Washington State Health Care Authority

Health Technology Assessment Program

Health Technology Clinical Committee
May 18, 2007 Meeting

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Washington State Health Care Authority

Today's Objectives

- HTA Program Overview
  - Program Background and Legislation
  - Program Purpose and Goal
  - Current Status
- Technology Selection
  - Technology Priority Criteria
  - Upright MRI

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Washington's Health Care Environment

- **US Spends More on Health Care**
  - US spends twice as much per capita as other developed countries, yet is not even in the top three for key health indicators (*IOM, Kaiser Family Foundation*)
- **US Scores poorly on key health indicators**
  - US patients only receive half recommended care *(RAND)*
  - U.S. mortality for conditions amenable to health care is 115 per 100,000 people, compared with 80 per 100,000 in the top-performer among 19 countries. *(Commonwealth Fund 2006)*
  - Increased spending is not reflected in greater health care resources such as hospital beds, physicians, nurses, MRIs, and CT scanners per capita. *Health Affairs 25(3) (May/June 2006): 819-831.*
  - As much as 1/3 of health care spending is wasted on procedures, drugs, or treatments that neither improve quality of life or extend life. *(IOM)*
- **Health Care Spending Continues to Rise beyond inflation**
  - Rise in health care spending outpaces general inflation by factor of 2 or 3
  - New medical technology estimated to account for about one-half or more of real long-term spending growth. (*IOM, Kaiser Family Foundation*)

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Technology News

- **What Factors Affect the Growth of a New Medical Technology?**
  - **Consumer demand** for better health is a prime factor.
  - Payment for new innovations by **health insurance** also encourage medical advances.
  - Direct **providers of care** may incorporate new technology because they want to improve the care they offer their patients, but they also may feel the need to offer the "latest and best" as they compete with other providers for patients.
  - **Commercial interests** (such as pharmaceutical companies and medical device makers) are willing to invest large amounts in research and development because they have found strong consumer interest in, and financial reimbursement for, many of the new products they produce.
  - Public and private investments in **basic science research** lead directly and indirectly to advancements in medical practice

Kaiser Family Foundation, March 2007: **How Changes in Medical Technology Affect Health Care Costs**

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Washington's Health Technology Assessment Program

- **Part of Governor's 2006 Five point health strategy for state to lead by example**
  - **Emphasize evidence-based health care**

    http://www.hca.wa.gov/contf/doc/GovGregoireHealthBrief.pdf

- **Program Purpose: Achieve better health by paying for technologies that work**
  - Better health with better information: investigate what works and maintain centralized website
  - Open and transparent process: publish process, criteria, and reports, committee decisions in public meeting
  - Eliminate Bias: contract for independent evidence report and independent clinical committee
  - Promote consistency: state agencies rely on a single, scientifically based source
  - Flexible: review evidence regularly to ensure update information is included

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Health Technology Assessment (HTA) Program

- **Program Creation: March 2006**
  - Legislation created new program to centralize inter-agency process for review of selected medical procedures, devices, or equipment
  - Contracts for an independent assessment of the evidence of health technologies
  - Assessment report used by an independent clinical committee of eleven practicing health care providers to make coverage decisions
- **Program Development: July - December 2006**
  - ✓ Hired Staff and formed Agency medical director workgroup
  - ✓ Recruited and Appointed Clinical committee
  - ✓ Contracted with two technology assessment centers
  - ✓ Adopted policy and administrative code
  - ✓ Prioritized first three technologies
  - ✓ Involved Stakeholders and developed website: www.hta.hca.wa.gov

