Washington State Health Care Authority
Health Technology Assessment

Hip Resurfacing

Clinical Expert

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For Dr. Chansky's conflict of interest disclosure and curriculum vitae, please see information provided for Hyaluronic Acid/ Viscosupplementation study.

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Order of Scheduled Presentations

No public comments are scheduled for this topic.

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Agency Medical Director Comments

Hip Resurfacing Re-Review

G. Steven Hammond PhD, MD, MHA
Chief Medical Officer
Department of Corrections
November 15, 2013

Topic Reviewed in 2009

- Topic selection criteria rankings in 2009:
  - **Safety** – medium
  - **Efficacy** – high
  - **Cost** – low
- HTCC decision: Covered with conditions
  - For OA or inflammatory arthritis
  - Failure of non-surgical management and patient is a candidate for THA
  - Device used is FDA-approved

Hip Resurfacing Re-Review

Re-review in 2013 prompted by safety-related reports

Reassessment topic selection criteria rankings:

- **Safety** – high
  - Concerns raised by accumulating reports of complications and revisions required
- **Efficacy** – medium
  - Related to relatively high rates of premature revision
- **Cost** – medium
  - Related to complications and required revisions
  - However, utilization seems to be decreasing

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Hip Resurfacing Re-Review

For Example: The Birmingham Hip Resurfacing System

smith&nephew http://www.smith-nephew.com/professional/products/all-products/bhr-birmingham-hip-resurfacing/

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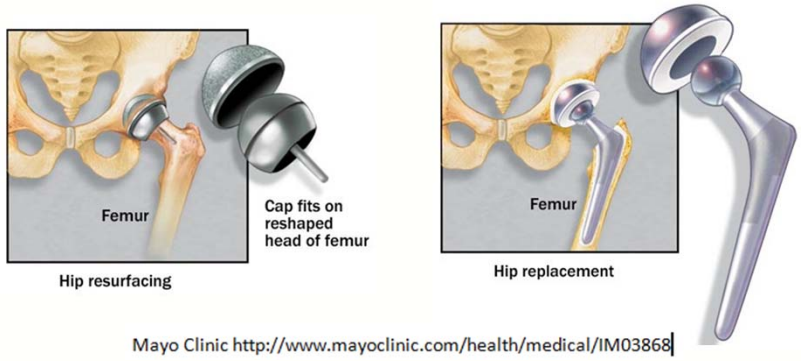
Hip Resurfacing (HR) vs. Total Hip Arthroplasty (THA)



Mayo Clinic http://www.mayoclinic.com/health/medical/IM03868

Femoral Neck Fracture in Hip Resurfacing

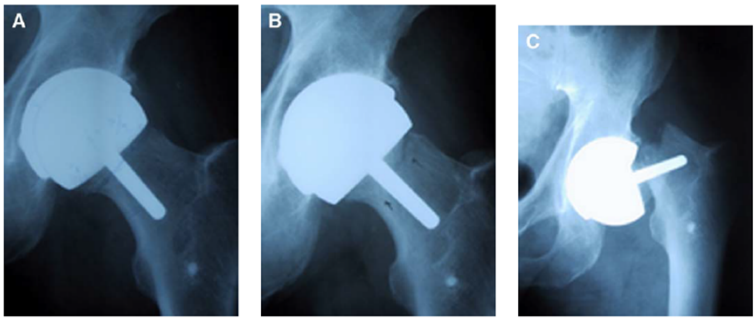


Fig. 2. (*A*) Postoperative radiograph of a femoral head prepared with a notch in the superior neck that may have contributed to the propagation of a fracture as seen evolving 6 weeks post surgery (*B*) and 10 weeks post surgery (*C*).

A.J. Shimmin, et al. Orthop Clin N Am 36 (2005) 187 – 193

Safety Concerns

- Significant rate of femoral neck fractures in HR, not seen in THA
- Local complications including pain and pseudotumor
- High rates of premature revision
- Growing concerns about Metal on Metal (MoM) arthroplasty systems
  - Local – inflammatory/hypersensitivity reactions to metal fragments
  - Systemic – evidence of systemic metallosis with unknown long-term consequences

- In 2009 review, HTCC found HR equivalent in efficacy with THA except that by expert opinion revision after HR thought to be less difficult than revision after THA.
- HR was considered by the HTCC on the basis of evidence available in 2009 to be associated with higher revision rate than THA

Updated review shows:

- Equivalent efficacy between HR and THA in terms of pain and function
- Safety evidence generally favors THA
  - Higher revision rates for HR at all intervals up to 10 years post-operatively (very little evidence > 10 yrs f/u available)
  - Greater incidence of femoral neck fracture, avascular necrosis, femoral component loosening, and heterotopic ossification with HR
  - Greater incidence of dislocation and deep infection with THA
- Metallosis concerns associated with HR (all of which are MoM) and MoM THAs)

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What is the evidence that revision after HR vs. THA differs in efficacy or safety?

- Evidence is sparse and of low quality due to small sample size and methodological weakness of the one cohort study reviewed.
  - WOMAC and SF-12 physical scores not significantly different after revisions for HR vs. THA.

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What population might benefit from HR?

- THA favored in developmental dysplasia, female, and smaller femoral head populations (fewer revisions required)

In light of updated findings is there any place for HR?

- Remains theoretically advantageous, despite safety concerns, in younger patients (<55?), those with favorable bone geometry, structure, and quality (usually men), who want/need to remain physically active and who would be expected to outlive a THA

How cost effective is HR?

