Washington State Health Care Authority

Artificial disc replacement – Re-review

Draft evidence report:
Peer review, comment and response

December 5, 2016

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Artificial Disc Replacement – Re-review

Provided by:

Spectrum Research, Inc.

Draft Evidence Report

Peer Review, Public Comment & Response

December 5, 2016

Responses to Clinical and Peer Reviewers (Section 1, Table 1)

Responses to Public Comments (Section 2, Table 2)

Spectrum Research is an independent vendor contracted to produce evidence assessment reports for the Washington HTA program. For transparency, all comments received during the public comment periods are included in this response document and appendix. Comments related to program decisions, process, or other matters not pertaining to the evidence report are acknowledged through inclusion only.

This first section responds to clinical and peer reviews received from the following parties:

Draft Report Peer Review

- Michael J. Lee, MD; Associate Professor, Spine, Department of Orthopaedics and Rehabilitative Medicine, University of Chicago Medical Center
- James S. Harrop, MD; Professor of Neurological Surgery and Orthopedic Surgery, Jefferson Medical College, Department of Neurosurgery

Specific responses pertaining to peer reviewer comments are included in Table 1.

Responses to public comment may be found in Table 2.

Full text of peer review and public comments follows in the Appendix.

Table 1. Responses to Clinical and Peer Reviewers

Comment		Vendor Response
Clinical, Peer Review: Michael J. Lee, MD		
	Specific comments:	
Background	The background section adequately reviews the current literature on the topic of spinal disc replacement in the lumbar and cervical spine	Thank you for your comments.
Objectives	The objectives are clearly defined in the key questions section	Thank you for your comments.
Methods	The methodology is transparent and reproducible. The authors of the report adequately abstracted and analyzed the data from the defined studies. Rating of Level of Evidence is clearly explained. Inclusion and exclusion criteria are clearly defined as well. There are no major objections to the methodology of this review.	Thank you for your comments.
Results	The results section is well organized. By the nature and number of studies addressing this topic, the results section is expectedly busy. However, the tables, figures and appendices are easy to follow. There are weaknesses in this literature, which the review very clearly describes.	Thank you for your comments.
CONCLUSIONS Comments	This section is a little bit challenging to read. Ideally a summary section of the conclusions based on the analyses would be in this section, but is not. Fortunately, the conclusion summaries with respective levels of evidence of support are listed in from pages 6-13. In addition, the authors include the summaries from the 2008 report. In general, the authors conclude that L-ADR appears to be comparable to lumbar fusion in the treatment of symptomatic degenerative disease (low quality evidence). They also conclude that 1-2 C-ADR may be superior to ACDF in safety and efficacy,(low to moderate quality evidence). After reviewing the methodology and the results, I do feel that these conclusions are supported by the results. The conclusions are valid but should also be interpreted cautiously. For example, when concluding that single level C-ADR is superior to ACDF in efficacy and safety (page 11), readers should keep in mind that the indications for C-ADR are strict and the minority of patients will have them. All patients who are candidates for C-ADR are also candidates for ACDF, but the converse is not true. Thus, while some evidence suggests that C-ADR is superior to ACDF, this should not be interpreted as a new standard of treatment but rather as an additional alternative for select patients. However, these results do suggest that ADR continues to be an efficacious and safe alternative to fusion of the spine (in appropriately selected patients).	Thank you for your comments and clinical pespective.

	Comment	Vendor Response
OVERALL PRESENTATION and RELEVANCY	Overall, the review is well structured and organized. The main points are clearly presented. I would have suggested that the conclusions listed in page 6-13 be listed in the conclusions section, but that is perhaps a preference of organization. This topic continues to be relevant to clinical medicine and also for public policy. This review suggests that ADR in general is at least comparable to or superior to spinal fusion in appropriately selected patients. Though the evidence is at best moderate quality, the evidence does not suggest that this technology is inferior to fusion. If discectomy and fusion continue to be accepted treatments for spinal disease, then this review suggests that there is a role for ADR. However, the indication and effectiveness of discectomy and fusion differ depending on if it is done in the cervical or lumbar spine.	Thank you for your comments and clinical pespective.
Quality of report	**Quality Of the Report** (Click in the gray box to make your selection) **Superior x** **Good** **Fair** **Poor**	Thank you.
	Comment	**Vendor Response**
Clinical, Peer Review: James S. Harrop, MD		
	Specific comments:	Responses
Introduction	• Overview of topic is adequate? Yes needed topic. • I would recommend changing the name to spinal arthroplasty since the title artificial disc is more of a layperson terminology as somewhat implies a less scientific approach. • Did you do an Artificial Hip review? • Further you may wish to clarify that cervical and lumbar regions are both included or even separate these 2 topics since they are not typically included in spine reviews or discussion • Topic of assessment is important to address? Yes rapidly evolving and poorly understood in terms of impact • The intro discusses back pain which is lumbar issue. If this is a combined review would discuss axial spine pain. • Discusses csm which is not typically an indication for cervical arthroplasty. Paragraph should discuss cervical spondylosis and radiculopathy in younger patients as	Thank you for your comments and clinical perspective. • To avoid confusion with the previous report, the name will remain the same but we have introduced the term “spinal arthroplasty” in the background. • No, we did not do a review for WA State on artificial hip. • Edits clarifying that both cervical and lumbar disc arthroplasty are part of the report have been made. In keeping with the format of the original report, the organization has been retained. For the original report, the State had requested that lumbar and cervical arthroplasty be combined into one report. • Reference to CSM has been amended and moved. Edits to

