

A09/S/e

**2013/14 NHS STANDARD CONTRACT  
FOR CARDIOLOGY: CARDIAC MAGNETIC RESONANCE IMAGING(CMR)  
(ADULT)**

**PARTICULARS, SCHEDULE 2- THE SERVICES, A- SERVICE SPECIFICATIONS**

<b>Service Specification No.</b>	A09/S/e
<b>Service</b>	Cardiology: Cardiac Magnetic Resonance Imaging (CMR) (Adult)
<b>Commissioner Lead</b>	
<b>Provider Lead</b>	
<b>Period</b>	12 months
<b>Date of Review</b>	

## 1. Population Needs

### 1.1 National/local context and evidence base

**Cardiovascular magnetic resonance (CMR)** is an advanced form of Magnetic Resonance Imaging utilising ECG gating to avoid cardiac motion blurring. It allows assessment of anatomy, function and viability of the heart, but also can detect ischaemia & infarction, assess congenital heart disease, the aetiology of heart failure, heart valve dysfunction and the presence of inherited diseases.

For many conditions, CMR is the gold standard test with an extensive and growing evidence base. It is safe (non-invasive, using no ionising radiation), accurate, provides prognostic evidence, changes patient management and reduces the need for other tests. CMR is supported by European and US consensus panel reports, and is considered appropriate for the majority of indications - particularly for complex patient presentations where clinical suspicion is high.

The British Cardiovascular Society (BCS) report on the future of cardiology over the next 10 years stated that CMR is the investigation likely to undergo the largest expansion of all imaging modalities. In 2007, two technology summaries by the National Horizon Scanning Centre suggested CMR was an important advance and may become the gold standard for assessing myocardial viability and the preferred option for perfusion imaging. The caveat was that CMR capability would need to be expanded through training and capital investment.

The National Heart Director has expressed an ambition to see a dedicated CMR scanner at every tertiary care centre in the country within 3-8 years, a goal not currently achieved. This is in line with the overall goal of the CHD National Service Framework which included the use of “appropriate investigations” in patients with suspected or established CHD. It is also in line with the 2010 NICE guideline update for Heart Failure, which requires identification of aetiology in patients with heart failure.

## **2. Scope**

### **2.1 Aims and objectives of service**

#### **Aims**

The aim of the service is to deliver consistent high quality CMR which is safe and accurate, provides prognostic evidence, changes patient management and reduces the need for other tests.

#### **Objectives**

The service will deliver this aim by

- ensuring appropriate equipment is in place and patients have access to it
- ensuring patients are seen in high volume centres fully integrated with cardiology services
- ensuring CMR reporting is clinically integrated with scan result availability at multidisciplinary review

### **2.2 Service description/care pathway**

Cardiac MRI is an imaging investigation that informs patient management decisions. Requests for imaging may come pre admission as part of the outpatient process, or post elective admission, or during an emergency admission. The recommendations in this Service Specification are based on a document published in 2010 titled “Delivering Cardiovascular Magnetic Resonance in the UK. BSCMR/BSCI guidelines” (available at <http://bscmr.org>). BSCMR is the British Society of Cardiovascular Magnetic Resonance and BSCI is the British Society of Cardiovascular Imaging.

#### **MINIMUM REQUIREMENTS FOR A CMR CENTRE (including mobile units)**

##### **Equipment**

MRI scanner: A fully maintained, shared or dedicated MRI scanner (minimum 1.5 Tesla) with cardiac capability.