- Results of cost-utility studies vary wildly (from cost-saving to >$2 million/QALY) depending on assumptions and no available study includes current estimates of increased revision rates required after HR
- Available studies do not provide clear guidance for coverage policy

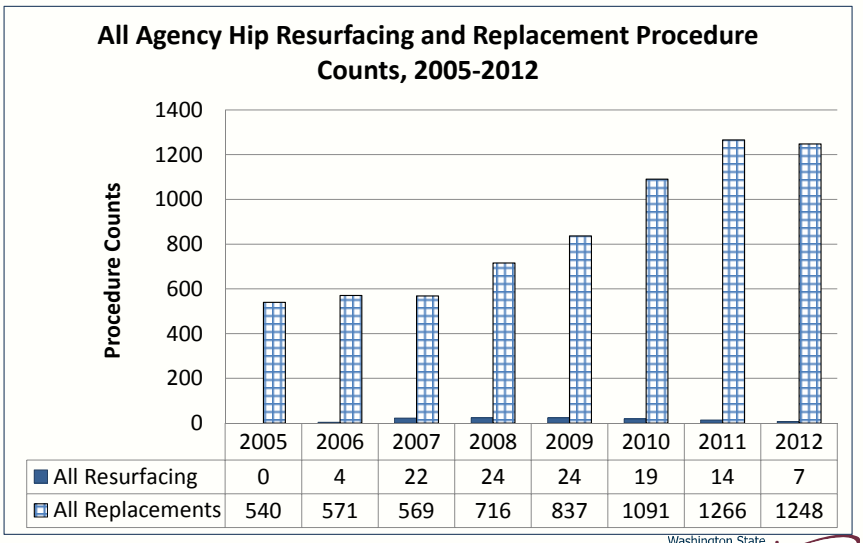
Current State Policy

- **Uniform Medical Plan** (UMP) – covered, PA
- **Medicaid** – covered, no PA
- **Labor & Industries** - covered, PA
- **Department of Corrections** - covered, PA
- **All Agencies** - incorporate HTCC 2009 coverage conditions

Other Agencies and Payers

- **Center for Medicare and Medicaid Services** – No National Coverage Decision.
- **Aetna** – Medically necessary as alternative to THA in physically active patients with hip OA
- **Blue Cross/Blue Shield** – Medically necessary in fit, active patients with appropriate bone geometry and quality, otherwise candidate for THA, likely to outlive a THA
- **Cigna** – Medically necessary when OA or inflammatory arthritis, THA candidate, age < 65, failed nonsurgical management
- **Harvard Pilgrim** – Covered in < 55 years old with chronic, persistent pain and/or disability, otherwise fit and active, appropriate bone geometry and quality, otherwise a THA candidate, expected to outlive conventional THA

Hip Resurfacing Re-Review:
State Agency Utilization



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Hip Resurfacing Re-Review:
State Agency Utilization

All Agency Procedure Counts, Current

PEBB ICD-9 Procedure Codes	2009	2010	2011	2012	Total
00.85 (total hip resurfacing)	13	10	8	7	**38**
81.51 (total hip replacement)	421	443	505	533	**1902**
81.52 (partial hip replacement)	43	43	58	40	**184**
Total	477	496	571	580	**2124**

Medicaid ICD-9 Procedure Codes	2009	2010	2011	2012	Total
00.85 (total hip resurfacing)	**9**	**7**	**4**	**0**	**20**
81.51 (total hip replacement)	**253**	**403**	**458**	**439**	**1553**
81.52 (partial hip replacement)	**28**	**119**	**169**	**161**	**477**
Total	**290**	**529**	**631**	**600**	**2050**

L&I ICD-9 Procedure Codes	2009	2010	2011	2012	Total
00.85 (total hip resurfacing)	**2**	**2**	**2**	**0**	**6**
81.51 (total hip replacement)	**85**	**81**	**72**	**70**	**308**
81.52 (partial hip replacement)	**7**	**2**	**4**	**5**	**18**
Total	**94**	**85**	**78**	**75**	**332**

Hip Resurfacing Re-Review:
State Agency Utilization

All Agencies Total Paid Amount, Current

PEBB ICD-9 Procedure Codes	2009	2010	2011	2012	Total
00.85 (total hip resurfacing)	$360,943	$203,250	$172,690	$198,528	**$935,411**
81.51 (total hip replacement)	$5,891,420	$6,161,986	$7,603,839	$7,432,837	**$27,090,082**
81.52 (partial hip replacement)	$200,536	$212,717	$202,715	$90,076	**$706,044**
Total	**$6,452,899**	**$6,577,953**	**$7,979,244**	**$7,721,441**	**$28,731,537**

Medicaid ICD-9 Procedure Codes	2009	2010	2011	2012	Total
00.85 (total hip resurfacing)	$94,856	$7,705	$1,897	$0	**$104,458**
81.51 (total hip replacement)	$4,103,593	$1,476,176	$703,657	$712,110	**$6,995,536**
81.52 (partial hip replacement)	$478,946	$134,395	$82,107	$183,220	**$878,668**
Total	**$4,677,395**	**$1,618,276**	**$787,660**	**$895,330**	**$7,978,662**

L&I ICD-9 Procedure Codes	2009	2010	2011	2012	Total
00.85 (total hip resurfacing)	$45,193	$36,114	$32,759	$0	**$114,066**
81.51 (total hip replacement)	$1,553,195	$1,569,076	$1,476,288	$1,269,552	**$5,868,111**
81.52 (partial hip replacement)	$120,391	$31,299	$62,664	$77,284	**$291,637**
Total	**$1,718,779**	**$1,636,489**	**$1,571,711**	**$1,346,836**	**$6,273,814**

* includes facility, professional and other payments 17

Hip Resurfacing Re-Review:
State Agency Utilization

All Agencies, Average Paid per Procedure, Current

PEBB ICD-9 Procedure Codes	2009	2010	2011	2012	All Year Average
00.85 (total hip resurfacing)	$26,213	$28,361	$24,644	$32,827	**$27,580**
81.51 (total hip replacement)	$26,989	$28,451	$31,181	$28,919	**$28,937**
81.52 (partial hip replacement)	$37,175	$32,465	$41,222	$20,584	**$33,990**

