Washington State Health Care Authority

Upright Magnetic Resonance Imaging (uMRI)

Assessing Signals for Update

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Effectiveness of Upright MRI for Evaluation of Patients with Suspected Spinal or Extra-spinal Joint Dysfunction: Assessing Signals for Update

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1. Introduction

A Comparative Effectiveness Review (CER) titled: *Effectiveness of upright MRI for evaluation of patients with suspected spinal or extra-spinal joint dysfunction*, was originally released in May 2007 by the Health Technology Clinical Committee. The coverage decision and findings summarized below. A signal update search report was submitted in June 2012. The 2012 signal update concluded that 2007 CER did not need updating and that its conclusions were still valid.

1.1 Previous Coverage Decision

HTCC Coverage Determination

Upright and positional MRI is **not a covered benefit** due to insufficient evidence to conclude that the health technology is safe, efficacious, and cost-effective.

Health Technology Background

Upright and positional MRI (uMRI) is a magnetic resonance imaging test designed to be performed with patients in weight bearing or different positions, (e.g. upright, sitting, standing, flexed or extended). Current alterative imaging tests used to diagnose spinal and other joint conditions are a regular MRI (lying down), Computerized Tomography (CT) myelogram, regular or flexion and extension radiographs (x-rays), and discography.

The potential advantage of a uMRI is that the weight bearing or positional images may capture additional findings. Also, the open MRI equipment may improve patient compliance by combating the claustrophobia of traditional MRI scanners and enhance patient comfort. Potential disadvantages are that weight bearing and different positions can cause patient pain and result in an inability to complete the test; and the magnet strength, which determines image quality, of a uMRI is lower (0.5T to 0.6T for uMRI compared to a standard MRI range of 1.0T to 3.0T).

The potential impact on the health system is unknown. Potential benefits may include more accurate findings, reduced reliance on other tests, and more appropriate treatments and better health outcomes. Potential risks are that lower quality images, less accurate findings, or more findings without an understanding of clinical significance lead to additional or unnecessary tests, inappropriate treatment, and poorer health outcomes.

Committee Findings

The HTCC reviewed and considered the upright and positional MRI technology assessment report, information provided by the Administrator, and invited public and agency comments.

Committee members were confident that scientific evidence confirms that the technology is safe because the technology is comparable to other MRI tests and administration of the test is unlikely to case a significant adverse health effect.

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

Taking safety and effectiveness data together, the committee found that there was insufficient evidence to conclude whether the use of uMRI would result in less, equivalent, or more health benefit. Most compelling evidence cited by committee members included:

- Technology is ten years old, but no accuracy studies and very few reliability studies.
- Of the studies available, most were poor quality and sample sizes were very small.
- Image quality is lower and some evidence of higher percentage of individuals not being able to complete the test due to pain from positioning.
- Other tests are currently available for diagnosing same conditions, even though it was noted that those tests might also have limitations.
- One study that was of higher quality raised the possibility that uMRI might be less beneficial due to decreased findings.
- Most other payers do not cover, though one payer does.
- There was no National Medicare Coverage Decision
- There are no evidence based clinical guidelines addressing appropriate uMRI usage.

Committee members found that there were no independent cost analyses, but the cost of use of the uMRI would be higher based on manufacturer reported costs of $1450 for a single image with additional images costs ranging from $350 to $1200.

2. Purpose of Report

The primary aim of this assessment is to determine whether there is new evidence that will change the conclusions of the most recent evidence report which was completed in 2007. The accuracy, reliability, and clinical utility of uMRI was unclear at the time of the 2007 review. As uMRI is not currently a covered benefit, this signal update will focus on identifying new evidence related to diagnostic accuracy and utility/therapeutic impact of uMRI for the evaluating the conditions included in the 2007 report. An updated literature search and report were done in 2012. Evidence from that report was combined with any new evidence for this updated signal search and report. The same key questions and scope from the 2007 report were used for the 2012 signal search and this signal update report. The key questions and scope for the 2007 review were developed by the Washington State Health Technology Assessment Program and are listed below. The aims of the prior review are found in Appendix A.

Each of the key questions was addressed with respect to the following abnormalities/conditions:

1. Suspected degenerative spondylolisthesis (>25% slip)
2. Suspected spinal stenosis (moderate/severe central stenosis (>1/3 canal), lateral recess stenosis (displacing or compressing nerve root, disc extrusion)
3. Radicular pain (moderate /severe central stenosis, lateral recess stenosis, nerve root compression, disc extrusion)
4. Non-specific spine pain (moderate/severe central stenosis, lateral recess stenosis, nerve root compression, disc extrusion)

5. Extra-spinal joint pain/function loss (e.g., narrowing, musculoskeletal only)

Key question 1

What is the evidence to describe the concordance (i.e., ability to detect clinically important findings associated with known conditions) of upright MRI compared with currently available diagnostic testing (e.g., standard MRI +/- loading, CT myelogram+/- upright, plain films [flexion and extension], discography, operative findings) in patients (including appropriate sub-populations) with conditions 1-5 above. If a reference standard is available for any of these conditions, what are the test characteristics, PPV (positive predictive value), NPV (negative predictive value), sensitivity and specificity, of upright MRI compared with standard diagnostic testing?

Key question 2

What is the evidence to describe the reliability (i.e., test-retest, intra-reader, inter-reader performance) of upright MRI and how does this reliability compare with available diagnostic testing in patients with 1-5?

Key question 3

What is the evidence to describe the diagnostic impact (i.e., effect on additional diagnostic testing, effect on limiting the differential diagnosis) of upright MRI compared with available diagnostic testing in patients with conditions 1-5?

Key question 4

What is the evidence to describe the therapeutic and patient impact (i.e., effect on treatments received, efficiency of moving from diagnostic testing to treatment, outcomes [pain, function, adverse events] of test-directed treatment [operative and non-operative]) of upright MRI compared with available diagnostic testing in patients with conditions 1-5 (e.g., what is the likelihood that positive upright MRI findings accurately predicts favorable outcome following test-directed treatment)?

Key question 5

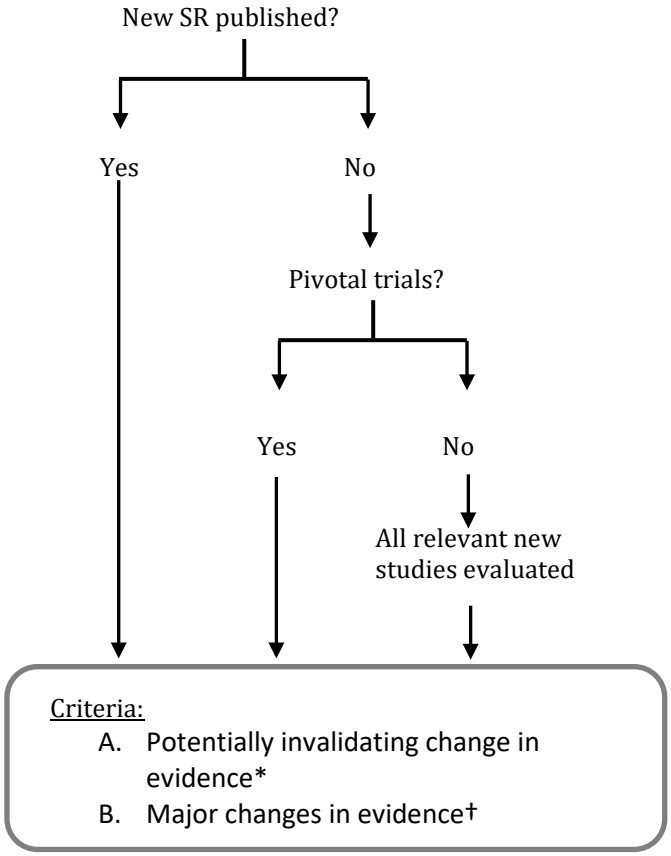
What is the evidence that upright MRI in the acute setting is more effective (diagnostic and therapeutic impact) than available diagnostic testing in the sub-acute/delayed setting in patients with conditions 1-5?

