Public Comments Summary
Elective Lumbar Fusion Surgical Bundle and Warranty

We appreciate the many valuable and constructive comments by over 60 respondents during our public comment period. As a result of these comments the workgroup:

- On page 2, added that "Medicaid should fund the elements of the bundle"
- On page 5, changed smoking avoidance to a minimum of four weeks.
- Agreed that imaging standards are not absolute. The workgroup changed the text on page 4 made the change to "a departure from these (imaging) guidelines requires discussion and resolution by the collaborative team…"
- Agreed that acupuncture is supported by evidence as a component of non-surgical care (citations 28 and 29 on evidence table). The workgroup changed the text on page 5 made the change to "…other evidence-based non-surgical therapies may be used at the discretion of the collaborative care team."
- Agreed that the bundle should explicitly include spine surgeon is a member the collaborative team. The workgroup changed the text on page 4 made the change to "…the care team should include…an appropriate spine surgeon… to ensure delivery of comprehensive non-surgical care…"
- Agreed that the definition of disability should be more explicit. The workgroup changed the text on page 5 changed to "At least two of the following should be considered in defining persistent disability:
    - Greater than 20% disability as defined by the Oswestry Disability Index
    - Persistent disability according to PROMIS indicators
    - Persistent disability on baseline physical function by physical therapist using the Therapeutic Associates Outcome Score, defined as equal to or greater than 20% disability."
- Agreed that outcome data is an option for satisfying the requirement for surgeons with less than 20 cases per year. The workgroup changed the text on page 7 changed to "If the surgeon performs less than twenty lumbar fusion surgeries in the previous 12 months, an alternative is presenting the results of the quality indicators as specified in this bundle."
- Agreed that while registries are an essential element of improving quality, they are also costly. Spine SCOAP is a local community standard. Other national registries in which providers are participating may also meet the Spine SCOAP standard. The workgroup changed the text on page 8 to "Hospitals should participate in the Spine SCOAP registry or an equivalent national registry that meets or exceeds Spine SCOAP standards with results available to purchasers."
- Added facility codes for lumbar fusion to the warranty.

While we anticipate that some provisions of the bundle and warranty remain areas in which there are differences of opinion, comments were reviewed by our workgroup and weighed against available

medical evidence. The Elective Lumbar Fusion Bundle and Warranty were adopted by the provider, purchaser, health plan, and quality organizations that comprise the Bree Collaborative on September 17th 2014 with two changes,

- Removing the alternative way of meeting the requirement on page 7 under Cycle III, Spinal Fusion Procedure, General standards for a surgical team performing surgery, “If the surgeon performs less than twenty lumbar fusion surgeries in the previous twelve months, an alternative is presenting the results of the quality indicators as specified in this bundle”
- Removing the alternative method of meeting the requirement of participating in a registry on page 8 to be used in place of Spine SCOAP, “Hospitals should participate in the Spine SCOAP registry or an equivalent national registry that meets or exceeds Spine SCOAP standards…”

Bree Lumbar Fusion Bundle Public Comment

SurveyMonkey

1. What sector do you represent? (Choose the option that is the best fit.)

	Response Percent	Response Count
Orthopedic surgeons	9.1%	5
Neurosurgeons	12.7%	7
Physiatrists	0.0%	0
Other health care providers (primary care physicians, physical therapists, nurses, etc.)	**40.0%**	**22**
Hospitals	9.1%	5
Government/Public Purchasers	0.0%	0
Employers	1.8%	1
Health Plans	5.5%	3
Consumers/Patients	3.6%	2
Self	1.8%	1
Other (please specify)	16.4%	9
	answered question	**55**
	skipped question	**0**

2. Do you support the concept of a bundled payment model for lumbar fusion?

		Response Percent	Response Count
Yes		**41.8%**	**23**
No		34.5%	19
Neutral/No Opinion		23.6%	13
		answered question	**55**
		skipped question	**0**

3. Do you have any comments about the bundled payment concept?

	Response Count
	24
answered question	**24**
skipped question	**31**

4. Do you agree with the proposed components of the first section (Disability Despite Non-Surgical Therapy)?

		Response Percent	Response Count
Yes		**56.4%**	**31**
No		30.9%	17
Neutral/No Opinion		12.7%	7
		answered question	**55**
		skipped question	**0**

5. Any comments about the first section?

	Response Count
	26
answered question	**26**
skipped question	**29**

6. Do you agree with the proposed components of the second section (Fitness for Surgery)?

		Response Percent	Response Count
Yes		**61.8%**	**34**
No		18.2%	10
Neutral/No Opinion		20.0%	11
	answered question		**55**
	skipped question		**0**

7. Any comments about the second section?

	Response Count
	17
answered question	**17**
skipped question	**38**

8. Do you agree with the proposed components of the third section (Spinal Fusion Procedure)?

	Response Percent	Response Count
Yes	**41.8%**	**23**
No	25.5%	14
Neutral/No Opinion	32.7%	18
answered question		**55**
skipped question		**0**

9. Any comments about the third section?

	Response Count
	19
answered question	**19**
skipped question	**36**

10. Do you agree with the proposed components of the fourth section (Post-Operative Care and Return to Function)?

	Response Percent	Response Count
Yes	**65.5%**	**36**
No	18.2%	10
Neutral/No Opinion	16.4%	9
answered question		**55**
skipped question		**0**

11. Any comments about the fourth section?

	Response Count
	12
answered question	**12**
skipped question	**43**

12. Do you agree with the proposed quality standards?

		Response Percent	Response Count
Yes		**61.8%**	**34**
No		25.5%	14
Neutral/No Opinion		12.7%	7
	answered question		**55**
	skipped question		**0**

13. Any comments about the standards (or other measures that you believe should be included)?

	Response Count
	18
answered question	**18**
skipped question	**37**

14. Do you support the concept of a warranty for lumbar fusion?

		Response Percent	Response Count
Yes		**45.5%**	**25**
No		32.7%	18
Neutral/No Opinion		21.8%	12
		answered question	**55**
		skipped question	**0**

15. Do you have any comments about lumbar fusion warranty?

	Response Count
	16
answered question	**16**
skipped question	**39**

16. Do you have any comments about the evidence table?

	Response Count
	15
answered question	**15**
skipped question	**40**

17. Please provide any general comments about the documents here:

	Response Count
	16
answered question	16
skipped question	39

18. Name:

	Response Count
	36
answered question	36
skipped question	19

19. Email address:

	Response Count
	36
answered question	36
skipped question	19

20. Organization:

	Response Count
	35
answered question	35
skipped question	20

Page 2, Q1. What sector do you represent? (Choose the option that is the best fit.)		
1	hospital and regional clinic network	Aug 19, 2014 4:07 PM
2	Patient Safety Advocacy Member WA State	Aug 14, 2014 11:28 AM
3	neuroradiologist	Aug 13, 2014 12:30 PM
4	Director Spine SCOAP Collaborative	Aug 12, 2014 9:05 PM
5	physical therapist	Aug 12, 2014 2:22 PM
6	pharmacist	Aug 10, 2014 2:54 PM
7	Mental health supervisor	Aug 10, 2014 8:51 AM
8	radiologists	Aug 8, 2014 3:27 PM
9	Academic	Jul 25, 2014 10:12 AM

Page 2, Q3. Do you have any comments about the bundled payment concept?		
1	I do simple and complex fusions. They are not the same. A one level and 5 level surgery are not the same. A one level surgery isn't the same as another one level surgery. Some people don't instrument and others find it essential to prevent complication. Those that don't shouldn't be reward and those that do shouldn't be penalized for doing the right thing for the patients. Some surgeons do almost nothing at the time of surgery (on-lay fusion only) while more modern surgeons try to correct deformity and improve nerve space (decompression and disc height restoration). Using the word "fusion" is a poor label of what modern spinal surgery for complex lumbar disease is and "fusion" doesn't describe the actual procedure.	Aug 19, 2014 1:12 PM
2	• The concept of a fixed payment for a bundle of services is a potentially promising payment approach which has gained attention by both commercial and public sectors. The unnecessary overuse of lumbar fusion surgery is a serious issue and WSHA fully supports efforts to improve care and reduce costs. We are also aware that recent reports illustrate issues in developing and successfully operationalizing a bundle payment (Health Affairs, 2014). Coordinating payment across different systems and across different provider types will be challenging. Adoption in integrated systems may be simpler than in those with independent physicians and facilities. If purchasers move forward with these approaches, they may be providing additional incentives to accelerate the move to integration and consolidation. Given some of the challenges, WSHA suggests Bree consider a one to two year pilot test of the bundle before major policy and payment reforms are adopted. A one to two year pilot period would allow stakeholders to disseminate and gain comfort with best practices, develop the appropriate technical infrastructure and links between providers while providing useful data on challenges or opportunities with the bundle. The information gained from the pilot period would aid the Bree Implementation Team in their efforts gain adoption of the bundle across Washington State. WSHA also would suggest Bree consider if there can be amendments to the specific proposed bundle that would still meet the state's objectives, if a system or payer adopts a similar but not identical model. Is there a process to review alternative configurations? We have specific comments on each of the sections as well. We look forward to having Bree consider and address these overall implementation issues as well as some of the specific concerns provided in sections below.	Aug 19, 2014 1:03 PM
3	Seems reasonable, but I do not fully understand the pros and cons of bundled payments. I agree with the standards used to determine which patients will benefit from the surgery.	Aug 18, 2014 8:36 PM
4	Many factors may monopolize a bundled concept, necessitating the allocation of resources to the most immediate at the expense of the long term	Aug 18, 2014 5:48 PM
5	Unintended consequences on the amount of total time spent on the care of the patient, especially those patients with complexities/acuity.	Aug 18, 2014 3:06 PM
6	There are many variables that will affect successful rehab. Some patients may take longer to heal. I equate the bundled payment concept with a capitated system and that is not always the best way to go.	Aug 15, 2014 7:10 PM
7	Lumbar spine pathology is quite varied with many patients requiring a unique surgical approach. For example, often patients may require an agressive	Aug 15, 2014 4:52 PM

Page 2, Q3. Do you have any comments about the bundled payment concept?		
	laminectomy and removal of facets to adequately decompress the neural elements and thus require a posterior stabilazation and fusion with/without an interbody support/fusion. This is a vastly different surgical procedure compared to a patient that is undergoing a fusion surgery with only mild stenosis, but mechanical back pain secondary to a spondylolisthesis. In this patient, a minimal decompression with stabilization may be the best surgical recommendation for the patient.	
8	The practical implications of meeting the metrics may be onerous and some recommendations may be too rigid to meet evidence based standards.	Aug 15, 2014 1:16 PM
9	The bundled payment concept suffers from a basic lack of understanding by its authors of the heterogeneity of low back pain patients and their underlying pathology and a increasingly diverse availability of treatment approaches.. Tellingly there is no discussion of the purpose of the Lumbar Fusion Payment bundle such as cost savings presented. The sole intended purpose appears to be a rather blatant restriction of access to care. The authors focus on a rather outdated and simplistic sagittal translational instability model as sole 'validated' indication for fusion, ignoring lateral listhesis, kyphosis, rotatory displacement and other degenerative conditions. Disease severity is not captured by the present bundle concept - clearly a lower grade spondylolisthesis has a lower risk profile than a higher grade spondylolisthesis. Clearly non modifiable risk profiles of a patient considered for fusion affect the invasiveness of a procedure as well. Single level and multilevel; procedures will require differentiated bundle packages as well. In terms of coding current ICD-9 coding is notoriously inadequate for accurately catching the disease entities at hand. With the pending conversion to ICD-10 a comprehensive relabeling using ICD-10 would seem apropos to avoid the need for dual coding.	Aug 14, 2014 10:16 PM
10	It seems somewhat odd that the document actually does not offer an argument for cost savings with transition to a bundled payment model. It may be difficult to bundle such a uniform procedure that treats such a heterogeneous population of patients with a wide array of diagnoses and conditions. There are many different indications for lumbar fusions, and many different reconstructive strategies that are used in the lumbar spine. Due to the variety of procedure options, individual patient treatments may be very different and are best captured with application of a CPT coding instead of ICD-9 or DRG nomenclature. An overly restrictive approach that reduces the breadth of lumbar spine fusion procedures to a few bundled payments will not properly reflect the diversity of lumbar pathology and the variety of treatment options available. This approach may be a significant disservice to patients, who may find their access to care for their lumbar disease limited. One approach would be to develop a variety of different, potentially overlapping treatment bundles. There could be one bundle for a grade one spondylolisthesis and another bundle for a grade two spondylolisthesis. Specific unique procedures, such as resection of a Gill fragment is treatment of an isthmic spondylolisthesis, could merit their own additional coding. Much more complex cases with higher risks of intraoperative lacerations, such as a revision lumbar fusion or revision of a previous laminectomy should similarly be identified. Realizing the impact of BMI on operative time, difficulty of positioning, and potential risk of post-operative complications could provoke developing a bundle for patients with a BMI above 35 and another bundle for patient with a BMI below 25. More extensive multi-level surgery will mandate separate bundles.	Aug 14, 2014 9:45 PM

Page 2, Q3. Do you have any comments about the bundled payment concept?		
11	Excellent approach with broad benefits for consumers, providers and hospitals	Aug 14, 2014 11:28 AM
12	The bundled concept puts an undue and unrealistic hardship on physicians to manage aspects of patients that affect post-surgical outcomes but that are not under their direct control, such as behavioral and psychosocial factors (weight management, mood, anxiety, active pain coping, employment, and the presence of secondary gain considerations). While these issues are mentioned in terms of pre-surgical work-up, they do not seem to receive as much attention in the post-surgical guidelines--even though they should be expected to affect outcomes. I believe that physicians should be paid for all of the work they do, including coordinating the care of more complex patients, and that this is not adequately addressed in bundled payment concepts.	Aug 13, 2014 5:37 PM
13	There is significant variability in patient characteristics that can require different lengths of stay, different implants, and different procedures to perform the fusion. Lumping them all together only works for very large groups where the variability averages out.	Aug 13, 2014 1:56 PM
14	MDs other than physiatrists should be able to manage the initial care process	Aug 13, 2014 12:30 PM
15	I disagree with the vast majority of recommendations in the bundle and appendix. These recommendations are capricious, arbitrary, lack evidence for efficacy in spine surgery, are contrary to and violate the collaborative relationships established between Wa State spine care stakeholders, participating in Spine SCOAP. The BREE Spine Work Groups's pronouncement is clearly designed from the perspective of payers and health plans, not from the perspective of the Spine SCOAP Collaborative,.based on evidence and measuring quality from the patient's perspective. This BREE Lumbar Spine Fusion Bundle should be condensed to one single, impactful, proven recommendation,.All spine surgery done in Wa. State should be tracked in Spine SCOAP.	Aug 12, 2014 9:05 PM
16	I am not sure if pre-operative or post-operative physical therapy is included in the bundled payment. If so, it does not seem appropriate to include PT due to high complication rate and cognitive/behavioral issues that might eat up payment.	Aug 12, 2014 2:22 PM
17	Not sure how this would work unless all the providers are under one roof in order to collaborate and communicate. Concept is good.	Aug 8, 2014 5:01 PM
18	this is not an assembly line. each patient is different and requires individualized care. bundling payments places too much risk on the organization that would deal with the complications that regularly occur. Including infection, implant failure, adjacent segment disease, fracture, pneumonia etc. The financial risk should fall to the patient and the insurance company. that is what insurance companies do, insure against risk.	Aug 8, 2014 4:30 PM
19	Bundles encourage performance of the procedure(s) in the bundle versus alternative care. Most of the warranty options have too easy a way to avoid. Does not represent a substantial portion of the total medical spend so very limited and resource consuming to operationalize	Aug 8, 2014 2:08 PM
20	The bundle appears to reflect an opportunity enhance specific components of medical necessity review guidelines and consider certain facilities as centers of	Aug 8, 2014 5:37 AM