Sufficient magnet access to achieve minimum annual unit numbers of at least 300 scans and more than 500 cases per annum for training centres

Written procedures in place to ensure a safe environment and quality ECG gating, patient monitoring (including BP, oxygen saturation)

For a new CMR installation, BSCMR recommendations are:

- RF receiver: should comprise 16 or more RF channels (torso/body/cardiac receiver array with multiple elements).
- Gradient specifications: 30mT/m, 150mT/m/msec
- Artefact resistant electrocardiogram (ECG) hardware/software (e.g. vectorcardiogram)

### **Specific cardiac sequences**

**The minimum is:**

- Steady State Free Precision (SSFP) cine imaging (bFFE, FIESTA or TrueFISP)
- Black blood prepared T1/T2W turbo spin echo (TSE) sequences with/without fat saturation
- Single shot black blood prepared TSE sequences (e.g. half-fourier acquisition single shot (HASTE))
- Phase contrast Flow/velocity sequences with quantification
- Large vessel angiography
- Late Gadolinium Enhancement imaging

**Recommended is**

- Real-time cine sequence
- Perfusion sequences
- Alternative late enhancement sequences (3D, phase sensitive inversion recovery (PSIR), inversion recovery prepared SSFP (IR\_SSFP))
- 3D whole heart other sequences (Short Tau Inversion Recovery (STIR), tagging, coronary sequence, cardiac iron)

### **Specialist software for analysis**

**The minimum is:**

- Volumetric quantification of left ventricle(LV)/right ventricle(RV) volumes and mass
- Quantification of velocity and flow

**Additional software may include:**

- complex 3D angiographic reconstruction, perfusion
- quantification, late enhancement quantification, LV analysis with long axis function, tagging analysis.

## Other equipment

- Resuscitation facilities (including defibrillation/oxygen/suction)
- An emergency trolley with specific drugs to deal with potential reactions to iv contrast media and stressors.
- Magnetic resonance (MR) safe wheelchair & trolley,
- MR compatible monitoring equipment such as: non-invasive blood pressure and saturation of peripheral oxygen (SpO<sub>2</sub>) monitoring equipment
- MR compatible power injectors and infusion pumps

## Staff

A unit will have:

- a nominated Director/Clinical Lead with appropriate training accreditation and Continuing Medical Education/Continuing Professional Development, who is on the UK Specialist Register for Cardiology, Radiology, Nuclear Medicine or who is subspecialty accredited in CMR.
- a nominated Cardiac MRI Radiographer will ideally be dedicated to this role. If this is not feasible the position will offer enough time and support to ensure quality clinical care is delivered to patients in a safe and effective environment to comply with Clinical Governance. In the absence of a formal Cardiac MRI qualification, training and experience will reflect a mixture of time spent at a recognised Cardiac Centre and training courses held at a local, national and international level. General MRI Qualifications will be to a minimum PGc /Diploma/MSc level. They will also be responsible for (or delegating) equipment management and maintenance
- appropriately trained medical and technical staff to deliver the service; these will be familiar with the local rules and procedures for safe working practice in the MR environment.
- arrangements for scientific and technical input from a medical physics expert appropriately trained in CMR methods.
- arrangements for appropriate staff development, (education, training, accreditation, continuing professional development (CPD), revalidation)
- current or planned (within 3 years) total activity sufficient to maintain individual accreditation
- where a Cardiology or Radiology CMR senior appointment is made, where equipment is to be shared, the appointment panels will have representation from both Cardiology and Radiology.

## Scanning

Patient confidentiality will be maintained at all times.

Units will base their scan protocols on nationally agreed scanning protocols

Units will have a clear written standard operating procedure for deviation from

nationally agreed scanning protocols

At least 2 members of staff will be present during scanning, both of whom will be trained in magnet safety, and at least one of whom will be appropriately trained in CMR scanning. For stress imaging, at least one available member of staff will be medically trained and up-to-date to deal with potential complications (including a valid Advanced Life Support or Immediate Life Support qualification).

## **Reporting**

All clinical CMR scans will have a report generated. Responsibility for CMR reports always lies with a consultant. No reports will be signed off without it being clear who this is. However, as with echocardiography and general radiology, it is possible that reporting can be delegated by the consultant under the following conditions:

- A level 3 CMR accredited physician will be available to discuss cases when needed.
- The reporter is a trainee at level 2 or above.

CMR reporting will be clinically integrated with scan result availability at multidisciplinary review at least fortnightly. CMR practitioners will avoid reporting in isolation. Should only one reporting level 3 physician be present in a unit, that unit will have a formal link-up with a separate centre or reporting physician at least six times a year.