The PICOTS inclusion and exclusion criteria used for the 2007 CER, the 2012 signal search and this update are provided in Appendix A Table 1.

3. Methods

We followed a modified Ottawa approach (see Figure 1) and examined full texts of new systematic reviews published since the prior review or signal search. As uMRI is not a covered diagnostic test, the focus of the signal search centered on efficacy. We evaluated abstracts from newly identified studies to evaluate their eligibility for inclusion primarily related to test accuracy and clinical utility based on the scope used for the 2007 CER. Data from included studies was abstracted and summarized; an initial risk of bias was completed. To assess whether the conclusions might need updating, the algorithm in Figure 1 was used.

Figure 1. Algorithm of the modified Ottawa Method of identifying signals for SR update



*A-1. Opposing findings: Pivotal trial or SR including at least one new trial that characterized the treatment in terms opposite to those used earlier

A-2. Substantial harm: Pivotal trial or SR whose results called into question the use of the treatment based on evidence of harm or that did not proscribe use entirely but did potentially affect clinical decision making

A-3. Superior new treatment: Pivotal trial or SR whose results identified another treatment as significantly superior to the one evaluated in the original review, based on efficacy or harm.

†B-1. Important changes in effectiveness short of "opposing findings"

B-2. Clinically important expansion of treatment

B-3. Clinically important caveat

B-4. Opposing findings from discordant meta-analysis or nonpivotal trial

3.1 Literature Searches

We conducted a limited literature search from January 1, 2012 to May 1, 2024 using the identical search strategy used for the original report and prior signal update. (Appendix B) This search included two main databases: PubMed and Cochrane Library. The search strategy is provided in Appendix B

3.2 Study selection

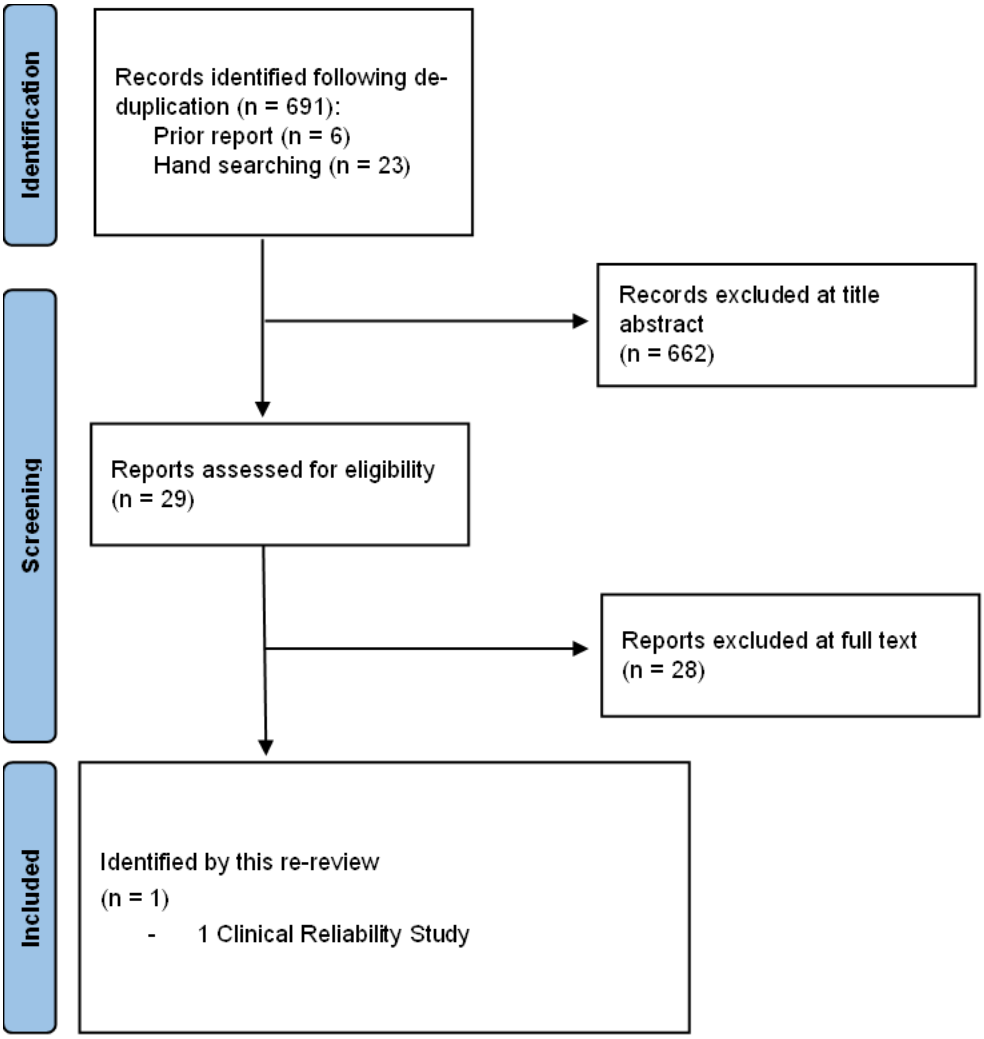
We sought systematic reviews of clinical studies of diagnostic accuracy and reliability, clinical utility, clinical impact with meta-analysis that included articles that met inclusion and exclusion criteria similar to the original report. In addition, we sought systematic reviews reflecting updates or new advances for the technology for safety. Due to the lack of includable systematic reviews returned by our search, we additionally included individual clinical studies of uMRI that met inclusion criteria based on the scope from the 2007 CER.

4. Results

4.1 Search

Our literature search generated 691 publications for review. Of these, 29 publications were reviewed at full text. We identified one poor quality systematic review,[1] three narrative reviews,[2-4] and one thesis[5] that were excluded because they reported on studies that did not meet the inclusion criteria or had been included in the prior HTA or signal update. . We reviewed the bibliographies of these publications to check for additional relevant studies.

Figure 2. Flow chart showing results of literature search



4.2 Identifying signals for re-review

Appendix A lists the inclusion and exclusion criteria and Appendix F summarizes the conclusions of the original 2007 HTA report, the 2012 signal update conclusions, and the new sources of evidence since the last signal update, including any new findings and recommendations regarding the need for update. A summary of the strength of evidence across conditions from the 2007 report is also found in Appendix F.

