan
Patients are managed in accordance with this policy	Audit of cases		At least biennially	Clinical governance committee of the cardiothoracic directorate

Review

24. This policy will be reviewed in 3 years, as set out in the Policy for the Development and Implementation of Procedural Documents, unless changing circumstances necessitate an earlier review.
25. The OUH Trust Clinical Governance Committee and the MR safety group will be the approving committees for the document.

References

1. Magnetic resonance imaging in patients with cardiac pacemakers: era of "MR Conditional" designs. Shinbane et al. *J Cardiovasc Mag Reson* 2011; 13: 63 [**good review of the many research studies**]

2. Immediate and 12 months follow up of function and lead integrity after cranial MRI in 356 patients with conventional cardiac pacemakers. Muehling M et al. *J Cardiovasc Mag Reson* 2014; 16: 39-46

3. Safe use of MRI in people with cardiac implantable electronic devices. Lowe et al .*Heart* 2015 (Dec); 101: 1950-3 [P**osition paper from British Heart Rhythm Society**]. (http://dx.doi.org/10.1136/heartjnl-2015-308495)

4. Magnetic resonance imaging in individuals with cardiovascular implantable electronic devices. Roguin et al. *Europace* 2008; 10: 336-46 [**Position paper from the European Heart Rhythm Association and the ESC Working group on Cardiovascular Magnetic Resonance, including literature review and suggested practical approach**]

5. Safety of Magnetic Resonance Imaging in Patients with Cardiovascular Devices: An American Heart Association Scientific Statement From the Committee on Diagnostic and

Interventional Cardiac Catheterization, Council on Clinical Cardiology, and the Council on Cardiovascular Radiology and Intervention. Levine et al. *Circulation* 2007; 116: 2878-91

6. Food and Drug Administration Perspective: Magnetic Resonance Imaging of Pacemaker and Implantable Cardioverter-Defibrillator Patients. Faris & Shein. *Circulation* 2006; 114: 1232-3

7. Reference Manual for Magnetic Resonance Safety, Implants, and Devices: 2013 Edition. Frank G. Shellock, *Biomedical Research Publishing Group*, Los Angeles, California, USA