Page 2, Q3. Do you have any comments about the bundled payment concept?		
	excellence for these procedures. The State should consider a consistent evaluation/ approach to identifying those meeting the standards delineated in the document. It would seem most consistent if the State identified those facilities and altered the benefit design to shift the utilization to those meeting the standards.	
21	It is not going to help patients nor physicians. It does not incorporate Level 1 evidence studies, but is mostly expert opinion.	Aug 6, 2014 10:41 AM
22	There is no mention of "alternative care" which some people find very helpful (acupuncture, massage)	Jul 28, 2014 11:33 AM
23	A step in the right direction for quality and payment.	Jul 28, 2014 10:53 AM
24	Making the payment model dependent upon hospitals' mandatory participation is too onerous and costly. The state should fund the project and collect data themselves. Hospitals are already inundated with state initiatives requiring data collection. I also disagree with using SCOAP spine as the vehicle for data collection. It is both cumbersome and costly to hospitals.	Jul 27, 2014 9:17 AM

Page 2, Q5. Any comments about the first section?

1	Section I A. I document Oswestry scores for patients. I do not think measurement of all of these measures is useful and it is cumbersome to patients in pain to complete all of these forms. Requiring a PT to document these would require in many cases, the patient to return at their own out of pocket cost back to the therapist for paperwork completion or in some cases where therapy isn't a covered of the insurance they have. I B. These numbers are not born out of any literature. The best data to date on listhesis comes from the SPORT study (J Bone Joint Surg Am. 2009 Jun;91(6):1295-304.). Grade I listhesis patients comprise most of this studies patients and most improved. Requiring mm's was not a part of that study and functionally doesn't make sense. If a patient has a 5 mm canal and has a 4 mm spondyolisthesis, that would be more significant that a 10 mm spondylolisthesis in a patient with 20 mm canal. Numbers don't also account for foraminal disease which is common in these patients. I C. Not every patient lives in a metropolis setting with access to PT, physiatrists, and a full team of people to care for their issues. Driving can take 3-4 hours just to find one person able to care for them. It is discriminatory to require them to make 3 3-hour trips for many times for 3 months just because they haven't chosen to live in a major city. I C 1 d. You are requiring surgeons to manage anxiety and depression prior to surgery. I have no expertise in the those fields and not every patient has access to mental health care in this state. That is a problem the state needs to solve and not one you can mandate on physicians that do not manage these problems. I C 3. You chose spinal manipulation as an option. Please cite even one scientific evidence for the reference that chiropractic care has a long-term positive effect on spondylolisthesis or back problems in general. I D. All of these requirements are arbitrary selections. If a patient starts with an ostwestry of 50 and makes it to 60, that is a good outcome? That is a horrible outcome. A PT outcome of 10% intially that gets 20% better is a good outcome? That is a horrible outcome. You can't label these things in stone. Since surgery has a statiscically better chance of helping patients, how can you exclude patients with horrible non-operative outcomes.	Aug 19, 2014 1:12 PM
2	• WSHA supports many of the concepts identified in the first section. We have specific concerns and questions with some components as they relate to access to care and assessment tools. These are noted in the subsequent section of the survey. • WSHA supports the concept of a collaborative care team model, but we do not understand the statement that, “The physiatrist is accountable for leading the team…” How does a purchaser or payer determine this is occurring and is it critical in order to determine if a provider system is offering the appropriate bundle of care? How is a physiatrist ‘accountable’ and for all services offered across different systems? WSHA encourages the Bree Collaborative to refine section one to reflect greater flexibility and collaboration across providers and the patient. Requiring a physiatrist to be “accountable for leading the team…” may impact access, especially in rural areas. A query of the American Academy of Physical Medicine and Rehabilitation database for practicing physiatrist members in Washington State shows a high concentration of physiatrists along the I-5 corridor. The rigidity of the bundle, coupled with the potential lack of available physiatrist in rural communities might require a patient who is experiencing back pain to travel a considerable distance over “at least [a] three month” period to a facility that could meet the model established in the bundle. WSHA encourages the Bree Collaborative to consider the potential unintended impact of the bundle on access to care and determine if there can be greater flexibility in the collaborative care team model. • The requirement of “at least three months of structured non-surgical therapy” and “active physical	Aug 19, 2014 1:03 PM

Page 2, Q5. Any comments about the first section?		
	therapy" appears to be premised on: 1) those services being readily available within a patient's immediate community, 2) providers ability to accept Medicaid patients, and 3) those services being covered benefits, as offered by the payer/purchaser. It is unclear what access to physical therapy services is across Washington State, especially in rural communities. Additionally, if the payer/purchaser does not offer a full range of coverage for the appropriate services, then a patient could be faced with the prospect of paying for those therapy services out-of-pocket. This represents a barrier to care and could impact patient health and well-being. WSHA recommends the Bree Collaborative consider the effect of these recommendations on Medicaid patients and those in rural areas. We are still gathering data on the geographic distribution of physical therapists and Medicaid reimbursement for physical therapy services and will share information when we know more. • Section I.A.3 "Document standardized baseline physical function by physical therapist using the Therapeutic Associates Outcome Score." Having spoken with representatives from Therapeutic Associates, Inc. (the copy write owner of the above mentioned tool) it is WSHA's understanding that the functional assessment tool is a proprietary product, and as such, would impose added operating expense on the provider. WSHA recommends the Bree Collaborative determine if alternative non-proprietary reporting options can be used. Also, it appears as if the 'Therapeutic Associates Outcome Score' has been changed to 'CareConnections Outcome System.'	
3	I use the Therapeutic Asso Outcomes measures (TAOS/Careconnections) for many years and appreciate it's usability and true results for outcomes.	Aug 19, 2014 10:59 AM
4	thorough	Aug 18, 2014 5:48 PM
5	I really support the use of the CareConnections functional assessment tool use by Therapeutic Associates. We use this tool in our clinics and find it very useful for setting goals and determining functional outcomes.	Aug 18, 2014 3:11 PM
6	CareConnection TAOS instrument delivered by PT is an effective idea to measure function	Aug 15, 2014 10:21 PM
7	No	Aug 15, 2014 7:10 PM
8	1. Instability definition of 4mm is stated, yet there is no reference and patients with severe radicular and axial back pain with movement of 3.5 mm are excluded. There is no standard in practice or in the literature. There are many instances that a grade II or III spondylolisthesis does not move on flex/ex imaging, but can obviously be the cause of the patient's disability. 2. The concept of a physiatrist leading the team and would be responsible for determining and approving the patient as a surgical candidate. This is quite alarming since physiatrist have absolutely no training in surgery and is beyond the scope of their practice. As a neurosurgeon and former fellowship director that has trained numerous spine surgeons throughout the country, I know that indications for surgical intervention are foremost on excellent outcomes. Neurosurgeons receive this education and training throughout the rigorous 6-7 years of residency and many often receive another year of training during fellowship. Orthopedic spine surgeons also receive training during their spine fellowship in regard to indications for surgery. If a physiatrist who does not perform these types of surgeries is mandated to determine surgical candidates,	Aug 15, 2014 4:52 PM

Page 2, Q5. Any comments about the first section?		
	this is a serious flaw. As stated in the Bree Collaborative, this lumbar model was taken from the TKR and THR, are physiatrist determing who has hip and knee surgeries as well. Also, one of the most alarming problems with this is the role of conflict of interest. I find it to be troublesome that there is a disproportionate number of physiatrists on the Bree Collaborative Lumbar Spine Work Group as outline on the website. This suggests that physiatrists are now going to be shunting more business to them....this is appalling. Finally, are the physiatrist going to assume the role of discussing why the surgery was not successful in the cases where the patient is unhappy with their outcome? 3. Although the Bree Collaborative is attempting to use the paucity of level I evidence to support lumbar fusions, is there really any evidence that a physiatrist or a team approach would demonstrate better outcomes. The only team approach that I know that is being utilized in the state of Washington is at Virginia Mason (which includes Group Health spine surgeons as well). This group approach was utilized after an intraoperative death occurred and there were serious patient care issues that arose leading to a moratorium on large spine surgeries until the development of a team was formed in order to determine surgical candidates. This may be beneficial in helping younger, more inexperienced surgeons with their judgment, but I am not sure there is any evidence to demonstrate a better surgical outcome.	
9	I B) Also needs: 3. When required decompression is anticipated to destabilize the spine due to extent of facet resection. (Otherwise complication rates (and costs) will actually increase in this subset of patients in whom re-operation would have to be performed to address the resulting instability) Comment regarding I D): I could envision a scenario where a patient improves by 11 points in their ODI with nonoperative care but is still dissatisfied with their quality of life due to either a very poor starting point or desire for better functional outcome than their 11-point improvement has allowed for. This criterion seems too stringent, as currently written. The resulting (rhetorical) questions would be: If the patient then stops improving but is stuck at an unsatisfactory level, would fusion then be ok? What is the time frame for this process? IE does the clock re-start once the patient has improved by 11 points and another 3 months of nonoperative therapy is performed to see if additional improvement has occurred?	Aug 15, 2014 1:16 PM
10	Disability definitions that attempt to express such with ODI, PROMIS and a 'Therapeutic Associates score' overly simplify patient impairment while attributing exaggerative accuracy to a tool validated for research, but not for clinical decision making. The ODI score has substantial limitations due to a significant floor and ceiling effect.Its effective response rate is around a 60 point range and likely of logarithmic response and not linear. The ODI remains a trending tool which is not of sufficient specificity to attribute clinical responsiveness based on 1 or 2 point differences. It is also very sensitive to other disorders and as such may influence patient reporting beyond what spin care of any sort can influence. The PROMOS 10 score is not validated for spine and therefore cannot reasonably be used for clinical decision making. This surgeon is entirely unfamiliar with the Therapeutic Associates Score and could not find any form of validation studies for it. It would be helpful for such a test to be exposed to peer review among spine practitioners and subjected to validation studies prior to being used as a clinical decision making and validation tool with undue specificity assigned to its scoring. Instability: Whose definition is being used here? These are reiterations of Posner's criteria, for which there has been insufficient correlation with pain and other patient reported symptoms. For some	Aug 14, 2014 10:16 PM

Page 2, Q5. Any comments about the first section?		
	reasons the authors excluded coronal and axial plane instability and perhaps the most relevant of all instability definitions: 'The Failure of the spinal column to bear physiologic loads' (White and Panjabi '76). -Collaborative team effort: This sounds good in theory. Placing such a team under directive of a physiatrist is out of scope of practice of a physiatrist. Even within the specialty of Rehabilitation Medicine there are very few with spine specific supplemental fellowship training. most PM&R residents pursue fellowships in interventional, inpatient, sports medicine , SCI, electrophysiology and disability administration care, but not spine. What qualifies any Physiatrist over a fellowship plus residency trained spine surgeon to a higher degree of expertise in that field? What is their liability? To have a Physiatrist certify non responsiveness to nonoperative care is not a care enhancing but care denying measure.How many multi specialty clinics fitting the 'collaborative' utopia are there in WA right now and where are they? Do the writers of the bundle proposal require all steps to eb fulfilled? CBT is clearly not available for many if not most Washingtonians to a satisfactory degree, even in Seattle.	
11	The issue in defining disability. The test is limited in only criticizing spine surgery while referencing only non-spine literature. Define arbitrary criteria without references which are all for non-operative care. The foundation for setting an instability definition at 4mm? No reference. It is unclear that this would be supported by either standards of practice or the literature. The requirement of patients undergoing a 3 month period of management with a multidisciplinary team may be difficult. Are there enough physiatrists in Washington State to set up, manage, and execute this labor intensive multimodality treatment plan? There may not be enough physiatrists to screen these patients. US News lists 307 physiatrists in Washington state for 143 neurosurgeons and 711 orthopedic surgeons (the magazine does not give fellowship breakdown, maybe assume 10-20% of the orthods are spine fellowship trained). This limitation could easily lead to inappropriate delays in care. Similarly, the requirement that a physiatrist recommend a fusion procedure in writing is a significant issue. Choice of candidates for surgery is beyond the scope of training for physiatrists. Consultation with a spine surgeon should be the primary source for recommendations for operative treatment. A collaborative approach to patient care is optimal, but a physiatrist does not have the training or the experience to make decisions with regard to operative therapy. Should this system be implemented, will the physiatrist be liable for operative results? If a physiatrist recommends surgery, and the surgery technically is successful but fails to eliminate the patient’s low back pain, is the physiatrist liable for the decision to proceed with surgery? Will physiatrists participating in this process need additional malpractice coverage to protect them in these instances? And is this decision making within the scope of practice of physiatrists in Washington State? How does the physiatrist recommendation factor into the informed consent process? While a collaborative approach is optimal, unilateral decisions made by individual team members is not appropriate. The limitation of BMI to values less than 40 is also not supported in the literature. While some reports note increase in complication incidence with elevated BMT, numerous spine papers show no relation of BMI to outcome.	Aug 14, 2014 9:45 PM
12	The first section seems to be very comprehensive in its considerations around disability.	Aug 13, 2014 5:37 PM
13	1.A - PROMIS is not validated for spine. ODI is adequate and validated. !.A -	Aug 13, 2014 1:56 PM