4.3 Summary of Results

No new studies reporting on the diagnostic accuracy of uMRI or its impact on clinical decision making or on clinical outcomes were identified. One publication[6] reporting inter-rater reliability comparing uMRI and supine MRI findings related to degenerative lumbar spine conditions was eligible for inclusion in this report for Key Question 2.

This moderately high risk of bias study[6] (N=59) assessed inter-rater reliability for evaluating degenerative changes for eight degenerative lumbar spine conditions (spondylolisthesis, scoliosis,

annular fissure, disc degeneration, disc contour, nerve root compromise, spinal stenosis, and facet joint degeneration) between uMRI and sMRI in participants with (N=35) and without (N=24) low back pain (LBP) (Appendix Table C1). Participants were recruited as part of a larger imaging study at the Department of Radiology, Diagnostic Centre, University Research Clinic for Innovative Patient Pathways, Silkeborg Regional Hospital, Denmark; Exact process for recruitment and enrollment was not further described. Average participant age was 38 years old and 46% were female; duration of LBP was > 4 weeks in 59% of participants with LBP. The study focused on evaluating the reliability of reporting changes between the two positions versus the presence of degenerative findings on MRI. All participants underwent both uMRI via the 0.5T Paramed MROpen (ASG Superconductors), machine as well as sMRI in the supine position; Participants with LBP received sMRI via a 3.0T or 1.5T Siemens MRI machine. Participants without LBP received sMRI via the 0.5T Paramed MROpen machine. Three raters (one radiologist, one Ph.D. student with prior imaging experience, and one senior researcher with prior imaging experience) examined images for the aforementioned eight different conditions using a set of standardized assessment criteria. (Appendix Table C2); they assessed 177 disc levels. Both upright and supine images were done the same day in all non-LBP participants, but for an undisclosed number of LBP participants uMRI imaging was delayed for up to 5 days. Supine images (via 1.5T or 3.0T MRI for LBP participants and 0.5T MRI for non-LBP participants) were presented to each rater first for evaluation and upright images were provided after with instructions to indicate “No Change,” “Appeared,” “Disappeared,” “Worsened,” or “Improved” respective to the supine image. From these ratings, a Gwet’s weighted agreement coefficient (Gwet’s AC2) was calculated to determine inter-rater reliability difference between MRIs. The study reported “near perfect” inter-rater reliability for all eight conditions. This was based on calculation of Gwet’s agreement coefficient and subsequent probabilistic evaluation to infer the degree of reliability according to the more standard Landis and Koch classification for Cohen’s kappa (Appendix Table C3).

No additional FDA approved systems consistent with the 2007 report inclusion criteria (i.e., 0.5T or 0.6T) were identified. The 2012 signal update had identified two additional uMRI systems that had received FDA clearance. This FDA approval history is summarized following Appendix Table F2.

4.4 Risk of Bias Evaluation

There are several limitations to of the included study.[6] It is unclear to what extent the participant population may represent a spectrum of patients with degenerative lumbar spine conditions who would require imaging. (See Appendix Table D1-2, Appendix Figure D1). Authors report that raters independently evaluated the images but provide no detail of how blinding was maintained and it is unclear whether raters were aware of participant symptoms or suspected degenerative findings. Given the differences in image protocols, namely use of higher resolution 1.5 to 3 T MRI for supine imaging in those with LBP, raters may have been inclined to report more positive findings for that group. Thus, blinding of ratings may have been compromised. The accuracy of the “almost perfect” agreement based on author’s use of Gwet’s methods and benchmarking of the results to correspond to Landis and Koch designations of Cohen’s kappa for degree of agreement is unclear. Gwet’s tests and Cohen’s kappa evaluate observed rates of agreement using different methodologies and results for them may differ based on the prevalence of specific ratings. [7-9] The risk of bias assessment is provided in Appendix D.

5. Conclusions

At the time of this signal update, there is still insufficient evidence to determine the effectiveness of uMRI as a diagnostic test for spinal and extraspinal conditions and an update to the prior (2007) review is not suggested. New evidence is limited to one new moderate high risk of bias study of reliability for

evaluation of degenerative spine pathology.[6] Its addition does not change the conclusions of the 2007 report for Key Question 2. No new studies were identified that addressed the other key questions (See Appendix F). Additional evidence on diagnostic accuracy (test performance), impact on clinical decision making and patient outcomes, is needed to determine the value, role and clinical utility of uMRI as a diagnostic tool for spinal and extraspinal conditions.

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APPENDIX A: AIMS AND SCOPE

Aims and scope (PICOTS) for the 2007 CER

Key questions and scope for the 2007 review were developed by the Washington State Health Technology Assessment Program and are listed below. Aims listed in the 2007 report were:

1. Evaluate research describing uMRI test characteristics and ability of uMRI to detect clinically important findings compared with currently available diagnostic methods for specific spinal and musculoskeletal conditions. Included in this objective is consideration of uMRI performance in acute and sub-acute/delayed settings.
2. Evaluate studies describing the extent to which upright/standing MRI may impact clinical decision making related to the need and frequency for further diagnostic testing, as well as the impact it may have on treatment and pertinent outcomes of treatment in the above conditions. Included in this objective is consideration of testing in acute and sub-acute/delayed settings.
3. Evaluate and summarize any formal economic or cost-related studies involving uMRI for evaluation of conditions listed and provide information on anticipated costs of uMRI as available.
4. Identify and describe gaps in current research/evidence and recommend priorities and approaches for further research.

Appendix Table A1. PICOTS inclusions and exclusion criteria (original 2007 CER and signal updates)

	Inclusion	**Exclusion**
Patients	Patients with suspected spine-related or joint related conditions: • Suspected degenerative spondylolisthesis (>25% slip) • Suspected spinal stenosis (moderate/severe central stenosis (>1/3 canal), lateral recess stenosis (displacing or compressing nerve root, disc extrusion) • Radicular pain (moderate /severe central stenosis, lateral recess stenosis, nerve root compression, disc extrusion) • Non-specific spine pain (moderate/severe central stenosis, lateral recess stenosis, nerve root compression, disc extrusion) • Extra-spinal joint pain/function loss (e.g. narrowing, musculoskeletal only)	All other conditions including: • Spine trauma or fractures • Studies of spine trauma or fractures (trauma) • Trauma-related fractures involving joints listed previously. • Cancer or tumor related evaluations • Visceral or non-mechanical causes of back pain (pelvic organ problems, renal problems, aortic aneurysm, gastrointestinal problems, neoplasia, infection osteochondrosis, Paget's disease) • Inflammatory or rheumatoid arthritis
Intervention	Upright, standing or positional MRI (uMRI) vertically open MRI with a field strength of 0.5 or 0.6T is included under the heading of uMRI	• Functional MRI, dynamic or kinematic MRI (e.g., brain evaluation, perfusion, supine MRI with patients in different positions, use of loading devices), • Low-field MRI, rapid MRI or cine