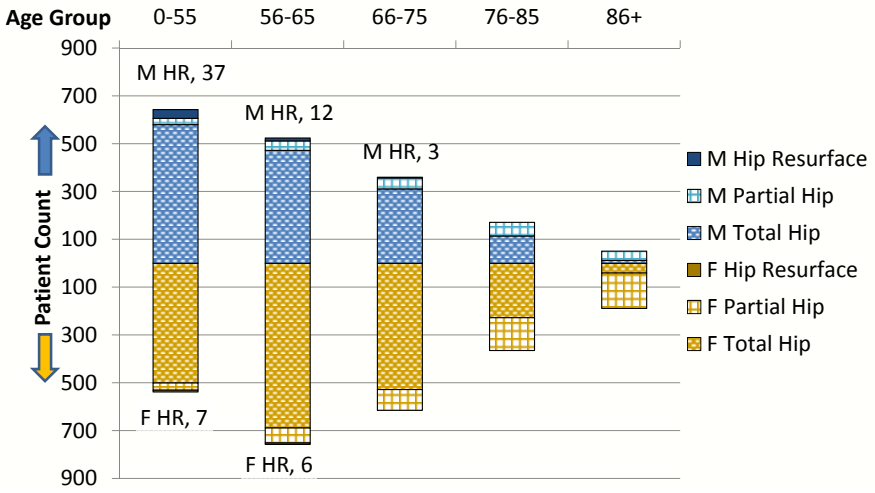
Medicaid ICD-9 Procedure Codes	2009	2010	2011	2012	All Year Average
00.85 (total hip resurfacing)	$11,844	$1,101	$486	$0	**$5,773**
81.51 (total hip replacement)	$16,504	$5,857	$2,967	$3,321	**$7,412**
81.52 (partial hip replacement)	$18,655	$4,807	$2,316	$4,353	**$6,794**

L&I ICD-9 Procedure Codes	2009	2010	2011	2012	All Year Average
00.85 (total hip resurfacing)	$22,596	$18,057	$16,380	$0	**$19,011**
81.51 (total hip replacement)	$18,273	$19,371	$20,504	$18,136	**$19,367**
81.52 (partial hip replacement)	$17,199	$15,649	$15,666	$15,457	**$16,202**

Medicare and Secondary coverage patients were excluded from averages

Hip Resurfacing Re-Review:
State Agency Utilization

Consolidated Agency Hip Resurfacing and Hip Arthroplasty Patients by Age and Gender, 2009-2012



Hip Resurfacing Re-Review

State Agencies' Recommendation:

Hip resurfacing not covered

– But, if covered:

Restrict to group with likely highest benefit and lowest risk, i.e., OA or inflammatory arthritis in setting of favorable bone structure, geometry, and quality (usually men), wanting/needing higher levels of physical activity, <55 years old.

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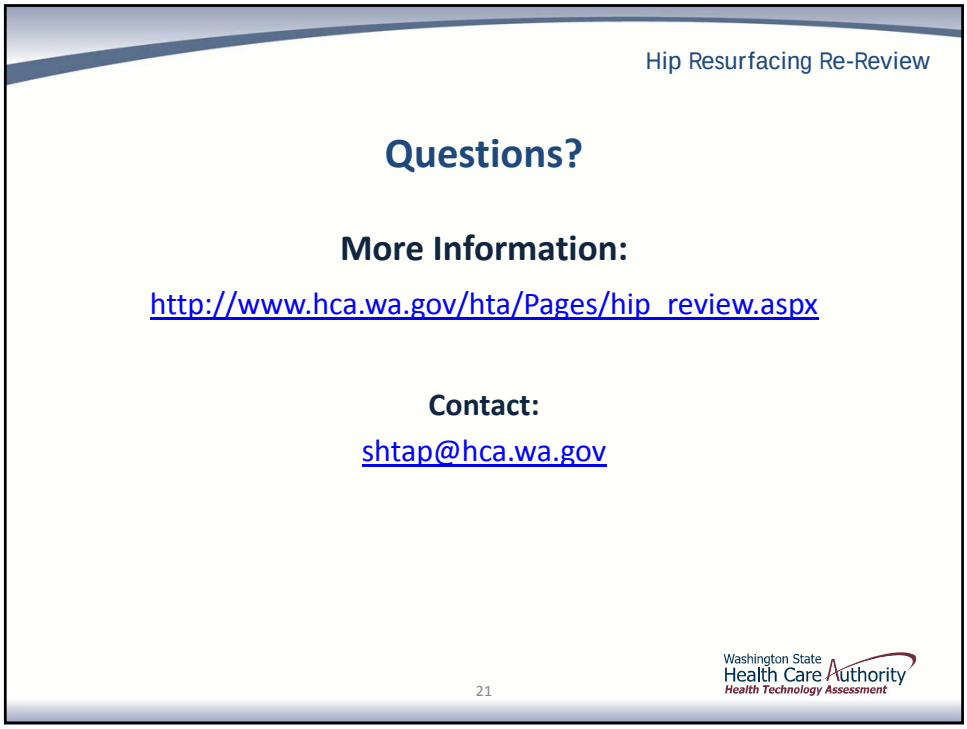
Hip Resurfacing Re-Review
Questions?
More Information:
http://www.hca.wa.gov/hta/Pages/hip_review.aspx
Contact:
shtap@hca.wa.gov
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Hip Resurfacing Technology Assessment an update

Presented by:

Spectrum Research, Inc.

Joseph R. Dettori, Ph.D., M.P.H.
Robin E. Hashimoto, Ph.D.
Kathryn Moran, B.A.

Health Technology Clinical Committee Meeting
WA - Health Technology Assessment Program
Seattle, Washington
November 15, 2013

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Plan for this presentation:

1. **Background for the update – why the update was indicated**
2. **Highlight some of the findings**
3. **Provide conclusions in the context of the strength of evidence and contrast the differences between the original report and the current report**

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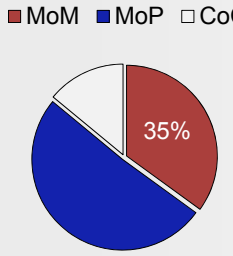
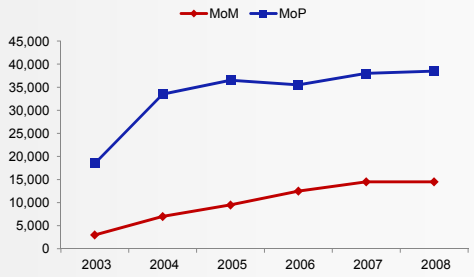
Why An Update?

