Technical guidelines for magnetic resonance imaging for the surveillance of women at increased risk of developing breast cancer

1

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CONTENTS

1.   INTRODUCTION

1.1 Aims of the guidance

The NHS Breast Screening Programme (NHSBSP) is responsible for setting and monitoring the standards for imaging surveillance of women below the screening age who are assessed as being at increased risk of developing breast cancer. This may be because of a family history of breast cancer or previous radiotherapy treatment for Hodgkin's disease. The guidance sets out the technical standards required for the provision of breast MRI as part of the imaging surveillance of women at increased risk, and describes the arrangements for reporting MRI examinations and for quality assurance of MRI surveillance. The guidance is based on the results of the magnetic resonance imaging breast study (MARIBS)[1] and has been compiled by a UK working party made up of members of the MARIBS steering group, representatives from industry including manufacturers of MRI equipment, and software companies producing tools for breast MRI analysis.

1.2 Background

The Cancer Reform Strategy[2] recognised that the opportunities and protocols for surveillance of women identified as being at increased risk of developing breast cancer have been variable across the country. The strategy recommended that all women identified as being at increased risk should be offered the opportunity to have their risk formally assessed and, if appropriate, to discuss their management options, in accordance with guidelines published by the National Institute for Health and Clinical Excellence (NICE).[3] The NHSBSP is responsible for managing this surveillance to national standards and ensuring that women receive a consistent and high quality service. Surveillance with digital x-ray mammography and magnetic resonance imaging should be provided where appropriate and previous guidance issued for surveillance of women treated for Hodgkin's disease with mantle radiotherapy[4] should be taken into account.

1.3 Provision of MRI and mammography surveillance

It is expected that 2500 women in England and Wales will be assessed by medical geneticists as being at high risk of breast cancer as a result of their family history and will qualify for imaging surveillance by MRI and mammographic screening. Women in this category will be screened only at breast screening centres that satisfy the criteria set out in these guidelines. It is anticipated that the risk assessment process will identify women in whom MRI or mammography is contraindicated. Centres that provide breast imaging using MRI must meet the national minimum standards relating to equipment, image acquisition and data storage. They must follow national protocols for reporting MRI examinations and should participate in the audit of MRI surveillance. It is anticipated that symptomatic examinations will be performed to the same high standard. The provision of MRI for surveillance will be monitored as part of breast screening quality assurance (QA) activities.

Three demonstration sites have been set up to develop the clinical and administrative protocols for MRI surveillance of women at high risk. These protocols will be circulated separately.

2. STANDARDS FOR EQUIPMENT AND IMAGE ACQUISITION

2.1 MRI system
High field modern MRI machines should be used. Very high field strengths (3 Tesla and above) can be used, provided images are of diagnostic quality and B1 transmit homogeneity is uniform

Minimum standard: at least 1 Tesla
Expected standard: 1.5 Tesla

2.2 Breast coil
Dedicated bilateral breast coils must be used (open or closed) with uniform signal homogeneity across the coils.

2.3 Breast movement
Breast movement should be minimised during the procedure in order to obtain the best quality dynamic data.

2.4 Contrast
Pump injection of at least 0.1mmol/kg contrast is recommended, with a 3cc/sec flow rate and 20ml bolus saline. The contrast pump should be set to start after the pre-contrast scans, so that the contrast's arrival in tissue coincides with the centre of the k-space (approximately 20 seconds from the start of injection). UK recommendations on avoiding contrast reactions and nephrogenic systemic fibrosis should be followed.[5]

2.5 Timing of examinations
The examination should be carried in the mid portion of the menstrual cycle to reduce normal parenchymal tissue enhancement.