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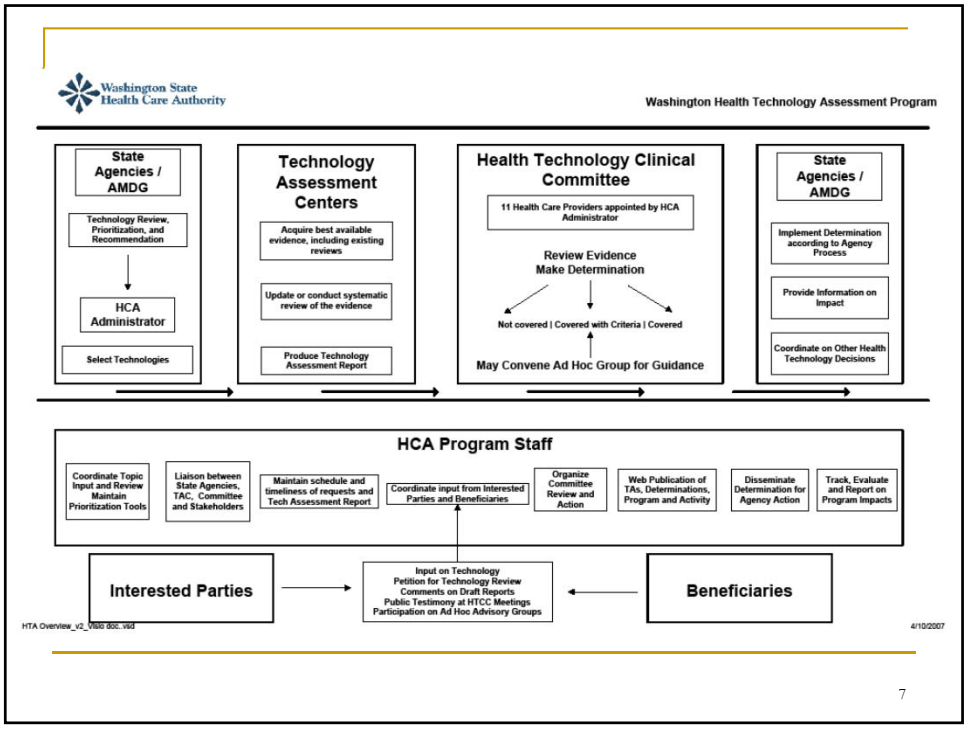
Washington State Health Care Authority
Washington Health Technology Assessment Program
State Agencies / AMDG
Technology Review, Prioritization, and Recommendation
HCA Administrator
Select Technologies
Technology Assessment Centers
Acquire best available evidence, including existing reviews
Update or conduct systematic review of the evidence
Produce Technology Assessment Report
Health Technology Clinical Committee
11 Health Care Providers appointed by HCA Administrator
Review Evidence
Make Determination
Not covered | Covered with Criteria | Covered
May Convene Ad Hoc Group for Guidance
State Agencies / AMDG
Implement Determination according to Agency Process
Provide Information on Impact
Coordinate on Other Health Technology Decisions
HCA Program Staff
Coordinate Topic Input and Review Maintain Prioritization Tools
Liaison between State Agencies, TAC, Committee and Stakeholders
Maintain schedule and timeliness of requests and Tech Assessment Report
Coordinate input from Interested Parties and Beneficiaries
Organize Committee Review and Action
Web Publication of TAs, Determinations, Program and Activity
Disseminate Determination for Agency Action
Track, Evaluate and Report on Program Impacts
Interested Parties
Input on Technology
Petition for Technology Review
Comments on Draft Reports
Public Testimony at HTCC Meetings
Participation on Ad Hoc Advisory Groups
Beneficiaries
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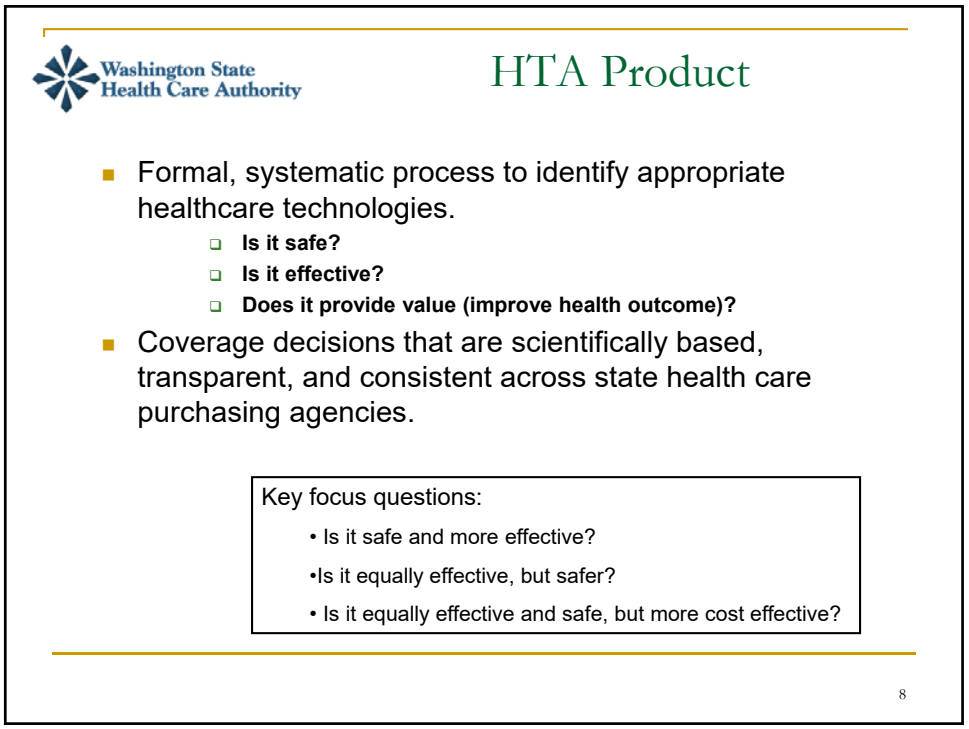
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HTA Product
Formal, systematic process to identify appropriate healthcare technologies.
Is it safe?
Is it effective?
Does it provide value (improve health outcome)?
Coverage decisions that are scientifically based, transparent, and consistent across state health care purchasing agencies.
Key focus questions:
• Is it safe and more effective?
•Is it equally effective, but safer?
• Is it equally effective and safe, but more cost effective?
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Coverage Decision Process

1. HCA Administrator Selects Technology

Nominate, Review, Prioritize, Public Input

Semi-annual

2. Vendor Produce Technology Assessment Report

Key Questions and Work Plan, Draft, Comments, Finalize

2-8 Months

3. Clinical Committee makes Coverage Determination

Review report, Public hearing

Meet Quarterly

4. Agencies Implement Decision

Implements within current process unless statutory conflict

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HTA Program Impact

Scope

- Fourteen technologies over two years
- Technology Assessment reports posted to website
- Clinical Committee coverage decisions apply to agency paid health care (fee for service and self-insured plans)
- State or regional carriers may voluntarily adopt same decision or use technology assessments

Technologies Under Review

- Upright MRI
  - May 2007
- Pediatric Bariatric Surgery
  - August 2007
- Lumbar Fusion and Discography
  - November 2007

