



## Use of an upright, standing or positional (open) MRI scanner

Leeds North CCG, Leeds South and East CCG and Leeds West CCG

Version:	final Draft
Ratified by:	Leeds West CCG Assurance Committee on (date) Leeds North CCG Governance, Performance and Risk Committee on (date) Leeds South and East CCG Governance and Risk Committee on (date)
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Name of responsible committee/individual:	Leeds West CCG Assurance Committee Leeds North CCG Governance, Performance and Risk Committee Leeds South and East CCG Governance and Risk Committee
Date issued:	
Review date:	April 2015
Target audience:	Primary and secondary care clinicians, individual funding request panels and the public
Document History:	nil

Produced on behalf of NHS Leeds West CCG, NHS Leeds North CCG and NHS Leeds South and East CCG

## 1.0 Introduction

This policy is designed to clarify the agreements between Leeds Clinical Commissioning Groups (CCGs) Leeds North CCG, Leeds South and East CCG and Leeds West CCG and providers regarding the commissioning of upright, standing or positional Magnetic Resonance Image (MRI) diagnostic scan.

It serves to agree the conditions which are automatically commissioned and those that require exception permission before they can proceed.

There is an agreement that for commissioning to proceed, information must be provided by clinicians from levels 2, 3, or 4 (see below).

This document is intended as an aid to decision making. It should be used in conjunction with Leeds CCG policies on Individual Funding Requests and associated decision making frameworks.

## 2.0 Definitions

Upright, standing or positional MRI (uMRI) is a type of vertically, open MRI that has been developed in recent years. Such systems are open at the front and top, with the magnetic poles placed on either side of the patient and allow for vertical (upright, weight bearing), horizontal (recumbent) positioning, and dynamic kinetic flexion and extension manoeuvres.

Current uMRI scanners generally use medium field magnets of 0.5T or 0.6T, uMRI here refers to any system of 0.5T or greater that allows for scanning in various positions, regardless of manufacturer. By comparison, the most advanced standard rMRI scanners have magnet strength of at least 1.0T and up to 3.0T allowing for the greatest resolution generally in a shorter amount of time. With 0.6T magnets, uMRI requires more time to obtain images with lower resolution.

Slower imaging times with uMRI may create difficulty for patients who are unable to remain still while in a standing or sitting position; not comfortable secondary to pain; or are unstable in such positions. Longer exam times may also decrease the overall patient flow and volume of patients that can be accommodated.

The proposed advantages of uMRI are based on the ability to scan the spine (or joints) in different positions (including the position where clinical symptoms are more pronounced) and assess the effects of weight bearing, position and dynamic movement.

Commissioner – Leeds CCGs

Providers – any hospital/clinic/centre with a commissioning agreement with NHS Leeds CCGs, (including NHS and independent sector providers).

Level 2 – Primary care

Level 3 – Extended primary care intermediate services

Level 4 – Hospital services

## 3.0 Commissioning position

<p><b><i>Not routinely commissioned</i></b></p>	<p>Standing, upright, weight-bearing or positional (open) MRI will not be routinely commissioned.</p> <p>Leeds CCGs regard the standing, axially loaded, positional (open) or weight bearing MRI, investigational. There is limited peer-reviewed scientific data available on the accuracy and diagnostic utility of these types of MRIs. Well-designed, larger, clinical trials are necessary to effectively determine the evidence showing the degree to which such methods are safe, effective and more accurate than conventional MRI for use as diagnostic tools.</p>
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	Leeds CCGs do not support whole spine or body imaging
<b><u>Routinely commissioned but require prior approval</u></b>	<p>Referral for open MRI scanning of at least 0.5T as an alternative to conventional MRI in is commissioned only for:</p> <ul style="list-style-type: none"> <li>patients who suffer from claustrophobia where an oral prescription sedative has not been effective (flexibility in the route of sedative administration may be required in paediatric patients as oral prescription may not be appropriate)</li> </ul> <p>or</p> <ul style="list-style-type: none"> <li>patients who are obese and cannot fit comfortably in conventional MRI scanners as determined by a Consultant Radiologist/Radiology department policy</li> </ul> <p>or</p> <ul style="list-style-type: none"> <li>Patients who cannot lie properly in in conventional MRI scanners because of severe pain</li> </ul> <p><b>AND</b></p> <p>There is a clear diagnostic need consistent with supported clinical pathways</p> <p><b>IN ADDITION</b> The CCGs will only fund uMRI of the specific anatomy requested.</p>