Minimum standard: examination in day 6-16 of the menstrual cycle

2.6 Scanning parameters

- **Time:** Total examination time <30 mins
- **Orientation:** Both breasts should be examined. This can be achieved by scanning in the axial (preferred) or coronal plane, or by using an interleaved sagittal approach. The choice of scanning plane will be determined by the viewer's preference and the need to optimise resolution. (See below.)
- **Resolution**
  - **Spatial resolution** High spatial resolution is needed to assess the lesion's morphology.
    - Slice thickness (as defined by the specific slice profile) ≤ 2mm
    - In plane resolution (as defined by the specific resolution) <1.0 mm
  - **Temporal resolution** High temporal resolution is needed for the dynamic sequences, so that lesion kinetics can be fully assessed.
    - Dynamic scan time < 120s.
    - Dynamic scan repeated out to 5-7 minutes after contrast is administered.

o **Optimisation** Spatial and temporal resolution should be optimised. If parallel imaging is available it should be used. The direction of parallel imaging may dictate the scanning orientation. Time saving techniques should be adopted: for example, reducing the field of view in the phase encoding direction when scanning in the coronal plane.

- **Sequences**
  - **T2-weighted fast spin echo**
    - Provides high resolution for characterizing lesions and improves specificity.
    - Requires no fat suppression.
  - **T1-weighted spoiled gradient echo**
    - Enables a dynamic set of sequences to be obtained before contrast is injected and then repeated as rapidly as possible for 5 to 7 mins after a rapid intravenous bolus of a contrast agent containing gadolinium.
    - Provides 3D or 2D (multislice) images.
    - A fat suppression technique should be used to improve the lesion's conspicuity. This can be obtained either by integral frequency based fat suppression (such as frequency-selective fat saturation or water excitation) of the dynamic sequence, or by using a subtraction technique.
      ⇒ If integral frequency based fat suppression is applied this sequence may be run prior to the dynamic set with no fat suppression to help characterize lesions.
    - Applying a 3D non-rigid registration may help to minimise the production of artefacts in the subtraction images if the patient moves during the examination.
  - **T1-weighted spoiled gradient echo with fat suppression**
    - Produces an ultra high resolution post contrast scan for assessing the lesion's morphology.
    - Should give a 50% improvement in voxel size compared with the dynamic scan (unless an in-plane resolution of 0.6mm is already achieved).
    - Includes an integral frequency based fat suppression, such as frequency-selective fat saturation or water excitation.

2.7   DICOM compliance and data import

It is expected that all modern MRI machines and workstations will be DICOM compliant.

Minimum standard: uncompressed DICOM 3.0

Data should be written to a CD (or equivalent) directly from the scanner or workstation and not via PACS, as some centres report that data have been rescaled by PACS. If using PACS, then a quality control (QC) process should be in place to ensure that the source data have not been modified.

2.8   Viewing tools

The following tools should be available on the reporting workstation

- o Subtraction, multiplanar reconstruction (MPR), and minimum intensity projection (MIP) software
- o signal enhancement analysis package with tools for selecting regions of interest (ROIs)
- o hotspot analysis for diagnosis (maximum signal intensity, guidance on scaling, presence of air or fat)
- o software package to support
    - ▪ image analysis
    - ▪ image registration features
    - ▪ the ability to change how images are displayed
- o pharmacokinetic modelling
- o pixel by pixel analysis of ROIs with wash-in and wash-out maps.

3.   REPORTING MRI EXAMINATIONS

3.1   Reading requirements

It is expected that the majority of women in the high risk group will undergo both x-ray mammography and breast MRI. Some of these may have MRI surveillance only, for example because of their young age, while a few may have mammography only because MRI is contraindicated. Mammograms must be acquired in full-field digital format. If possible mammography should be performed on the same day as the MRI. The minimum standard is that mammography should be performed within two weeks of the MRI examination. The mammograms and the MRI images should be read together and must be independently double read.

At least one of the MRI readers should be a breast radiologist who satisfies the NHSBSP standards as a breast screening film reader (among them, conducting a minimum of 5000 mammograms per year).[5] The MRI readers should each report a minimum of 100 breast MRI examinations (including screening and symptomatic cases) per year.

The results of a client's previous screening MR and mammography examinations should be available for comparison.