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HTA Program Expected Benefits

Direct

- Better decisions – covering technologies proven to work, reduce funds to ineffective care
- State resource for technology assessments
- Scientific and independent review and report
  - Reduce industry and agency bias claims
- Eliminates replication of assessment and policy development effort among agencies for chosen technologies

Potential

- Broader application - State or regional carriers may voluntarily adopt
  - Value – more funds available for access or effective care
- Spur creation of evidence where gaps identified
  - Create health care discussion based on evidence first
- Technology Assessment Summaries used by physicians and patients
- Larger collaborative efforts

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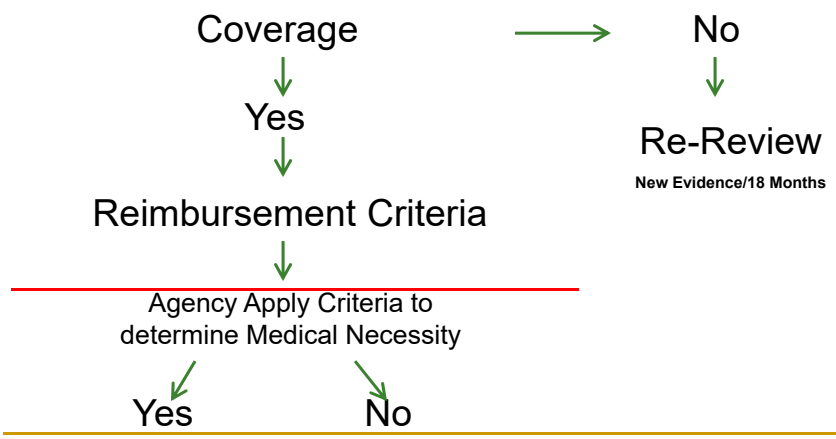
Committee Meeting Purpose Evidence-Based Determination

- Conceptual Framework -



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HTCC Meeting

- **Clinical Committee Information Gathering**
  - Must review and consider Health Technology Assessment
  - May consider other relevant information
    - Information Provided by administrator
    - Reports and testimony from advisory groups
    - Submission or comments from public

WAC 182-55-030: Committee coverage determination process

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HTCC Meeting

- **Clinical Committee Decision must give greatest weight to most valid and reliable evidence**
  - Objective Factors for evidence consideration
    - Nature and Source of evidence
    - Empirical characteristics of the studies or trials upon which evidence is based
    - Consistency of outcomes with comparable studies
  - Additional evaluation factors
    - Recency (date of information)
    - Relevance (applicability of the information to the key questions presented or participating agency programs and clients)
    - Bias (presence of conflict of interest or political considerations)

WAC 182-55-030: Committee coverage determination process

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Introduction – Technology Selection and Topic

- Review Technology Selection Process
- Review Technology Selection Criteria
- Upright MRI Recommendation

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Technology Selection Process

Administrator Selects Technologies

- Selection is based on a list of technologies prioritized by Agency Medical Directors
  - Identify potential topics - Medical director suggestion and Interested party petitions
  - Brief selected technologies likely to meet legislative criteria
  - Participating agency initially scores technology using prioritization tool
  - Subsequently, workgroup meets and reaches a consensus decision on the technology priority
  - Top ranked technologies are recommended to the HCA Administrator; and other technologies can remain on the list for future consideration.
  - HCA Administrator selects technologies for review

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Technology Selection Criteria

- **Primary Criteria:**
  - Patient Harm or Safety Concerns
  - Concerns about therapeutic efficacy or diagnostic accuracy and appropriateness of outcomes for patients
  - Cost impact for state purchasing agencies
- Secondary Criteria:
  - Number of persons affected
  - Severity of condition
  - Policy related urgency/diffusion concern
  - Potential or observed variation in care
  - Special populations or ethical concerns

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Upright MRI

- **Upright/Positional MR Imaging Description**
  - New diagnostic technology used primarily in diagnosis of joint related conditions of the spine, shoulder, and knee.
  - This technology is a vertically open MRI that permits multiple position images and weight bearing images
  - Proponents claim that uMRI scanning in a variety of positions and/or loading help show pathology that is expressed more fully with positional and loading presented.
- Issues/Concerns
  - Highest concern is diagnostic accuracy and theraputic impact
    - Image quality of uMRI may be compromised by field strength and time required to remain still in differing positions
    - Unclear whether additional findings in images are clinically significant
    - Unclear (1) whether treatment decisions are changed based on added findings, and (2) whether additional findings that are questionable lead to poor or worse diagnosis and inappropriate care
  - Cost of additional views in (showing varying positions or load) significantly increases imaging cost over other imaging (single MRI; X-ray)

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Upright MRI

- **Agency Experience**
  - Imaging for diagnosis of conditions for the spine, knee and joint are a high expense, and are rising
    - Example: MR Imaging for Uniform Medical Plan amount paid was $11 million in 2006
    - Example: MR Imaging for spine diagnosis for Labor and Industries exceeded $10 million in 2005
  - Utilization of uMRI instead of MRI would increase imaging cost significantly; and if additional findings cause uncertainty may increase utilization of additional diagnostics and interventions