Page 2, Q5. Any comments about the first section?		
	Physical; Therapists in out community do not use the Therapeutic Associates Outcome Score. Who will train them, how will it be paid? 1.B - 4mm movement on Flexion / extension is arbitratry. There is inconsistent radiology reading. There are other appropriate reasons for performing lumbar fusio. i.e. Instability is expected to occur after the adequate decompression because of the need for total facetectomy. 1.C - There is inadequate physitry coverage in our community. (3 Month wait for consults) Our physiatrists handle neurological disability like stroke rehab and are not very familiar with back pain management. 1.D- Most of my patients have already had 3 months of conservative care before they see me but none would have had ODI measured by their primary care doctor before the conservative therapy began. There is no way to show failure of improvement.	
14	Physiatrists should not be the only MDs to manage conservative care	Aug 13, 2014 12:30 PM
15	Only one article, an overview published in 2007, mentioned acupuncture and East Asian medicine. Given recent research, the exclusion of acupuncture from treatment options is questionable.	Aug 13, 2014 8:59 AM
16	Only ODI is a validated tool for spine surgery. The Therapeutic Associates Outcome Score is an agenda-driven recommendation and, along with the PROMIS 10, has never been validated in spine surgery. These metrics have never been used in practice in any spine surgeon's office, to measure pain. Flexion/extension x-rays are not a reliable metric to demonstrate instability and are limited by patient pain/function. Discouraging opiods is a great idea yet no standard. Failure to improve ODI by 11 points is not an accepted standard for spine surgery. Require PM&R sign-offon the need for surgery-not enough PM&R Docs to accommodate in the community. No evidence this results in better surgical outcomes. PM&R physicians are not trained to be responsible for making decisions spine surgery indications.	Aug 12, 2014 9:05 PM
17	1) The inclusion of physical therapist in documenting physical function and disability is to be commended. 2) What is the basis for use of the Therapeutic Associates Outcome Score? The evidence for this tool is limited and it is not widely recognized or utilized. 3) What is the basis for the physiatrist being designated as the team leader?	Aug 12, 2014 7:17 PM
18	a minimally detectable change of 11 points for ODI should be relevant to starting score. The less disabled, the smaller change should be expected. What is the score cut-off to determine disability? Who delivers the cognitive behavioral care? It seems to me that a mental health specialist should be designated as a key team member. All practitioners should be delivering same messages regarding the neuroscience and psychobiology of pain. What is evidence for spinal manipulation in persons with advanced disability involving the L/S?	Aug 12, 2014 2:22 PM
19	There is measurement error - interobserver and intraobserver so the measurements listed in subsection B should include a range of translation as opposed the fixed of 4mm or 5mm. Whose translational or angular measurement would be considered? The physiatrist, the radiologist, the surgeon, the physical therapist? Who will pay for the necessary ODI documentation, data storage etc.?	Aug 8, 2014 5:01 PM
20	there must be disability despite non surgical therapy before considering surgery, but it is too burdensome to use the tools outlined. I don't think the provider	Aug 8, 2014 4:30 PM

Page 2, Q5. Any comments about the first section?		
	should collect and store the data. it should be the payor. It is impractical to have a meeting with all of the team members. There is also a great bias against surgical treatment of lumbar ddd. In carefully selected patients lumbar fusion is a very cost effective treatment. I suggest that there be limits on how long one can continue on the non surgical pathway without seeing a surgeon for a consultation to get another viewpoint on their condition.	
21	When the discussing angular instability.... The "compared to an adjacent level" is new to me. Radiology has just been measuring the angular excursion at the level in question and not including measurements for an adjacent level comparision. Should we be doing this? Does it really mean the angular excursion at the treatment level must be more than 11 than the adjacent level's angular excursion? In my review of the literature on this about 1.5 years ago, most papers referred to single level measurement of 11-15 degrees angular excursion as defition of cutoff for instability. Where is the literature for what you are suggesting as the criteria? I did not see it in the evidence list.	Aug 8, 2014 3:27 PM
22	Seems to be too easy to document instability and erform fusion for degenerative disc disease without significant instability	Aug 8, 2014 2:08 PM
23	Not evidence based. Are OK guidelines, but will be used to deny appropriate rapid treatment to workers who are losing much needed financial renumeration because of the delay these definitions will create.	Aug 6, 2014 10:41 AM
24	Challenging for many patient state wide to be seen by a "team" and evaluated by a PMR physician given the distribution of PMR physicians statewide.	Jul 30, 2014 5:26 PM
25	"Active physical therapy" needs further defining. Physical therapy isn't a commodity, rather it's patient-centered care provided by or at the direction of a physical therapist. I suggest changing the terminology to "active modalities and manual therapy".	Jul 30, 2014 4:16 PM
26	Appropriateness standards are a plus.	Jul 28, 2014 10:53 AM

Page 2, Q7. Any comments about the second section?		
1	II A Fitness is an assessment of risk. As a surgeon, I do not advise those unfit to have surgery but it is my expertise that determines the fitness relative to a procedure. A BMI of 45 patient can do better than a BMI of 20 patient and have less risk. A smoker the 3/5 strength that is rapidly progressing should not be allowed to become a 0/5 strength even if there is additional risk. Psychiatric patients have pain too. Are you saying someone with bipolar disorder can't have pain and function perserving surgery ever? These criteria exclude progressive patients and are discriminatory against large groups of other patients. One label apparantly can invalidate your option to live pain free, return to work, and be more functional at home or work. There isn't evidence for most of these exclusions. Just because a study excludes them doesn't mean they should be excluding from care outside of a study. II B As long as the state will provide resources (staff and tech support) you can mandate database participation. Until those resources are committed from state funding, the extra requirements will just make it harder for patients in this state limited by these constraints to get care. Already, medicaid and L&I pays little and patient's are denied care by providers. By making it more honorous, you will exclude more and more patients from care and flood clinics that are willing to care for the indigent and those that are injured at work. II C. Again, surgeons assess risk. That is our job. Not the job of this collaborative group. Surgery can not be made risk free. You can't require all of these things because again not every patient has the time or access to get these things done. I would like perfect teeth on my patients but many don't have dental care. So, you will deny a surgery of limb saving significancy because they don't have money for a dentist in the future or can't see an anesthesia provider because the out of pocket cost is $500? This is very harmful to the poor, minorities, and underprivileged and is very regressive toward their care.	Aug 19, 2014 1:12 PM
2	• The second section identifies a range of requirements and screening tools to assess ‘fitness for surgery’. Some of the requirements are specific while others are intentionally not defined or specified. This flexibility allows for different approaches to alcohol abuse management, depression screening and treatment or other evidence-based interventions deemed appropriate by the care team. We appreciate the current flexibility in the bundle and believe it will allow for greater adoption and innovation. Given the existing flexibility in the bundle, we think the Bree Collaborative should develop a process to vet and allow for alternative evidenced-based bundles which reduce unnecessary fusion surgery. The above process would allow hospitals to innovate and adapt to local community/patient needs while still reducing unnecessary lumbar fusions. A bundle that is too prescriptive may face development delays as the ‘right’ components are negotiated or as payers and providers experience challenges in broad implementation.	Aug 19, 2014 1:03 PM
3	No.	Aug 15, 2014 7:10 PM
4	The requirement ofr PT consultation is redundant since all patients had to undergo PT preoperatively as part of their nonsurgical management.	Aug 15, 2014 4:52 PM
5	Comment regarding II A): This suggests that a BMI of 40 or above is an absolute contraindication to lumbar fusion surgery, and that patients with such a high BMI and a presumably disabling lumbar spine condition would be able to lose significant amounts of weight, which I believe to be, in large part, a fallacy. Clearly, patients with such a high BMI have a considerably higher risk of	Aug 15, 2014 1:16 PM

Page 2, Q7. Any comments about the second section?		
	complications, and it makes sense that this would be considered a relative contraindication. That these patients should be absolutely precluded from the option of operative intervention, however, seems overly draconian and discriminatory. Additional comment regarding II A: Although I agree with the general intent of this section, the list of conditions under this heading is not well-defined. For instance, who specifically decides what constitutes "adequate nutritional status," "sufficient liver function," or "severe osteoporosis?"	
6	Fitness of surgery is a great concept and pursues good intentions in many points. The proposal at hand unfortunately overshoots its goals by adding many items for which there is little or no evidence based foundation or which are frankly discriminatory. No surgeon I know likes to operate on a patient with BMI >40. There are, however, very clear fusion indications especially in that patient collective. Denying access to care for a patient due to BMI in absence of other contraindications to spine surgery and/or General Anesthesia is simply discriminatory and not supported by the literature including the references provided in the evidence table. Insistence on certain tests such as liver function tests again introduces further cost with unclear response opportunities for treating providers. Nasal swab testing is another example of unproven infection curtailment measures having failed to produce tangible results. Depsite extensive nasal swab precautions in at least on of the teaching hospitals the rate of MRSA infections has not been affected and the occurrence of infections remains independent of culture status or treatment implementation.	Aug 14, 2014 10:16 PM
7	The requirement for physical therapy consultation seems redundant, since patients had to undergo physical therapy evaluation preoperatively as nonsurgical management.	Aug 14, 2014 9:45 PM
8	Very important component for patient recovery and surgical success factors. Excellent.	Aug 14, 2014 11:28 AM
9	2.A - BMI 40 is arbitrary and discriminatory. Sometimes the neurological impairment requires surgery before a weight loss program can be effective. (i.e. foot drop) 2.B.2. - some patients do net have a care partner. This is discriminatory 2 B-. Advanced directives are not always needed. (i.e.healthy 22 y.o. with spondylolysis sponylolisthesis) 2.C.1. - Staph cultures not proven important for spinal fusion surgery. Adds expense without proven benefit.	Aug 13, 2014 1:56 PM
10	Tracking peri-op blood glucose is a great idea,.and Spine SCOAP already benchmarks glucose metrics. There is no evidence that a HgA1C<8 is a standard in spine surgery. Adequate nutrition-great idea, no standard Sufficient liver function- largely irrelevant in this population, no standard, leads to over testing BMI<40-not evidence based and is discriminatory, how many Seattle Seahawk professional athletes would be not be allowed access to indicated surgery?!? Pre-op plan for post-op opiod management-graet idea, no standard, not enough pain clinics to support this 8 week smoking cessation, 4 weeks has equal benefit and should be the standard (e.g.cotenine). Alcohol screening/management- no standard amount of time required sober, discriminatory Screening for Psychiatric disorders-no standard, no accepted treatment approach No terminal conditions-good idea No other source of disability-discriminatory, i.e. kidney disease, upper extremity disability,..	Aug 12, 2014 9:05 PM
11	Although it was clearly stated in the introduction, it could be reiterated here these	Aug 12, 2014 7:17 PM

Page 2, Q7. Any comments about the second section?		
	minimal standards do not apply in cases of trauma, tumor, infection, etc...	
12	Screen for yellow and blue flags BMJ 2002;325:534–7.	Aug 12, 2014 2:22 PM
13	Fitness for surgery should be determined prior to seeing the surgeon. I am unaware what the validated decision aids are. The lab recommendations seem vague. are they all required, or only as indicated.	Aug 8, 2014 4:30 PM
14	Not evidence based	Aug 6, 2014 10:41 AM
15	Personal care partner may be overly onerous on certain populations	Jul 30, 2014 5:26 PM
16	Important safety and appropirateness standard.	Jul 28, 2014 10:53 AM
17	Need to add a stronger requirement for cigarette cessation and opioid minimization for patients being considered for surgery-these are the number 1 and 2 predictors of bad functional outcomes, especially among L&I and Medicaid patients	Jul 25, 2014 10:45 AM

Page 2, Q9. Any comments about the third section?		
1	Participation in the Spine SCOAP registry requires resource-intensive chart abstraction. While we agree with the practice of collecting and reporting outcome measures, we strongly suggest an alternative method of gathering this information should be identified without the additional administrative burden the SCOAP methodology requires.	Aug 19, 2014 4:07 PM
2	The report recommends a minimum volume standard of 20 for spine surgeons to perform spinal fusions. Pediatrics should be exempted from this volume standard because it is highly unlikely that any pediatric neurological or orthopedic surgeon would meet this standard. There simply are not enough of these surgeries performed overall on children and youth for this standard to reasonably apply to pediatrics.Spinal fusions in children are not done for the same indications as in adults; the spectrum of diseases are different (e.g. congenital anomalies and metabolic diseases vs. degenerative disease) and should not be painted with the same brush. Excluding pedistric specialists from being able to perform this surgery on account of the 20 surgeries threshold would subject children and youth to the sort of treatment in the pediatric age group to care by surgeons who do not have experience with the underlying pediatric conditions. Volume and quality relationships notwithstanding, this would be compromising ideal care for this population of patients. For children, these surgeries are done when there is evidence of instability such as a spondylolysis with spondlolisthesis (congenital or degenerative or traumatic slip of vertebral bodies). In these children they are indicated especially if there is radiculopathy or motor weakness. This tends to occur mostly in athletes and particularly gymnasts and for congenital reasons. Often they do not need surgery but occasionally when there is weakness and nerve root entrapment it is indicated. In summary, due to a much overall lower volume of spinal fusions in children and youth than adults, we respectfully recommend that pediatric surgeons (neurological and orthopedic) be exempted from the 20 surgery (volume) threshold requirement.	Aug 19, 2014 2:25 PM
3	III A. 1. Spinal fusion restrictions are hospital credentials and not something the state should regulate and specify. While I agree more in a year would be advise, there may be many reasons why someone might change specialties and move from cranial to spinal surgery from one location to the next. Leave this to local credentialling committees to make sound decisions about this and not the state. III A. 2. Consistent teams at my hospital are not available because I live in a small town. Again, not everyone lives in 1M plus cities with infinite resources. My surgeries for my patients are safer than large city and study data with very low complication rates despite the "team." III A. 4. Not every surgeon works 8-5 like outpatient doctors can. Sometimes schedules have to be adjusted. This stipulation can't be a blanket and allowances need to be made. III B. 1. You are mandating how an anesthesia doctor provides care when this is a very patient specific field. Some require significant opioids and some can't take non-narcotic medications due to allergies. How multimodal can someone be in these settings without even more side effects and where is the evidence that this reduces hospital stays or improves long-term outcomes? III C. Again, the state must provide state funded employees to capture this data or increase reimbursement for those providing this care. You can't mandate this without offering some way to cover cost or you will just shut out your patients access to care that is already limited in most regions.	Aug 19, 2014 1:12 PM
4	• WSHA broadly agrees with the elements of an optimal surgical process, but	Aug 19, 2014 1:03 PM