Standard MRI screening reporting categories should be used

> MRI 1: normal
> MRI 2: benign
> MRI 3: indeterminate
> MRI 4: suspicious
> MRI 5: malignant

MRI screening and assessment forms have been developed for the national breast screening system (NBSS). These will be used to record the MRI opinion and also the

outcome of the assessment of MRI detected abnormalities. These forms are shown at Appendix 1. Protocols for their use by MRI units and breast screening centres are being developed by the three demonstration sites for MRI surveillance of women at high risk, and will be circulated separately.

3.2   Assessment of abnormalities

Abnormalities detected by MRI and/or digital mammography should be assessed by the local NHSBSP screening team and preferably by the radiologist who has read the MRI examination. This assessment need not take place in an NHSBSP screening assessment unit, provided the assessing team satisfies the NHSBSP requirements. Initial assessment should be with conventional imaging (further mammography and ultrasound). The reporting forms at Appendix 1 should be used to record data on the national breast screening system (NBSS).

Indeterminate MR abnormalities (MRI 3: enhancing mass < 5mm or area of enhancement <10mm) detected by conventional imaging should trigger a repeat MR examination within six months.

Suspicious MR abnormalities (MRI 4 and 5: enhancing mass lesions > 5mm or areas of enhancement > 10mm or lesions with suspicious morphology) detected by conventional imaging should be considered for MRI guided biopsy.

3.3   MRI guided biopsies

MRI guided biopsies should only be performed at a designated MRI biopsy screening centre.

Minimum standards

o   designated screening MRI centres must perform a minimum of 12 MRI guided breast biopsies per year
o   all MRI guided biopsies should be performed using vacuum assisted mammotomy (VAM) in a centre that has recognised expertise in VAM and carries out at least 50 image guided VAM procedures per year.

Audits should be undertaken to ensure that reporting accuracy and biopsy rates are at an acceptable standard. It is expected that the great majority of significant abnormalities detected by MRI will be identified at assessment and biopsied using conventional imaging, and that MRI guided biopsy will rarely be required. Standards for radiological experience are set out at Appendix 2. Standards for reporting accuracy and biopsy rates will be developed in due course in the light of operational experience.

3.4   Recall rate

The number of women recalled for further imaging or biopsy should be kept to a minimum.

Minimum standard <10%
Expected standard <7%

4. QUALITY CONTROL AND QUALITY ASSURANCE

4.1 Quality control
There must be regular quality control checks to ensure that MRI screening centres meet the NHSBSP minimum standards for equipment, image acquisition, and data storage.

Annual checks

The following checks are to be carried out by a physicist with the required MRI expertise. They should be performed at least annually and after all major software or hardware upgrades

1. Check that screening sequences meet the specified criteria

2. Evaluate the performance of the system and screening sequences

   a) spatial and slice resolution, using a test object
   b) contrast performance over a range of T1s
   c) signal to noise performance
   d) uniformity of excitation
   e) homogeneity of scanner
   f) effectiveness of fat suppression sequences
   g) effectiveness of shimming
   h) accuracy of image data recording, on output and storage
   i) archiving process
   j) targeting and alignment of biopsy apparatus and process, where applicable
   k) a range of tests on the evaluation software to ensure that it reads and analyses image data accurately.

Routine weekly quality control checks

The following simple QC checks should be performed on site by a competent radiographer or physicist using a phantom in the breast coil provided for the purpose. These should monitor

   a) signal to noise
   b) contrast sensitivity at fixed T1s
   c) fat suppression

4.2 Accreditation
As part of the routine commissioning process, commissioners should ensure that all MRI screening centres meet the minimum standards for

   o equipment and measurement set up
   o performance of routine QC checks
   o radiological training and experience.

The relevant standards are summarised at Appendix 2.

4.3   MRI audit database

In consultation with the NHS National Office, a database of all MRI measurements will be established for each MRI screening centre. National Office will support this new development, the training of MRI readers, and evaluation of the effectiveness of the surveillance process. The MRI physicist will be responsible for image data archiving and analysis. Standards for image acquisition, reading and assessment are summarised at Appendix 2.