CMR reports will conform to appropriate national standards and/or adjust international reporting standards to local UK needs.

When reporting, all areas of all images will be reviewed – including scout images and any extra-cardiac areas cropped out by some viewing software. This includes situations when the aim of imaging is designed for import into other systems (e.g. atrial angiograms for electrophysiology procedures, stent design).

Where a cardiologist/nuclear physician is reporting alone, radiology advice will be available to discuss extra-cardiac pathology; similarly expert cardiology advice will be available for discussion of findings in radiology based services.

## **Quality control**

The quality assurance programme will be defined in a written policy with regular audit of all policies and procedures. Radiographers/technologists and medical physics staff will be fully involved in this process with appropriate analysis and monitoring of the data obtained. Guidance relating the quality control measures has been provided by the Institute of Physics and Engineering in Medicine (IPEM).

A written policy will be in place for CMR equipment image quality testing. Signal and geometric parameters should be monitored. Information will be provided by the MR safety advisor or medical physics expert in MRI.

The unit will have an effective framework for the safe use of the MR equipment which will comply with the detailed guidance available in the Medicines and Healthcare products Regulatory Agency (MHRA) Device Bulletin, DB2007, Dec 2007: Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use. These guidelines cover all aspects of safety including unit design and maintenance.

Each unit will have a specified MR responsible clinician (in most cases the director or the superintendent radiographer of the unit) who is in charge of MR safety. The MR responsible clinician will work closely with a MR safety advisor, a clinical scientist with MR physics expertise, who will advise on necessary engineering, scientific and administrative aspects of the safe use of MR.

### **Emergency procedures**

Emergency procedures will be reviewed and audited at regular intervals (at least annually)

- Cardiac arrest
- Fire
- Magnet quench
- Decreased oxygen level
- Power loss / loss of lighting

The service will comply with Medicines and Healthcare products Regulatory Agency (MHRA) guidelines DB2007(3) which are applicable to all clinical MRI units.

### **Exposure limits**

RF exposure for most routine clinical scans will fall within an uncontrolled or upper level scanning mode. All scans incurring an experimental mode of exposure (i.e. controlled mode scanning) must have ethical approval from the local institutional ethics committee. Scanning pregnant patients will be considered on a risk/benefit basis.

Detailed information is available from the MHRA guidelines DB2007. Exposure limits are similar for all clinical MRI units.

### **Minimum number of scans for a CMR centre**

CMR requires a high degree of operator input and expertise during scanning. The diverse nature of clinical indications and findings in clinical context means that CMR reporting benefits from minimum numbers to maintain quality and competency, even in trained staff.

The BSCMR/BSCI guidelines recommend that Institutional CMR numbers are

- a minimum of 300 cases per annum
- 500 cases per annum for training centres.

In centres performing under 500 cases per year, level 1 (core) training can be performed, as can some advance modules/sub-specialty training – but the advanced module/sub-speciality trainee will require additional experience at an accredited training centre for at least one year (half of their advanced modules/sub-speciality training).

Should a centre not be performing 300 cases per year, then the BSCMR/BSCI guidelines recommend:

- robust plans will be in place to achieve this minimum standard within 3 years. The unit will have a formal link-up with a high volume centre to ensure consistent quality until such time as 300 scans per annum are being performed. This will include access to joint reporting facilities, participating in CMR audit and governance meetings and may include scanning/reporting sessions at the high volume centre.
- If 300 cases per year cannot be achieved within 3 years, the centre stops CMR scanning and transfers the activity to a high volume centre.

Less than 300 cases per year is acceptable for a site where an established CMR team do outreach lists, in which case this activity should be considered as part of the main site's activity.