	Comment	Vendor Response
	this is the population targeted with cervical arthroplasty	the introduction and background include additional information on axial back pain, and discussion of spondylosis and radiculopathy.
Background	See comments above	Thank you for your comments.
Objectives	• Key questions are appropriate. The relevant questions are asked about effectiveness, safety and cost. Could be improved by clearly identifying the subpopulations that the review includes and discusses • The series excludes lumbar patient with prior surgeries. There is some indication that lumbar arthroplasty was effective in patients with persistent pain after a discectomy which would fall out in this review	Thank you for your comments. • Yes, patients with prior surgery were excluded in keeping with the scope of the original report.
Methods	• "The scope of this report and final key questions were refined based on input from clinical experts from a variety of disciplines and public comments received on draft key questions." Why not list all the expert fields to show diversity? • Pertinent studies were critically appraised independently by two reviewers based on Spectrum's Class of Evidence (CoE) system" Was there any disagreement? And how was this resolved? This should be included in the manuscript	Thank you for your comments • Clinical expertise included spine surgery and physical therapy. Edits have been made accordingly. • Edits describing resolution have been added. Discrepancies in assessment were rare; they were discussed and resolved by consensus; a third reviewer was consulted if needed.
Results	• In lumbar the analysis notes that in 2008 there was moderate evidence but in 2016 there is low quality evidence but his was using the same data (2 rct studies) why were 2 RCT downgraded? As noted "Evidence is based on the same two IDE trials included in the2008 report." • Lumbar Same issues with data downgrade in safety. Would think 5 yr fu would indicate improved safety profile • Cervical data well done	Thank you for your questions and comments. • The strength of evidence (SoE) rating for the 2008 report was based on a modified approach to GRADE; since then, additional guideance on the application of GRADE has been published by the GRADE Working Group and AHRQ. The SoE grading in the updated report reflects the more contemporary detailed approach. • Lumbar safety results were down graded for the same risk of bias concerns noted for the efficacy outcomes and for earlier time frames for the safety outcomes. In addition for one trial, data were only available for 43% of the original study population at 5 years, which may

	Comment	Vendor Response
		create selection bias. Additional down grading was done for precision for some safety outcomes; sample size may have been inadequate particularly for rare events.
Conclusions	• Conclusions summaries are somewhat lost in the context of the data. Bolding and separating these sections would improve their visibility and usefulness to the readers. The data and conclusions are valid based on the data • Would separate into 2 reports	Thank you for your comments • We've attempted to highlight major conclusions across outcomes in the Executive Summary in the results tables beginning on page 7 of the report. Separate tables for lumbar and cervical arthroplasty are presented. For Section 5, which has detaile SoE tables, we have directed readers to this somewhat more concise summary. The more detailed strength of evidence tables - we agree that these may be challenge to work through, yet they provide a transparent basis for the conclusions in the results summaries tables comparing the 2008 and current report. • In keeping with the format of the original report, both lumbar and cervical arthroplasty are in the same report.
Overall Presentation and Relevancy	• See above	
Quality of Report	*Quality Of the Report* (Click in the gray box to make your selection) **Superior x** **Good** **Fair** **Poor** • Very well done with a great deal of data • Overall would break into a cervical and lumbar Report in that these are completely separate patient populations and indications.	Thank you!

RESPONSES TO PUBLIC COMMENT ON DRAFT REPORT

Spectrum Research is an independent vendor contracted to produce evidence assessment reports for the Washington HTA program. For transparency, all comments received during the public comment periods are included in this response document. Comments related to program decisions, process, or other matters not pertaining to the evidence report are acknowledged through inclusion only.