REFERENCES

1. Leach MO, The MARIBS Advisory Group, Staff and Collaborating Centres. The UK national study of magnetic resonance imaging as a method of screening for breast cancer (MARIBS). *Journal of Experimental and Clinical Cancer Research*, 2002, 21 (Suppl. 3): 107-114.

2. *Cancer Reform Strategy.* Department of Health, 2007. Available at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/dh_081006 .

3. *Familial breast cancer: the classification and care of women at risk of familial breast cancer in primary, secondary and tertiary care*. National Institute for Health and Clinical Excellence (NICE), 2006 (Clinical Guideline CG41: partial update of CG14). Available at http://www.nice.org.uk/article.asp?a=30600 .

4. *Increased risk of breast cancer after radiotherapy for Hodgkin's Disease: patient notification exercise. Updated Toolkit*. Department of Health, Letter and attachment, dated 31 October 2003.

5. Gadolinium-based contrast media and Nephrogenic Systemic Fibrosis. Royal College of Radiologists, 2007. Available at http://www.rcr.ac.uk/docs/radiology/pdf/BFCR0714_Gadolinium_NSF_guidanceNov07.pdf

6. *Quality Assurance Guidelines for Breast Cancer Screening Radiology*. NHS Cancer Screening Programmes, 2005 (NHSBSP Publication No 59)

7. *Consolidated Guidance on Standards for the NHS Breast Screening Programme (Version 2).* NHS Cancer Screening Programmes, 2005 (NHSBSP Publication No 60)

APPENDIX 1: MRI SCREENING FORMS AND ASSESSMENT FORM

FORM A: BSP MRI screening request (To be sent to the MRI service undertaking the procedure)

For MRI use	Date received:	Reference:

For BSP use	Location: _____ Hospital code: _____.
	(Affix return address label here)

Client details

Surname: _____

Forenames: _____   Date of birth: _____

Hospital number: _____

SX number: _____   NHS number: _____.

Address:

Telephone No 1: _____   Telephone No. 2: _____

Ethnic origin code: _____   Year mastectomy performed (right): _____ (left): _____

GP name: _____

GP address:

MRI appointment

Appointment date: _____ Time: _____

Appointment note: _____.

Status: ○ Booked   ○ Attended   ○ Attended not screened
○ Not attended   ○ MRI contraindicated

Status comment: (Use this space to enter free text about the appointment)

FORM B: BSP MRI screening request (to be completed by MRI radiographer)

Client details (may be completed in advance by referring screening office)
Surname:

Forenames: _____ Date of birth: _____

Hospital number: _____

SX number: _____ NHS number: _____

MRI screening results (MRI radiographer may note here any breast problems reported by the client or observed. No clinical examination should be undertaken)

Date of MRI examination: _____ MRI scanner (make and model) _____

Clinical findings	**Right**	**Left**
Recent lump	O	O
Distortion/change in breast shape	O	O
Nipple discharge	O	O
Nipple eczema	O	O
Recent nipple inversion	O	O
Skin tethering or dimpling	O	O

Other relevant breast information (eg surgery details)
Right: _____
Left: _____ _____

Reporting (choose 'Clinical' if the MRI was normal but client needs to be clinically recalled; choose 'N/A' if that breast was absent)

Date reported: _____

Clinician name/ code	**Right** Normal	Abnormal	Clinical	N/A	**Left** Normal	Abnormal	Clinical	N/A
1 _____	O	O	O	O	O	O	O	O
2 _____	O	O	O	O	O	O	O	O
Overall _____	O	O	O	O	O	O	O	O

FORM C: BSP MRI screening request (to be used if results were abnormal and further examination of the MRI is needed)

Client details

Surname: _____

Forenames: _____   Date of birth: _____

Hospital number: _____

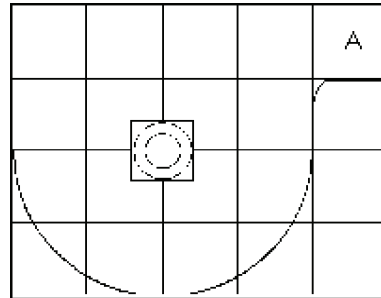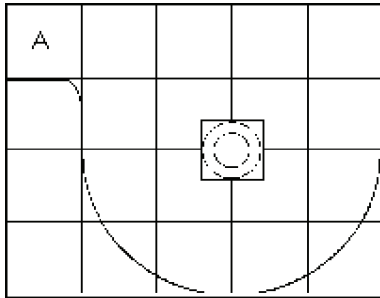SX Number: _____   NHS number: _____