#### 4.0 Background

Washington State Health Care Authority Health Technology Assessment identifies upright, standing or positional MRI (uMRI) as a type of vertically, open MRI that has been developed in recent years. Such systems are open at the front and top, with the magnetic poles placed on either side of the patient and allow for vertical (upright, weight bearing), horizontal (recumbent) positioning, and dynamic kinetic flexion and extension manoeuvres. Current uMRI scanners generally use medium field magnets of 0.5T or 0.6T). uMRI is any system of 0.5T or greater that allows for scanning in various positions, regardless of manufacturer. By comparison, the most advanced standard rMRI scanners have magnet strength of at least 1.0T and up to 3.0T allowing for the greatest resolution generally in a shorter amount of time. With 0.6T magnets, uMRI requires more time to obtain images with lower resolution. Slower imaging times with uMRI may create difficulty for patients who are unable to remain still while in a standing or sitting position; not comfortable secondary to pain; or are unstable in such positions. Longer exam times may also decrease the overall patient flow and volume of patients that can be accommodated. The proposed advantages of uMRI are based on the ability to scan the spine (or joints) in different positions (including the position where clinical symptoms are more pronounced) and assess the effects of weight bearing, position and dynamic movement. It is hypothesised that uMRI scanning in a variety of positions could help elucidate pathology that may be expressed more fully with positional changes or weight bearing.

MRI has in many instances, become the diagnostic modality of choice for evaluating suspected causes of such pain. It is hypothesized that uMRI, by obtaining images in the axial-loaded condition, and/or while the patient is in a position which elicits symptoms, may facilitate the diagnosis of various abnormalities that cause the symptoms. No formal technology assessments, systematic reviews or critiques of evidence quality related to the diagnostic accuracy or reliability of uMRI used in the evaluation of the spine and extra-spinal joints have been found in the published, peer-reviewed literature.

One study by Hirasawa et al. (2007) recruited 29 healthy male subjects to undergo MR imaging of the spine in the supine, standing, and seated (neutral, flexion, and extension) positions. Changes in the

mean cross-sectional areas and diameters comparing these positions were reported. The authors found significantly smaller mean dural sac cross-sectional areas at all spinal levels in the supine position versus the upright positions. This percent decrease was as large as 25.4% (supine versus seated extension at the L5/S1 level). Measurements of the mean dural sac diameter showed both increases and decreases comparing the different positions. This study utilized a 0.6T open MRI for all images.

Karadimas et al. (2006) studied 30 subjects with chronic degenerative low back pain who were wait-listed for surgery. They evaluated changes in mean end plate angles and disc height for all lumbar intervertebral levels in the supine position versus the seated neutral position. They utilized a 0.2T open MRI for images in the supine position, and a 0.6T upright scanner for images in the seated position. They also assessed lumbar lordosis. The authors classified discs into four degrees of degeneration (healthy, mild, moderate, or severe). For degenerated discs and healthy discs below degenerated discs, there was a significant reduction in mean end plate angles ranging from  $-1.7^{\circ}$  to  $-6.8^{\circ}$  in the seated position relative to the supine position. The authors reported both increases and decreases in disc height for degenerated discs and healthy discs comparing the supine to the sitting position. There was no clear trend in these changes. Finally, no significant change in lumbar lordosis comparing the two positions was found. This study contributes to a greater Upright MRI report understanding of spinal kinematics; however, it does not address whether uMRI improves diagnosis of disc degeneration compared with rMRI.

A study by Kanno et al. (2011) reported the findings of a study of 44 consecutive subjects who underwent imaging with conventional MRI, axial MRI and upright myelogram. The measurements of the transverse and anteroposterior diameters, as well as the cross sectional areas of the dural sac from L2/3 to L5/S1 from all three imaging methods were compared. The authors reported that results from axial loaded MRI demonstrated a significant reduction in the dural sac size and significant correlations of the dural sac diameters with the upright myelogram ( $p < 0.001$ ). Furthermore, the axial loaded MRI had higher sensitivity and specificity than the conventional MRI for detecting the severe constriction observed in the myelogram (96.4% vs. 83.9% and 98.2% vs. 87.0%, respectively). While these findings are promising, further investigation into how axial MRI can improve health outcomes compared to conventional MRI is warranted.