MoM hip systems (both THA and HR) have received widespread use

Prevalence of bearing surfaces in US in 2006



Frequency of bearing surfaces over time in Australia



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As more information available … safety of MoM hip systems are questioned

J Arthroplasty. 2011 Jun;26(4):511-8. **"Asymptomatic" pseudotumors after metal-on-metal hip resurfacing arthroplasty: prevalence and metal ion study.** Kwon YM et. al.

BMJ. 2011 Sep 20;343:d5977. **Revision rates for metal on metal hip joints are double that of other materials.** Cohen D

BMJ. 2012 Jul 3;345:e4542. Roehr B. **Panel calls for FDA to issue safety advice for metal-on-metal hip replacements.**

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As a result . . .

Assessment (Year)	
American Academy of Orthopaedic Surgeons (AAOS) (2011)	Concerns about increased revision rates, local metal debris release, adverse tissue reactions, and elevated serum metal ion levels in MoM articulations, although not enough data to report clinical significance
FDA Executive Summary Memorandum (2012)	Concerns with local complications, early device failure and the need for revision surgery, and systemic complications form metal ion exposure

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More specifically with respect to total HR:

Assessment (Year)	
California Technology Assessment Forum (2011)	Recent studies, particularly registry evidence shows an increased revision rate with HRA compared with THA Increasing concerns about metal ion levels; need to prove safety and efficacy in RCTs before subjecting young patients to significant potential harm over their lifetimes
Ontario Health Technology Assessment Series (2012)	Concerns about adverse tissue reactions and biological effects of high metal ion levels in the blood were reported by several studies
The Canadian Coordinating Office for Health Technology Assessment (2012)	MoM HR patients experienced higher rates of revision, femoral neck fractures, and component loosening than THA recipients

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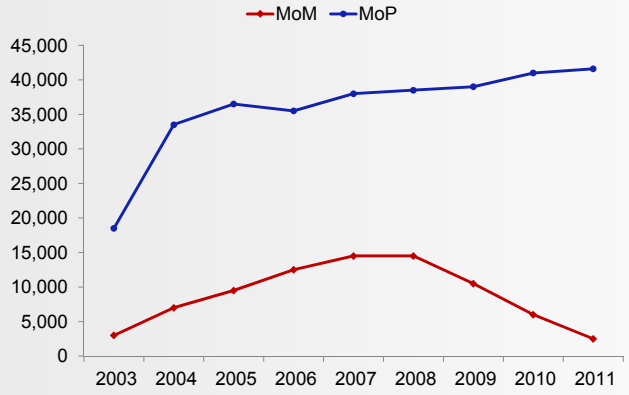
Since these reports surfaced, there has been a dramatic reduction in the number of MoM implants

Frequency of bearing surfaces over time in Australia



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As a result of these concerns, we were asked to update the 2009 report with new available data.

Key Questions

1. What is the evidence of efficacy and effectiveness of hip resurfacing (HR) compared with total hip arthroplasty (THA)?
2. What is the evidence related to the safety profile of HR?
3. **What is the evidence of efficacy, effectiveness and safety of revisions of HR compared with revisions of THA?**
4. Is there evidence of differential efficacy or safety issues with use of HR?
5. What is the evidence of cost implications and cost effectiveness of HR?

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Methods

- **Efficacy / effectiveness**
  Physical function/disability (clinical success, pain, activity, or motion), QoL
- **Safety**
  Revision, complications

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Studies Included

Key Questions	Original	Added to this update
KQ 1,2,4	(n = 4 RCTs) (n = 20 non-RCTs) (n = 3 registry reports)	(n = 2 RCTs) (n = 3 non-RCTs) (n = 3 registry reports)
KQ 3	(n = 2 non-RCTs)	(n = 5 non-RCTs)
KQ 5	(n = 4)	(n = 2)

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Registry studies comparing HR with THA

3 international registry studies:

- **Australian Joint Replacement Registry (2012)**
  - Started in 1999
  - Data from ~300 hospitals
  - THA: 223,000 - HR: 14,900
- **National Joint Registry for England and Wales (2012)**
  - Started 2003
  - Data from National Health Service and private providers
  - THA: 397,000 - HR: 28,000
- **Swedish Hip Arthroplasty Register (2011)**
  - Started in 1979
  - Data from 79 public and private hospitals
  - THA: 347,000 - HR: 1,959

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Key Question 1

What is the evidence of efficacy and effectiveness of total HR compared with THA?

Outcomes efficacy / effectiveness

1. Functional outcome measures (WOMAC, HHS, Oxford; Merle D'Aubigné scores)
2. Quality of life (SF-36, SF-12, EQ-5D)
3. Activity (UCLA, Mont's scoring system)
4. Pain

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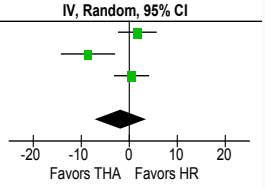
Results –Short Term Efficacy (RCTs)

WOMAC scores

Study or Subgroup	HR Mean	HR SD	HR Total	THA Mean	THA SD	THA Total	Weight	Mean Difference IV, Random, 95% CI
Garbuz	39.3	9.54	48	37.6	10.9	56	34.7%	1.70 [-2.23, 5.63]
Lavigne	45.3	9.97	24	53.9	9.6	24	29.4%	-8.60 [-14.14, -3.06]
Vendittoli	46.6	9.65	82	46.1	12.2	70	35.9%	0.50 [-3.04, 4.04]
Total (95% CI)			**154**			**150**	**100.0%**	**-1.76 [-7.17, 3.65]**

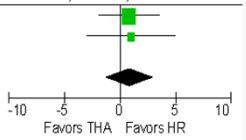
Heterogeneity: Tau² = 17.95; Chi² = 9.69, df = 2 (P = 0.008); I² = 79%
Test for overall effect: Z = 0.64 (P = 0.52)