		• Contrast with MRI, MRI with axial loading *unless* there is explicit comparison with upright/standing MRI for conditions specified above
Comparator, Referent	• Standard rMRI with axial loading • one or more currently available diagnostic modality(ies) for one (or more) of the conditions, e.g., myelogram, CT-myelogram, plain and extension/flexion radiographs, discography • For KQ 3, 4, studies comparing use of uMRI with other strategies or usual care	
Outcomes	• Test characteristics: PPV (positive predictive value), NPV (negative predictive value), sensitivity and specificity • reliability (i.e., test-retest, intra-reader, inter-reader performance) • Outcomes related to additional testing • clinical decision-making strategies • Treatment related outcomes based on condition	-
Settings	• Acute, subacute	-
Studies	• Published in a peer-reviewed journal and written in English • All studies explicitly designed to evaluate reliability (e.g., test-retest, etc.) in clinical populations or formal economic analyses (e.g., cost-effectiveness studies) specific to uMRI • Studies comparing clinical strategies using uMRI	• Studies where uMRI and its comparator were not used for diagnostic evaluation of one of the conditions • Reviews, editorials, case reports, letters to the editor, commentaries • Studies written in languages other than English • Studies with fewer than 5 patients • Animal, in vitro or cadaver studies • Meeting abstracts that have not resulted in peer-reviewed publication • White papers • Unpublished studies • Clinical guidelines that do not contain an appropriate evidence-based evaluation

CT = Computed Tomography; MRI = Magnetic Resonance Imaging; NPV = Negative Predictive Value; PPV = Positive Predictive Value; uMRI = Upright Magnetic Resonance Imaging

APPENDIX B. SEARCH STRATEGIES

We employed the same search strategy used for the original CER and signal update. Search dates for each report were as follows: January 1, 1975 to April 15, 2007 for the original CER; January 1, 2007 to May, 2012 for the 2012 signal update; and January 1, 2012 to May 1, 2024 for the current signal update.

Key Question 1 and 2

1.	Search (dynamic [TI] OR vertical [TI] OR upright [TI] OR stand-up [TI] OR standing [TI] OR seated [TI] OR open [TI] OR position* [TI] OR weight bearing [TI])
2.	Search ("Magnetic Resonance Imaging"[TI] OR MRI [TI])
3.	Search #1 AND #2
4.	Search "dynamic MRI" [TI] OR "dynamic magnetic resonance imaging" [TI] OR "vertical MRI" [TI] OR "vertical magnetic resonance imaging" [TI] OR "upright MRI" [TI] OR "upright magnetic resonance imaging" [TI] OR "stand-up MRI" [TI] OR "stand-up magnetic resonance imaging" [TI] OR "standing MRI" [TI] OR "standing magnetic resonance imaging" [TI] OR "seated MRI" [TI] OR "seated magnetic resonance imaging" [TI] OR "open MRI" [TI] OR "open magnetic resonance imaging" [TI] OR "position* MRI" [TI] OR "position magnetic resonance imaging" [TI] OR "weight bearing MRI" [TI] OR "weight bearing magnetic resonance imaging" [TI]
5.	Search "Low Back Pain"[MeSH] OR "Intervertebral Disk Displacement"[MeSH] OR "Sciatica"[MeSH] OR "Radiculopathy"[MeSH] OR "Spondylolisthesis"[MeSH] OR "Spinal Stenosis"[MeSH] OR "Intervertebral Disk"[MeSH] OR "Lumbar Vertebrae"[MeSH] OR spine[TI] OR dural sac[TI] OR facet[TI] OR "low back"[TI] OR "intervertebral disc"[TI] OR sciatica[TI] OR radicul*[TI] OR spondylolisthesis[TI] OR "spinal stenosis"[TI] OR lumbar [TI] OR "cervical vertebrae"[MeSH] OR "neck"[MeSH] OR "neck pain"[MeSH] OR "cervical myelopathy" OR "cervical spondylotic myelopathy" OR "radiculopathy"[MeSH] OR "thoracic vertebrae"[MeSH] OR "spinal curvatures"[MeSH] OR neck[TI] OR "cervical spine" [TI] OR scoliosis[TI] OR kyphosis[TI] OR lordosis[TI] OR "spinal osteophytosis"[MeSH] OR spondylosis [TI] OR "Whiplash Injuries"[MeSH]
6.	Search #3 AND #5
7.	Search #4 AND #5
8.	Search #6 OR #7
9.	Search ("Reproducibility of Results"[MeSH] OR "Validation Studies"[Publication Type])
10.	#8 AND #9
11.	Search ("Joints"[MeSH] OR foot OR feet OR knee* OR hip OR hips OR tmj OR temporomandibular OR shoulder* OR elbow OR wrist* OR hand OR hands)
12.	Search #3 AND #11
13.	Search #4 AND #11
14.	Search #12 OR #13
15.	#9 AND #14
16.	Limit: NOT (letter OR editorial)

Key Question 3, 4, 5

1.	Search (dynamic [TI] OR vertical [TI] OR upright [TI] OR stand-up [TI] OR standing [TI] OR seated [TI] OR open [TI] OR position* [TI] OR weight bearing [TI])

2.	Search ("Magnetic Resonance Imaging"[TI] OR MRI [TI])
3.	Search #1 AND #2
4.	Search "dynamic MRI" [TI] OR "dynamic magnetic resonance imaging" [TI] OR "vertical MRI" [TI] OR "vertical magnetic resonance imaging" [TI] OR "upright MRI" [TI] OR "upright magnetic resonance imaging" [TI] OR "stand-up MRI" [TI] OR "stand-up magnetic resonance imaging" [TI] OR "standing MRI" [TI] OR "standing magnetic resonance imaging" [TI] OR "seated MRI" [TI] OR "seated magnetic resonance imaging" [TI] OR "open MRI" [TI] OR "open magnetic resonance imaging" [TI] OR "position* MRI" [TI] OR "position magnetic resonance imaging" [TI] OR "weight bearing MRI" [TI] OR "weight bearing magnetic resonance imaging" [TI]
5.	Search "Low Back Pain"[MeSH] OR "Intervertebral Disk Displacement"[MeSH] OR "Sciatica"[MeSH] OR "Radiculopathy"[MeSH] OR "Spondylolisthesis"[MeSH] OR "Spinal Stenosis"[MeSH] OR "Intervertebral Disk"[MeSH] OR "Lumbar Vertebrae"[MeSH] OR spine[TI] OR dural sac[TI] OR facet[TI] OR "low back"[TI] OR "intervertebral disc"[TI] OR sciatica[TI] OR radicul*[TI] OR spondylolisthesis[TI] OR "spinal stenosis"[TI] OR lumbar [TI] OR "cervical vertebrae"[MeSH] OR "neck"[MeSH] OR "neck pain"[MeSH] OR "cervical myelopathy" OR "cervical spondylotic myelopathy" OR "radiculopathy"[MeSH] OR "thoracic vertebrae"[MeSH] OR "spinal curvatures"[MeSH] OR neck[TI] OR "cervical spine" [TI] OR scoliosis[TI] OR kyphosis[TI] OR lordosis[TI] OR "spinal osteophytosis"[MeSH] OR spondylosis [TI] OR "Whiplash Injuries"[MeSH]
6.	Search #3 AND #5
7.	Search #4 AND #5
8.	Search #6 OR #7
9.	Limit: NOT (letter OR editorial)
10.	Search ("Joints"[MeSH] OR foot OR feet OR knee* OR hip OR hips OR tmj OR shoulder* OR elbow OR wrist* OR hand OR hands)
11.	Search #3 AND #10
12.	Search #4 AND #10
13.	Search #11 OR #12
14.	Search "Arthritis, Experimental"[MeSH] OR "Arthritis, Infectious"[MeSH] OR "Spondylarthritis"[MeSH] OR "Arthritis, Rheumatoid"[MeSH]
15.	Search #13 NOT #14