## **CMR REFERENCE CENTRES**

The BSCMR recommends centres aim to become 'reference centres', This is a voluntary process but represents a standard that the NHS has adopted for commissioning purposes. The title of 'reference centre' is attached to a named unit and Director and is recommended within 3 years of an institution commencing scanning. This service is provided by BSCMR as part of their society objectives and is free of charge provided the applicant (unit director) is a society member. It is not meant to be arduous, bureaucratic or restrictive and consists of the following 3 types of information:

1. Written confirmation of appropriate equipment and trained staff.
2. Central (BSCMR/BSCI subcommittee) review of the images of any ten cases submitted from the unit, the cases representing at least five pathologies out of the 14 referenced in SMCR standard protocols.
3. Central (BSCMR/BSCI subcommittee) review of the reports of the above cases.

It is expected that such centres will have, in addition:

- access to educational material,
- journal clubs,
- interesting case reviews and
- research opportunities for trainees – although these are not formally assessed as part of accreditation.

Each reference centre will submit an annual return to BSCMR. This return will relate

to unit activity, growth, numbers of trainees etc. allowing BSCMR to provide activity statistics to help Department of Health planning and CMR service delivery/commissioning.

## 2.3 Population covered

The service outlined in this specification is for patients ordinarily resident in England\*; or otherwise the commissioning responsibility of the NHS in England (as defined in Who Pays?: Establishing the responsible commissioner and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges).

- Note: for the purposes of commissioning health services, this EXCLUDES patients who, whilst resident in England, are registered with a GP Practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP Practice in England.

Specifically, this service is for adults with cardiac conditions requiring specialised imaging and management, as outlined within this specification.

A comprehensive and integrated service will be available to the whole population of the UK, either through local CMR centres or CMR reference centres. Access to these services will be guided by clinical need.

### Number of scans

It is recognised that the following represents a reasonable estimate of service capacity requirements over the next 5 years. This will need to be reappraised annually given the rapid changes in the field:

a) Perfusion and viability: NICE (TA73) suggest that the UK need is for 4000/million/annum SPECT scans. Several UK centres have switched to CMR and no longer perform nuclear studies. Evidence suggests that CMR is equivalent and in some circumstances better than nuclear scanning with no use of ionising radiation. Accordingly, an estimate of 30% of the above scans will be done using CMR for the assessment of ischaemia and/or viability.

**1,200 scans per million**

b) Cardiomyopathy: with 340,000 inherited cardiovascular condition patients in the UK, 220,000 once familial hypercholesterolemia is excluded, demand can be considered as half of all new patients (New patients: 10,000 per year, 50% need CMR = 5000 per year) and half of all follow-up patients every 5 years (22,000, less new patients - 21,000 per annum); total 26,000 per annum.



### 520/million/annum

c) Grown Up Congenital Heart disease (GUCH): growing by 100 scans per million per year

d) All other scan indications (aortas, valves, pericardium, poor echo windows etc). These constitute a major CMR workload, in the largest survey (the German registry), 20% of the workload, i.e.25% more than the above.

### 455 scans per million

*Accordingly, the BSCMR/BSCI document estimates total CMR need is **2275 scans per million adults per year**, approximately equivalent to 52 full time CMR magnets each undertaking 2250 scans per year in the UK. For England alone, the number would be 40-45.*

### Number of centres

Currently, there are 61 CMR centres in the UK, 11 of which have scanners dedicated for CMR. The BSCMR/BSCI considers that, as a minimum, every cardio-thoracic centre in the UK should have access to CMR (42 centres), and as a maximum, based on the activity outlined below, there should be no more than 50 CMR centres.

### 2.4 Any acceptance and exclusion criteria

The service will accept inward referrals from cardiology physicians and cardiac surgeons.

### Referral Criteria

Cardiac MRI allows assessment of anatomy, function and viability of the heart, but also can detect ischaemia & infarction, assess congenital heart disease, the aetiology of heart failure, heart valve dysfunction and the presence of inherited diseases.