MRI assessment results (complete a separate form for each lesion, as multiple lesions will be recorded by NBSS)

Date performed: _____ Location name or code: _____ Clinician name or code: _____

Side Assessed: ☐ Right   ☐ Left

Lesions and abnormalities:

Lesion or abnormality

Background enhancement: ○ Widespread ○ Moderate   ○ Low
○ Homogenous ○ Heterogenous
○ Rim   ○ Central

Segmental enhancement: ○ Segmental ○ Non segmental

Enhancement curve: ○ Type I   ○ Type II   ○ Type III

Mass: ○ Benign   ○ Intermediate   ○ Suspicious   ○ None

Morphology: ☐ Smooth   ☐ Well defined   ☐ Lobulated   ☐ Spiculate

Size (mm):   _____

Axilla Normal: ○ Normal   ○ Abnormal

MRI Lesion notes:

MRI Lesion description: _____

Type of site: ○ Single   ○ Multiple

Opinion: ○ G1 Normal   ○ G2 Benign   ○ G3 Uncertain   ○ G4 Suspicious   ○ G5 Malignant

(NB Opinion codes are consistent with NBSS. 'G' is used because NBSS already uses 'M' for mammography.)

APPENDIX 2:   QUALITY ASSURANCE STANDARDS FOR MRI BREAST SURVEILLANCE

Objective	Criteria	Minimum standard
Equipment		
To optimise diagnostic image quality	Field strength	Minimum standard: ≥ 1 Tesla Expected standard: 1.5 Tesla
	Number of elements	Minimum standard: 4 channel Expected standard: 7 channel
Image acquisition		
To optimise diagnostic image quality	MRI sequences Dynamic sequence	Minimum standard: ≤ 60 sec Expected standard: ≤ 45 sec
	Total examination time	< 30 mins
	Fat suppression	Minimum standard: subtraction Expected standard: integrated fat suppression
	Breast movement	Support of breasts to minimise motion
	Examine both breasts with isotropic voxels	
	Uniform excitation and received signal homogeneity across image	
	Slice thickness	≤ 2 mm
	In-plane resolution	< 1.0mm
To optimise diagnostic image quality	Timing of examinations	Day 6-16 of the menstrual cycle
Data storage		
To ensure accurate data storage	All machines and workstations to be DICOM compliant	Uncompressed DICOM 3.0

Objective	Criteria	Minimum standard
Radiological experience		
To ensure that MRI readers are suitably experienced	Reader 1 No of mammograms	5000 per year (screening and/ or symptomatic)
	No of MRI examinations	100 per year (screening and/ or symptomatic)
	Reader 2 No of mammograms per year	Only reader 1 is required to meet above standard
	No of MRI examinations per year	100 per year(screening and/or symptomatic)
To ensure that screening MRI centres have sufficient experience	Number of MRI guided breast biopsies per centre	At least 12 per year
	Number of image guided VAM procedures per centre	At least 50 per year
Reading and assessment		
To ensure comparison with digital screening mammograms	Availability of digital screening mammograms	Always available
To ensure that standard MRI reporting categories are used	Reporting categories used	Standard MRI reporting categories must used
To minimise anxiety for women who are awaiting the results of their screening imaging[7]	Percentage of women who are sent their result within two weeks	Minimum standard: 90% Target: 100%
To minimise the number of women who are recalled for further tests	Number of women recalled for further imaging or biopsy	Minimum standard < 10% Expected standard <7%
To minimise the interval from the screening imaging to assessment[7]	Percentage of women who attend an assessment centre within three weeks of attendance for their screening imaging.	Minimum standard: 90% Target: 100%