Electronic Database Searches

The following databases have been searched for relevant information: PubMed, Cochrane Library

APPENDIX C: SUMMARY OF INCLUDED STUDIES

Appendix Table C1: Demographic and methodological data for Doktor, 2022

Author, year	Study Design	Demographics	Patients	uMRI	sMRI	Protocol	Diagnostic Criteria	Methods Concerns
Doktor, 2022[6]	Fully crossed inter-rater reliability study	N=59 Age: 38.1 (14.1) Sex: 45.8% Race/Ethnicity: NR	LBP only: 39.0% (23/59) LBP + Leg Pain: 20.3% (12/59) No LBP: 40.7% (24/59) Symptoms longer than 4 weeks: 59.3% (35/59)	Upright MRI via Paramed MROpen 0.5 T (Paramed Medical Systems, Genoa, Italy), dedicated spine coils; Sagittal 2D T2W Spin Echo (SE) sequence and an axial 2D T2W SE sequence	Supine MRI via Siemens Avanto.ft 1.5 T (software release E11c) or a Siemens Skyra 3 T MRI system (Software release E11a, Siemens Healthineers GmbH, Erlangen, Germany), dedicated spine coils; Sagittal 2D T2W Turbo Spin Echo (TSE) sequence as well as an axial 2D T2W TSE sequence. The sagittal sequence on the 3.0 T MRI system included the DIXON fat	Imaging performed on both machines in the same day in all non-LBP participants and mostly on the same day in LBP patients with some exceptions where uMRI was done up to 5 days later; Three raters (radiologist, Ph.D. student with prior experience, senior researcher with prior experience) reviewed images based on evaluation manual developed with two practice image samples (N=10, N=5)	Diagnostic criteria for the following conditions are in Appendix Table C2 below Raters provided diagnosis and classification for 8 conditions (spondylolisthesis, scoliosis, annular fissure, disc degeneration, disc contour, nerve root compromise, spinal stenosis, and facet joint degeneration) based on supine images and then provided classifications for the corresponding upright images as follows: "No change," and for positional- or grade-type differences classified into "Appeared," "Disappeared," "Worsened," or "Improved"	Inappropriate reference standard for non-LBP participants (used 0.5T sMRI instead of standard 1.5T or 3T sMRI); Lack of blinding to condition (Supine imaging for non-LBP participants was done in 0.5T instead of 1.5T or 3.0T, which makes them discernible from LBP participants); Use of Gwet's alpha coefficient in concert with Landis and Koch agreement scale may provide overestimation of reliability

					suppression technique. In addition, a sagittal 2D T1W TSE sequence was added to the 1.5 T protocol, while the 3.0 T protocol also included a sagittal 2D T1W Short TI Inversion Recovery (STIR) sequence			

2D = Two-Dimensional; LBP = Low Back Pain; NR = Not Reported; uMRI = Upright Magnetic Resonance Imaging; STIR = Short TI Inversion Recovery; SE = Spin Echo; sMRI = Supine Magnetic Resonance Imaging; T = Tesla; T1W = T1 Weighted Image; T2Q = T2 Weighted Image

Appendix Table C2: Overview of general diagnostic criteria for degenerative spine pathologies used by raters by condition

Condition	Scale/classification	Criteria
Spondylolisthesis	Grade I-IV	Degree of vertebral body displacement (Meyerding criteria)*
Scoliosis (sinistro convex, dextro convex, rotational)	Yes/No	Spinal curvature of Cobb's angle >10 degrees (Cobb)*
Annular fissure	Yes/No	Diameter >1.5mm, high T2 MRI signal in otherwise normal annulus, visible annulus material (April)*
Disc degeneration	Grade I-V	Based on visual homogeneity and signal intensity of the nucleus pulposus, distinction of the nucleus and annulus and intervertebral disc height (Pfirrmann criteria)*
Disc contour	Normal/bulge, protrusion, extrusion, sequestration, combination	Based on % of disc periphery (90-degree angle) affected surface, distance between disco- vertebral corners/disc material; combination is combined protrusion and extrusion (Fardon)*
Nerve root compromise	None (normal, no contact with root), contact and deviation, compression	Based on amount, location of perineural fat obliteration, morphological changes, visible nerve root collapse (Lee)*

Spinal stenosis	None, relative, absolute	Based on % of reduced space and if cerebrospinal fluids visible and stenotic area (central, lateral recess, foraminal) (Lee)*
Facet joint degeneration	None, mild, moderate, severe,	Based on joint space narrowing and sclerosis/osteophyte formation (Ross/Moore; Pathria)*

mm = Millimeter; MRI = Magnetic resonance imaging
*References for criteria as provided in Doktor, 2022

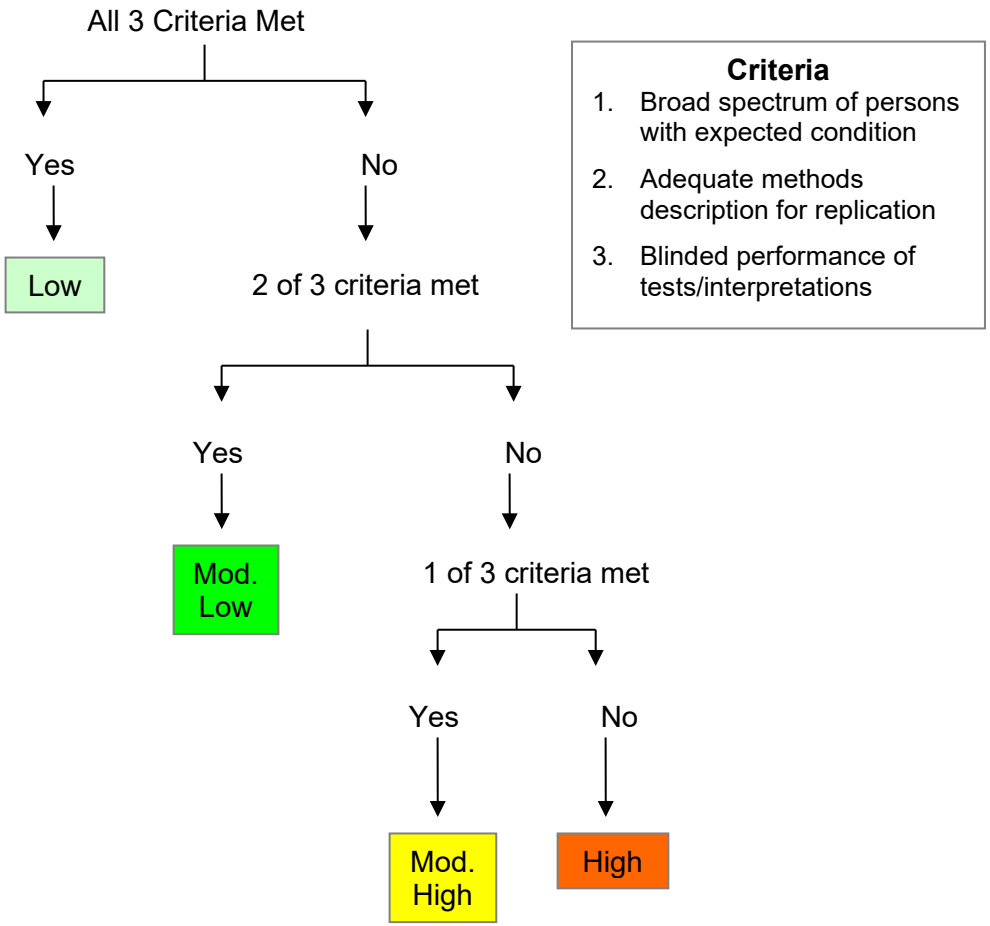
Appendix Table C3: Inter-rater reliability results from Doktor, 2022