SF-36 scores

Study or Subgroup	HR Mean	HR SD	HR Total	THA Mean	THA SD	THA Total	Weight	Mean Difference IV, Random, 95% CI
Garbuz	18.5	6.75	48	17.7	7.33	56	68.4%	0.80 [-1.91, 3.51]
Lavigne	7.5	6.75	24	6.5	7.33	24	31.6%	1.00 [-2.99, 4.99]
Total (95% CI)			**72**			**80**	**100.0%**	**0.86 [-1.38, 3.10]**

Heterogeneity: Tau² = 0.00; Chi² = 0.01, df = 1 (P = 0.94); I² = 0%
Test for overall effect: Z = 0.76 (P = 0.45)



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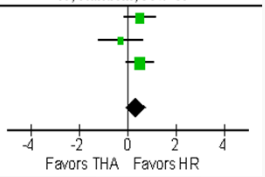
Results –Short Term Efficacy (RCTs)

UCLA activity scores

Study or Subgroup	HR Mean	HR SD	HR Total	THA Mean	THA SD	THA Total	Weight	Mean Difference IV, Random, 95% CI
Garbuz	6.8	1.7	48	6.3	1.7	56	35.6%	0.50 [-0.16, 1.16]
Lavigne	8	1.5	24	8.3	1.7	24	20.5%	-0.30 [-1.21, 0.61]
Vendittoli	7.2	1.9	82	6.7	1.7	70	43.9%	0.50 [-0.07, 1.07]
Total (95% CI)			**154**			**150**	**100.0%**	**0.34 [-0.10, 0.77]**

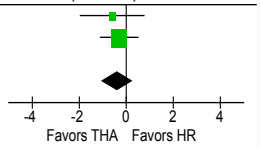
Heterogeneity: Tau² = 0.03; Chi² = 2.44, df = 2 (P = 0.30); I² = 18%
Test for overall effect: Z = 1.51 (P = 0.13)



Merle D'Aubigné scores

Study or Subgroup	HR Mean	HR SD	HR Total	THA Mean	THA SD	THA Total	Weight	Mean Difference IV, Random, 95% CI
Lavigne	6.9	2.49	24	7.5	2.3	24	25.6%	-0.60 [-1.96, 0.76]
Vendittoli	5.9	2.49	82	6.2	2.5	70	74.4%	-0.30 [-1.10, 0.50]
Total (95% CI)			**106**			**94**	**100.0%**	**-0.38 [-1.06, 0.31]**

Heterogeneity: Tau² = 0.00; Chi² = 0.14, df = 1 (P = 0.71); I² = 0%
Test for overall effect: Z = 1.08 (P = 0.28)



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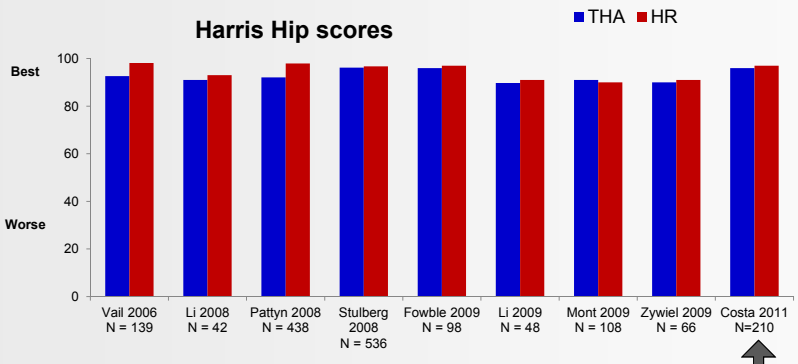
Short Term Effectiveness (Cohort Studies)



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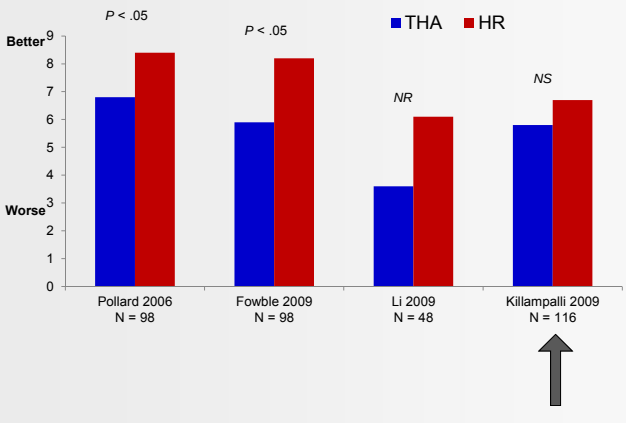
Short Term Effectiveness (Cohort Studies)



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Key Question 2

What is the evidence of safety of HR?

Safety outcomes:

1. Revision
2. Complications
3. Metal Ion

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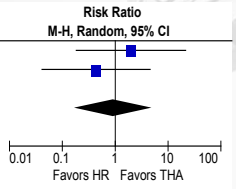
Results – Short Term Revision

RCTs (1-2 year f/u)

Study or Subgroup	HR Events	HR Total	THA Events	THA Total	Weight	Risk Ratio M-H, Random, 95% CI
Vendittoli 2006	2	103	1	102	49.4%	1.9806 [0.1824, 21.5028]
Smolders 2011	1	38	2	33	50.6%	0.4342 [0.0412, 4.5745]
Total (95% CI)		**141**		**135**	**100.0%**	**0.9185 [0.1719, 4.9063]**
Total events	3		3			

Heterogeneity: Tau² = 0.00; Chi² = 0.79, df = 1 (P = 0.37); I² = 0%

Test for overall effect: Z = 0.10 (P = 0.92)

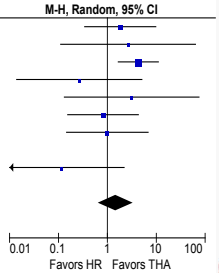


Cohort studies (2-5 year f/u)