This second section responds to comments received from the following parties:

- Jeffrey D. Zigler, JD; Senior Director- Market Access, Health Economics and Reimbursement, Zimmer Biomet
- Spencer Parr, Washington Law Center, Tukwila, Washington (email only)

Specific responses pertaining to comments are included in Table 2 below.
Complete comments submitted are attached following responses in the Appendix.

Table 2. Responses to Public Comment

	Comment	Vendor Response
Commenter: **Jeffrey D. Zigler, JD, Zimmer Biomet**		
	Specific comments:	
General comment	We recognize that you made a clear delineation between lumbar and cervical ADR in your evidence report, which reflects key clinical and evidentiary distinctions between these two treatment options. We provided comment on the draft Key Questions to this point, and are pleased to see the evidence report takes these nuances into account.	Thank you for your comments.
Background Section 1.1	It may initially be unclear to readers of this evidence report that reference to "six months" of failure of nonoperative (conservative) care is specific to lumbar ADR, and not to C-ADR. In relevant part, we recommend the following edit: *"Surgery may be considered when nonoperative treatments ~~for at least six months~~ fail to relieve symptoms attributed to spinal DDD or to prevent progression of nerve damage in the case of adiculopathy or myelopathy. " (redaction added)* Though this distinction in length of conservative care as a prerequisite to surgery is clarified in subsequent paragraphs, the mention of "six months" without qualification is confusing.	Thank you for your suggestion. The background has been edited to reflect the FDA approved indications for C-ADR which include: • Failure of at least six weeks of nonoperative treatment (except ProDisc-C and Prestige LP)

	Comment	Vendor Response
Section 2.6 Medicare and Representative Private Insurer Coverage Policies	we recommend more accurately depicting the current state of U.S. commercial health insurers with publicly available medical policies that favor use of one- and two-level C-ADR for their members. Based on membership in America's Health Insurance Plans (AHIP), we have tracked over 95 organizations with coverage policies favoring one level C-ADR; and 36 with favorable two-level C-ADR coverage policies. Based on AHIP medical plan enrollment data, we estimate that more than 200 million commercially insured Americans have access to one-level C-ADR; and over 150 million have access to two-level C-ADR. This is over twice the amount of people who had access since just one year ago. We find it extremely compelling that all of these distinct payer organizations, many of which maintain robust, thorough evidence reviews and scientific committees to annually review and update policies now allow coverage of the C-ADR treatment option for single- and two-level cervical disc disease. The list of health insurers with coverage policies for one- and two-level CADR, as well as enrollment numbers based on 2016 AHIP estimates, is attached.	Thank you for your comments Per the vendor contract with the State, the CMS NCD and information from a minimum of two bellwether payers are provided in secion 2.6; the list is not intended to be exhaustive. Information from Aetna, United Healthcare, Cigna, Harvard Pilgrim Healthcare and Premara Blue Cross is provided all of which are represented on the commenter's list. (Appendix at the end of this response document contains commenter's list of payers.)
Included Literature	The list of publications used for this review, while extensive, does not cover all the relevant C-ADR literature. We recommend three papers from two FDA IDE studies to be included within this review, as they add valuable analysis of the outcomes for C-ADR versus ACDF. In 2014, Dr. Reginald Davis published a detailed report of the comparison of the safety and effectiveness of two-level treatment with Mobi-C to ACDF at a mid-term time point (Davis R. et al Two-Level Total Disc Replacement with Mobi C Over 3- Years Coluna 13(2):97-103, 2014). Including this paper adds to the evidence of C ADR's clinically relevant benefits over ACDF. Dr. Matthew Gornet has published both two- and seven-year outcomes for the Prestige LP FDA IDE study (Gornet M. et al Cervical disc arthroplasty with Prestige LP disc versus anterior cervical discectomy and fusion: a prospective, multicenter investigational device	Thank you for your comments. The citations listed do not meet inclusion criteria for this report and/or data from the trial are already represented in the report. 1. Davis, *Coluna* 2014 citation provides results at 36 months. With regard this Mobi-C trial, we have reported 48 and 60 month data from Davis 2015 (ref #22) and Radcliff 2016 (ref #61) (subsequent publications for the Mobi-C 2 level IDE trial). These publications also included 36 month results. As stated in our methods, outcomes were stratified by duration of follow-up based on commonly reported time points: 24 months, 48-60 months, and 84 months. When more than one follow-up time was reported within the 48-60 month category, data from the longest duration available within that category was used. The *Coluna* journal does not appear to be indexed in PubMed.