Condition Assessed	Gwet's AC (all raters)	Agreement based on Probabilistic benchmarking to Landis and Koch scale
Spondylolisthesis	0.996	Almost perfect
Scoliosis	0.966	Almost perfect
Annular fissure	0.931	Almost perfect
Disc degeneration	0.981	Almost perfect
Disc contour	0.930	Almost perfect
Nerve compromise	0.929	Almost perfect
Spinal stenosis	0.958	Almost perfect
Facet degeneration	0.994	Almost perfect

APPENDIX D: RISK OF BIAS

We assessed and defined risk of bias for the included study using the following criteria:

Appendix Figure D1. Risk of bias algorithm – reliability studies



Appendix Table D1. Definitions of the different levels of evidence for reliability studies

RoB	Study type	Criteria
Low	Good quality study	Broad spectrum of persons with the expected condition Adequate description of methods for replication Blinded performance of tests, measurements or interpretation Second test/interpretation performed independently of the first
Moderately Low	Moderate quality	Violation of any one of the criteria for a good quality study
Moderately High	Poor quality study	Violation of any two of the criteria
High	Very poor-quality study	Violation of all three of the criteria

Appendix Table D2: Risk of bias for included study of interrater reliability

Methodological Principle	**Doktor, 2022**[6]
Broad spectrum of patients with expected condition	Unclear
Adequate description of test and reference for replication	Yes (imaging schedule)
Blinded/independent comparison of tests/interpretations	No/unclear
Risk of Bias	**Moderately High**

Risk of Bias Notes

It is unclear to what extent the patient population may represent a spectrum of patients with degenerative lumbar spine conditions who would require imaging based on authors' comparison patient characteristics of their reliability sample with those in a broader cross section of patients who had been invited to participate in the study. Notable differences between the reliability sample and broader population were seen in the proportions of patient presenting with LBP plus leg pain (20% vs. 42% respectively) and symptom duration of > 4 weeks (59% vs. 73%).
While authors report that raters independently classified the pathologies, details of how blinding was maintained were not described.

APPENDIX E: ONGOING STUDIES OF RELEVANCE

Study Author NCT ID Completion date	Purpose	Inclusion/exclusion	Intervention	Outcomes
Author NR NCT02958241 Est 11/2018	Investigate the possible differences in images obtained in patients with lumbar spondylolisthesis when positioned in an upright weight bearing position compared with traditional supine positioning for lumbar MRI.	Inclusion Criteria: Diagnosis of degenerative or isthmic lumbar spondylolisthesis by a spine specialty physician based on clinical evaluation and lumbar radiographs No previous lumbar spinal fusion at the level of the spondylolisthesis or a procedure resulting in the presence of metallic implants at the level of interest (if a device such as an interspinous device was implanted and later removed, the patient may participate in the study) Be able and willing to provide written consent to participate in the study Willing to undergo a second MRI approximately 6 months after surgery, if surgery is performed Exclusion Criteria: Pregnancy Any condition that would prevent the patient from undergoing MRI Recent lumbar vertebral body fracture	Intervention: Weight bearing MRI Control: Supine MRI	Primary: Superior vertebral body translation (mm) Disc space height (mm) Secondary: Foraminal area (mm2) Meyerding grade and facet fluid fill sign VAS pain (back and leg) Anteroposterior distance across spinal canal (mm) Spinal canal area (mm2)

Mm = Millimeter; mm2 = Square Millimeter; MRI = Magnetic Resonance Imaging; NR = Not Reported

APPENDIX F: SUMMARY OF CONCLUSIONS

Appendix Table F1: Summary of conclusions from 2007 CER, 2012 signal update, and the current signal update

Key Question 1. What is the evidence to describe the concordance (i.e., ability to detect clinically important findings associated with known conditions) of upright MRI compared with currently available diagnostic testing (e.g., standard MRI ± loading, CT myelogram ± upright, plain films [flexion and extension], discography, operative findings) in patients (including appropriate sub-populations) with conditions 1-5*? If a reference standard is available for any of these conditions, what are the test characteristics, PPV (positive predictive value), NPV (negative predictive value), sensitivity and specificity, of upright MRI compared with standard diagnostic testing?					
Conclusions from 2007 CER	Literature Search from 2012 Update	Conclusions from 2012 Update	New Sources of Evidence	New Findings	Conclusion
-Disc pathology Three retrospective cohort studies[10-12] with the lowest quality of evidence (LoE IV) found similar agreement comparing rMRI with uMRI in identifying disc pathology in both the cervical and lumbosacral spine. In the cervical spine, rMRI detected 61% of posterior disc herniations compared with 70% in uMRI.[10] In the lumbosacral spine, rMRI detected 31% of posterior disc herniations compared with 45% in uMRI.[10] Complete agreement was found when comparing rMRI with uMRI in the seated neutral position in the qualitative determination of posterior disc bulge (100% agreement).[12] Seated flexion had a 95% agreement and seated extension had a 91% agreement with supine neutral in the diagnosis of disc form (normal, bulging, protrusion, or sequestration).[11]	One prospective cohort study with low quality of evidence (LoE III) found no difference between uMRI and rMRI concerning mean disc height[13] rMRI had a mean cumulative disc height of 174.8mm compared with uMRI mean of 172.2mm (no significant difference) in patients with lumbar spinal stenosis.[13]	This section of the report is still valid and does not need updating.	None	None	This section of the report is still valid and does not need updating.