The following conditions may all benefit from CMR

- CMR of cardiovascular anatomy
- CMR of ventricular volumes, function and mass
- CMR of cardiovascular flow and shunting
- CMR of valvular heart disease
- CMR of adult congenital heart disease
- CMR of myocardial perfusion (adenosine stress)
- CMR stress ventriculography (dobutamine)
- CMR of cardiomyopathy and myocarditis
- CMR of iron storage diseases (T2\*)
- CMR of infarction and viability

- CMR of cardiac and paracardiac masses 'tumours'
- CMR of pericardium
- CMR of aortic pathology
- CMR angiography (great vessels)
- CMR angiography (coronary arteries and veins)
- CMR of atrial anatomy (for epicardial (EP) mapping systems)
- CMR spectroscopy
- CMR of post-cardiac transplantation.

### **Exclusions**

All other cardiac conditions

### **2.5 Interdependencies with other services**

- Co-located services – fully integrated with cardiology and radiology departments
- Interdependent services – Paediatric and Adult congenital heart disease; Specialist cardiomyopathy and complex revascularisation (e.g. coronary artery bypass graft (CABG))
- Related services – Nuclear cardiology, cardiac ultrasound, cardiac CT

## **3. Applicable Service Standards**

### **3.1 Applicable national standards e.g. NICE, Royal College**

#### **Audit and risk assessment**

CMR centres will undergo regular audit as part of the clinical governance of the service. Although at this stage, national and international guidelines and audit standards are poorly developed, specific areas for attention will include those where interpretation may be particularly complex, for example perfusion CMR, arrhythmogenic right ventricular cardiomyopathy (ARVC), dobutamine stress and congenital heart disease.

The BSCMR also recommends regular patients' view audit, as recommended in the Royal College of Radiologists audit live website.

A reporting discrepancy occurs when a retrospective review, or subsequent information about patient outcome, leads to an opinion different from that expressed in the original report. Not all reporting discrepancies are errors.

The BSCMR recommends discrepancy meetings ~4 times a year, either separately, as part of 'hits and misses' meeting or as part of a multimodality imaging meetings or

audit meetings. The purpose of these is to facilitate collective learning thereby improving patient safety. They do require sensitive handling and specific, detailed guidance exists from the Royal College of Radiologists on them. Such meetings form an important part of the audit process and the structure of these meetings must ensure a blame-free learning orientated environment.

### **Core Standards**

- a nominated Director/Clinical Lead with appropriate training accreditation and continuing medical education (CME)/CPD
- at least 2 members of staff will be present during scanning, both of whom will be trained in magnet safety, and at least one of whom will be appropriately trained in CMR scanning. For stress imaging, at least one available member of staff will be medically trained and up-to-date to deal with potential complications
- Each unit will have a specified MR responsible clinician (in most cases the director or the superintendent radiographer of the unit) who is in charge of MR safety
- A fully maintained, shared or dedicated MRI scanner (minimum 1.5 Tesla) with cardiac capability.
- Sufficient magnet access to achieve minimum annual unit numbers of at least 300 scans and more than 500 cases per annum for training centres
- Written Procedures in place to ensure a safe environment and quality

### **Specific cardiac sequences**

#### **The minimum is:**

- SSFP cine imaging (bFFE, FIESTA or TrueFISP)
- Black blood prepared T1/T2W TSE sequences with/without fat sat
- Single shot black blood prepared TSE sequences (e.g. HASTE)
- Phase contrast Flow/velocity sequences with quantification
- Large vessel angiography
- Late Gadolinium Enhancement imaging

### **Recommended Standards**

- A nominated Cardiac MRI Radiographer will ideally be dedicated to this role

### **Specific cardiac sequences**

#### **Recommended**

- Real-time cine sequence
- Perfusion sequences
- Alternative late enhancement sequences (3D, PSIR, IR\_SSFP)

- 3D whole heart
- Other sequences (STIR, tagging, coronary sequence, cardiac iron)

#### 4. Key Service Outcomes

The service utilises the most up-to-date technology for assessing myocardial viability and represents the preferred option for perfusion imaging

The service will provide patients with access to safe, non-invasive, accurate, diagnostic service.

The service will give clinicians access to the highest standard prognostic evidence, enabling informed changes to patient management to be made and reducing the need for other tests.

Interim for Adoption from 01/10/13