Washington State Health Care Authority found that there was insufficient scientific evidence to make any conclusions about upright MRI's effectiveness, including whether upright MRI: accurately identifies an appropriate diagnosis; can safely and effectively replace other tests; or results in equivalent or better diagnostic or therapeutic outcomes.

A number of studies have reported that positional MRI can identify abnormalities in patients where conventional MRI did not identify significant abnormal findings. As yet, no studies have been noted that describe clinical outcomes of patients whose treatments were selected based on the new findings of positional MRI. Additionally, the incremental benefit of this imaging in clinical practice is not yet known.

The majority of the articles found on 'Stand-Up MRI's' are from the various radiology groups and are in the form of reviews. Additional evidence-based studies are needed to determine the characteristics of patients who might benefit from positional MRI studies. In addition, the clinical benefit of basing treatment decisions, including surgery, on these additional findings need to be established. Another concern that needs further study is that positional scans, which use lower strength magnets, may be of lesser quality than those from traditional supine MRI.

In summary, there continues to be minimal published and peer-reviewed scientific evidence from studies designed to minimize potential biases showing how weight-bearing MRI contributes to the planning and delivery of therapy or to improved health outcomes among patients.

Subacute and chronic low back pain is a significant health problem, affecting approximately 80% of adults at some time in their lives. In many cases, this pain is due to arthritis, abnormal spinal curvature, pinched or compressed nerves, or deterioration of the discs that separate vertebrae. Other less common causes of back pain are cancer, infection, injury, and damage from prior surgery. Although back pain occurs most often in the lower spine, it can also occur in the mid and upper spine.

Imaging techniques that have been used to diagnose spinal disorders include magnetic resonance imaging (MRI), computed tomography (CT), discography, and myelography. The latter two techniques

involve taking series of x-rays after injection of a contrast agent into the spinal disc or into the space around the spinal cord. However, all of these techniques except MRI expose patients to radiation and myelography and discography are invasive. The National Institute for Health and Care Excellence (NICE) suggests considering MRI when a diagnosis of spinal malignancy, infection, fracture, cauda equina syndrome or ankylosing spondylitis or other inflammatory disorders are suspected but only to offer an MRI scan for non-specific low back pain within the context of a referral for an opinion on spinal fusion.

#### **4.1 Conventional MRI**

Conventional MRI is established as the most sensitive imaging test of choice of the spine in routine clinical practice. MRI imaging of the spine is performed to:

- Assess the spinal anatomy;
- Visualize anatomical variations and diseased tissue in the spine;
- Assist in planning surgeries on the spine such as decompression of a pinched nerve or spinal fusion;
- Monitor changes in the spine after an operation, such as scarring or infection;
- Guide the injection of steroids to relieve spinal pain;
- Assess the disks, (i.e. bulging, degenerated or herniated intervertebral disk, a frequent cause of severe lower back pain and sciatica);
- Evaluate compressed (or pinched) and inflamed nerves;
- Explore possible causes in patients with back pain (compression fracture for example);
- Image spinal infection or tumours that arise in, or have metastasized to, the spine;
- Assess children with daytime wetting and an inability to fully empty the bladder.

The absence of axial loading and lumbar extension results in a maximization of spinal canal dimensions, which may in some cases, result in failure to demonstrate nerve root compression. Attempts have been made to image the lumbar spine in a more physiological state, either by imaging with flexion–extension, in the erect position or by using axial loading.

#### **4.2 Axially Loaded MRI**

A modification of conventional MRI, known as axially loaded MRI, has been developed. The axial loading refers to the application of a force on a subject's body to simulate weight-bearing. For this technique, patients put on a special harness that compresses the spine while they lie in the MRI scanner but this procedure may not accurately reproduce the weight-bearing state.

#### **4.3 Positional MRI**

Positional MRI has been developed to provide images of the spine under true weight-bearing conditions. This technique relies on a vertically open configuration MRI scanner in which the circular magnets have been turned on end. The patient sits or stands between the magnets during image collection and can adopt various positions such as flexion or extension of the neck or back, allowing imaging of the spine under conditions that occur in daily life.