-Foraminal stenosis There is limited evidence (three retrospective cohort studies[11,12,14] each with LoE IV) to suggest that uMRI provides similar diagnostic information compared with rMRI with respect to foraminal stenosis. Seated neutral position had complete agreement (100%) with rMRI in determining foraminal size.[12] Seated flexion had 84% and seated extension had 86% agreement compared with supine neutral position of evaluating the degree of foraminal stenosis.[11] Agreement was also seen in the score of foraminal stenosis in supine neutral, extension and flexion position comparing uMRI to myelography (94% and 92% agreement, respectively).[14]	No new data	This section of the report is still valid and does not need updating.	None	None	This section of the report is still valid and does not need updating.
-Nerve root compromise The evidence for concordance between rMRI and uMRI is very low (two LoE IV retrospective cohort studies[11,14] with respect to lumbar nerve root compromise. Comparing seated flexion and extension with supine neutral positions provided 74% and 77% agreement, respectively.[11] Comparing uMRI with myelography, there was substantial concordance (93%) in mean sagittal diameter of the dural sac within each position (supine neutral, extension, and flexion) at five separate intervertebral spaces.[14]	One prospective cohort study[13] with low quality of evidence (LoE III) found no difference between uMRI and rMRI concerning mean dural sac cross-sectional area (DCSA) values. No significant differences were found between the	This section of the report is still valid and does not need updating.	None	None	This section of the report is still valid and does not need updating.

	mean DCSA values of uMRI and rMRI at any of the five lumbar levels.[13]				
-Spondylolisthesis The evidence for concordance between rMRI and uMRI is very low (one LoE IV retrospective cohort study)[10] with respect to spondylolisthesis. rMRI identified spondylolisthesis seven times (15%) compared with uMRI 11 times (24%). Percent agreement between the two was 91%.[10]	No new data	This section of the report is still valid and does not need updating.	None	None	This section of the report is still valid and does not need updating.
-Juxtafacet cysts (JFC) No data	There is insufficient evidence (one retrospective cohort study with the lowest level of evidence (LoE IV)) to suggest that uMRI provides additional diagnostic information compared with rMRI with respect to JFC[15] MRI in the standing (extension) position had a detection rate of 97%, supine	There is insufficient evidence to update the HTA with respect to JFC.	None	None	This section of the report is still valid and does not need updating.

	had a rate of 89%, and sitting had a rate of 78%.[15] The size (mm) of the JFCs was significantly bigger in the standing position, compared to supine and sitting (6.7±2.3 vs. 5.5±2.9 vs. 4.6±3.0, respectively).[15]				
Extra-Spinal Conditions					
-Morton neuroma One LoE III prospective study[16] provided no evidence to suggest uMRI images contribute towards the identification of Morton neuroma compared with existing diagnostic tests. Prone position was judged best, followed by supine, then upright weight-bearing position last.[16]	No new data	This section of the report is still valid and does not need updating.	None	None	This section of the report is still valid and does not need updating.
-Glenohumeral instability One prospective LoE II study[17] provided no evidence to suggest uMRI images add to the identification of glenohumeral instability. uMRI underestimated instability in 70% of the cases compared to clinical exam under anesthesia.[17]	No new data	This section of the report is still valid and does not need updating.	None	None	This section of the report is still valid and does not need updating.
Key Question 2: What is the evidence to describe the reliability (i.e., test-retest, intra-reader, inter-reader performance) of upright MRI and how does this reliability compare with available diagnostic testing in patients with 1-5*?					

Conclusions from CER Executive Summary	Literature Search from 2012 Update	Conclusions from 2012 Update	New Sources of Evidence	New Findings	Conclusion
One retrospective LoE II cohort study[14] limited evidence that lumbar foraminal stenosis may be determined reliably between radiologists using seated uMRI in patients whose symptoms are severe enough to warrant a myelogram. The kappa statistic calculated and reported was 0.62 (substantial agreement) between two observers independently determining the grade of foraminal stenosis.[14]	No new data	This section of the report is still valid and does not need updating.	One prospective cohort study[6]	One prospective cohort[6] With moderate high risk of bias found near perfect inter-rater agreement comparing uMRI and sMRI in identifying various pathologies of the lumbar spine. Presence and grading of disc herniation showed 98.1% agreement between uMRI and sMRI.[6] Presence and grading of disc contour showed 93.0% agreement between uMRI and sMRI.[6] Presence and grading of facet degeneration showed 99.4% agreement between uMRI and sMRI.[6] Presence and grading of scoliosis showed 96.6% agreement between uMRI and sMRI.[6] Presence and grading of spinal stenosis showed 95.8% agreement between uMRI and sMRI.[6]	This section of the report is still valid and does not need updating.

				Presence and grading of nerve root compromise showed 92.9% agreement between uMRI and sMRI.[6] Presence and grading of spondylolisthesis showed 99.6% agreement between uMRI and sMRI.[6]	
Key Question 3: What is the evidence to describe the diagnostic impact (i.e., effect on additional diagnostic testing, effect on limiting the differential diagnosis) of upright MRI compared with available diagnosis testing in patients with conditions 1-5*?					
Conclusions from CER Executive Summary	Literature Search from 2012 Update	Conclusions from 2012 Update	New Sources of Evidence	New Findings	Conclusion
No Data	No new data	This section of the report is still valid and does not need updating.	None	None	This section of the report is still valid and does not need updating.
Key Question 4: What is the evidence to describe the therapeutic and patient impact (i.e., effect on treatments received, efficiency of moving from diagnostic testing to treatment, outcomes [pain, function, adverse events] of test-directed treatment [operative and non-operative]) of upright MRI compared with available diagnostic testing in patients with conditions 1-5* (e.g., what is the likelihood that positive upright MRI findings accurately predicts favorable outcome following test-directed treatment)?					
Conclusions from CER Executive Summary	Literature Search from 2012 Update	Conclusions from 2012 Update	New Sources of Evidence	New Findings	Conclusion
No data	No new data	This section of the report is still valid and does not need updating.	None	None	This section of the report is still valid and does not need updating.
Key Question 5: What is the evidence that upright MRI in the acute setting is more effective (diagnostic and therapeutic impact) than available diagnostic testing in the sub-acute/delayed setting in patients with conditions 1-5*?					

Conclusions from CER Executive Summary	Literature Search from 2012 Update	Conclusions from 2012 Update	New Sources of Evidence	New Findings	Conclusion
No data	No new data	This section of the report is still valid and does not need updating.	None	None	This section of the report is still valid and does not need updating.

CT = Computed Tomography; DSCA = Dural Sac Cross-Sectional Area; HTA = Health Technology Assessment; JFC = Juxtafacet Cyst; LoE = Level of Evidence; mm = Millimeter; MRI = Magnetic Resonance Imaging; NPV = Negative Predictive Value; PPV = Positive Predictive Value; rMRI = Reference Magnetic Resonance Imaging; sMRI = Standing Magnetic Resonance Imaging; uMRI = Upright Magnetic Resonance Imaging

Appendix Table F2: FDA approved systems description from 2007 CER and 2012 signal update report

System	Approval	Description/Indication
FONAR Upright™ MRI System	510(K) (2000)	Indicated for use as an imaging device for multiple planes of the head and body
GE Signa™ SP/I MRI System	510(K) (2001)	Marketed for interventional, intra-operative and research use
Paramed Srl MROpen 05	510(K) (2010)	Indicated for use as a diagnostic total body imaging device with the following limitation: no angiography, no cardiac imaging, no breast imaging
Esaote G-Scan	510(K) (2004 original, 2011 updated)	Intended for use on the limbs, joints, and spinal column, including upper limb (hand, wrist, forearm, elbow, arm, and shoulder), lower limb (foot, ankle, calf, knee, thigh, and hip), and imaging portions of the spinal column (cervical, thoracic, and lumbo-sacral sections)

MRI = Magnetic Resonance Imaging

Appendix Table F3: Strength of Evidence from 2007 Report: Summary of studies on the concordance, reliability and impact of uMRI for specific spinal and extra-spinal conditions