	Comment	Vendor Response
	exemption study. J Neurosurg Spine 23:558-573, 2015. Gornet M. et al Cervical Disc Arthroplasty with Prestige LP Disc Versus Anterior Cervical Discectomyand Fusion: Seven-Year Outcomes. IJSS 10:24. 2016). Both of these papers contribute Level 1 evidence proving statistical superiority of C-ADR over ACDF in overall success.	2. Gornet M. J Neurosurgery Spine 23:558-573 2015 was excluded at title abstract level. Per methods used for our review, studies other than RCTs or comparative studies with *concurrent* controls were excluded. The Gornet 2015 study compares ADR trial data with an historical control group data and thus did not meet inclusion criteria. 3.Gornet IJSS 10:24. 2016 similarly compares ADR trial data with an historical control group data and thus did not meet inclusion criteria and would be excluded at title/abstract level. This study was published after our search dates.
NASS and ISASS Statements	In addition, both NASS and ISASS have issued policy statements on the use of C-ADR as a viable alternative treatment option for select patients with symptomatic 1- and 2-level cervical myelopathy or radiculopathy (Coric D. ISASS Policy Statement - Cervical Artificial Disc. IJSS 8:6. 2014). Including policy statements from key spine surgeon societies underscores the support for C-ADR from experts in the community.	The report includes formal evidence-based clinical practice guidelines formulated by professional organizations. The intention is to focus on those that are listed/indexed by the National Guideline Clearinghouse. Coverage policy statements by organizations are not included. The NASS *Diagnosis and Treatment of Cervical Radiculopathy from Degenerative Disorders (2010)* is included in the report. The Coric article provides a summary of selected C-ADR trial data but does not constitute a formal evidence-based clinical guideline. Data from the trials described in this citation that met our inclusion criteria were included and synthesized in our report.
Key Question 3	In addition to the peer-reviewed publications on RCTs and comparative analyses, it should also be noted that an analysis of 575 Mobi-C IDE trial patients, randomized to either CADR with the Mobi-C device or ACDF surgery at one or two levels, was stratified for age, and followed-up at 5 years. [Hisey M. et al Impact of Age on Patient Outcomes after Cervical Disc Arthroplasty or Anterior Cervical Discectomy and Fusion: Comparison at 5-Year Follow-up. Paper presented at the meeting of the International Society for the	Thank you for your comments and information. The Hisey citation is from a conference proceeding and does not meet the pre-specified inclusion criteria for this report.

	Comment	Vendor Response
	Advancement of Spine Surgery, Las Vegas, NV. (2016, April)] Results were presented by Hisey et at. at the 2016 International Society for the Advancement of Spine Surgery conference. Researchers found that age was not a significant predictor of success in terms of NDI or subsequent surgical intervention when adjusting for gender, treatment, or levels treated. Alternatively, there was a trend in younger ACDF patients to have a higher rate of subsequent surgery.	
	In addition, we compared patients receiving a Mobi-C Cervical Disc in the IDE trial, based on workers compensation status. Notably, we found no subsequent surgeries following the initial cervical ADR for workers compensation patients. Other improvements were similar between the two groups receiving cervical ADR, which was sustained at 84 months' follow-up:	Thank you for your comments. The data provided do not compare ADR with ACDF. (The data related to this comment can be found in the appendix.)
Subsequent Surgery	We believe the rate of subsequent surgery following one- and two-level C-ADR deserves further review than is apparent in the draft evidence report, as an important surrogate for meaningful clinical improvement aside from the success criteria as defined in the FDA IDE studies of this therapy option. You appropriately cite the 5-year analysis of subsequent surgeries from the Mobi-C study, reported by Jackson et al (Journal of Neurosurgery 2016). The results reported in this study are further evidence of the positive treatment effect seen in C-ADR patients, because it looks at freedom from subsequent surgeries in a different way than in other articles. In reporting the results of the FDA IDE study at 5 years' follow-up, Radcliff et al (Journal of Neurosurgery 2016) found the reoperation rate was significantly lower with Mobi-C versus ACDF. However, this article defines secondary cervical surgery in terms of study failure, meaning an index level reoperation only. By this definition, the proportion of Mobi-C patients who were deemed "study failure" by secondary surgery at the index level (4%) was lower than that of the ACDF patients (16%).	Thank you for your comments. We have reviewed them and our reporting of subsequent surgery. Across included studies, definitions of success, failure and subsequent surgeries varied substantially. Our analysis reflects data that could be synthesized across studies. Radcliff defined subsequent surgeries this way: "…in either treatment group was strictly defined as a revision, removal, reoperation, or supplemental fixation at the index level." Jackson defined subsequent surgeries this way: "…was considered to be any operation that occurred at the initial treatment level or at adjacent levels after the primary operation." In the report we analyzed subsequent surgery at the index and adjacent level separately, and reported as such (We do not report overall subsequent surgeries but the info is available in the appendix). We specifically chose not to use subsequent index surgeries in terms of "study failure" because it is hard to know what that means