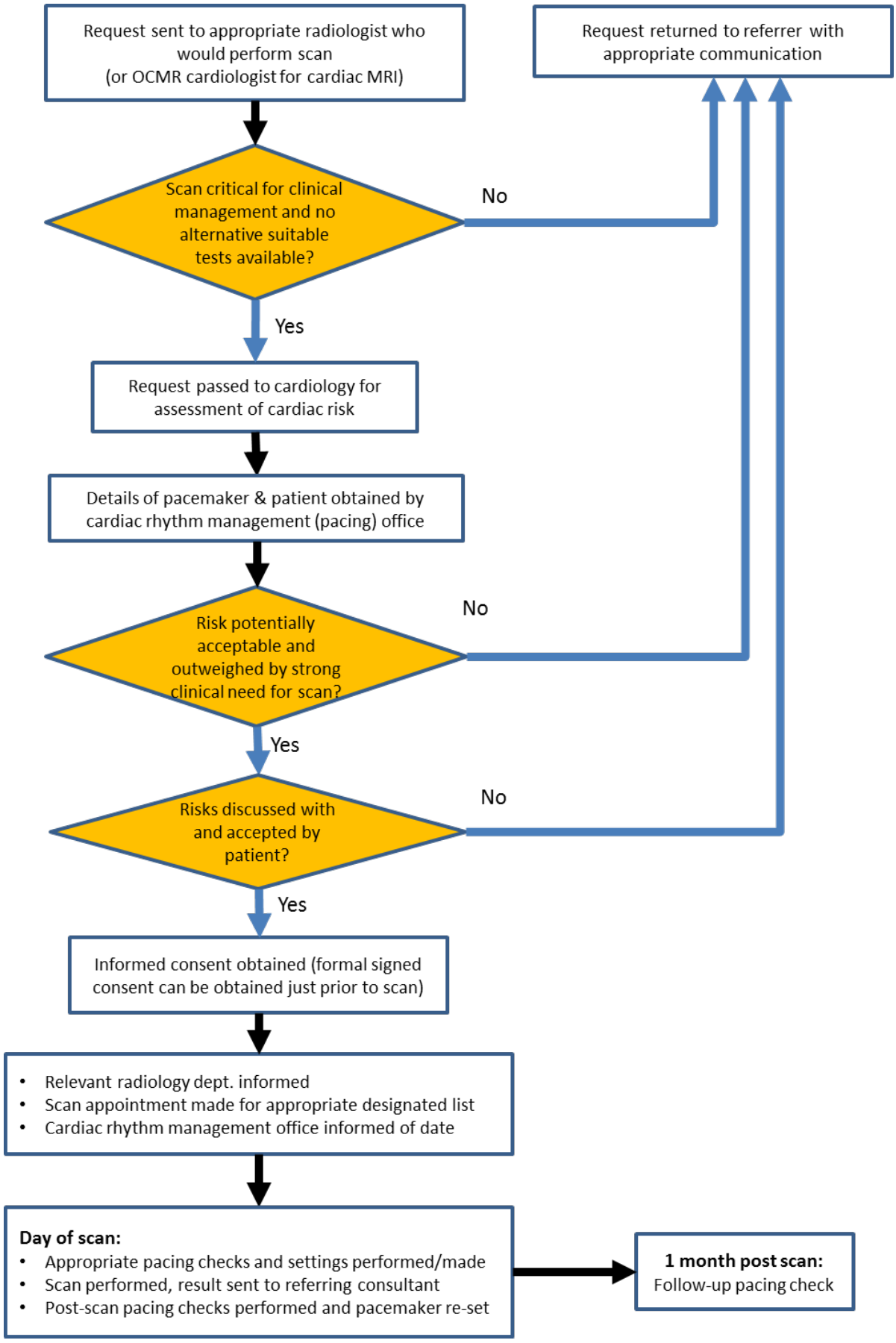
Equality Impact Assessment

As part of its development, this policy and its impact on equality has been reviewed, and no detrimental impact was identified on any group. The full assessment is in appendix 6.