Study or Subgroup	HR Events	HR Total	THA Events	THA Total	Weight	Risk Ratio M-H, Random, 95% CI
Vendittoli 2010	4	109	2	100	16.0%	1.8349 [0.3435, 9.8013]
Fowble 2009	1	50	0	44	5.9%	2.6471 [0.1106, 63.3614]
Stulberg 2008	24	283	5	253	29.5%	4.2912 [1.6621, 11.0787]
Costa 2011	0	73	3	137	6.7%	0.2664 [0.0139, 5.0885]
Li 2009	1	39	0	41	5.9%	3.1500 [0.1322, 75.0822]
Vail 2006	2	57	4	93	16.2%	0.8158 [0.1543, 4.3122]
Mont 2009	2	54	2	54	13.2%	1.0000 [0.1461, 6.8437]
Zywiel 2009	0	33	0	33		Not estimable
Pattyn 2008	0	250	3	200	6.6%	0.1144 [0.0059, 2.2019]
Total (95% CI)		**948**		**955**	**100.0%**	**1.4730 [0.6496, 3.3402]**
Total events	34		19			

Heterogeneity: Tau² = 0.36; Chi² = 9.59, df = 7 (P = 0.21); I² = 27%

Test for overall effect: Z = 0.93 (P = 0.35)



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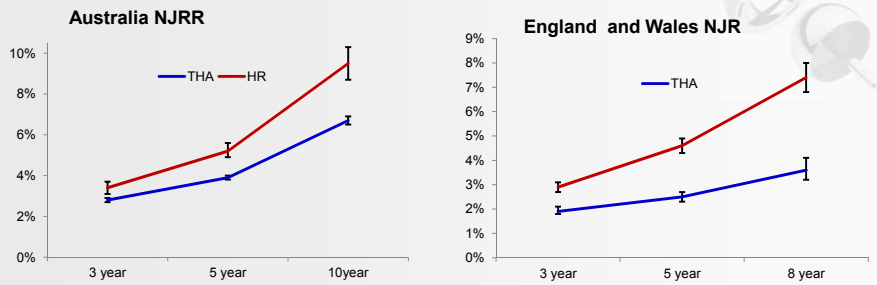
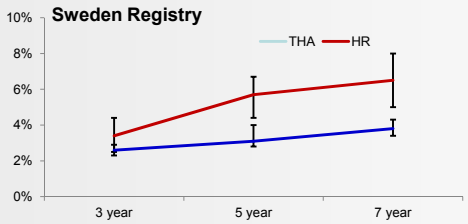
Mid Term Revisions





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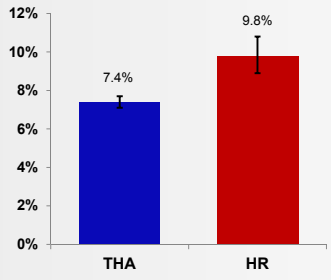
Long Term Revisions



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Other Complications

Complication	THA	HR
Femoral neck fracture	--	2%
Avascular necrosis	--	1%
Femoral component loosening	0.3%	2.7%
Heterotopic ossification	11.4%	19.8%
Dislocation	2.8%	0.5%
Deep infection	1.8%	0.4%

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Metal ion safety concerns

details on pages 80-88 of HTA report

- Elevated Co and Cr serum levels are likely to occur following metal-on-metal HR and THA.
- Concerns over safety of and risks associated with prolonged exposure to metal ions
- High vs. low blood levels of Co and Cr are associated with increased risk of pseudotumors and poor outcomes (revision or poorly functioning hip)
- No association has been found with current lengths of follow-up between metal-on-metal prostheses and cancer or renal function.

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Key Question 3

What is the evidence of efficacy, effectiveness and safety of revisions of HR compared with revisions of THA?

Index Primary Hip Resurfacing (HR_i) —*revised to*→ Hip Resurfacing revised to Total Hip Arthroplasty (HR_{THA})

Index Total Hip Arthroplasty (THA_i) —*revised to*→ Revised Total Hip Arthroplasty (THA_r)

One study
HR_{THA} (n = 23)
THA_r (n = 12)

No difference in SF-12 physical and mental scores; WOMAC pain, stiffness, function and total scores at f/u (2-8 years)

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Key Question 4

Is there evidence of differential efficacy or safety issues with use of hip resurfacing?

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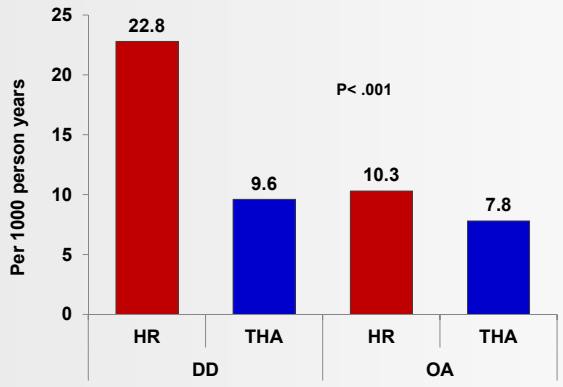
Differential Safety (revisions)

HR in dysplasia vs. other arthritic conditions



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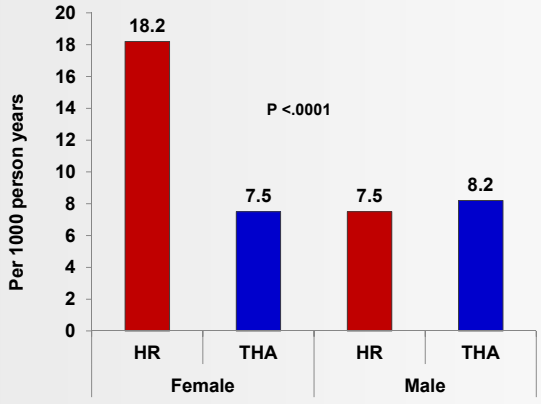
Differential Safety (revisions)

HR in females vs. males:



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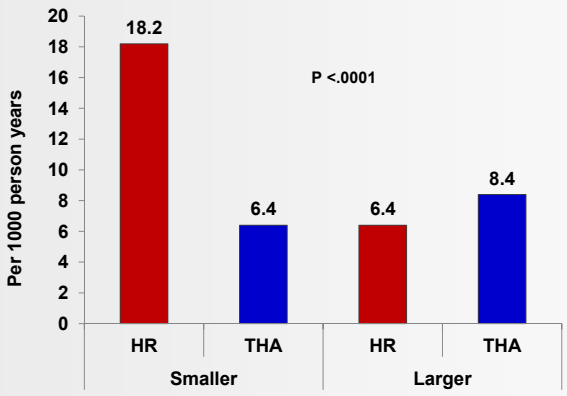
Differential Safety (revisions)



Smaller: HR <50 mm, THA ≤32 mm;
Larger: HA≥50 mm, THA >32 mm

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Key Question 5

What is the evidence of cost implications and cost effectiveness of hip resurfacing?