Page 2, Q9. Any comments about the third section?		
	has strong concerns regarding the volume standard. • The report recommends a minimum volume standard (twenty) for spine surgeons to perform spinal fusions. It is unclear how the volume standard was developed and what data was used to establish the threshold. Has analysis been done on how many spine surgeons are currently meeting this standard and how it would impact access to care? Based on hospital discharge data for 2013, approximately 150 providers and ten out of 43 hospitals would NOT have met the volume requirement. Are there additional variables that need to be considered? For example, do pediatric surgeons also need to meet the same standard as adults and are there pediatric surgeons in the state doing more than the minimum number? Given the low volume of pediatric lumbar fusions performed across the state an exemption from the volume requirement may be warranted. Are there other factors that also should be considered as well for other patient populations? From available data, there is no difference in length of stay (a quality proxy) for patients whose providers or hospitals had fewer than the minimum volume threshold when compared to those who performed more than 20 fusions in a year. In terms of the general concept, a volume standard may not prevent poor quality and may have the unintended impact of encouraging some low volume providers to do more cases. We would prefer the bundle use quality standards to assess eligibility as opposed to a volume standard, potentially a standard developed from a one or two year pilot as suggested earlier.	
5	Should include PT post surgery	Aug 18, 2014 7:22 PM
6	No	Aug 15, 2014 7:10 PM
7	1. We agree that is important to set some generalized standards regarding physicians performing spine fusion surgery as well as optimizing the processes surrounding authorization, surgical scheduling, streamlining intraoperative processes, as well as maintaining a database to assess outcomes on the patients. We realize that registries may play a pivotal role in answering some of these questions, but we also realize the cost associated with the registries as well as the implementation of this type of product. There are many neurosurgeons in the state that are actively participating in the SCOAP registry and it may provide us with some insight in regard to outcomes. 2.In regard to Section A, Item 4, Elective spine surgery should aim to begin before 5 pm. This is most likely one of the items that has been taken from the VM/GH guideline, but it has an impact in many neurosurgeons that are operating out of larger tertiary care centers. I have had many of my elective cases "bumped" for an emergency and I have started elective lumbar fusion cases later in the evening with no consequence. 3. In regard to Section C, we agree that registries will play a large role in evaluating outcomes from surgical procedures. There are a few registries that are already being employed in many of the state's hospitals and these should be evaluated and consideration of their usage should be evaluated.	Aug 15, 2014 4:52 PM
8	Comment regarding III A: I don't understand the need to absolutely restrict case scheduling to before 5PM. If a facility has the resources to handle this type of procedure after 5PM, why should they not be allowed to do so? Some surgeons only have afternoon block time on certain days, so fatigue may not be a factor. I'm assuming that this guideline precludes situations in which a case is indeed scheduled before 5PM but gets delayed until afterward, but that is not entirely clear. Although I really doubt many elective spine fusions are being scheduled	Aug 15, 2014 1:16 PM

Page 2, Q9. Any comments about the third section?		
	after 5pm, trying to dictate the appropriateness of a procedure based on the time of day seems beyond the purview of this type of process.	
9	Restrictions 1,3,5 are all arbitrary and unfounded by EBM standards. Regarding procedure numbers - how will the next generation of surgeons start practicing? What about surgeons returning from illness or disability? Does long term experience count for anything? Restrictions to start elective surgeons before 5pm are entirely devoid of evidence base and would discriminate against facilities having to render emergency procedures while imposing additional NPO times to waiting patients. Ambulatory surgery centers are gaining data on the reliability of their performance while showing dramatic cost reductions. The separate detailed mentioning of SCIP measures is redundant as every hospital in Washington participating in CMS programs will obtain and seek to follow SCIP. There is no need to duplicate this effort again with a Bree collaborative. The registry requirement is in principle laudable. However, the infrastructure of Spjne SCOAP currently does not support the mandatory addition of the currently non-enrolled hospitals. Current EMR technology (specifically EPIC_ is not conducive to obtaining and analyzing Patient Reported Outcomes. Running registries is expensive (150-280 US$/year and patient). WHo is supposed to fund this?	Aug 14, 2014 10:16 PM
10	We agree that it is reasonable come up with general standards for teams performing spine fusion surgery, ways to optimize surgical processes, and the discussion of registries and their potential utility. While we agree that these sections are relevant in spine fusion surgery, there are several points that may not be generalizable to 100% of all spine fusion procedures. As such, some guideline may need to be amended. For section A) item 4. We would like to change this statement to: Elective spine surgery should aim to begin before 5pm. For surgeons operating out of large tertiary care centers, a variety of circumstances (i.e. emergency cases) may lead to elective cases starting after 5pm. While we agree that elective spine fusions should start before 5pm, it is not always feasible, and the timing of surgery should be left to the discretion of the surgeon, his or her team, and the patient. For section B) item 6. We agree with most of the recommendations regarding BMP-2 use from the Washington Health Technology Program policy. This policy focuses on BMP-2 use in revision cases and in anterior lumbar fusions. We strongly agree with these recommendations, however there are many other situations where BMP-2 may be reasonable. In patients with osteopenia or osteoporosis, we feel that BMP-2 is reasonable to use during initial spine fusion. We also feel that BMP-2 utilization is reasonable to use in deformity cases with long segment constructs (greater than 3 levels) with or without osteotomies. For section C), we agree that participation in registries will play an important role in our ability to perform quality control assessments. We feel that surgeons should have more choice with regard to the choice of registry, but feel that universal outcome measuring tools should be implemented.	Aug 14, 2014 9:45 PM
11	3.A. I have been performing spinal fusion for 18 years but only do 15-18 per year. This is because I am a general neurosurgeon and I serve the needs all of my community. Most lumbar patients do not need spinal fusion. I make conservative surgical descisions This cutoff number is arbitrary. 2. A. 5- In the past few years I have had excellent results with outpatient lumbar fusion.	Aug 13, 2014 1:56 PM
12	Surgeons must do >20/year-arbitrary, capricious, discriminatory, no evidence for	Aug 12, 2014 9:05 PM

Page 2, Q9. Any comments about the third section?		
	this, does not take into account cumulative volume, discriminates against new surgeons, Ortho's must have fellowship training and NSGN's do not?!? No evidence NSGN's must be board certified-and Ortho's do not?!? No evidence Roster of team members must be consistent-no evidence, no standard, discriminatory against smaller community hospitals No surgery after 5pm-capricious, arbitrary and no evidence Reps must adhere to ACS standard-the technical nature of spine surgery innovations are not included in the ACS standards Multimodal pain relief-no standard Minimize opiods-good idea, no standard SCIP metrics to decrease SSI-good idea, evidence based Urinary catheters-good idea, no evidence in spine Limit blood loss, IV fluid protocol,VTE risk reduction using SCIP-good ideas, no standard and only mechanical DVT prophylaxis needed for spine Avoid hyperglycemia-good idea, no standard, Spine SCOAP already benchmarks blood glucose BMP only in accordance with HTA-that means BMP only in anterior lumbar cage fusions, we agree its off-label yet may be indicated in the 20% TLIF/PLIF's that now use BMP, used in difficult fusion healing environment Spine SCOAP participation- we agree and think this should be the only BREE Fusion Bundle recommendation with new metrics included over time that are evidence based, practical and patient (not agenda or single stakeholder) centered. Maintain a registry with PRO's- Spine SCOAP tracks Patient Reported Outcomes (PRO's) and can adjust metrics to focus on time points and metrics of greater interest to the BREE than NRS and ODI	
13	I agree in general. It would be great to have a consistent surgical team, but this rarely happens. Anesthesiologists take multiple breaks, are never consistently in the same OR, scrub techs rotate as do circulating nurses. I don't think the hospital can do this. We have been trying my whole career. The only people that are there for the whole case, every case are myself, my PA, and the implant vendor. I don't know what the policy is for Infuse, but I think it works well and endorse its routine use. I think registries are great, but who pays?	Aug 8, 2014 4:30 PM
14	health plans have specific criteria for coverage. Too easy to document instability	Aug 8, 2014 2:08 PM
15	In general, are useful, but will be used to deny appropriate surgery.	Aug 6, 2014 10:41 AM
16	section A is strong. particularly agree with start time and number of procedures--how can a surgeon regain "competency" if procedure number is low?	Jul 30, 2014 5:26 PM
17	Covering only single level fusions is picking low-hanging fruit and avoiding a big area of concern. This may push surgeons to do multip0le level fusions to avoid this review.	Jul 30, 2014 1:25 PM
18	did wonder why inpatient facility versus a center of excellence - i am not a clinician so this may be an obvious answer for such significant surgery	Jul 28, 2014 11:33 AM
19	Definitely should add these above comments about cigarette smoking and opioids, I would suggest endorsing Strong for Surgery as a way to optimize patients before surgery. Some of the requirements, like a volume standard are not evidence based-what if you did 200 cases 2 years ago but only 19 last year....	Jul 25, 2014 10:45 AM

Page 2, Q11. Any comments about the fourth section?		
1	IV A. 1 d. Not every patient can do home exercise at the time of discharge and in some patients this will cause harm. IV C. 1. Again not every patient is appropriate to do exercises 3 times daily. This is a patient specific treatment recommendation made by the surgeon based on too many factors to account for in a protocol. IV D. 3. Most patients require up to 3 months of narcotics. This is the current state limit of 90 days. 6 weeks is too short and would require significant patient inconvenience to coordinate long-term opioid management at just 6 weeks.	Aug 19, 2014 1:12 PM
2	No	Aug 19, 2014 1:03 PM
3	return to function needs to accommodate the wide variety of personal abilities to deal with pain and altered functions	Aug 18, 2014 5:48 PM
4	We agree that post operative care and follow up of our surgical patients is critical. However, to impose a 48 hour follow up may be difficult for patients that are operated on at the end of the week compared to beginning of the work week. It is my practice to have a follow up appointment within 1 week for all of the surgical patients and if there is any problem before that timepoint, then a call from the pateint or patient's family should suffice.	Aug 15, 2014 4:52 PM
5	There are many good intentions compiled in this section. Yet again the good intentions are overshadowed by regimenting care in a duplicative fashion to existing practices. The introduction of a Care partner is interesting but again fails to address the real life scenarios of patient who don't have a reliable care partner, where nursing home care, transfers or prolonged hospitalizations are a reality.	Aug 14, 2014 10:16 PM
6	We agree that it is reasonable to have a standardized process for postoperative care as well as in regards to the discharge process. We agree with the importance of close follow-up for high-risk patients and the benefits of a follow-up phone call for patients. However, the recommendations are for the appointment / phone call to be within 48 hours. As patients may be discharged on a Thursday or a Friday, we would like to change this recommendation to within 3 business days. Furthermore, certain patients may require early follow-up with their PCP rather than their surgeon for re-evaluation of their medical conditions postoperatively. As the timing of discharge may be uncertain, we would also like to change this recommendation to within 3 business days so that appropriate follow-up can be scheduled with increasingly busy outpatient primary care providers. One further note, section IV.B.4.c recommends providing contact information for the orthopedist and primary care provider. We would recommend amending to “neurosurgeon or orthopedist.”	Aug 14, 2014 9:45 PM
7	Essential for both patient safety, likelihood for recovery and success for procedures. Important to obtain direct patient feedback for future bundle improvements; and for hospital warranty aspects as well.	Aug 14, 2014 11:28 AM
8	We already do all of this.	Aug 13, 2014 1:56 PM
9	Acupuncture was not adequately considered as a component of the return to function plan.	Aug 13, 2014 8:59 AM
10	Rapid Recovery Track-no evidence, no standard WSHA d/c and care	Aug 12, 2014 9:05 PM

Page 2, Q11. Any comments about the fourth section?		
	coordination-nobody uses it, no way to pay for it Home Rehab Ex's-good idea, already done After 6 weeks opiod use, pain management plan-good idea, no standard	
11	Inclusion/emphasis on the following items is to be commended: 1) Accelerated physical therapy and mobilization 2) Addressing social and resource barriers 3) Emphasis on education to patient and family/caregiver 4) Use of standardized outcomes	Aug 12, 2014 7:17 PM
12	I would add post operative patient education regarding neuroscience of pain to reduce use of pharmaceutical agents. I do not see measures for post-operative PT in out-patient setting with guidance on return to function and fitness.	Aug 12, 2014 2:22 PM

Page 2, Q13. Any comments about the standards (or other measures that you believe should be included)?		
1	Again if the state requires now documentation of 1000 different measures without state funded support, surgery will not be available to any of these patients in any market. These are also not quality measures. They are just random measures for the most part selected without evidence as to why they were selected.	Aug 19, 2014 1:12 PM
2	• The Washington Health Alliance and the Foundation for Health Care Quality are specifically named in the bundle as ‘quality organizations’ who will have access to registry data. On what basis is access to the data permitted? While WSHA was not explicitly named, the association has a large number of quality improvement project underway across Washington State. WSHA would like to be granted access to the registry data in an effort to support collaboration on quality improvement efforts.	Aug 19, 2014 1:03 PM
3	Variability needs to be allowed to individualize each person specific goals outside of the 80% in the middle of the "bell curve" Therapeutic Associates Care Connections survey, completed by the patient is relatively straight forward with application to common activities	Aug 18, 2014 5:48 PM
4	Quality standards need to be clinician friendly and able to be understood by the patient as well. I think that CareConnections is a reliable tool that is well used by PTs in WA state and can be easily used.	Aug 18, 2014 3:37 PM
5	We agree with the proposition of quality standards, but in it's current form as proposed by the Bree Collaborative group, there will need to be further discussions and debate on the final product. There are a number of questions that exist regarding the standards as proposed in this early form: 1) The cost of maintaing registries is costly. Who will ultimately be paying for this and how can it be implemented universally? 2) How will this registry be utilized? How will the registry be chosen? Will this be a mandate from the Bree Collaborative? Will ASCs performing lumbar fusion surgeries be required to participate? 3) The PROMIS-10 Global Health survey has not been validated for spine surgery? Why is there no "evidence based" component to the Bree Collaborative's implementation of measures? 4) There is a comment regarding reducing blood loss, but this is not defined. I am concerned that this may be another component from the VM/GH guidelines since an intraoperative death occurred secondary to massive intraoperative blood loss. I would believe that all surgeons that I have had to opportunity to train with or train would want to reduce intraoperative blood loss. 4) Many of the patients undergoing lumbar spinal fusions also have other co-morbidities. How does the co-morbidities factor into their post operative disability? 5) How does the HCAHPS data that is obtained reflect the individual provider performing these surgeries? 6) 30 day re-admission rates are often reported for the hospital or clinical service, but rarely for the provider. If a patient is re-admitted under a different attending for an un-related problem, is this captured?	Aug 15, 2014 4:52 PM
6	Will there be a standardized method for assessing compliance with these metrics across all institutions? How will the process work and how will the integrity of the process at each institution be verified? Line 2 should replace fracture with trauma. Ground level falls and other traumatic spinal injuries may not have a fracture, but have a critical instability requiring stabilization.	Aug 15, 2014 1:16 PM
7	Shared decision making: What do the authors consider to be 'formal shared	Aug 14, 2014 10:16 PM