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Upright MRI

Primary Criteria	
Potential patient **harm/safety** concerns:	**Med**
Concerns about therapeutic **efficacy or diagnostic accuracy** and appropriateness of outcomes for patients:	**High**
Estimated total direct **cost** per year (estimated increase/decrease):	**Med**
Secondary Criteria	
Number of persons affected per year:	**High**
Severity of condition treated by technology:	**Med**
Policy related urgency/diffusion concern:	**High**
Potential or observed variation:	**High**
Special populations/ethical concerns:	**Low**

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HTA Program

Effectiveness of upright MRI for evaluation of patients with suspected spinal or extra-spinal conditions

Report: May, 2007

Spectrum Research, Inc. for the
Health Technology Assessment Program

Andrea C. Skelly, MPH, PhD
Elya Moore, MS, PhD
Joseph R. Dettori, PhD, MPH

Purpose and Process

Purpose:

Provide an independent, methodologically rigorous, formal evaluation of published scientific literature

- Comparing uMRI with currently available diagnostic modalities
- Describing evidence for the diagnostic accuracy, reliability and effectiveness of positional, standing or upright MRI (uMRI)

Purpose and Process (continued)

Process:

- ✓ Systematic search and literature review
- ✓ Critique of individual study quality based on AHRQ domains
- ✓ Evaluation of overall strength of evidence for specific topic areas based on AHRQ and GRADE precepts
- ✓ Peer review

Relevant MRI Systems

Standard rMRI

- 1.0T - 3.0T, closed
- Recumbent, +/- load

"Open" MRI

High-field

- >1.0T
- Some position, +/- load

Mid-field - uMRI

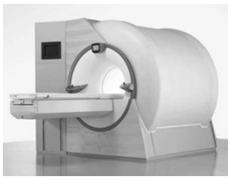
- 0.5T or 0.6T
- Positional + recumbent

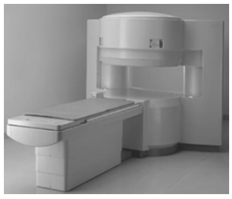
Low-field - excluded

- <0.5 T
- Positional; extremities

Sources:

mr-tip.com; radiologyinfo.org; fonar.com;





Background: Lumbar Spinal Conditions

Low Back Pain (LBP)

- >80% population during lifetime (Quebec Task Force)
- >$50 Billion annually (Harvard Men's Health Watch)
- Cause found in only 12-15% (Skinner)
- Mechanical causes: ~ prevalence (Jarvik 1996)
  - Lumbar sprain/strain ~70%
  - Degenerative processes – disc or facet ~10%
  - Disc herniation ~4%
  - Spinal stenosis ~3%
  - Spondylolisthesis ~2%
- Acute LPB (< 4-6 wks) – Serious Causes ~1% - 4% (Atlas 2001)

Background: Lumbar Spinal Conditions

Diagnostic Imaging – LBP

- Uncomplicated LBP – often resolves with conservative management
- ACR Guidelines: Imaging indicated
  - "Red Flag" symptoms/history
  - pain >6 wks
- Modality: Presentation, suspected pathology
- MRI high prevalence of findings in asymptomatic - Dx or clinical significance? (Jarvik 2001)

Imaging: Extra-spinal joints

- Modality: Depends on suspected pathology
- ACR Guidelines
  - Radiograph generally most appropriate
    - Non-traumatic knee pain
    - Chronic wrist pain
    - Shoulder instability
    - Chronic foot pain
  - MRI is suggested for ankle instability
- No uMRI specific guidelines for spine or joints were found

Proposed/Hypothesized uMRI Advantages

- Assess effects of weight-bearing, position and dynamic movement and possibly the relationship between movement and symptoms.
- May help elucidate pathology that may be expressed more fully with positional changes or weight bearing
- Proposed to be more sensitive and specific than rMRI for dx spinal & extra-spinal joint pathology

Diagnostic Test Evaluation

Validation (diagnostic accuracy)

– Test compared to an appropriate reference standard

		True Classification: Disease present (+)	True Classification: Disease absent (-)
Diagnostic Test	Disease present(+)	a = TP	b = FP
	Disease absent(-)	c = FN	d = TN
		a + c	b + d

Diagnostic Test Evaluation

Validation (diagnostic accuracy)

- Test characteristics can be determined
  - Sensitivity = % pts with disease who test +
  - Specificity = % pts without disease who test -
- Appropriate referent + broad pt spectrum*
  - PPV = % pts with + test who have ds
  - NPV = % pts with - test who do NOT have ds

*freq of ds in study pop ~ that in population to be tested

Diagnostic Test Evaluation

Validity studies (continued)

- Sources of bias (see Lijmer 1999)
- No "gold" standard - options/considerations

Reliability (Reproducibility) – how well can a measure be replicated

- A reproducible test may still not be valid
  - Test-retest reliability (intra-rater)
  - Inter-rater reliability

Key Questions: Conditions

- Suspected degenerative spondylolisthesis
  >25% slip
- Suspected spinal stenosis
  Central: Moderate/severe, >1/3 of the canal
  Lateral recess: nerve root compression or displacement, disc extrusion
- Radicular pain
  (stenosis, nerve root compression, disc extrusion)
- Non-specific spine pain
  (stenosis, nerve root compression, disc extrusion)
- Extra-spinal joint pain/function loss
  e.g., narrowing, musculoskeletal only

Key Questions:
Currently Available Diagnostic Testing

- Standard MRI +/- Axial Loading
- CT-Myelogram +/- upright
- Plain films (flexion and extension)
- Discography
- Operative findings

Key Questions

1. What is the evidence to describe the concordance of uMRI with currently available diagnostic testing?

   If reference standard available, what are the test characteristics?