Standing or sitting MRIs may be performed with patients in different positions (eg. extension, flexion, neutral) for comparison of anatomy in various positions. It is theorized that such positional imaging may provide information not available from methods currently used (i.e. supine conventional MRI) and that this added information will lead to improved diagnosis, treatment and outcomes.

Madsen et al. (2008) completed two separate studies of patients with lumbar spinal stenosis, including 16 and 20 patients, respectively. In section 1, MRI scans were performed during upright standing and supine positions with and without axial load. In section 2, MRI scans were performed exclusively in supine positions, one with flexion of the lumbar spine (psoas-relaxed position), an extended position (legs straight), and an extended position with applied axial loading. Disc height, lumbar lordosis, and dural sac cross-sectional area (DCSA) were measured and the different positions were compared. In section 1, the only significant difference between positions was a reduced lumbar lordosis during standing when compared with lying ( $P = 0.04$ ), most probably a consequence of precautions taken to

secure immobility during the vertical scans. This seemingly makes our standing posture less valuable as a standard of reference. In section 2, DCSA was reduced at all 5 lumbar levels after extension, and further reduced at 2 levels after adding compression ( $P < 0.05$ ). Significant reductions of disc height were found at 3 motion segments and of DCSA at 11 segments after compression, but these changes were never seen in the same motion segment. Horizontal MRI with the patient supine and the legs straightened was comparable to vertical MRI whether axial compression was added or not. Extension was the dominant cause rather than compression in reducing DCSA. Axial load was not considered to have a clinically relevant effect on spinal canal diameters.

Karadimas et al. (2006) completed a peer-reviewed study that compared upright MRI with conventional MRI. This study enrolled 30 patients with chronic, degenerative low back pain, who were candidates for surgery due to failure of conservative treatments. The mean patient age was 44.5 years (range 25 to 61) and 16 (53%) of the patients were women. Imaging studies were used to examine 5 intervertebral discs in the lower back and disc disease on a per-disc basis was classified as mild (11%), moderate (23%), or severe (9%). The remaining discs were deemed healthy. After classifying disc degeneration, end-plate angles and disc heights were compared for patients in the supine and sitting positions. For degenerated discs and healthy discs below degenerated discs, there was a statistically significant  $1.7^\circ$  to  $6.8^\circ$  decrease in mean end-plate angle in the sitting position versus the supine position ( $P < 0.02$ ). Likewise, for degenerated discs and healthy discs above degenerated discs, there were statistically significant differences in mean anterior and/or middle disc heights in the sitting versus the supine position ( $P < 0.05$ ). However, in some cases mean disc heights increased and in other cases mean disc heights decreased. No significant changes in lumbar lordosis were observed when patients were in the sitting versus the supine positions. They do not address whether positional MRI improves diagnosis of disc degeneration compared with conventional MRI.

Washington State Department of Labor and Industries: Washington State published a Health Technology Assessment on Standing, Weight-Bearing, Positional, or Upright MRI (2006). They concluded:

- There is limited scientific data available on the accuracy and diagnostic utility of standing, upright, weight-bearing or positional MRI.
- There is no evidence from well-designed clinical trials demonstrating the accuracy or effectiveness of weight-bearing MRI for specific conditions or patient populations.
- Due to the lack of evidence addressing diagnostic accuracy or diagnostic utility, standing, weightbearing, positional MRI is considered investigational and experimental.

Jinkins et al. (2005) stated that weight-bearing open-design MRI allows for improved sensitivity and specificity; however, no supporting data was provided. Vitaz et al. (2004) used a 0.5 T MRI scanner to prospectively evaluate the first 20 patients referred for MRI for neck pain. There was no comparator; no comparison to conventional MRI can be drawn.

Weishaupt et al. (2003) stated that conventional MRI of the lumbar spine (i.e., in the supine position) remains the imaging method of choice for the assessment of degenerative disk disease.