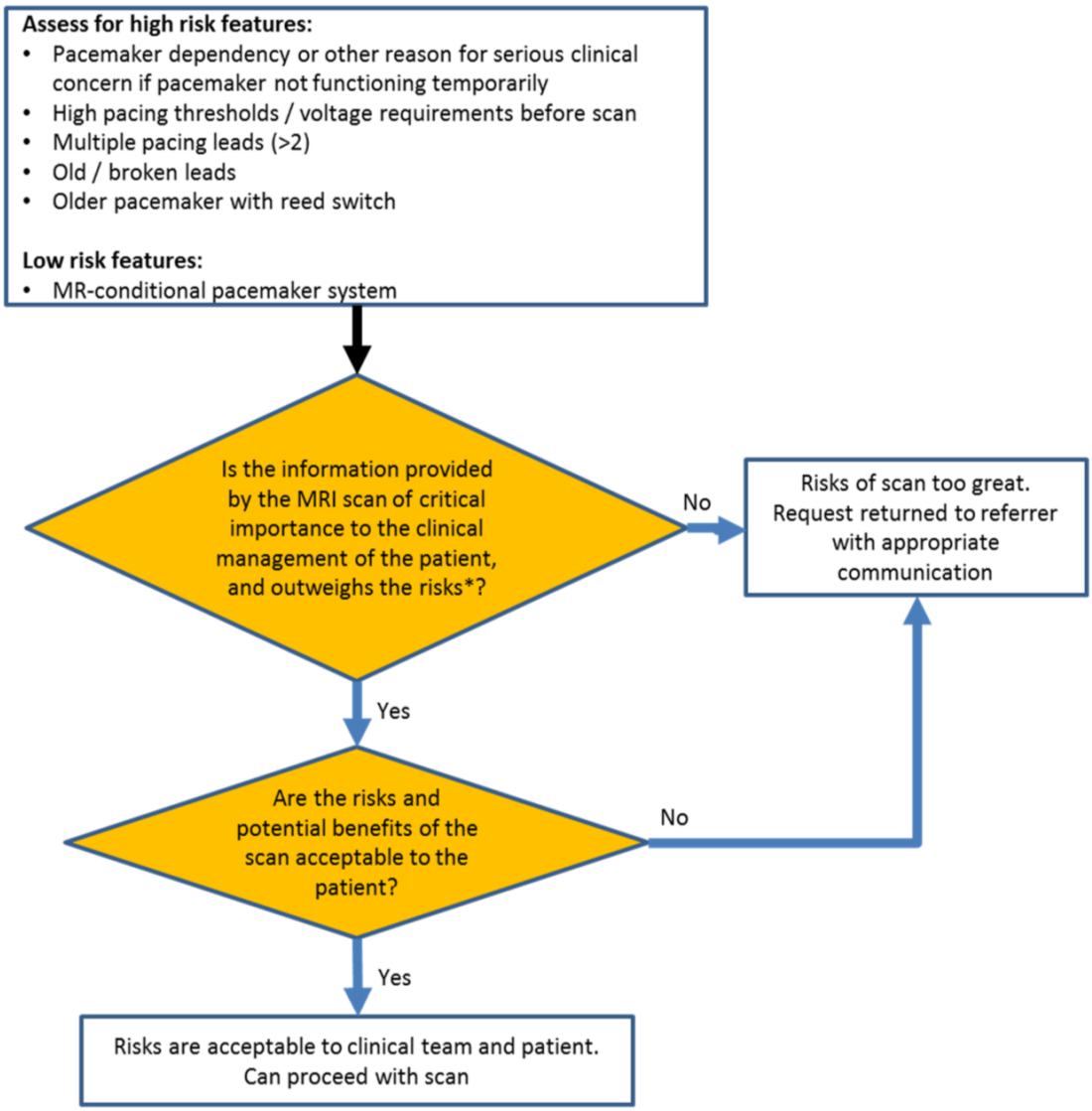
Document History

Date of revision	Version number	Reason for review or update

Appendix 1: Summary flow-chart of process



Appendix 2: Risk assessment guide



*Summary of main potential risks IF appropriate procedures followed		Consequence	Estimated prevalence
• **Worsening of pacing lead parameters** (e.g. higher threshold / poor capture), due to heating/inflammation/scarring at lead tip – may lead to shorter battery life and/or need to replace lead, or pacing failure in worst case		Moderate	Up to 10% <1%]
• **Failure to pace** Due to lead failure or inappropriate inhibition	Non-pacemaker dependant : Pacemaker-dependant :	Low High (potentially fatal)	Low but uncertain
• **Cardiac arrhythmia** • Tachyarrhythmia through induction of current through pacing lead • Bradyarrhythmia from failure to pace appropriately		High	< 2%
• **Asynchronous pacing during scan** • Planned - if unable/undesirable to halt pacing – minimal risk if pacing rate appropriate; occasional induction of ectopy • Unplanned – if reed switch held open (in older pacemakers) – well tolerated unless default pacing rate is very high		Low Moderate	- <1%
• **Heating of pacing box or leads sufficient to cause discomfort**		Moderate	< 1%

Appendix 3:

Safety checklist for patients with standard (non-MR-conditional) pacemakers scanned at the Oxford University Hospitals NHS Trust

MRI referral accepted by …… (Consultant Radiologist)
Patient name ……
DOB……. Date of scan…….
NHS number…… Examination .....

Information and actions required from Cardiology / Pacing clinic	
Cardiologist name and hospital base	
Type of pacemaker device and date fitted (must have been in situ for > 6 weeks at time of scan)	
Any old leads in place?	
There are no fractured or non-compatible leads	**Confirmed** ☐
Lead impedance value is > 200 Ω but < 1500 Ω	**Confirmed** ☐
A documented risk assessment has been carried out and confirm that the benefits from the scan clearly outweigh the risks	**Confirmed** ☐
The patient understands the risks and has signed a consent form/letter	**Confirmed** ☐
Pacemaker set to sensing only mode (VOO) or off completely	**by ……** (Cardiac physiologist) Date…… Time……..
Pacemaker reset to 'normal' mode	**by ……** (Cardiac physiologist) Date…… Time……..

Information and actions required from Consultant Radiologist	
MRI to be supervised by ……..…… (Consultant Radiologist [or cardiologist in OCMR])	
Scan protocol devised to minimise scan time and SAR <2.0W/kg and booked on ***1.5T scanner only in neuroradiology department (or OCMR for cardiac MRI)***	**Confirmed** ☐
Radiologist to accompany patient between MRI scanner and pacing clinic ?	
Nursing or medical staff member from radiology/OCMR (familiar with the	**Confirmed** ☐

department) in attendance	
ECG monitoring and/or pulse oximetry in place	**Confirmed** ☐
BP monitoring in place if required	
For pacing-dependant patients: Cardiologist in attendance and external pacing available in immediate vicinity	**Confirmed** ☐

Information and actions required from Radiographer	
Radiographer performing MRI scan ……	
Ensure scan is performed on 1.5T magnet and patient *not* positioned on their side	**Confirmed** ☐
Ensure maximum slew rate per axis does not exceed 200 T/m/s	**Confirmed** ☐
Ensure whole body SAR < 2 W/kg	**Confirmed** ☐
Ensure local transmit-only coils or local transmit receive coils are not placed directly over the pacemaker, wherever possible	**Confirmed** ☐

Appendix 4: Template letter to patient

Dear (patient name),

This letter summarises the issues around performing an MRI scan of (*body area*). It is important that you are aware of the risks involved in having an MRI scan with your cardiac pacemaker, and that some of these risks are difficult to measure precisely. Because of the serious nature of the problem with your xxxxx, we feel that the information from the MRI scan is important enough to warrant the risks of the scan, hence our consideration of this.