Page 2, Q13. Any comments about the standards (or other measures that you believe should be included)?		
	decision making aids'? Who pays for these? While a positive catch word the intent of shared decision making is to a) reduce litigation and b) increase preoperative patient participation while c) decreasing utilization of elective surgery. None of these 3 hypotheses have been proven to date, and especially not in spine.	
8	We commend the Bree Collaborative on taking an innovative approach to how the delivery of health care is paid. It is clear that healthcare can be expensive particularly when there is significant variation in practice and performance. We agree that payment of healthcare should reflect quality, as well, as patient satisfaction and safety. In the current quality era, all stakeholders (patients, providers, hospitals and payers) share these common ideals. The proposed lumbar fusion bundle outlines various “Quality Standards” that detail appropriateness for surgery, evidence-based best practices related to the peri-operative process, and measuring patient recovery, experience and safety. As the Bree Collaborative moves forward with developing this lumbar fusion bundle, we suggest several issues that warrant further inquiry. 1. The lumbar fusion bundle indicates that the “provider group must maintain or participate in a registry of all patients having first-time single level lumbar fusion.” a. We ask for better clarification as to what constitutes the “provider group.” How will the lumbar fusion bundle distinguish individual providers in solo or group practices, hospital based practices, and larger academic university based practices? b. The administrative resources necessary for maintaining and updating a registry are costly. How will the responsibility of these costs be distributed among provider, hospital, and/ or payer? c. There are numerous existing patient registries (e.g.. N2QOD, NASS). Will providers be expected to participate in a specific registry, and if so, what is the criteria by which this registry will be selected over others? d. Please clarify how the data from the registry will be utilized. If the intent is for purchasers to have access to provider outcomes data before making decisions, will the data be presented with an appropriate risk adjustment factor to reflect differences in patient characteristics? 2. The lumbar fusion bundle proposes that patients receive “formal shared decision-making decision aids pre-operatively” as a standard for appropriateness in documenting patient engagement. a. What formal shared decision-making decision aids are required, and what is the evidence to support their utility for specifically lumbar fusion? 3. The PROMIS-10 Global Health survey is listed as a specific measure to document appropriateness for surgery. a. What is the evidence to support the use of the PROMIS-10 Global Health survey to document patient disability and appropriateness for surgery, as it particularly relates to lumbar fusion (as opposed to other global health instruments such as SF-36 or EQ-5D)? b. The PROMIS system, while attractive and supported by the National Institutes of Health, has not been explored in evaluation of spine surgery patients, and has not been validated as a means of assessing outcomes in spine surgery procedures. 4. Various evidence-based best practices related to the peri-operative process are listed. a. Peri-operative multimodal anesthesia can be administered by various types of providers, (e.g. surgeon, anesthesiologist, hospitalist, acute pain service, etc.). What is the proposed method of documenting that multi-modal anesthesia was delivered, and how will this be reported when the provider is someone other than the treating surgeon? b. Surgical Care Improvement Project (SCIP) measures indicate best practices with regards to prophylactic antibiotics and venous thrombo-embolism prophylaxis. SCIP measure compliance, however, is generally reported for an entire hospital or clinical service, and not by individual provider. How does the lumbar fusion	Aug 14, 2014 9:45 PM

Page 2, Q13. Any comments about the standards (or other measures that you believe should be included)?		
	bundle propose parceling out individual provider data? c. Best practices for maintaining optimal blood sugar control is a standard SCIP measure for cardiac surgery patients. What is the evidence to support this standard for lumbar fusion patients? d. Please define specifically appropriate measures for reducing blood loss and the method by which this is to be documented. 5. The proposed standard for measuring patient recovery includes disability and quality of life assessment at six months and two years following surgery. a. For certain lumbar fusion indications, postoperative follow up may not extend to 6 months or two years. Patients may also elect to not follow up at these later time points. What is the basis for mandating patient follow up in these circumstances? b. Lumbar fusion is often performed in patients with other medical comorbidities that can impact disability and global health. For example, a patient may undergo a lumbar fusion, and at some point postoperatively, undergo a total hip replacement for unrelated hip osteoarthritis. How does the proposed lumbar fusion bundle delineate changes in disability and global health for patients that have multiple unrelated conditions/ procedures? 6. The proposed standard for ensuring rapid and durable return to function includes reporting the number of patients with documented physical therapy within 24 hours of surgery. a. The standard of initiating physical therapy < 24 hours after surgery may not be indicated or safe for all patients. Some patients undergoing lumbar fusion may be discharged from the hospital within 24 hours. Others may not be medically stable to begin physical therapy at this early time point. What is the evidence for establishing a standard that all lumbar fusion patients undergo physical therapy, and that this be initiated within 24 hours? 7. Standards for measuring patient care experience include the results of HCAHPS surveys a. HCAHPS data is generally reported for an entire hospital or clinical service, and not by individual provider. How does the lumbar fusion bundle propose to parcel out individual provider data for HCAHPS results? b. Patient responses to HCAHPS surveys may reflect their general overall hospital experience as they interact with multiple various health care providers (physicians, nurses, allied health professionals). How does the lumbar fusion bundle propose to parcel out specifically the patient care experience as it relates to the delivery of lumbar fusion? 8. Reducing 30-day readmissions and avoiding complications are listed as standards for patient safety and affordability. a. 30-day readmission rates are generally reported for an entire hospital or clinical service, and not by individual provider. How does the lumbar fusion bundle propose to parcel out individual provider data for 30-day readmission rates? How will this be affected if the admitting and/ or discharging provider is someone other than the treating surgeon? b. The occurrence of complications such as those listed in the lumbar fusion warranty can be due to multiple factors. How does the proposed lumbar fusion bundle factor an appropriate risk adjustment for those patients with higher risk? Also, multiple providers are frequently involved in the episode of care. How will responsibility for a given complication be assigned to an individual provider?	
9	In the bundle, there is a requirement to participate in Spine SCOAP program. Our hospitals are on a multi year program to implement a national surgical outcomes registry NSQIP. It is cost prohibitive for us to participate in both NSQIP and a Spine SCOAP surgical registry, especially for the small volume of one level lumbar fusions done each year at our facility. We request that this requirement be removed from the standard or that NSQIP be included as another surgical registry that would satisfy criteria.	Aug 14, 2014 3:34 PM
10	From a patient safety perspective such quality standards are essential to	Aug 14, 2014 11:28 AM

Page 2, Q13. Any comments about the standards (or other measures that you believe should be included)?		
	increase success rate; and to avoid complications post-surgery that may reduce viability of procedures, recovery and basic health of patients.	
11	SCOAP has all this data	Aug 13, 2014 1:56 PM
12	the entire appendix is filled with recommendations that are not evidence based and should not be used.	Aug 12, 2014 9:05 PM
13	Consistent participation in physical therapy might be a good addition to the standards of appropriateness. In addition, the inclusion of performance-based measures may be a useful addition to the self-report measures listed. Perhaps select items from a functional capacity evaluation as measured by the physical therapist could be included pre and post surgery.	Aug 12, 2014 7:17 PM
14	Add measures for yellow and blue flags. Add measures of fitness as it relates to BMI, bone density, heart rate, BP, etc.	Aug 12, 2014 2:22 PM
15	More oversight.	Aug 10, 2014 8:51 AM
16	gathering and storing this is too burdensome for the individual practitioners. it should be done by the payor. this is probably more appropriate.	Aug 8, 2014 4:30 PM
17	Measurement and reporting by providers is another aspect of accountability.	Jul 28, 2014 10:53 AM
18	Again, the burden you propose to place on hospitals, both in labor and cost to mandatorily participate in SCOAP are onerous.	Jul 27, 2014 9:17 AM

Page 2, Q15. Do you have any comments about lumbar fusion warranty?		
1	We need additional clarity on how the warranty will be administered. As an example, “death” is a complication included in the warranty. How exactly will the warranty apply in the case of a patient’s death?	Aug 19, 2014 4:07 PM
2	Some patients are at high risk of complication. This is based on their medical comorbidities. Some patients and their surgeons elect to proceed with the risks to obtain the benefits of the fusion. I will operate on patients with a high risk of hardware failure and a high risk of complication using minimally invasive techniques to mitigate some of the risk, but I can't eliminate it all. If the state will warrant good health of all patients preoperatively, you can require a warranty from the surgeons. If you require a warranty, many surgeons will not offer the surgery to high risk patients leading them to a life of pain and suffering and likely long-term narcotics. I don't this is something the state wants more of based on recent legislation.	Aug 19, 2014 1:12 PM
3	• We hope a warranty drives more attention to the issue of consistently providing appropriate care. WSHA would ask the Bree Collaborative to consider if some hospitals or systems are more likely to be unable to deliver a warranty than others. For example, is warranty risk higher for lower volume providers and/or those providers that treat more complicated patients? • Per our discussions with Bree staff, thank you for updating the warranty code set.	Aug 19, 2014 1:03 PM
4	Needs more definition. It is unclear how it works.	Aug 18, 2014 8:36 PM
5	Warranty should be proportionately tied to poor medical status prior to surgery, e.g., high A1C (between 6 and 8) would extend less of a warranty than someone with an A1C <6	Aug 15, 2014 10:21 PM
6	The proposted lumbar fusion warranty does not increase patient safety, nor does it minimize complications. The lumbar fusion warranty is only to "balance the financial gain for providers and institutions performing the procedure". Once again, this is quite disturing since many individuals that are on the Bree Collaborative Work Group have a vested interest in driving patients to their institutions as they have tried setting up their model and will be the recipients since many of the other private practice neurosurgeons and orthopedists do not have this model. As stated previously, the work group consists largely of physiatrist and only one surgeon, this again is a conflict of interest and may need to be examined more closely as this could be construed as a violation of the Stark law.	Aug 15, 2014 4:52 PM
7	Bad idea	Aug 15, 2014 2:32 PM
8	A warranty is a concept developed for an innate device, manufacturing process or substance. It runs fundamentally afoul of the concept of life - with its vagaries and unpredictability. Frankly this is a likely unethical concept and worthy of a formal investigation by a Medical Ethics department. The very merit of a 'warranty' in spine surgery eludes me as there is a 90 day 'Global period. Reporting of adverse events such as mentioned is desirable to learn for the future. Insistence on a warranty like the one mentioned also will deprive patients with elevated risk factors from receiving care - such as patients on anticoagulants, cardiac disease, transplant patients etc. Risk profiling and developing risk minimization strategies is desirable, but the present warranty system for sone surgery is not a patient centric approach but instills selectionism	Aug 14, 2014 10:16 PM

Page 2, Q15. Do you have any comments about lumbar fusion warranty?		
	over patient care.	
9	The proposed lumbar fusion warranty in its current form does not increase patient safety and does not minimize complications. The implementation of the purpose lumbar fusion warranty will compromise access to care for our patients. The Bree Collaborative has developed a warranty for elective lumbar fusion based in large part on a similar initiative that created a warranty for total knee and hip replacement. The authors of this initiative state the primary intent of the warranty proposed is to set a high priority on patient safety. The secondary intent is to balance the financial gain for providers and institutions performing the procedure. Since there is nothing more paramount to a surgeon performing an elective lumbar fusion than the safety of his or her patient, the primary intent of this warranty is redundant. If this were in fact the sole purpose of this document, it would be unnecessary. It is that surgeon who has evaluated the patient and after careful assessment of the clinical and radiographic data has made a recommendation for a surgical procedure with the expectation that the patient who has been counseled for the surgery will have a decrease in their pain and disability. It is that surgeon who has assumed the greatest responsibility and the greatest risk for the care of that patient, more so than the institution where the surgery is provided or the insurance carrier. To mitigate the risk of a postoperative complication, the surgeon is already working within a constellation of guidelines in place to minimize infection, pulmonary embolism and other untoward events. The proposed warranty does not add any new element that would result in increasing the safety of a single level lumbar fusion procedure. Therefore, it stands to reason that the sole purpose of this document is stated in the third paragraph: “to distribute financial risk across professional and facility components in proportion to the revenue generated by the procedure.” It is this statement that bears further examination and clarification. From the surgeon’s standpoint, lumbar fusion in its current form is covered under a 90 day global period. In the event that any of the complications listed in this warranty occurs, the surgeon manages them, whether it is a surgical site infection, pulmonary embolism, pneumonia etc. Because of the structure of a 90 day global period, there are no professional fees associated with the management of these events. It is unclear how the proposed warranty would change this. It may be implied from the current language that the surgeon and the institution both will be held accountable for the costs related to that complication. Does the proposed warranty state that if a patient with a strong family history of heart disease but normal EKG and normal lipid profile undergoes an elective lumbar fusion and has a cardiac event that requires an extensive intensive care stay, cardiac catherization and potentially surgery, the surgeon and the institution assume the financial responsibility for that event? If so, to what extent? Does the surgeon forgo his or her professional fee or is that surgeon responsible for even more? The scenario above, while not exceedingly common, is plausible and introduces a concerning element into the healthcare arena. Our main concern with employing such a warranty is that it does not increase patient safety, it will not minimize complications. It is, however, a paradigm shift that will ultimately and detrimentally impact the access to care. When we as surgeons consider what a warranty means in the context of a surgery we perform, there is a difficulty with applying the pure definition of the word. A warranty is defined as: “a written guarantee, issued to the purchaser of an article by its manufacturer, promising to repair or replace it if necessary within a specified period of time.” Such a definition may be readily applied to a mechanical device. The article in the case of surgery is our patient, which is irreplaceable. Our patient is also not static,	Aug 14, 2014 9:45 PM