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Economic Summary

From four published studies and one HTA, results uncertain and dependent on assumptions:

		Revision assumption	Results
McKenzie	cost utility	HR: 1.52% THA: 1.36%	HR slightly more costly throughout 20 yr F/U
Vale (HTA)	cost utility	HR: 0.5% THA: 1.0%	HR more costly than waiting followed by THA
Buckland	cost consequence	Unknown	HR less costly than waiting followed by THA
Bozic 2010	cost utility	Males HR: 0.45% THA: 0.55%	Depends on assumptions HR tended to be cost effective in younger males
Edlin	cost utility	Varying	HR cost effective 78% of time testing various assumptions

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Conclusions Efficacy

Results From 2009 HTA Report	Results From This 2013 Updated HTA Report
Efficacy **(≤1 year):** There is MODERATE evidence from three small randomized controlled trials that total HR is similar to THA with respect to short-term **(1 year)** functional, quality of life, and activity outcome.	Efficacy **(≤2 year)**: There is MODERATE evidence from three small randomized controlled trials that total HR is similar to THA with respect to short-term **(<2 year)** functional, quality of life, and activity outcome.
Efficacy **(>1 year)**: There are NO DATA available to assess efficacy beyond one-year follow-up.	Efficacy **(>2 year):** There are NO DATA available to assess efficacy beyond two-year follow-up.

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Conclusions Effectiveness

Results From 2009 HTA Report	Results From This 2013 Updated HTA Report
Effectiveness (Short-term, <5 years): There is LOW evidence from studies directly comparing total HR with THA to suggest that short-term (≤5 years) patient-reported outcomes, clinician-based outcomes, and pain are similar comparing total HR and THA.	Effectiveness (Short-term, <5 years): There is LOW evidence from studies directly comparing total HR with THA to suggest that short-term (≤5 years) patient-reported outcomes, clinician-based outcomes, and pain are similar comparing total HR and THA.
Activity scores tend to be slightly higher (better) in total HR patients.	Activity scores tend to be slightly higher (better) in total HR patients.
Effectiveness (Mid-term, 5-10 years): There is VERY LOW evidence.	Effectiveness (Mid-term, 5-10 years): There is INSUFFICIENT evidence

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Conclusions Revisions

Results From 2009 HTA Report	Results From This 2013 Updated HTA Report
Revision (Short-term, ≤5 years)	Revision (Short-term, ≤5 years)
There is **MODERATE** evidence that short-term revision rates are slightly higher in patients treated with total HR compared with those treated with THA.	There is **HIGH** evidence that short-term revision risks are higher in patients treated with total HR compared with those treated with THA.
At 3 years: absolute risk: 2.5-4% HR, 1-2.5% THA	At 3 years: 20-50% higher absolute risk: 3% HR, 2-3% THA
	At five years: 30-80% higher. absolute risk: 5-6% HR, 1-4% THA

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Conclusions Revisions

Results From 2009 HTA Report	Results From This 2013 Updated HTA Report
Revision (Mid-term, 6-10 years) There is **LOW** evidence that 7-year revision rates are higher in patients receiving total HR versus THA (hazard ratio = 1.42, rate difference = 1.3%).	Revision (Mid-term, 6-10 years) There is **HIGH** evidence that 7 and 10-year revision risks are higher in patients receiving total HR vs. THA. **At 7-10 years: 40-100% higher absolute risk: 6-9% HR, 3-4% THA**

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Conclusions Revisions

Results From 2009 HTA Report	Results From This 2013 Updated HTA Report
Revision (Long-term, 10+ years) There is **NO** evidence comparing long-term revision rates between total HR and THA.	Revision (Long-term, 10+ years) There is **LOW** evidence that 11-year revision risks are higher in patients receiving total HR (10%) versus THA (7%). **At 11 years: 45% higher absolute risk: 10% HR, 7% THA**

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Conclusions Other Complications

Results From 2009 HTA Report	Results From This 2013 Updated HTA Report
There is **LOW** evidence that the risks of complications are as follows: Femoral neck fractures: 0.4-2.6% avascular necrosis: 0.4-2% femoral component loosening: 0-3.6%, Heterotopic ossification: 0-42.7%	There is **HIGH** evidence that . femoral component loosening **8xs more** in HR vs. THA, 2.7% vs. 0.3% . HO: **2x more** in HR vs. THA, 19.8% vs. 11.4% . **Dislocation 6x less in HR vs. THA, 0.5% vs. 2.8%** **There is MODERATE evidence that deep infection 4x less in HR vs. THA, 0.4% vs. 1.8%** **femoral neck fracture and AVN in HR: 2% and 1%, respectively.**

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Conclusions Metal Ions

Results From 2009 HTA Report	Results From This 2013 Updated HTA Report
Elevated serum Co and Cr in HR Concerns about safety of prolonged exposure to ions with respect to cancer or metabolic disorders	Higher blood Co and Cr in HR vs. conventional THA **High levels of Co and Cr associated with poor outcomes and pseudotumor** **No evidence that MoM hip systems (both HR and THA) are associated with increased cancer risk or renal dysfunction**

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Conclusions, Outcomes of Revisions

Results From 2009 HTA Report	Results From This 2013 Updated HTA Report
This was not a key question in the 2009 HTA report	There is **INSUFFICIENT** evidence to compare the outcomes of revised HA with revised primary THA

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Conclusions Differential Safety

Dysplasia vs. other arthritic conditions

Results From 2009 HTA Report	Results From This 2013 Updated HTA Report
There is **LOW** evidence to suggest that revision rates are twice as high in patients who receive total HR for a primary diagnosis of dysplasia compared with patients of primary osteoarthritis.	There is **HIGH** evidence from a large registry study that the diagnosis of developmental dysplasia (DD) modifies (increases) the rate of revision in HR but not in THA