Key Question	Strength of Evidence*	Summary: Study Design and Imaging Comparisons	Conclusions/Comments
Key Question 1: Diagnostic Concordance in the Following Conditions			
Cervical disc herniation	Very Low	• 1 retrospective cohort study • uMRI vs. rMRI	• There is limited evidence (very low) to suggest that uMRI may provide similar diagnostic information as rMRI with respect to disc pathology of the cervical spine. • There is no evidence comparing uMRI to a diagnostic reference standard for cervical disc pathology.
Lumbar disc pathology	Low	• 3 retrospective cohort studies • uMRI vs. rMRI	• There is limited evidence (low) to suggest that uMRI may provide similar diagnostic information as rMRI with respect to disc pathology of the lumbar spine. • There is no evidence comparing uMRI to a diagnostic reference standard for lumbar disc pathology.
Lumbar foraminal stenosis	Low	• 3 retrospective cohort studies • uMRI vs. rMRI (2 studies) • uMRI vs. myelography (1 study)	• There is limited evidence (low) to suggest that uMRI may provide similar diagnostic information as rMRI or myelogram with respect to foraminal stenosis of the lumbar spine. • There is no evidence comparing uMRI to a diagnostic reference standard for foraminal stenosis.
Lumbar nerve root compromise	Very Low	• 1 retrospective cohort study • uMRI vs. rMRI	• There is limited evidence (very low) to suggest that uMRI may provide similar diagnostic information as rMRI with

			respect to nerve root compromise of the lumbar spine. • There is no evidence comparing uMRI to a diagnostic reference standard for nerve root compromise.
Lumbar spondylolisthesis	Very Low	• 1 retrospective cohort study • uMRI vs. rMRI	• There is limited evidence (very low) to suggest that uMRI may provide similar diagnostic information as rMRI with respect to spondylolisthesis of the lumbar spine. • There is no evidence comparing uMRI to a diagnostic reference standard for spondylolisthesis.

Appendix Table F4. Strength of Evidence from 2007 Report: Summary of studies on the concordance, reliability and impact of uMRI for specific spinal and extra-spinal conditions (CONTINUED)

Key Question	Strength of Evidence	Summary	Conclusions/Comments
Morton neuroma	Very Low	• 1 prospective cohort study • uMRI vs. rMRI	• There is no evidence to suggest uMRI images contribute towards the identification of Morton neuroma compared with existing diagnostic tests.
Shoulder instability	Very Low	• 1 prospective cohort study • uMRI vs. exam under anesthesia	• There is no evidence to suggest uMRI images add to the identification of shoulder instability compared with existing diagnostic tests.
Key Question 2: Reliability			
Spinal stenosis	Low	• 1 retrospective cohort study assessing inter-rater reliability	• There is limited evidence from one study that lumbar foraminal stenosis may be determined reliably between radiologists using seated uMRI in

	patients whose symptoms are severe enough to warrant a myelogram. • There is no evidence that uMRI is reliable in detecting degenerative spondylolisthesis, lateral recess stenosis, radicular pain, non-specific spine pain or extra-spinal conditions.
Key Question 3: Diagnostic Impact • No studies of diagnostic impact were found. • No determination can be made with respect to the effect uMRI has on the use of additional diagnostic testing or its effect on limiting the differential diagnosis using uMRI	
Key Question 4: Therapeutic Impact • No studies of therapeutic impact were found. Lack of data from included studies prevents one from drawing conclusions on the likelihood that positive upright MRI findings accurately predict favorable outcome following test-directed treatment.	
Key Question 5: Effectiveness in Acute vs. sub-acute/delayed setting • No studies were found evaluating diagnostic or therapeutic impact in acute versus sub-acute or delayed setting. • Lack of data addressing this issue precludes evaluation of the effectiveness of uMRI as a diagnostic imaging tool in these populations.	

* Strength of Evidence expresses the confidence in the stability of the estimate as further research is done: High= Very unlikely to change confidence in effect estimate; Moderate = Likely to have an important impact on confidence in estimate and *may* change the estimate; Low = Very likely to have an important impact on confidence in estimate and *likely* to change the estimate; Very Low = Any effect estimate is uncertain

APPENDIX G: PUBLICATIONS EXCLUDED AT FULL TEXT REVIEW

Citation	Reason for Exclusion
Baker, 2021	Lit review including ineligible studies, results not reported separately; Bibliography searched
Charen-Morin, 2021	Ineligible outcomes
Charoensuk, 2023	Ineligible intervention
Do, 2011	
Donelson, 2019	Ineligible outcomes
Fiani, 2020	Lit review including ineligible studies, results not reported separately; Bibliography searched
Graves, 2014	Ineligible outcomes
Hansen BB, Bouert R, Bliddal H, m.fl. External pneumatic compression device prevents fainting in standing weightbearing MRI: A cohort study. Skeletal Radiol 2013;42:1437–42.	Ineligible intervention
Hansen BB, Bendix T, Grindsted J, Bliddal H, Christensen R, Hansen P, et al. Effect of lumbar disc degeneration and low-back pain on the lumbar lordosis in supine and standing: a cross-sectional MRI study. Spine 2015;40(21):1690e6. https://doi.org/10.1097/BRS.0000000000001120	Ineligible intervention
Hansen, 2017	Lit review including ineligible studies, results not reported separately; Bibliography searched
Hansen BBM, Hansen P, Christensen AF, Trampedach C, Rasti Z, Bliddal H, et al. Reliability of standing weight-bearing (0.25T) MR imaging findings and positional changes in the lumbar spine. Skeletal Radiol 2018;47(1):25e35. https:// doi.org/10.1007/s00256-017-2746-y.	Ineligible intervention
Hansen, 2019	Lit review including ineligible studies, results not reported separately; Bibliography searched
Health Quality Ontario, 2015	Ineligible population
Khalil, 2012	Ineligible publication type
Lao, 2014	Lit review including ineligible studies, results not reported separately; Bibliography searched
Lim, 2017	Ineligible outcomes
Lord, 2014	Lit review including ineligible studies, results not reported separately; Bibliography searched
Mahdavi, 2024	Lit review including ineligible studies, results not reported separately; Bibliography searched
Muto M, Giurazza F, Guarnieri G, Senese R, Schena E, Zeccolini F, et al. Dynamic MR in patients affected by neurogenical claudication: technique and results from a single center experience. Neuroradiology 2016;58(8):765e70. https:// doi.org/10.1007/s00234-016-1697-7.	Invalid comparator
Nguyen, 2016	Invalid comparator
Nicholson, 2023	Invalid comparator

Niggemann P, Kuchta J, Hoeffer J, Grosskurth D, Beyer HK, Delank KS. Juxtafacet cysts of the lumbar spine: a positional MRI study. Skeletal Radiol 2012;41(3): 313e20. https://doi.org/10.1007/s00256-011-1186-3.	Included in previous signal update
Nordberg, 2019	Ineligible publication type
Panagopoulos, 2017	Ineligible outcomes
Peterson, 2013	Ineligible outcomes
Segebarth B, Kurd MF, Haug PH, Davis R: Routine upright imaging for evaluating degenerative lumbar stenosis: incidence of degenerative spondylolisthesis missed on supine MRI. J Spinal Disord Tech. 2015, 28:394-397. 10.1097/BSD.0000000000000205	Ineligible intervention
Shapiro, 2012	Ineligible publication type
Shin, 2022	Ineligible outcomes
Tan, 2012	Ineligible comparator