Page 2, Q15. Do you have any comments about lumbar fusion warranty?		
	mechanical or predictable. Therefore in this instance, we are limited to applying the pure definition of a warranty. While we have the capacity to take every measure to mitigate risk to our patient for a procedure, it is impossible to make that risk absent. It is our opinion that the proposed warranty that exposes the institution and the surgeon to the financial burden of an untoward event be valid only when one of the various safety measures already in place is not observed, e.g. preoperative antibiotics, removal of foley catheter within 24 hours, deep vein thrombosis prophylaxis, etc. If the surgeon has observed all of the current guidelines that have been demonstrated to optimize outcomes and mitigate risk, it is inconceivable that he or she should bear the financial responsibility for an unforeseeable and unavoidable event outside of his or her control. Therefore, in its current form, we do not support the concept of a lumbar fusion warranty.	
10	The warranty is very limited in scope as defined by this bundle. This seems to be a minimal scope for warranty but very important for tracking complications that can reverse success or recovery. Some type of clear documentation by patients and advocates that this warranty is valid only for the hospital where procedures were done must be provided. This relates to the fact that warranty is limited and requires post-operative complications to be made at the specific hospital that surgical services were originally provided.	Aug 14, 2014 11:28 AM
11	I don't think it makes logical sense to hold the physician responsible for infection in the event that prophylaxis protocols are followed.	Aug 13, 2014 5:37 PM
12	It is not clear what the warranty means in terms of balancing financial risk to the hospital and providers. If it involves take-backs from the hospital and providers than that would not make sense. If it means that the costs of dealing with complications are not further reimbursable then that also does not make complete sense because all patients are unique and despite all protocols in place to minimize complications, they can occur and the costs to take care of these complications can be high. I don't think enough information is provided here to come to an agreement on the warranty for lumbar fusion.	Aug 8, 2014 5:01 PM
13	These conditions are complications/occurrences that everyone on the team is trying to minimize. even with all that is done, sometimes things are unavoidable. the burden shouldn't fall on the treating team. they must ensure the patient is cared for in the most appropriate manner and that is what is done. The financial burden should fall on the patient, insurer.	Aug 8, 2014 4:30 PM
14	Relatively easy to avoid. No description of the consequences for the provider in cases of death, MI, and/or surgical complications	Aug 8, 2014 2:08 PM
15	n/a	Jul 30, 2014 5:26 PM
16	Patients are key components in the outcome of surgery-to put a warranty on the docs and hospitals without controlling the patient's role is not realistic or appropriate	Jul 25, 2014 10:45 AM

Page 2, Q16. Do you have any comments about the evidence table?		
1	You list good evidence for spinal fusion in several papers but then show article selection bias showing papers by authors that only write about non-operative care. Alot of references apply to non-spinal surgery (orthopaedic joint surgery) and lump those findings in with spinal fusion patients.	Aug 19, 2014 1:12 PM
2	No	Aug 19, 2014 1:03 PM
3	Excellent, informative	Aug 18, 2014 8:36 PM
4	Like the Therapeutic Care Connections tool	Aug 15, 2014 10:21 PM
5	No.	Aug 15, 2014 7:10 PM
6	The evidence table that was provided clearly demonstrates a bias towards non-operative care versus surgery. This should not be shocking as this is commonly seen in the research and evidence typically provided by the HTA when assessing the various spinal surgeries over the past few years. It is disappointing to review the comments and find out that in the Weinstein SPORT trial for degenerative spondylolisthesis (2007), the surgical complication was "high" compared to the non-operative group-this is not a fair comparison. Also, the evidence provided for smoking and obestiy is somewhat contradictory and I am concerned that the arbitrary recommendations that the Bree Collaborative Group has proposed is grounds for discrimination.	Aug 15, 2014 4:52 PM
7	This is a very biased table with strong preponderance of studies taking a negative or slanted approach against spine surgery.	Aug 14, 2014 10:16 PM
8	In general the selection of the evidence sources and in some cases the interpretation of the data in those sources reveals a clear bias toward nonoperative care over surgery or decompression alone procedures over fusion procedures. For example, in the 1st reference (Weinstein et al SPORT degen spondy 2007), the reviewer admits that surgery was superior to nonoperative care but the the complication rate was “high.” This attribution fails to take into account that the reported complication rates in SPORT included a majority of minor or transient complications and also fails to account for the fact that the nonoperative cohorts do not have a “complication rate” attributed to them despite the fact that continued pain and disability may indeed contribute to medical complications associated with immobility. Similarly, the reviewers include the 2011 NASS guidelines on the treatment of lumbar stenosis (presumably to emphasize a role for decompression alone in lumbar degenerative conditions) but completely fail to cite the 2008 NASS guideline on the treatment of lumbar degenerative spondylolisthesis, in which lumbar fusion is recommended as the treatment of choice for this condition. They also reach a bizarre conclusion in reviewing the affect of obesity on lumbar spine surgery from the SPORT trial (Rihn et al Spine 2012). Specifically, after noting the conclusion that obesity does not affect the clinical dominance of surgery over nonoperative care (despite a higher complication rate for obese vs nonobese patients) and that obese patients do not show improvement with nonoperative care unlike many nonobese paitents, the reveiwers generate a recommendation for weight loss in obese patients prior to surgery. This ignores the data presented and also ignores the fact that most obese patients with symptomatic lumbar degenerative conditions are essentially unable to lose weight due to the associated disability and immobility. They also cite cost data (Hill et al Lancet 2011) that is based on	Aug 14, 2014 9:45 PM

Page 2, Q16. Do you have any comments about the evidence table?		
	a population in the United Kingdom making generalization to the US market and patients difficult at best. This last study and many others cited by the reviewers are often studies investigating “all comers” with back pain that may or may not have a surgical diagnosis, rather than specific lumbar degenerative diagnoses. These types of “generic back pain” studies are not useful when implementing a lumbar fusion bundle program. It is also curious how the recommendations elaborated in the “bundle” do not match the literature cited in the evidence base. For example, they cite literature noting a benefit to smoking cessation as late as 4 weeks prior to surgery, but then they recommend an 8 week cessation in the bundle. Similarly, they clearly state that they were unable to find any literature to support the use or need of a “Care Partner” for lumbar fusion patients, yet this becomes an absolute necessity in the bundle. Finally, there are a number of other relevant publications, including EBM guidelines that would impact on the evidence-base for this topic. A short list of highlights includes: The entire Guideline Update for the Performance of Fusion Procedures for Degenerative Disease of the Lumbar Spine J Neurosurg Spine, July 21(1), 2014, most notably: Resnick DK, Watters WC 3rd, Sharan A, Mummaneni PV, Dailey AT, Wang JC, Choudhri TF, Eck J, Ghogawala Z, Groff MW, Dhall SS, Kaiser MG. Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 9: Lumbar fusion for stenosis with spondylolisthesis. J Neurosurg Spine. 2014 Jul;21(1):54-61 Eck JC, Sharan A, Ghogawala Z, Resnick DK, Watters WC 3rd, Mummaneni PV, Dailey AT, Choudhri TF, Groff MW, Wang JC, Dhall SS, Kaiser MG. Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 7: Lumbar fusion for intractable low-back pain without stenosis or spondylolisthesis. J Neurosurg Spine. 2014 Jul;21(1):42-7 Watters WC 3rd, Resnick DK, Eck JC, Ghogawala Z, Mummaneni PV, Dailey AT, Choudhri TF, Sharan A, Groff MW, Wang JC, Dhall SS, Kaiser MG. Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 13: Injection therapies, low-back pain, and lumbar fusion. J Neurosurg Spine. 2014 Jul;21(1):79-90 Other relevant publications: North American Spine Society. Evidence-based Clinical Guidelines for Multidisciplinary Spine Care. Diagnosis and Treatment of Lumbar Degenerative Spondylolisthesis. 2008. Kleinstueck FS, Fekete TF, Mannion AF, Grob D, Porchet F, Mutter U, Jeszenszky D. To fuse or not to fuse in lumbar degenerative spondylolisthesis: do baseline symptoms help provide the answer? Eur Spine J. 2012 Feb;21(2):268-75 Mardjetko SM, Connolly PJ, Shott S. Degenerative lumbar spondylolisthesis. A meta-analysis of literature 1970-1993. Spine (Phila Pa 1976). 1994 Oct 15;19(20 Suppl):2256S-2265S	
9	From a layman's perspective the evidence table seems thorough, exhaustive and well-documented. A very professional team effort seems obvious in assessing the bundle alternatives.	Aug 14, 2014 11:28 AM
10	The table should not include protocols from insurance companies or other agencies. It should only include peer reviewed medical literature. The guidelines from Washington L&I and the private insurance companies are not purely evidence based.	Aug 13, 2014 1:56 PM
11	The evidence table should be expanded to include research on acupuncture.	Aug 13, 2014 8:59 AM
12	Lengthy with variable evidence for surgery vs. non-surgical. Cost differential at years between surgery vs non-surgery and level of function. What is value of	Aug 12, 2014 2:22 PM

Page 2, Q16. Do you have any comments about the evidence table?		
	non-surgical (PT, CBT) and outcomes as compared to high cost of surgery and complications.	
13	there wasn't much supporting the efficacy of surgery vs non op care. It is out there if you look.	Aug 8, 2014 4:30 PM
14	Does not apply to individual patients.	Aug 6, 2014 10:41 AM
15	n/a	Jul 30, 2014 5:26 PM

Page 2, Q17. Please provide any general comments about the documents here:		
1	Virginia Mason strongly supports the work of the Bree Collaborative. We have long believed that addressing unnecessary variation in the way health care is delivered is a key component in both higher quality and lower cost. Recommendations made by the Bree collaborative will go a long way toward advancing health care delivery in Washington State. The recently released draft Lumbar Fusion Bundle and warranty are no exception.	Aug 19, 2014 4:07 PM
2	This collaborative is an obvious attempt to reduce access for spinal care in this state. The bias and arbitrary selections of unsupported guidelines and measures is easily noticed. Should this be inacted as is, I will consider the state to be in the practice of medicine and recommend malpractice lawsuits be filed against the state, it's lawmakers, and the Bree Collaborative for restricting patient access to care that can be provided for them that when properly used provides the best possible outcome to situations that will otherwise never improve. I would be happy to attend the next review and show 100 cases of good outcomes that would be excluded by these measures and ask what plan the Bree has for these people. Permanent disability from work and activities of daily living? High dose opioids? Life long weakness and paralysis? Life long suffer? I would suggest the state halt further development of this model and look at some other way of evaluating surgeons like state funded measurements before arbitrarily restricting care to millions of patients. If there was prospective evidence that these measures would do anything, you could argue that a change to the standard of care would be valid but what this is really doing is just shutting down what is sometimes the only and best option for a patient without any evidence to support such a change.	Aug 19, 2014 1:12 PM
3	• Along with our comments to pilot test before implementation and to allow for appropriate variations in the bundle, we also think there should be future evaluation and reconsideration. WSHA recommends that the Bree Collaborative adopt an appropriate assessment process and revisit the recommendation at a specified interval to gauge the impact of the policy, track quality and assess for any unintended outcomes on access or quality. The Bree Collaborative should make changes to the bundle based on data or changes to evidence-based practice.	Aug 19, 2014 1:03 PM
4	No	Aug 15, 2014 7:10 PM
5	Although the Bree Collaborative has attempted to take on the daunting task of trying to develop guidelines regarding the utilization of lumbar spinal fusions in the treatment of intractable back pain, it has provided a disappointing bundle and warranty to the patient's of Washington state that suffer from this problem, as well as for the neurosurgeons and orthopedic surgeons that treat patient's with this problem. I am deeply disturbed that there were only a few neurosurgeons involved in this process, of which only one is fellowship trained in spinal surgery. Furthermore, the mandate of having a physiatrist determining the surgical candidate is astonishing. However, if one looks at ratio of physiatrist to surgeons in the work group, it is not surprising. As President of the Washington State Association of Neurological Surgeons, I have received numerous emails from our constituents that are deeply disturbed with the process and the product that has been listed. Many neurosurgeons have expressed displeasure and have stated that they will no longer treat L and I patients and are refusing the treat DSHS patients. I think that this type of backlash is inappropriate, but I can understand their disappointment. The patients of Washington state deserve the	Aug 15, 2014 4:52 PM

Page 2, Q17. Please provide any general comments about the documents here:		
	best possible care in a cost-containment model. I would be happy to meet with anyone on the Bree Collaborative committee to help ease tensions between my constituents and the Bree Collaborative group. Sincerely, Trent L. Tredway, MD, FAANS President, Washington State Association of Neurological Surgeons	
6	Need alot more work.	Aug 15, 2014 2:32 PM
7	There is however, an ongoing concern regarding the delivery of informed consent and required patient engagement standards, as well as pursuit of feedback from patients following treatment. No matter how clearly stated and evidence based this sort of information is, patient understanding and engagement will only be as good as the delivery, which is highly dependent upon the frame of reference of the provider. Even use of specific models and templates suffers from variation in effectiveness based upon provider delivery. There seems to be a step missing between issuance of standards to be included in patient consent and the buy-in or skill of the system providing the care. This issue is vitally important, but is more a matter of attitude change, training, and improved tools than it is guidance.	Aug 15, 2014 8:43 AM
8	The Bree Collaborative deserves recognition for their efforts and the opportunity to provide a response. The responses herein are motivated out of concern for the well-being and access to care of patients with serious and disabling spinal disorders in this state. The following statements are supported by my 25 year experience of taking care of a wide variety of spine patients in an academic practice setting and are not an official statement of my employer. On a basic level I wonder about this effort by the Bree collaborative. The enclosed proposals will likely increase cost of care / patient without a known or predictable improvement of the quality of care. The likely intent of decreasing utilization for elective lunar fusion surgery is clearly not a patient centric approach. From a data gathering and analytical approach this author is surprised that the way more practical approach of making Spine SCOAP the official State of Washington assessment and quality surveillance told was apparently not considered. Instead a more onerous and cost inefficient administrative approvals process is recommended based on oversimplified concepts.	Aug 14, 2014 10:16 PM
9	The Joint Section of Spine and Peripheral Nerves, a section of the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS), appreciate the opportunity to comment on the Bree Collaborative's lumbar fusion proposals. The AANS and CNS represent over 4000 practicing neurosurgeons in the United States and internationally. This response was crafted by the Rapid Response Team of the Joint Spine Section, led by Joseph Cheng, MD. Nearly20 member physicians contributed to this effort. Please feel free to contact Dr. Cheng (joseph.cheng@Vanderbilt.Edu), Dr. John Ratliff (jratliff@stanford.edu) or our staff, Cathy Hill (chill@neurosurgery.org), with any questions. Contributing physicians: Peter Angevine Joseph Cheng Kurt Eichholz Daryl Fourney Todd Francis Kai Ming Fu Kojo Hamilton James Harrop Daniel Hoh David Okonkwo John O'Toole John Ratliff Charles Sansur Greg Smith Karin Swartz Lou Tumialan Cheerag Upadhyaya Rishi Wadhwa Michael Webb	Aug 14, 2014 9:45 PM
10	As a patient advocate whose family member (spouse) was a candidate for lumbar fusion in 2009, I can clearly understand the vital importance of this particular bundle. It is extremely complicated and difficult to find medical	Aug 14, 2014 11:28 AM