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Conclusions Differential Safety
Sex

Results From 2009 HTA Report	Results From This 2013 Updated HTA Report
There is **MODERATE** evidence that 3- and 5-year revision rates are higher in females than in males (hazard ratios range from 1.57 to 2.5). Much of the difference in rates between sexes disappears when controlling for femoral component head size; the smaller the head, the higher the failure rate.	There is **HIGH** evidence that sex modifies the rate of revision in hip replacement. Females increase the rate of revision if receiving HR but not THA

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Conclusions Differential Safety
Femoral component head size

Results From 2009 HTA Report	Results From This 2013 Updated HTA Report
Per previous slide	There is **HIGH** evidence that femoral head size modifies the rate of revision in hip replacement. Smaller head size increases the rate of revision in HR but not THA

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Conclusions Cost Effectiveness

Results From 2009 HTA Report	Results From This 2013 Updated HTA Report
There is limited evidence on the economic implications of hip resurfacing.	There is limited evidence on the economic implications of hip resurfacing.
Revision rates are important input factors in the prediction models, and no study estimated the revision rates using current data.	Revision rates are important input factors in the prediction models, and no study estimated the revision rates using current data.

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SPECTRUM RESEARCH

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 three questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

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

Using Evidence as the Basis for a Coverage Decision

Arrive at the coverage decision by identifying for 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 identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. Sufficiency of the Evidence:

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence[4] using characteristics 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).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

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

At the end of discussion a vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome 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

Medicare Coverage and Guidelines

[from page 47 of evidence report]

No national coverage decisions were found for hip resurfacing.

[from page 31 of evidence report]

Clinical Guidelines

National Guideline Clearinghouse

A search of the National Guideline Clearinghouse for metal-on-metal hip resurfacing retrieved one guideline for the use of hip resurfacing.

American College of Occupational and Environmental Medicine (2011)
Hip resurfacing arthroplasty is recommended with a grade of "C" for select patients with osteonecrosis or bilateral osteoarthritis or hip joint disease.
Recommendations are made under the following categories:
Strongly recommended, "A" level
Moderately recommended, "B" level
Recommended, "C" level
Insufficient-recommended (consensus-based), "I" level

National Institute for Health and Clinical Excellence

The National Institute for Health and Clinical Excellence (NICE), (which provides guidance on health technologies and clinical practice for the National Health Service in England and Wales) provided the following guidance in 2012:

a. Metal on metal (MoM) hip resurfacing arthroplasty is recommended as one option for people with advanced hip disease who would otherwise receive and are likely to outlive a conventional primary total hip replacement. In considering hip resurfacing arthroplasty, it is recommended that surgeons take into account activity levels of potential recipients and bear in mind that the current evidence for the clinical and cost effectiveness of MoM hip resurfacing arthroplasty is principally in individuals less than 65 years of age.

b. When MoM hip resurfacing arthroplasty is considered appropriate, the procedure should be performed only in the context of the ongoing collection of data on both the clinical effectiveness and cost effectiveness of this technology. Ideally, this data collection should form part of a UK national joint registry.

c. This guidance should be read in conjunction with the Institute's guidance on devices for total hip replacement (Guidance on the selection of prostheses for primary total hip replacement: NICE Technology Appraisal Guidance No 2. April 2000). In that guidance, the Institute recommended that the best prostheses (using long-term viability as the determinant) should demonstrate a 'benchmark' revision rate (the rate at which they need to be replaced) of 10% or less at 10 years or, as a minimum, a 3 year revision rate consistent with this 10-year benchmark. Establishing and confirming similar benchmarking criteria will be necessary for MoM hip resurfacing arthroplasty and will be facilitated by a UK national joint registry. In the interim, the 3 year minimum benchmark should apply to MoM hip resurfacing devices.

c. MoM hip resurfacing arthroplasty should be performed only by surgeons who have received training specifically in this technique.

d. Surgeons should ensure that patients considering MoM hip resurfacing arthroplasty understand that less is known about the medium- to long-term safety and reliability of these devices or the likely outcome of revision surgery than for conventional total hip replacements. This additional uncertainty should be weighed against the potential benefits claimed for MoM devices.

HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

Discussion Document: What are the key factors and health outcomes and what evidence is there?

Safety Outcomes	**Safety Evidence**
Revision	
Complications	
Metal ion effects	
Femoral neck fractures	
Avascular necrosis	
Component loosening	
Heterotopic ossification	
Dislocation	
Infection/deep infection	
Safety of revision	
Efficacy – Effectiveness Outcomes	**Efficacy / Effectiveness Evidence**
Pain	
Physical Function/disability	
Quality of Life	
Activity (level)	
Motion	
Revision- efficacy/effectiveness	
Special Population / Considerations Outcomes	**Special Population Evidence**
Age	

Race/ethnicity	
Gender	
Condition-dysplasia, OA	
Femoral head size	
BMI	
Cost	**Cost Evidence**
Direct cost, product/procedure	
Cost-effectiveness	

Clinical Committee Evidence Votes

First Voting Question
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.

Is there sufficient evidence under some or all situations that the technology is:

	Unproven (no)	**Equivalent** (yes)	**Less** (yes)	**More** (yes)
Effective				
Safe				
Cost-effective				

Discussion
Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second Vote
Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is

_____Not Covered _____ Covered Unconditionally _____ Covered Under Certain Conditions

Discussion Item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon?

Clinical Committee Findings and Decisions

Next Step: Cover or No Cover
If not covered, or covered unconditionally, the Chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next Step: Cover with Conditions
If covered with conditions, the Committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?
   - Refer to evidence identification document and discussion.
   - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
   - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.

2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
   - What are the known conditions/criteria and evidence state
   - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff ; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

fficacy Considerations:

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices

Safety

- What is the evidence of the effect of using the technology on 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.
- Other morbidity concerns
- Short term or direct complication versus long term complications
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost Impact

- 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?

Overall

- What is the evidence about alternatives and comparisons to the alternatives
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?