   Reference standards set *a priori*
   - Spinal conditions– Upright myelogram + CT-Myelogram (HTA conference call/consultant)
   - Extra-spinal joint conditions – radiographs

Key Questions

Compared with available diagnostic testing, what is the evidence:

2. To describe the reliability of uMRI?
3. To describe the diagnostic impact of uMRI?
4. To describe the therapeutic and patient impact of test-directed treatment of uMRI?
5. That uMRI in the acute setting is more effective (dx and tx impact) than available diagnostic testing in the sub-acute/delayed setting?

Methods

Search

- MEDLINE/PubMED
- EMBASE, CINHAL, PyscINFO, others
- National Guideline Clearinghouse
- Google
- Manufacturer and payer Websites

Contact

- Manufacturer, clinics

Methods

Inclusion:

- Peer-reviewed studies comparing uMRI w/currently available diagnostic method in patients with key question conditions; English
- Reliability or formal economic analysis

Exclusion:

- No comparison with current method, not diagnostic or reliability focused; did not address key question condition
- Case-series <5 pts, white papers, reviews

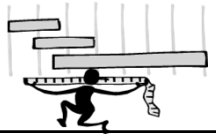
Level	Study type	Criteria
I	Good quality prospective study	▪ Broad spectrum of persons with the expected condition ▪ Appropriate reference standard used ▪ Adequate description of test and reference for replication ▪ Blinded comparison of tests with appropriate reference standard ▪ Reference standard performed independently of diagnostic test
II	Moderate quality prospective study	▪ Violation of any one of the criteria for a good quality prospective study (LoE I)
	Good quality retrospective study	▪ All five diagnostic study criteria met in a retrospective study
III	Poor quality prospective study	▪ Violation of any two or more of the criteria for a good quality prospective study (LoE I)
	Moderate quality retrospective study	▪ Violation of any one of the criteria for a good quality retrospective study (LoE II)
IV	Poor quality retrospective study	▪ Violation of any two or more of the criteria for a good quality retrospective study (LoE II)
	Case-Control Study	

LoE – reliability studies

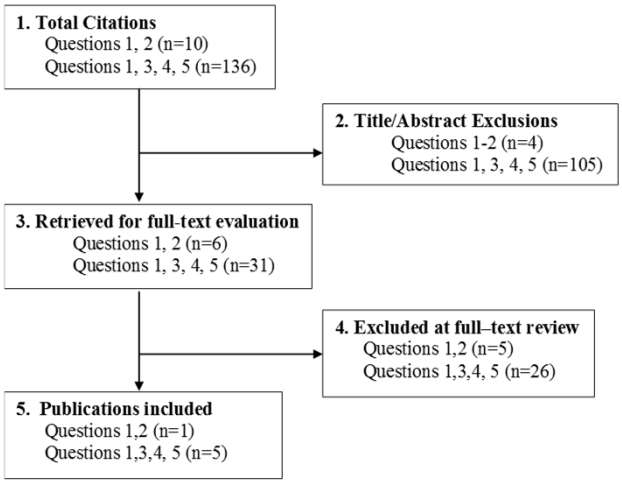
Level	Study type	Criteria
I	Good quality study	• Broad spectrum of persons with the expected condition • Adequate description of methods for replication • Blinded performance of tests, measurements or interpretation • Second test/interpretation performed independently of the first
II	Moderate quality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

Analysis of Concordance

- In the absence of diagnostic accuracy (validation) studies, concordance was assessed
  - Percent Agreement (observed concordance)
  - Kappa
    - A proportion of % agreement occurs by chance
    - Kappa reflects amount by which observed concordance exceeds what would occur just by chance



Results: Literature Search



Results: Key Question 1- Concordance

Spinal Condition studies: N=4
Extra-spinal conditions: N=2

Methodological Principle	Weishaupt (2000) N=30	Zamani (1998) N=15	Ferreiro (2007) N=89	Wildermuth (1998) N=30
Study Design				
Prospective cohort design				
Retrospective cohort design	■	■	■	■
Case-control design				
Broad spectrum of patients with expected condition			■	
Appropriate reference standard used				
Adequate description of test, reference for replication	■	■	■	■
Blinded comparison with appropriate reference				
Reference standard performed independently of test			■	
Evidence Level	**IV**	**IV**	**IV**	**IV**

Results: Key Question 1
Spinal Conditions – Disc Pathology

Cervical Spine				
	Posterior focal disc herniation Ferreiro Perez et al. 2007[48]	rMRI vs. seated neutral MRI	DNA*	IV
Lumbosacral Spine				
	Posterior focal disc herniation Ferreiro Perez et al. 2007[48]	rMRI† vs. seated neutral MRI	DNA*	IV
	Disc Form Weishaupt et al. 2000[45]	rMRI† vs. seated flexion MRI	94.7	IV
		rMRI† vs. seated extension MRI	90.8	IV
	Posterior disc bulge Zamani et al. 1998[47]	rMRI‡ vs. seated neutral MRI	100	IV

*DNA=data not available to calculate

†Recumbent supine neutral or extended not specified

‡Recumbent supine neutral (knees slightly flexed)

Results: Key Question 1
Spinal Conditions – Disc Pathology

Cervical Spine

- Posterior herniations seen in 61% (27/44) with rMRI; 70% (31/44) with uMRI (Ferreiro-Perez)