	Comment	Vendor Response
	By contrast, the Jackson article covers the entire spectrum of secondary cervical surgery at index and I or adjacent level(s), and this reflects the overall total. The significant difference is sustained, at 7.3% subsequent surgery rate for C-ADR patients, versus 21.0% of ACDF patients having some kind of secondary cervical surgery at the index and I or adjacent level(s).	exactly (since so many of the IDE trials used composite outcomes which include index level surgery as a criteria). Radcliff specifically makes the following 2 statements at the bottom of p.5: "…There were significantly fewer index-level secondary surgeries (p=0.0003) that were classified as study failures in the cTDR (4% [9/225]) vs. ACDF group (16.2% [17/105])"… and then says in the following paragraph…"There were significantly more index-level reoperations in the ACDF group (16.2%) than in the cTDR group (4.3%)." It was unclear how these two statements differed exactly (the % is slightly different in the cTDR group). Thus, we reported only the pure index level surgeries and chose to go with Jackson. The numbers reported by Jackson – 4.7% (11/234) for TDR and 18.1% (19/105) – are very close to those reported by Radcliff and in fact make cTDR look better. Regarding Jackson, the denominator in the TDR group is different from that used in Radcliff and includes 9 training cases assessed for safety/subsequent surgery (234 vs. 225). Inclusion of training cases violates random assignment and is a potential source of bias.
	Finally, we continue to study the long-term impact of C-ADR with recently released results of 7 years' followup. We recognize that your inclusion criteria for this evidence report does not allow for abstracts, podium presentations or posters presented at scientific congresses. However, please let us know if you would like to better understand these results as we would be happy to provide them	Thank you for your comments.
Commenter: **Spencer Parr, JD, Washington Law Center**		
General Comments	Spencer Parr's comments are included in their entirety in the appendix to this response document.	Thank you for your comments. The email/comment is addressed to the Health Technology Clinical Committee. The comments relate to the Health Technology Assessment Program process and function of the Health Technology Clinical Committee and do not require a response from the evidence vendor, Spectrum Research, Inc.

APPENDIX: CLINICAL/PEER REVIEWS AND PUBLIC COMMENTS RECEIVED

CLINICAL/PEER REVIEW # 1: Michael J. Lee, MD

Thank you for your willingness to read and comment on the Comprehensive Evidence-Based Health Technology Assessment Review for the **Artificial Disc Replacement Re-review Report** Your contribution and time are greatly appreciated.

The general time commitment ranges between 2 and 4 hours; we are able to pay a maximum of 6 hours.

The report and appendices are available at: http://www.hca.wa.gov/about-hca/health-technology-assessment/artificial-discs

This form can be filled out electronically on your personal computer. Enter your identification information and comments directly into the shaded areas; use the **TAB** key to move from field to field. Please enter the section, page, and line numbers where relevant. The shaded comment field will expand as you type, allowing for unlimited text. You have been provided comment fields in each section. Should you have more comments than this allows for, please continue with a blank page. Additionally, we are very interested in your evaluation of the ease of use of our Peer Review Form. Please use the last field to enter suggestions for improvement.

We will be going through the draft for typographical errors as well as grammatical and minor edits, allowing you to focus on the substance/content of the report.

When the Peer Review form is complete, save it to your hard drive and return as an e-mail attachment to: andrea@specri.com

I will need your review by November 18, 2016 at the latest. If you have questions or concerns please contact andrea@specri.com. Thanks!

Reviewer Identification Information

Reviewer Name	**Michael J Lee**
Address	**Street 5841 S Maryland Ave MC3079** **City Chicago** **State IL** **Zip Code 60637**
Phone	**7738343531**
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E-mail	**Mlee5@bsd.uchicago.edu**

INTRODUCTION Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Overview of topic is adequate?
- Topic of assessment is important to address?

- Public policy and clinical relevance are well defined?

Page	Line

Enter Comments Here

The overview of this important topic is certainly adequate in the introduction section. The objectives and policy relevance are clearly described.

BACKGROUND Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Content of literature review/background is sufficient?

Page	Line

Enter Comments Here

The background section adequately reviews the current literature on the topic of spinal disc replacement in the lumbar and cervical spine.