Page 2, Q17. Please provide any general comments about the documents here:		
	expertise and guidance in WA State regarding this procedure. After almost 9 months of extensive imaging and medical testing, physical therapy and many diagnostic tests it came down to a patient-selected medical panel of independent specialists (four different doctor's opinions) that three of the four advised us AGAINST the lumbar fusion procedures due to health risk factors; low probability (25%) of success; and unknowns in selection of a medical team to perform the operation. Also, the selection of hardware was fraught with risks (implant, bolts, nuts, screws) due to difficulty in obtaining information about the benefits and outcomes of various devices on the market. Also the fact that some devices on the market had been withdrawn by manufacturers and FDA recalls due to design flaws or serious medical complications leading to death or disabilities.	
11	It would be good to know why acupuncture and East Asian medicine were excluded in this discussion.	Aug 13, 2014 8:59 AM
12	The BREE Lumbar Fusion Bundle is a transparent example of the influence of payers, health plans and purchasers,.a clear demonstration of the exercise of power and devoid of collaboration around shared interests. The only recommendation that merits support is the universal enrollment of all spine surgery patients in Spine SCOAP. All stakeholders (patients, payers, purchasers, health plans, policy makers, product/device makers, physicians) can bring new metrics to Spine SCOAP for evaluation and implementation.	Aug 12, 2014 9:05 PM
13	I am completing this survey as the co-chair of the American Academy of Orthopaedic Manual Physical Therapists (AAOMPT) practice affairs committee. We commend the inclusion of a physical therapist in the development of these documents. We feel the documents are consistent with current evidence for best practice and appreciate the recognition of physical therapists as important members of an interdisciplinary team.	Aug 12, 2014 7:17 PM
14	I believe much more needs to be done to include standardized yellow and blue flag testing as well as incorporating CBT into physical therapy patient education as well as involving CB therapist as needed. The psychobiology of pain is not well enough represented as a legitimate treatment option. Physical therapists can provide patient education regarding the neuroscience of pain along with movement training and progression toward health, wellness, and fitness at a fraction of the cost of surgery.	Aug 12, 2014 2:22 PM
15	extremely thorough and well thought out.	Aug 8, 2014 10:52 PM
16	It is very positive to see this work and the quality steps.	Jul 28, 2014 11:33 AM

Page 3, Q18. Name:		
1	Kathleen Paul	Aug 19, 2014 4:08 PM
2	Joseph Rank	Aug 19, 2014 2:41 PM
3	Hugh Ewart	Aug 19, 2014 2:25 PM
4	David A. Yam	Aug 19, 2014 1:13 PM
5	Ian Corbridge	Aug 19, 2014 1:03 PM
6	Jennifer Lesko PT, DPT	Aug 19, 2014 11:00 AM
7	John McWilliams	Aug 18, 2014 5:49 PM
8	Gordon E. Marx PT	Aug 18, 2014 3:12 PM
9	Lori O. Marx PT, MHA	Aug 18, 2014 3:07 PM
10	Linnea Comstock PT	Aug 15, 2014 10:21 PM
11	Trent L. Tredway, MD FAANS	Aug 15, 2014 4:53 PM
12	David Baker, M.D.	Aug 15, 2014 2:32 PM
13	Patty Calver RN BSN CQHP	Aug 15, 2014 1:17 PM
14	Linda J. L. Radach	Aug 15, 2014 8:44 AM
15	Tung M. Ha	Aug 14, 2014 11:37 PM
16	Jens R Chapman, M.D.	Aug 14, 2014 10:16 PM
17	John Ratliff	Aug 14, 2014 9:45 PM
18	Allison Houtsma	Aug 14, 2014 3:35 PM
19	Vernon Dwight Schrag	Aug 14, 2014 11:30 AM
20	Barry J Landau MD	Aug 13, 2014 1:57 PM
21	Steven Pollei	Aug 13, 2014 12:31 PM
22	Mercy Yule	Aug 13, 2014 9:01 AM
23	Neal Shonnard MD Dir Spine SCOAP	Aug 12, 2014 9:10 PM
24	Raine Osborne	Aug 12, 2014 7:18 PM
25	Carrie Hall	Aug 12, 2014 2:22 PM
26	Tammy Goeken	Aug 10, 2014 8:52 AM
27	Hans Albert Quistorff, LMP Antalgic Posture Pain Specialist	Aug 8, 2014 10:56 PM

Page 3, Q18. Name:		
28	Justin Esterberg	Aug 8, 2014 5:01 PM
29	Jeff Garr, MD	Aug 8, 2014 4:32 PM
30	Dawn Hastreiter	Aug 8, 2014 3:27 PM
31	Nancy White, Senior Director for Clinical Practice and Research	Aug 7, 2014 2:25 PM
32	W. Allen Fink, DO, MHA	Jul 30, 2014 5:27 PM
33	Elaine Armantrout, PT, DSc, ECS	Jul 30, 2014 4:16 PM
34	John D. Loeser, M.D.	Jul 30, 2014 1:25 PM
35	Phyllis Gabel	Jul 28, 2014 11:33 AM
36	Pam Martino Manager, Quality Management Deppartment	Jul 27, 2014 9:17 AM

Page 3, Q19. Email address:		
1	Kathleen.Paul@vmmc.org	Aug 19, 2014 4:08 PM
2	jrank@cellnetix.com	Aug 19, 2014 2:41 PM
3	hugh.ewart@seattlechildrens.org	Aug 19, 2014 2:25 PM
4	david.yam@providence.org	Aug 19, 2014 1:13 PM
5	ianc@wsha.org	Aug 19, 2014 1:03 PM
6	jlesko@taiweb.com	Aug 19, 2014 11:00 AM
7	jemcwilliamsjr@gmail.com	Aug 18, 2014 5:49 PM
8	Gordmarx@aol.com	Aug 18, 2014 3:12 PM
9	Loriomarx@aol.com	Aug 18, 2014 3:07 PM
10	lcptmpa@msn.com	Aug 15, 2014 10:21 PM
11	ttredway@neospine.net	Aug 15, 2014 4:53 PM
12	debaker@hinet.org	Aug 15, 2014 2:32 PM
13	ppr@uw.edu	Aug 15, 2014 1:17 PM
14	linda.radach@gmail.com rolinrad4@comcast.net	Aug 15, 2014 8:44 AM
15	tmha@hinet.org	Aug 14, 2014 11:37 PM
16	jenschap@uw.edu	Aug 14, 2014 10:16 PM
17	jratliff@stanford.edu	Aug 14, 2014 9:45 PM
18	ahoutsma@peacehealth.org	Aug 14, 2014 3:35 PM
19	dwights30@comcast.net	Aug 14, 2014 11:30 AM
20	bjlandau@hinet.org	Aug 13, 2014 1:57 PM
21	srpollei@cdirad.com	Aug 13, 2014 12:31 PM
22	mercyyule@earthlink.net	Aug 13, 2014 9:01 AM
23	n.shonnard@qualityhealth.org	Aug 12, 2014 9:10 PM
24	raine.osborne@brooksrehab.org	Aug 12, 2014 7:18 PM
25	chall@movementsystemspt.com	Aug 12, 2014 2:22 PM
26	Tlgoeken@gmail.com	Aug 10, 2014 8:52 AM
27	hquistorff@gmail.com	Aug 8, 2014 10:56 PM

Page 3, Q19. Email address:		
28	j.esterberg@proliancesurgeons.com	Aug 8, 2014 5:01 PM
29	j.garr@proliancesurgeons.com	Aug 8, 2014 4:32 PM
30	dhastreiter@radiax.com	Aug 8, 2014 3:27 PM
31	nancywhite@apta.org	Aug 7, 2014 2:25 PM
32	wallenfink@gmail.com	Jul 30, 2014 5:27 PM
33	armantrout@cypresslabspllc.com	Jul 30, 2014 4:16 PM
34	jdloeser@uw.edu	Jul 30, 2014 1:25 PM
35	gabelp@inhs.org	Jul 28, 2014 11:33 AM
36	pam.martino@swedish.org	Jul 27, 2014 9:17 AM

Page 3, Q20. Organization:		
1	Virginia Mason Health System	Aug 19, 2014 4:08 PM
2	Cellnetix Pathology	Aug 19, 2014 2:41 PM
3	Seattle Children's Hospital	Aug 19, 2014 2:25 PM
4	Providence Neuroscience Institute	Aug 19, 2014 1:13 PM
5	WSHA	Aug 19, 2014 1:03 PM
6	Therapeutic Association Inc.	Aug 19, 2014 11:00 AM
7	Bellingham Physical Therapy LLC	Aug 18, 2014 5:49 PM
8	Kirkland and Novelty Hill Physical Therapy	Aug 18, 2014 3:12 PM
9	Kirkland Physical Therapy	Aug 18, 2014 3:07 PM
10	Comstock Physical Therapy	Aug 15, 2014 10:21 PM
11	President, Washington State Association of Neurological Surgeons	Aug 15, 2014 4:53 PM
12	4CNSA	Aug 15, 2014 2:32 PM
13	Harborview Medical Center	Aug 15, 2014 1:17 PM
14	Washington Advocates for Patient Safety	Aug 15, 2014 8:44 AM
15	Fourth Corner Neurosurgical Associates	Aug 14, 2014 11:37 PM
16	University of Washington	Aug 14, 2014 10:16 PM
17	Joint Section of Spine and Peripheral Nerves American Association of Neurological Surgeons Congress of Neurological Surgeons	Aug 14, 2014 9:45 PM
18	PeaceHealth	Aug 14, 2014 3:35 PM
19	Washington Advocates for Patient Safety	Aug 14, 2014 11:30 AM
20	Director, Spine Center at PeaceHealth St Joseph Hospital, Bellingaham, WA	Aug 13, 2014 1:57 PM
21	Center for Diagnostic imaging	Aug 13, 2014 12:31 PM
22	Washington East Asian Medicine Association, Research Committee	Aug 13, 2014 9:01 AM
23	Foundation for Health Care Quality	Aug 12, 2014 9:10 PM
24	American Academy of Orthopaedic Manual Physical Therapists (AAOMPT)	Aug 12, 2014 7:18 PM
25	Movement Systems Physical Therapy	Aug 12, 2014 2:22 PM
26	Community Psychiatric Clinic	Aug 10, 2014 8:52 AM
27	Hans Massage	Aug 8, 2014 10:56 PM

Page 3, Q20. Organization:		
28	OPA Ortho	Aug 8, 2014 5:01 PM
29	Proliance Surgeons, INC	Aug 8, 2014 4:32 PM
30	American Physical Therapy Association	Aug 7, 2014 2:25 PM
31	PNWU-COM	Jul 30, 2014 5:27 PM
32	PTWA	Jul 30, 2014 4:16 PM
33	University of Washington	Jul 30, 2014 1:25 PM
34	INHS	Jul 28, 2014 11:33 AM
35	Swedish Edmonds Hospital	Jul 27, 2014 9:17 AM

Bree Member - Lumbar Fusion Public Comment

1. What sector do you represent? (Choose the option that is the best fit.)

	Response Percent	Response Count
Orthopedic surgeons	0.0%	0
Neurosurgeons	0.0%	0
Physiatrists	0.0%	0
Other health care providers (primary care physicians, physical therapists, nurses, etc.)	25.0%	1
Hospitals	0.0%	0
Government/Public Purchasers	0.0%	0
Employers	0.0%	0
Health Plans	0.0%	0
Consumers/Patients	0.0%	0
Self	25.0%	1
Other (please specify)	**50.0%**	**2**
	answered question	**4**
	skipped question	**0**

2. Are you a Bree Collaborative Member?

	Response Percent	Response Count
Yes	50.0%	2
No	50.0%	2
answered question		4
skipped question		0

3. Do you support the concept of a bundled payment model for lumbar fusion?

	Response Percent	Response Count
Yes	50.0%	2
No	0.0%	0
Neutral/No Opinion	50.0%	2
answered question		4
skipped question		0

4. Do you have any comments about the bundled payment concept?

	Response Count
	0
answered question	0
skipped question	4

5. Do you agree with the proposed components of the first section (Disability Despite Non-Surgical Therapy)?

	Response Percent	Response Count
Yes	**75.0%**	**3**
No	25.0%	1
Neutral/No Opinion	0.0%	0
	answered question	**4**
	skipped question	**0**

6. Any comments about the first section?

	Response Count
	2
answered question	**2**
skipped question	**2**

7. Do you agree with the proposed components of the second section (Fitness for Surgery)?

	Response Percent	Response Count
Yes	**50.0%**	**2**
No	0.0%	0
Neutral/No Opinion	**50.0%**	**2**
	answered question	**4**
	skipped question	**0**

8. Any comments about the second section?

	Response Count
	0
answered question	**0**
skipped question	**4**

9. Do you agree with the proposed components of the third section (Spinal Fusion Procedure)?

		Response Percent	Response Count
Yes		**50.0%**	**2**
No		0.0%	0
Neutral/No Opinion		**50.0%**	**2**
	answered question		**4**
	skipped question		**0**

10. Any comments about the third section?

	Response Count
	0
answered question	**0**
skipped question	**4**

11. Do you agree with the proposed components of the fourth section (Post-Operative Care and Return to Function)?

		Response Percent	Response Count
Yes		**50.0%**	**2**
No		0.0%	0
Neutral/No Opinion		**50.0%**	**2**
		answered question	**4**
		skipped question	**0**

12. Any comments about the fourth section?

	Response Count
	0
answered question	**0**
skipped question	**4**

13. Do you agree with the proposed quality standards?

		Response Percent	Response Count
Yes		**50.0%**	**2**
No		0.0%	0
Neutral/No Opinion		**50.0%**	**2**
		answered question	**4**
		skipped question	**0**

14. Any comments about the standards (or other measures that you believe should be included)?

	Response Count
	1
answered question	1
skipped question	3

15. Do you support the concept of a warranty for lumbar fusion?

	Response Percent	Response Count
Yes	50.0%	2
No	0.0%	0
Neutral/No Opinion	50.0%	2
answered question		4
skipped question		0

16. Do you have any comments about lumbar fusion warranty?

	Response Count
	0
answered question	0
skipped question	4

17. Do you have any comments about the evidence table?

	Response Count
	0
answered question	0
skipped question	4

18. Please provide any general comments about the documents here:

	Response Count
	1
answered question	1
skipped question	3

19. Name:

	Response Count
	2
answered question	2
skipped question	2

20. Email address:

	Response Count
	2
answered question	2
skipped question	2

21. Organization:

	Response Count
	2
answered question	2
skipped question	2

Page 2, Q1. What sector do you represent? (Choose the option that is the best fit.)		
1	Chiropactor	Aug 17, 2014 12:08 PM
2	TRR	Aug 14, 2014 8:59 AM

Page 2, Q6. Any comments about the first section?