Lumbar Spine

- Posterior herniations: 31% (n=22) seen with rMRI; 45% (n=24) (Ferreiro-Perez)
- Disc bulge: 100% agreement; qualitative (Zamani)
- Disc form, neutral vs. seated flexion and extension 95% and 91% agreement, HOWEVER, 17% (n=36) couldn't finish seated uMRI due to pain (Weishaupt)

Results: Key Question 1
Spinal conditions – Foraminal stenosis

Condition	Imaging Comparison	agreement	LoE
Foraminal stenosis Weishaupt et al. 2000[45]	rMRI† vs. seated flexion MRI	84.2	IV
	rMRI† vs. seated extension MRI	85.5	IV
Foraminal size Zamani et al. 1998[47]	rMRI‡ vs. seated flexion MRI	100	IV
Foraminal stenosis score Wildermuth et al. 1998[46]	myelogram vs. seated flexion MRI	94	IV
	myelogram vs. seated extension MRI	92	IV

†Recumbent supine neutral or extended not specified
‡Recumbent supine neutral (knees slightly flexed)

Results: Key Question 1
Nerve root compromise and spondylolisthesis

Condition	Imaging Comparison	Agreement	LoE
Nerve root compromise Weishaupt et al. 2000[45]	rMRI† vs. seated flexion MRI	73.7	IV
	rMRI† vs. seated extension MRI	77.6	IV
Spondylolisthesis Ferreiro Perez et al. 2007[48]	rMRI† vs. seated neutral MRI	DNA*	IV

†Recumbent supine neutral or extended not specified

Results: Key Question 1 - Spinal Conditions

Some additional shortcomings – may lead to over-estimation of concordance

- Small sample sizes (<30) and/or few patients in a given diagnostic category
- Exclusion of patients who could not complete exams due to pain OR those with motion artifacts on image OR similar exclusions
- Poorly specified assessment protocols and/or qualitative assessment of diagnostic criteria

Key Question 1: Concordance
Extra-spinal Conditions (N=2)

Methodological Principle	Weishaupt (2003) N=18	Hodge (2001) N=10 (KUA)
Study Design		
Prospective cohort design	■	■
Retrospective cohort design		
Case-control design		
Broad spectrum of patients with expected condition		■
Appropriate reference standard used	■	■
Adequate description of test and reference for replication	■	■
Blinded comparison with appropriate reference	■	
Reference standard performed independently of test		■
Level of Evidence	**III**	**II**

Key Question 1: Concordance Extra-spinal Conditions

Condition	Imaging Comparison	Percent agreement	LoE
Foot neuroma visibility score Weishaupt et al. 2003[50]	rMRI* vs. standing MRI	50	III
Shoulder instability Hodge et al. 2001[49]	Exam under anesthesia vs. seated MRI	30	II

* Prone position

Key Question 1: Concordance Extra-spinal Conditions

- Morton Neuroma
  - Prone, non-weight-bearing position best, 100% of 20 neuromas seen
  - Supine, 60% good visibility rating; Weight-bearing, 50%
  - Only pts with neuroma >5mm included
- Glenohumeral Instability (N=10 patients)
  - uMRI underestimated instability compared with EUA in 7/10 cases

Summary Key Question 1

Spinal conditions

- Limited evidence (SoE low) to suggest uMRI provides similar diagnostic information compared with rMRI for disc pathology or foraminal stenosis of lumbar spine
- Evidence for concordance between uMRI and rMRI is low for cervical disc herniation, lumbar nerve root compromise and spondylolisthesis
- Some evidence that seated uMRI not well tolerated

Summary Key Question 1

Extra-spinal conditions

- No evidence to suggest uMRI contributes additional information to identification of Morton neuroma or shoulder instability
- No comparative studies of uMRI evaluation of the hip, knee or ankle were found.

Key Question 2: Reliability (n=1)

Methodological Principle	Wildermuth (1998)
Broad spectrum of patients with expected condition	
Adequate description of methods for replication	■
Blinded comparison of tests/interpretations (interrater)	■
Evidence Level	II

Condition	Observers	Kappa	LoE
Foraminal stenosis score Wildermuth et al. 1998[46]	Radiologists (n=2)	0.62	II

Key Question 2: Reliability

- Lumbar foraminal stenosis graded independently by two radiologists (N=30) in patients whose condition warranted myelogram
- Suggests that LFS can be reliably determined in such patients
- Extension of findings to those with different levels of severity is unknown

Key Questions 3, 4, and 5

- No published reports were found
- Evaluation of diagnostic and therapeutic impact and clinical utility requires consideration of
  - test performance in those who do and do not have the condition (e.g., sensitivity and specificity)
  - Extent to which meaningful tx options available
  - If findings from new test improve patient outcomes beyond those based on the old test

Cost Impact

- No formal economic analyses of uMRI (e.g., cost-utility)
- Global clinic charges range from $1365-$1650 for basic exam based on information from three clinics
- Additional views: $350-$1200 each

Cost Impact: Washington Agency Reimbursement

- UMP considers uMRI experimental and investigational based on internal review and does not currently cover; 46 claims received in 2006 prior to policy and did not pay for additional views
- DSHS currently has not have a policy for uMRI. Payment for imaging is under "By Report" indicator. When BR verified, DSHS would pay 45% of billed charges.