REPORT OBJECTIVES & KEY QUESTIONS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Aims/objectives clearly address relevant policy and clinical issue?
- Key questions clearly defined and adequate for achieving aims?

Page	Line

Enter Comments Here

The objectives are clearly defined in the key questions section.

METHODS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Method for identifying relevant studies is adequate?
- Criteria for the inclusion and exclusion of studies are appropriate?
- Method for Level of Evidence (LoE) rating is appropriate and clearly explained?
- Data abstraction and analysis/review are adequate?

Page	Line

Enter Comments Here

The methodology is transparent and reproducible. The authors of the report adequately abstracted and analyzed the data from the defined studies. Rating of Level of Evidence is clearly explained. Inclusion and exclusion criteria are clearly defined as well. There are no major objections to the methodology of this review.

RESULTS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Amount of detail presented in the results section appropriate?
- Key questions are answered?
- Figures, tables and appendices clear and easy to read?
- Implications of the major findings clearly stated?
- Have gaps in the literature been dealt with adequately?
- Recommendations address limitations of literature?

Page	Line

Enter Comments Here

The results section is well organized. By the nature and number of studies addressing this topic, the results section is expectedly busy. However, the tables, figures and appendices are easy to follow. There are weaknesses in this literature, which the review very clearly describes.

CONCLUSIONS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Are the conclusions reached valid?

Page	Line

Enter Comments Here

This section is a little bit challenging to read. Ideally a summary section of the conclusions based on the analyses would be in this section, but is not. Fortunately, the conclusion summaries with respective levels of evidence of support are listed in from pages 6-13. In addition, the authors include the summaries from the 2008 report. In general, the authors conclude that L-ADR appears to be comparable to lumbar fusion in the treatment of symptomatic degenerative disease (low quality evidence). They also conclude that 1-2 C-ADR may be superior to ACDF in safety and efficacy,(low to moderate quality evidence). After reviewing the methodology and the results, I do feel that these conclusions are supported by the results.

The conclusions are valid but should also be interpreted cautiously. For example, when concluding that single level C-ADR is superior to ACDF in efficacy and safety (page 11), readers should keep in mind that the indications for C-ADR are strict and the minority of patients will have them. All patients who are candidates for C-ADR are also candidates for ACDF, but the converse is not true. Thus, while some evidence suggests that C-ADR is superior to ACDF, this should not

be interpreted as a new standard of treatment but rather as an additional alternative for select patients. However, these results do suggest that ADR continues to be an efficacious and safe alternative to fusion of the spine (in appropriately selected patients).

OVERALL PRESENTATION and RELEVANCY Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Is the review well-structured and organized?
- Are the main points clearly presented?
- Is it relevant to clinical medicine?
- Is it important for public policy or public health?

Page	Line

Enter Comments Here

Overall, the review is well structured and organized. The main points are clearly presented. I would have suggested that the conclusions listed in page 6-13 be listed in the conclusions section, but that is perhaps a preference of organization. This topic continues to be relevant to clinical medicine and also for public policy. This review suggests that ADR in general is at least comparable to or superior to spinal fusion in appropriately selected patients. Though the evidence is at best moderate quality, the evidence does not suggest that this technology is inferior to fusion. If discectomy and fusion continue to be accepted treatments for spinal disease, then this review suggests that there is a role for ADR. However, the indication and effectiveness of discectomy and fusion differ depending on if it is done in the cervical or lumbar spine.

QUALITY OF REPORT

Quality Of the Report
(Click in the gray box to make your selection)

Superior x
Good
Fair
Poor

Page	Line

Enter Comments Here

We would appreciate any feedback you have on the usability of this form. Please add comments in the field below.

This form was relatively easy to use.

CLINICAL/PEER REVIEW #2: James S. Harrop, MD

Thank you for your willingness to read and comment on the Comprehensive Evidence-Based Health Technology Assessment Review for the **Artificial Disc Replacement Re-review Report** Your contribution and time are greatly appreciated.

The general time commitment ranges between 2 and 4 hours; we are able to pay a maximum of 6 hours.

The report and appendices are available at: http://www.hca.wa.gov/about-hca/health-technology-assessment/artificial-discs

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We will be going through the draft for typographical errors as well as grammatical and minor edits, allowing you to focus on the substance/content of the report.

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I will need your review by November 18, 2016 at the latest.

If you have questions or concerns please contact andrea@specri.com. Thanks!