A Medline search identified five studies that evaluated upright MRI for spinal disorders; three that compared upright MRI with conventional MRI and one that compared upright MRI with myelography. Results of these studies suggest that upright MRI provides diagnostic information similar to that provided by conventional imaging techniques; however, these studies do not provide convincing evidence that upright MRI improves diagnosis of spinal disorders. Although some altered spinal features were seen with upright MRI that were not seen with conventional MRI, the incidence of these altered features was either not statistically significant, the statistical significance was not reported, or it was not clear whether the altered features could be relied on to provide a more accurate diagnosis. For example, one small study found that upright MRI revealed statistically significant changes in the positions of vertebrae next to degenerated spinal discs but these discs had already been diagnosed as degenerate based on images from conventional MRI. In comparison with myelography, a small study found that this technique and upright MRI provided comparable data concerning the mean diameters of dural sacs, the membranous sacs that surround the spinal cord. A serious shortcoming of the studies that compared upright MRI with conventional MRI is that none of them involved axially loaded conventional MRI to

determine whether this modification would reveal spinal alterations similar to those observed during upright MRI. Moreover, all of the available studies were relatively small and none of these studies investigated whether information provided by upright MRI improved the management of patients or their final outcomes. Well-designed studies with larger study populations are needed to determine whether upright MRI provides benefits compared with current standard imaging techniques.

There is only minimal evidence from well-designed clinical trials demonstrating the accuracy or effectiveness of weight-bearing MRI for specific conditions or patient populations. Though positional, weight-bearing MRI is cited as allowing for improvement in sensitivity and specificity, no studies appear to have addressed the diagnostic accuracy compared to conventional MRI or other diagnostic tests. There is minimal published and peer-reviewed scientific evidence from studies designed to minimize potential biases showing how weight-bearing MRI contributes to the planning and delivery of therapy (therapeutic impact) or to improved health outcomes (impact on health) among patients generally or among injured workers. Due to the lack of evidence addressing diagnostic accuracy or diagnostic utility, standing, weight-bearing, and positional magnetic resonance imaging are considered investigational.

## 6.0 References

**This policy is based on the following evidence-based guidelines:**

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**Appendix B: Plan for Dissemination of Framework Documents**

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

Acknowledgement: University Hospitals of Leicester NHS Trust.

<b>Title of Framework:</b>			
<b>Date finalised:</b>		<b>Dissemination lead:</b>	CCG
<b>Previous framework already being used?</b>	No	<b>Print name and contact details</b>	Medical Director
<b>If yes, in what format and where?</b>	n/a		
<b>Proposed action to retrieve out-of-date copies of the document:</b>	n/a		
<b>To be disseminated to:</b>	<b>How will it be disseminated, who will do it and when?</b>	<b>Paper or Electronic</b>	<b>Comments</b>
Clinicians		Electronic	
Clinicians		Electronic/ Paper	
Panel Members		Electronic and	

**Dissemination Record - to be used once framework is approved.**

<b>Date put on register / library of framework documents</b>		<b>Date due to be reviewed</b>	
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<b>Disseminated to: (either directly or via meetings, etc)</b>	<b>Format (i.e. paper or electronic)</b>	<b>Date Disseminated</b>	<b>No. of Copies Sent</b>	<b>Contact Details / Comments</b>

**Appendix C: Equality Impact Assessment**

Produced on behalf of NHS Leeds West CCG, NHS Leeds North CCG and NHS Leeds South and East CCG

To ensure the Individual Funding Requests Policy for the Clinical Commissioning Groups in Leeds reflects due process for identifying the effect, or likely effect, of the policy on people with Equality Act protected characteristics – age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex, sexual orientation - and that the policy demonstrates due regard to reducing health inequalities, addressing discrimination and maximising opportunities to promote equality the following steps have been taken.

The update to the policy results from the iterative refresh process, and the requirement to make changes to care as indicated by an evolving evidence-base. This means that access is broadened as more treatments and interventions become available without the need for an IFR. There is no change to the underlying principles of the policy. In order for an IFR to be approved according to the core principles for managing Individual Funding Requests, it must be demonstrated that the patient's case is exceptional.

The following consultation and engagement activities have been undertaken. The evidence-based policy has been circulated to all GPs and secondary care consultants for comment, and has been made available on the internet to the public, along with Plain English patient information leaflets. The core principles for managing Individual Funding Requests in Leeds have been made available online for twelve weeks and disseminated through Patient Advisory Groups and Patient Reference Groups along with a cascade through the Community and Voluntary Service network. Feedback from all these sources has been collected by the Clinical Commissioning Groups. There is also an open and transparent approach to the processes of the decision making panel with an established mechanism for appeals.