Cost Impact: Washington Agency Reimbursement

- LNI completed a technology assessment in 2006. Based on this it doesn't cover standing, weight-bearing or positional MRI, effective 7/1/2006.
- LNI received and paid ~111 imaging claims for uMRI prior to policy with 2.5 positional scans, on average, per patient, completed and billed.
- LNI estimated that uMRI could significantly increase total MRI imaging costs for the spine significantly if widely adopted.

Payer Coverage Policies

CMS
- No National Coverage Determination

Premera-Blue Cross
- Vertical, upright, positional, dynamic MRI considered investigational – Lack of evidence

Regence
- Positional or upright MRI for dx and management of any condition… considered investigational
- Lack of data on analytical, clinical validity and clinical utility

Payer Coverage Policies

Aetna
- "Open" MRI including those allowing standing or sitting imaging-acceptable alternative to standard "closed" MRI
- Repeat scans in different positions considered experimental and investigational
- Clinical value [of positional] not systematically evaluated…no demonstration of consistent detection of problems that cannot be detected with standard MRI

Cigna
- "low field" not covered unless medically necessary for guidance during interventional or intra-op procedures
- Few small studies do not address relevance, value or impact…in dx, tx or outcomes of pts with neck or back pain
- Lack of data on role in knee or shoulder evaluation

Overall Strength of Evidence (SoE)

Domain	Definition/Criterion
Quality	• At least 80% of the studies are LoE I or II
Quantity	• There are at least three studies which are adequately powered to answer the study question
Consistency	• Study results would lead to a similar conclusion (similar values, in the same direction) in at least 70% of the studies

Overall Strength of Evidence (SoE)

SoE	Description	Further Research Impact	Domain Criterion Met		
			Quality	Quantity	Consistency
1	High	Very unlikely to change confidence in effect estimate	+	+	+
2	Moderate	Likely to have an important impact on confidence in estimate and *may* change the estimate	+	-	+
			+	+	-
3	Low	Very likely to have an important impact on confidence in estimate and *likely* to change the estimate	+	-	-
			-	+	+
4	Very Low	Any effect estimate is uncertain	-	+	-
			-	-	+
			-	-	-

Evidence-Based Bottom Line- SoE

Key Question 1- SoE for concordance estimates – spinal

- Cervical disc herniation – VERY LOW
- Lumbar disc pathology - LOW
- Lumbar foraminal stenosis - LOW
- Lumbar nerve root compromise – VERY LOW
- Lumbar spondylolisthesis – VERY LOW

Evidence-Based Bottom Line- SoE

Key Question 1- SoE for concordance estimates – extra spinal conditions

- Morton neuroma identification – VERY LOW
- Shoulder instability – VERY LOW

Key Question 2- SoE for reliability estimates

- Grading of lumbar foraminal stenosis in those pts with severe enough sy to warrant myelogram - LOW

Evidence-Based Bottom Line- SoE

Key Question 3

- No studies of diagnostic impact were found
- No determination with respect to uMRI's effect on additional dx testing or on limiting the differential dx

Key Question 4

- No studies of therapeutic impact were found
- Lack of data from included studies prevents conclusions on likelihood that + uMRI accurately predicts outcome

Evidence-Based Bottom Line- SoE

Key Question 5

- No studies were found evaluating the diagnostic or therapeutic impact in acute versus sub-acute or delayed settings
- Lack of data precludes evaluation of the effectiveness of uMRI as a diagnostic imaging tool in these populations

Other Issues

- uMRI is done in OP clinics, standard CPT codes used, thus cost/coverage evaluation is a challenge
- Coverage of additional and/or positional views may be important policy issue in light of evidence

Summary and Conclusions

- All included studies had significant methodological limitations which may bias estimates
- Confidence in the stability of concordance and reliability estimates for uMRI is low to very low for the conditions evaluated
- Available studies are limited in scope, sample size and number

Recommendations for further research

- Validation studies with appropriate reference standard (with discussion of appropriate standard)
- Reliability studies in a broad range of patients
- Correlation of findings with symptoms and outcomes

Recommendations for further research

- Evaluation of treatment decisions and influence of uMRI on them
- Studies comparing standard rMRI at 1.0T-3.0T
- Studies of axial loading with rMRI vs. upright axial loading and positional changes

HTCC Coverage and Reimbursement Determination Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on these questions:

1. Is it safe and effective?
2. Is it more effective or safer?
3. Is it equally effective and safe, and more cost-effective?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are Evidence based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective[1] as expressed by the following standards. [2]

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms.[3]

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.
- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

[1] Based on Legislative mandate: See RCW 70.14.100(2).

[2] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

[3] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

HTCC Evaluation Factors

HTCC implements the program mandate and key principles that the decision be evidence based and that it be weighted most importantly on whether a given technology is safe and improves health through a decision tool.

Using Evidence as the basis for a Coverage Decision

Evaluate the primary coverage question by identifying for each primary factor (Safety, Effectiveness, and Cost) whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. Availability of Evidence:

Committee members decide whether information is available - Yes/No

2. Confidence in the Evidence:

Committee members decide how confident they are in the scientific evidence by identifying the type and quality of evidence[4] for consideration such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- the amount of evidence (sparse to many number of evidence or events or individuals studied);
- consistency of evidence (results vary or largely similar);
- recency (timeliness of information);
- directness of evidence (link between technology and outcome);
- relevance of evidence (applicability to agency program and clients);
- bias (likelihood of conflict of interest or lack of safeguards).