Reviewer Identification Information

Reviewer Name	**James Harrop MD**
Address	**Street 909 Walnut Street – third floor** **City Philadelphia** **State PA** **Zip Code 19107**
Fax	**215-503-7007**
E-mail	**James.harrop@jefferson.edu**

INTRODUCTION Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Overview of topic is adequate? Yes needed topic. I would recommend changing the name to spinal arthroplasty since the title artificial disc is more of a layperson terminology as somewhat implies a less scientific approach. Did you do an Artificial Hip review? Further you may wish to clarify that cervical and lumbar regions are both included or even separate these 2 topics since they are not typically included in spine reviews or discussion
- Topic of assessment is important to address? Yes rapidly evolving and poorly understood in terms of impact

- Public policy and clinical relevance are well defined?

Page 1	Line 1

The intro discusses back pain which is lumbar issue. If this is a combined review would discuss axial spine pain.

Page 1	Line para 2

Discusses csm which is not typically an indication for cervical arthroplasty. Paragraph should discuss cervical spondylosis and radiculopathy in younger patients as this is the population targeted with cervical arthroplasty

Page	Line

Enter Comments Here

BACKGROUND Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Content of literature review/background is sufficient?

Page	Line

See comments above

Page	Line

Enter Comments Here

REPORT OBJECTIVES & KEY QUESTIONS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Aims/objectives clearly address relevant policy and clinical issue?
- Key questions clearly defined and adequate for achieving aims?

Page	Line

Key questions are appropriate. The relevant questions are asked about effectiveness, safety and cost. Could be improved by clearly identifying the subpopulations that the review includes and discusses

Page	Line

The series excludes lumbar patient with prior surgeries. There is some indication that lumbar arthroplasty was effective in patients with persistent pain after a discectomy which would fall out in this review

Page **Line**

METHODS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Method for identifying relevant studies is adequate?
- Criteria for the inclusion and exclusion of studies is appropriate?
- Method for Level of Evidence (LoE) rating is appropriate and clearly explained?
- Data abstraction and analysis/review are adequate?

Page 3 **Line**

"The scope of this report and final key questions were refined based on input from clinical experts from a variety of disciplines and public comments received on draft key questions." Why not list all the expert fields to show diversity?

Page 3 **Line**

"**Pertinent studies were critically appraised independently by two reviewers based on Spectrum's Class of Evidence (CoE) system**"
Was there any disagreement? And how was this resolved? This should be included in the manuscript

Page **Line**

RESULTS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Amount of detail presented in the results section appropriate?
- Key questions are answered?
- Figures, tables and appendices clear and easy to read?
- Implications of the major findings clearly stated?
- Have gaps in the literature been dealt with adequately?
- Recommendations address limitations of literature?

Page 6 **Line**

In lumbar the analysis notes that in 2008 there was moderate evidence but in 2016 there is low quality evidence but his was using the same data (2 rct studies) why were 2 RCT downgraded? As noted "Evidence is based on the same two IDE trials included in the2008 report. "

Page 7 **Line**

Lumbar Same issues with data downgrade in safety. Would think 5 yr fu would indicate improved safety profile

Page	Line

Cervical data well done

CONCLUSIONS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Are the conclusions reached valid?

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Conclusions summaries are somewhat lost in the context of the data. Bolding and separating these sections would improve their visibility and usefulness to the readers. The data and conclusions are valid based on the data

Page	Line

Would separate into 2 reports

Page	Line

Enter Comments Here

OVERALL PRESENTATION and RELEVANCY Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Is the review well structured and organized?
- Are the main points clearly presented?
- Is it relevant to clinical medicine?
- Is it important for public policy or public health?

Page	Line

See above

Page	Line

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Page	Line

Enter Comments Here

QUALITY OF REPORT

Quality Of the Report
(Click in the gray box to make your selection)

Superior x
Good
Fair
Poor

Page	Line

Very well done with a great deal of data

Page	Line

Enter Comments Here

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Enter Comments Here

We would appreciate any feedback you have on the usability of this form. Please add comments in the field below.

Overall would break into a cervical and lumbar Report in that these are completely separate patient populations and indications.
PUBLIC COMMENT #2: Spencer Parr, Washington Law Center

Received by Spectrum Research via email from the Health Technology Assessment Program 11/22/2016.

From: Spencer Parr [mailto:spencer@washingtonlawcenter.com]
Sent: Tuesday, October 25, 2016 3:35 PM
To: HCA ST Health Tech Assessment Prog <SHTAP@HCA.WA.GOV>
Subject: artificial disc replacement comments

Dear HTCC members:

It is an awesome and terrible responsibility to decide the civil rights of those needing to choose between equally dispiriting medical options such as multi-level fusion and multi-level disc replacement. Those with "MPH" behind their names seem (by program indoctrination & "training") to be so enthralled with practicing population-based medicine rather than permitting expert physicians to practice patient-based medicine with each individual seeking treatment for sometimes quite different conditions. Why an Endocrinologist, Chiropractor, Naturopath, Family Medicine Physician or any of the rest of you committee members think you should have the UNAPPEALABLE power to decide Neurosurgery standards for the rest of us and our entire Washington citizenry is a mystery. The morality and medical ethics of deciding without any deference to each and every more-qualified practicing physician and her/his patient is deficient and should see every one of you lose your medical license for complicity.