There are several potential problems with performing MRI scans in patients with pacemakers, and I have listed the major ones here:

1) Rhythm problems
There is a small risk of inducing a current through the pacing leads, which could cause pacing of your heart at an abnormally high rate and could lead to a dangerous rhythm. The likelihood of this is less than 1% (less than 1 in 100 patients) in published studies, but it is difficult to give a precise estimate. Although the majority of these rhythm problems would not be a concern, in the worst case scenario this could cause your heart to stop. If this occurred, we would need to remove you from the scanner quickly which may cure the problem, but if not, we would need to use drugs or an electric shock to return the heart to a normal rhythm. We would make every effort to achieve a normal heart rhythm, but it is difficult to guarantee the outcome, and there is a remote possibility of death.

2) Pacemaker function
There is a risk that the pacemaker would not function in the scanner. The chance of this is low, but the precise risk is unknown. In the majority of cases, the pacemaker would function again once you were removed from the scanner and the short period of non-function would be unlikely to lead to harm.

There is a chance that the function of the pacing leads may worsen as a result of the scan, resulting in the need to re-programme your pacemaker. The likelihood of this is relatively low (<10%). This might result in a shorter battery life (and earlier replacement of the pacemaker generator box) or a new replacement lead for the pacemaker.

There is also a small risk that the pacemaker function would be permanently damaged from being in the scanner. The likelihood of this is extremely low (much less than 1%). If your heart had an underlying rhythm (even a very slow one), this would be a stable situation in the short term and we could arrange for a replacement pacemaker, with little harm to yourself. However, if you were dependent on the pacemaker, your heart may not have any rhythm at all and would effectively stop beating. This would require emergency pacing, either with external pacing pads or internal pacing wires, inserted into one of your veins. Emergency pacing takes a short time to administer, and while we would make every effort to achieve this, the outcome cannot be guaranteed.

3) Environment
During the MRI scan, you are in an environment which makes it very difficult to perform emergency procedures, and we would need to move you out of the scanner room to perform any of these. This adds a delay, which makes the scan more risky than other types of scan, where emergency procedures can take place in the scanner room.

In summary, the main risks to you are of pacemaker/pacing lead malfunction, and a small risk of a rhythm problem. The risks are low and in the majority of cases the problem is treatable. For these reasons, we need to be clear about the risk-benefit balance of the scan, and the information from (referring clinician) is that the (clinical problem) could potentially cause

(clinical consequences). The information from the MRI scan would be important for assessing xxxxx, and we feel that this information is important enough to warrant the risks of the scan.

If you are in agreement with the plan to go ahead, we will arrange a date and time for the scan. We will make certain arrangements to minimize the risk to you, including:

- A check and programming of the pacemaker immediately beforehand
- Careful monitoring of you and your heart rhythm at all times during the scan
- Ensuring the availability of the equipment and expertise for emergency pacing and/or programming of your pacemaker and/or emergency resuscitation adjacent to the scanning room
- A check and re-programming of the pacemaker after the scan.

I hope that this explains the background to the scan. If you have any further queries, I would be very happy to answer these, and also look forward to meeting you in person at the time of the scan.

Yours sincerely,

Dr. xxxxx
Consultant Cardiologist/Radiologist

I have read and understood the risks involved with MRI scanning, as outlined in this letter, and I agree to undertake the scan.

Signed: _____ Print name: _____

Date: _____

Appendix 5: Current cardiologists within the Trust with expertise in this area

Name	Role
Dr. Saul Myerson	Consultant Cardiologist & Clinical Lead for Cardiac Imaging
Dr. Tim Betts	Consultant Cardiologist & Clinical Lead for Cardiac Rhythm Management

Appendix 6: Equality Impact assessment

Equality Analysis
Identify the main aim and objectives and intended outcomes of the policy Who will benefit from the policy? – All patients with standard pacemakers requiring high risk MRI scans.
Disability Patients with a disability (including learning disability) would not be adversely impacted by the SOP. The usual Trust arrangements for interpretation / access to information would apply.
Sex There would be no adverse impact on any gender or sexual orientation.
Age There would be no adverse impact on any age group
Race There would be no adverse impact on any racial group
Pregnancy and maternity There would be no adverse impact on pregnant women or new mothers; they are very unlikely to have had a pacemaker implanted in any case
Religion or belief. There would be no adverse impact on any religious group or belief
Safeguarding people who are vulnerable There would be no adverse impact on vulnerable people
Other potential impacts, for example culture, human rights, socio economic, for example homeless people None