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

3. Factors for Consideration - Importance

Committee members also consider the degree of importance that particular evidentiary information has to the policy and coverage decision. Factors used to assess level of importance are topic specific but most often include, for areas of safety, effectiveness, and cost:

- risk of event occurring;
- the degree of harm associated with risk;
- the number of risks; the burden of the condition;
- burden untreated or treated with alternatives;
- the importance of the outcome (e.g. treatment prevents death vs relief of symptom);
- the degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- value variation based on patient preference.

[4] Based on GRADE recommendation: http://www.gradeworkinggroup.org/FAQ/index.htm

DIAGNOSTIC HEALTH TECHNOLOGY

Safety

Morbidity

- Does scientific evidence confirm that use of the technology is free of or unlikely to produce significant morbidity?

  Significant morbidity: Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
  Adverse effect on health that can result in lasting harm or can be life-threatening.

  ☐ Yes
  ☐ No
  ☐ Not Studied/No Evidence

- In terms of morbidity, level of confidence that the evidence confirms use of the technology is safe:

  ☐ Not confident
  ☐ Confident

Mortality

- Does scientific evidence confirm that use of the technology is not likely to increase mortality?

  ☐ Yes
  ☐ No
  ☐ Not Studied/No Evidence

- In terms of mortality, level of confidence that use of the evidence confirms the technology is safe:

  ☐ Not confident
  ☐ Confident

Overall

- Does scientific evidence confirm that use of the technology is safe?

  ☐ Yes
  ☐ No

- Level of confidence that the evidence confirms that use of the technology is safe?

  ☐ Not confident
  ☐ Confident

DIAGNOSTIC HEALTH TECHNOLOGY
Effectiveness

Does the scientific evidence confirm that use of technology more accurately identifies both those with the diagnosis being evaluated and those without the diagnosis being evaluated? That is, does the use of the technology result in better sensitivity and better specificity?

- ☐ Yes
- ☐ No
- ☐ Not Studied/No Evidence

- Level of confidence that the use of the technology results in more accurate diagnosis?
  - ☐ Not confident
  - ☐ Confident

Does the scientific evidence confirm that use of the technology increases diagnostic sensitivity but reduces test specificity? That is, does use of the technology increase both true positive and false positive diagnostic test results?

- ☐ Yes
- ☐ No

Does the scientific evidence confirm that use of the technology increases diagnostic specificity but reduce test sensitivity? That is, does use of the technology increase both true negative and false negative diagnostic test results?

- ☐ Yes
- ☐ No

Does the scientific evidence confirm that use of the technology can safely and effectively replace other tests?

- ☐ Yes
- ☐ No

- Level of confidence that the evidence confirms that use of the technology can safely and effectively replace other tests?
  - ☐ Not confident
  - ☐ Confident

Overall Efficacy: Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?

- ☐ Yes
- ☐ No
- ☐ Not Studied/No Evidence

- Level of confidence that the evidence confirms that use of the technology results in better health outcomes?
  - ☐ Not Confident
  - ☐ Confident

DIAGNOSTIC TEST TECHNOLOGY
Cost Impact

- Are independent cost analyses (cost benefit; cost effectiveness; or other cost analysis) identified?
  - ☐ Yes
  - ☐ No

If Yes:

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?
  - ☐ Greater
  - ☐ Equivalent
  - ☐ Lower

If No:

- Does the evidence available to the committee indicate that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?
  - ☐ Greater
  - ☐ Equivalent
  - ☐ Lower

DIAGNOSTIC TEST TECHNOLOGY
Benefit Evaluation

- Based on the current level of evidence regarding the technology's safety and effectiveness relative to currently available diagnostic methods, is use of the technology likely to have a net benefit, an equivalent benefit or a net harm?
  - ☐ Net Benefit
  - ☐ Equivalent Benefit
  - ☐ Net Harm
  - ☐ The available evidence does not permit a conclusion

- Based on the current level of evidence regarding the technology's cost impact relative to currently available diagnostic methods, is use of the technology likely to increase cost, result in equivalent cost or reduce cost?
  - ☐ Increase Cost
  - ☐ Equivalent Cost
  - ☐ Lower Cost

Relative to currently available diagnostic methods, into which category does the evidence indicate use of the new technology will fall?

Net Harm Increased Cost	Equivalent Benefit Increased Cost	Net Benefit Increased Cost
Net Harm Equivalent Cost	Equivalent Benefit Equivalent Cost	Net Benefit Equivalent Cost
Net Harm Reduced Cost	Equivalent Benefit Reduced Cost	Net Benefit Reduced Cost

DIAGNOSTIC TEST TECHNOLOGY
Coverage Determination

The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

- Based on the evidence that regarding the technology's safety, effectiveness, and cost-effectiveness, the use of the technology should be covered?

☐ No. Evidence is insufficient to conclude that the health technology is safe, efficacious, and cost-effective or the evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective

or

☐ Yes. The evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions.

or

☐ Yes, under certain conditions. Coverage is allowed with special conditions (e.g. population, conditions, timing, adjunct services, qualifications, etc.) because the evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective only when:

_____

_____

_____

_____

☐ This determination is consistent with the identified Medicare decisions and expert guidelines.

☐ Based on the evidence, this determination is inconsistent with either the identified Medicare decisions or expert guidelines.