BECAUSE, there exists no study anywhere that can tell you committee members how much intractable pain and disability it takes before a particular parent will eventually take their life due to a lack of hopeful treatment options. Approximately every 18 months or so (average) a client of the undersigned attorney takes their life due to having no hope remaining after treatment options are denied by state agencies ("just following the rules") or otherwise exhausted. The worst case in undersigned counsel's memory involved a family that subsequently introduced the fallen mother's six year old little girl, all of us ashamed that our systems of government and justice absolutely forgot the collateral damage left in the wake of very stupid, big-brained people like yourselves sitting around talking so optimistically about "statistical powers," as if those were the sole consideration when practicing medicine. Shame on that grotesque idea.

But you all have to do it, right? It has to be done by someone, correct? This is why the HTCC exists… You have to divorce your statistics-based decision from uncollected, unanalyzed human factors when deciding whether to authorize a two-level disc replacement at non-adjacent discs versus having the patient submit to a five-level, complex instrumentation and fusion that will permanently destroy the mobility of their spine, right? That kind of medical problem solving shouldn't just be deferred to the treating Neurosurgeon as inappropriate for strictly-construed written mandates, right? Because that is precisely the disastrous choice presented to one of my clients at present, with all insurance interests now waiting intently by agreement to see what the HTCC "determination" will be. Will it be for patient choice if there are no clear contra-indications? Will that be a recognized or guiding principle? Will you decide that a 61-year old

might still have enough productive vitality as to be given all the available medical options if they are relatively fit for their age, or will you quite arbitrarily ration all care at age 60 as before?

No, you all still have moral choices to make even though you sit on the HTCC. Moreover, you don't get to celebrate the nobility of your profession while abandoning the scientific reality that bright-line rules in medicine are generally detrimental to the quality of patient care, even across large populations, no matter what the MPH-induced myopia sufferers say. You have no proper moral place to pronounce by your grossly-underqualified group fiat that real men and women should be denied their freedoms of medical choice and self-determination to undergo such surgical options as may be tailor-fit to their specific medical facts. You especially act with moral indecency when you know that the decisions of the committee bind all participating state agencies, and the courts have thus far DISALLOWED ANY APPEAL even if the patient might otherwise be able to prevail should the questions of medical propriety and necessity be tried favorably in a court of law. The courts do not even allow a workers' compensation claimant, for example, to challenge the Department of Labor and Industries for an exception to the "guideline" decision pronounced by your committee. See Joy v. Department of Labor & Industries if you haven't read it already.

Every one of you should either vote consistently to approve all procedures, thereby leaving the choices to doctors who practice real clinical medicine, or you should protest the lack of appealable nature for all pronouncements of your committee by withholding your votes or resigning your posts until an appeal process is allowed by the state of Washington. Your votes do not form "guidelines," in the sense that term is utilized by honorable medical professionals and scientific academies elsewhere. They have instead been interpreted as pure medico-legal mandates (which cannot even be appealed on the merits) whenever you have recommended denying coverage, including when you denied OATS ankle surgery merely because you didn't know if you had enough information to approve it (the reasoning shown in the minutes of that particular meetings are so embarrassing).

Your votes denying OATS ankle surgery (as just one horrific example of medical hubris) have left people crippled. Your votes denying other procedures, including implantable spinal chord stimulators, have literally caused suicides and other excess deaths nowhere recorded by the lackluster researchers at Spectrum Research, Inc., or elsewhere. Congratulations on that….of literally acting to the detriment of patients because you weren't wise enough to ensure that there is an appeal outlet by which to test the propriety of the most obscene denials of care under supposed authority of your determinations. Your attempt to decide really complex medical questions by bright-line rules of statistics, devoid of the fundamental compassion or humble awareness (those things which are supposed to drive the "honor" of your "healing" profession), instead renders your function quite despicable. You might just as well be sorting people out in lines in a WWII concentration camp, deciding between those who get to work themselves to death and those who must instead march straight to the ovens.

Shame on you. Shame on all of you for participating. You are literally terrible human beings.

Too strong? Come meet a little six-year old girl I know.

Sincerely,

Spencer Parr

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