1	Section 1. C) Document at least three months of structured non-surgical therapy delivered by a collaborative team 3. Spinal manipulation may be used in conjunction with other non-surgical therapy This perspective is inconsistent with the literature and represents a step backward in non-surgical spine care. I refer you to: "Tracking Low Back Problems in a Major Self Insured Workforce" Allen et al. JOEM;56:6, 604-620 "The use of short-term therapeutic courses of manipulation treatment may likewise be indicated but guidelines have proposed that physical therapy referrals should not be made-at least-within the first two weeks of onset." "The Chiro approach, was consistently, lined to the lowest costs. It's per employee total stayed at the lowest level across all three groups for each year. Physical Therapy was associated with relatively high costs in year 1 but tapered off in years 2 and 3" "The EEs accessing the Chiro approach will tend to be the least expensive because they are less likely to be prescribed medications or end up with complex medical procedures and because they are less likely to record guideline incongruent use of imaging, procedures and medications when the latter are delivered." "In 1 of the 11 instances examined here, where the recommendation is that the first visit to PT or chiropractor should be made at least 2 weeks after the episode start date, incongruent care actually led to significantly less total cost." "Early Predictors of Lumbar Spinal Surgery After Occupational Back Injury; Results from a Prospective Study of Workers in Washington State" Spine 12.12.2012. "Even after controlling for injury severity and other measures workers with an initial visit for the injury to a surgeon had almost 9 times the odds of receiving lumbar spine surgery, compared to those seeing a primary care provider, whereas workers whose first visit was to a chiropractor had significantly lower odds of surgery" Comment: The odds of surgery—even after controlling for severity with first consultation with a surgeon was 42.7% as opposed to odds of surgery when the first consultation was with a chiropractor of 1.5%. "Cost of Care for Common Back Pain Conditions, Liliedahl et al., JMPT 2010;33:640-643" "Results: Paid costs for episodes of care initiated with a DC were almost 40% less than episodes initiated with an MD. Even after risk adjusting each patient's cost we found that episodes of care initiated with a DC were 20% less expensive" "After risk adjusting each patient's costs, episodes of care initiated with a DC are less expensive that episodes initiated with an MD" Comment: The data reflected in this study show a 32% reduction in the incidence of surgery with chiropractic management of the patient. "Manipulation or Microdiskectomy for Sciatica? A Prospective Randomized Clinical Study" Mc Morland et al. JMPT 2010:33;576-584 "Conclusion: Sixty percent of patients with sciatica who had failed other medical management benefitted from spinal manipulation to the same degree as if they underwent surgical intervention" "After a year, no significant complications were seen in either treatment group, and the 60 percent patients who benefitted from spinal manipulation improved to the same degree as their surgical counterparts." "Do Chiropractic Physician Services for Treatment of Low Back and Neck Pain Improve the Value of Health Benefit Plans", Choudhry and Milstein, 2009, Foundation for Chiropractic Progress (www.f4cp.org) "Chiropractic care is more effective than other modalities for treating low back and neck pain" "Chiropractic physician care for low-back and neck pain is highly cost-effective and represents a good value in comparison to medical physician care and to widely accepted cost-effectiveness thresholds." "UPMC Health Plan, POLICY AND PROCEDURE MANUAL, POLICY NUMBER: MP.043 SUBJECT: Surgical Management of Chronic Low Back Pain" (https://www.upmchealthplan.com/pdf/PandP/MP.043.pdf) "Spinal surgery will be considered medically necessary for chronic low back pain caused by degenerative conditions with spinal instability or chronic discogenic pain	Aug 18, 2014 10:02 AM

Page 2, Q6. Any comments about the first section?

	without instability when members have failed conservative management and surgical management is the most appropriate course of action. 3. Early referral to chiropractor or physical therapist, but before advanced imaging, for: • Manipulation/mobilization • Stabilization exercises • Directional preference strategies – member and/or provider movements that abolish or cause centralization of pain (McKenzie self treatment repeated movements that centralize pain) • Traction – with radicular symptoms or failure to centralize Comment: This policy is not permissive in that chiropractic referral may be in order. This policy is a requirement for such care before surgical consideration absent red flags Discussion: The very passive, almost dismissive reference to spinal manipulation in the pending document "3. Spinal manipulation may be used in conjunction with other non-surgical therapy" fails to grasp the significant contribution spinal manipulation can make in terms of allowing patients to avoid more complex, costly and dangerous procedures. If the desire is to improve patient outcomes, improve patient satisfaction and lower costs then the role of spinal manipulation must be paramount in a guideline of this nature. The use of spinal manipulations and failure of the same before progressing to more expensive, dangerous and complex interventions deserves far stronger positioning and language. The non-pharmaceutical oriented approach of chiropractic care assisting the patient in avoiding the use of addictive and secondary effect laden products is an additional benefit to positioning chiropractic care much higher and more prominently in the hierarchy of care approaches. Secondarily with respect to Section 1. C) Document at least three months of structured non-surgical therapy delivered by a collaborative team 2. Trial of one or more of the following medications if not contraindicated: Acetaminophen. "Efficacy of paracetamol for acute low-back pain: a double-blind, randomised controlled trial" Williams et al. The Lancet - 24 July 2014 DOI: 10.1016/S0140-6736(14)60805-9 "Our findings suggest that regular or as-needed dosing with paracetamol does not affect recovery time compared with placebo in low-back pain, and question the universal endorsement of paracetamol in this patient group."	
2	My comments are related primarily to: Section 1. C) Document at least three months of structured non-surgical therapy delivered by a collaborative team 3. Spinal manipulation may be used in conjunction with other non-surgical therapy. This perspective is inconsistent with the literature and represents a step backward in non-surgical spine care. I refer you to: "Tracking Low Back Problems in a Major Self Insured Workforce" Allen et al. JOEM;56:6, 604-620 "The use of short-term therapeutic courses of manipulation treatment may likewise be indicated but guidelines have proposed that physical therapy referrals should not be made-at least-within the first two weeks of onset." "The Chiro approach, was consistently, linked to the lowest costs. It's per employee total stayed at the lowest level across all three groups for each year. Physical Therapy was associated with relatively high costs in year 1 but tapered off in years 2 and 3" "The EEs accessing the Chiro approach will tend to be the least expensive because they are less likely to be prescribed medications or end up with complex medical procedures and because they are less likely to record guideline incongruent use of imaging, procedures and medications when the latter are delivered." "In 1 of the 11 instances examined here, where the recommendation is that the first visit to PT or chiropractor should be made at least 2 weeks after the episode start date, incongruent care actually led to significantly less total cost." "Early Predictors of Lumbar Spinal Surgery After Occupational Back Injury; Results from a Prospective Study of Workers in	Aug 17, 2014 12:08 PM

Page 2, Q6. Any comments about the first section?

Washington State" Spine 12.12.2012. "Even after controlling for injury severity and other measures workers with an initial visit for the injury to a surgeon had almost 9 times the odds of receiving lumbar spine surgery, compared to those seeing a primary care provider, whereas workers whose first visit was to a chiropractor had significantly lower odds of surgery" Comment: The odds of surgery—even after controlling for severity with first consultation with a surgeon was 42.7% as opposed to odds of surgery when the first consultation was with a chiropractor of 1.5%. "Cost of Care for Common Back Pain Conditions, Liliedahl et al., JMPT 2010;33:640-643" "Results: Paid costs for episodes of care initiated with a DC were almost 40% less than episodes initiated with an MD. Even after risk adjusting each patient's cost we found that episodes of care initiated with a DC were 20% less expensive" "After risk adjusting each patient's costs, episodes of care initiated with a DC are less expensive that episodes initiated with an MD" Comment: The data reflected in this study show a 32% reduction in the incidence of surgery with chiropractic management of the patient. "Manipulation or Microdiskectomy for Sciatica? A Prospective Randomized Clinical Study" Mc Morland et al. JMPT 2010:33;576-584 "Conclusion: Sixty percent of patients with sciatica who had failed other medical management benefitted from spinal manipulation to the same degree as if they underwent surgical intervention" "After a year, no significant complications were seen in either treatment group, and the 60 percent patients who benefitted from spinal manipulation improved to the same degree as their surgical counterparts." "Do Chiropractic Physician Services for Treatment of Low Back and Neck Pain Improve the Value of Health Benefit Plans", Choudhry and Milstein, 2009, Foundation for Chiropractic Progress (www.f4cp.org) "Chiropractic care is more effective than other modalities for treating low back and neck pain" "Chiropractic physician care for low-back and neck pain is highly cost-effective and represents a good value in comparison to medical physician care and to widely accepted cost-effectiveness thresholds." "UPMC Health Plan, POLICY AND PROCEDURE MANUAL, POLICY NUMBER: MP.043 SUBJECT: Surgical Management of Chronic Low Back Pain" (https://www.upmchealthplan.com/pdf/PandP/MP.043.pdf) "Spinal surgery will be considered medically necessary for chronic low back pain caused by degenerative conditions with spinal instability or chronic discogenic pain without instability when members have failed conservative management and surgical management is the most appropriate course of action. 3. Early referral to chiropractor or physical therapist, but before advanced imaging, for: • Manipulation/mobilization • Stabilization exercises • Directional preference strategies – member and/or provider movements that abolish or cause centralization of pain (McKenzie self treatment repeated movements that centralize pain) • Traction – with radicular symptoms or failure to centralize Comment: This policy is not permissive in that chiropractic referral may be in order. This policy is a requirement for such care before surgical consideration absent red flags Discussion: The very passive, almost dismissive reference to spinal manipulation in the pending document "3. Spinal manipulation may be used in conjunction with other non-surgical therapy" fails to grasp the significant contribution spinal manipulation can make in terms of allowing patients to avoid more complex, costly and dangerous procedures. If the desire is to improve patient outcomes, improve patient satisfaction and lower costs then the role of spinal manipulation must be paramount in a guideline of this nature. The use of spinal manipulations and failure of the same before progressing to more expensive, dangerous and complex interventions deserves far stronger positioning and language. The non-pharmaceutical oriented approach of chiropractic care assisting the patient in avoiding the use of addictive and

Page 2, Q6. Any comments about the first section?		
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Page 2, Q14. Any comments about the standards (or other measures that you believe should be included)?		
1	I would like to see Spine SCOAP referenced again under the Quality Standards section, where it states that "must maintain or participate in a registry...." I would like Spine SCOAP to be called out specifically in that sentence, just to further establish its requirement.	Aug 14, 2014 8:59 AM

Page 2, Q18. Please provide any general comments about the documents here:		
1	Excellent work by the sub-group! I would like to sub-group to propose how this could get started at major health systems and not let the rural issues get in the way getting started on this.	Aug 18, 2014 10:48 AM

Page 3, Q19. Name:		
1	Lori Grassi	Aug 18, 2014 10:02 AM
2	Gerard W. Clum, D.C.	Aug 17, 2014 12:10 PM

Page 3, Q20. Email address:		
1	LGrassi@chirohealth.org	Aug 18, 2014 10:02 AM
2	gerrycdc@aol.com	Aug 17, 2014 12:10 PM

Page 3, Q21. Organization:		
1	Washington State Chiropractic Association	Aug 18, 2014 10:02 AM
2	Life Chiropractic College West, Hayward, CA Life University, Marietta, GA	Aug 17, 2014 12:10 PM

Washington
State
Hospital
Association

August 19, 2014

Steve Hill, Chair (steven.r.hill@comcast.net)
Dr. Robert Bree Collaborative

Robert Mecklenburg, MD, Chair (robert.mecklenburg@vmmc.org)
Accountable Payment Models Workgroup

Foundation for Health Care Quality
705 Second Avenue, Suite 410
Seattle, Washington 98104

Re: Dr. Robert Bree Collaborative - Lumbar Fusion Bundle & Lumbar Fusion Warranty

Dear Steve and Bob,

The Washington State Hospital Association (WSHA) respectfully offers the following comments on the draft Lumbar Fusion Bundle and Warranty.

As an active participant in the Bree Collaborative, WSHA fully supports efforts to improve patient safety and reduce costs associated with lumbar fusions. WSHA acknowledges the considerable efforts by the Accountable Payment Models (APM) Workgroup in developing the lumbar fusion bundle and warranty, which seeks to address the potentially unnecessary overuse of lumbar fusion surgery.

The public comment period affords interested stakeholders an opportunity to provide input into the development of Bree Collaborative recommendations. It is in this context that WSHA respectfully submits the following comments on behalf of our 99 member hospitals. WSHA has also encouraged our member hospitals to submit comments directly to the Bree Collaborative, if appropriate.

On behalf of our members we appreciate your attention to these comments and recommendations. We look forward to your response and any opportunity to work more directly with the AMP Workgroup. Should you have any questions, please contact Ian Corbridge, Policy Director, Clinical Issues at (206) 216-2514 or Ianc@wsha.org.

Sincerely,

Claudia Sanders

Claudia Sanders
Senior Vice President, Policy Development
Washington State Hospital Association

ec: Ginny Weir, Program Director gweir@qualityhealth.org
Bob Perna, Senior Director rjp@wsma.org
Carol Wagner, Senior Vice President, Patient Safety carolw@wsha.org

Enclosure

300 Elliott Avenue West
Suite 300
Seattle WA 98119
Phone 206-281-7211
Fax 206-283-6122
www.wsha.org

Enclosure: Lumbar Fusion Surgery Bundle & Warranty

WSHA's comments on the Bree Collaborative Lumbar Fusion Bundle and Warranty appear in order and format as they do on the Bree Collaborative public comment survey tool.

1. **What sector do you represent? (Choose the option that is the best fit.)**
   - Hospitals/health care

2. **Do you support the concept of a bundled payment model for lumbar fusion?**

   Yes, we think this has promise for improving quality and controlling costs.

3. **Do you have any comments about the bundled payment concept?**

   - The concept of a fixed payment for a bundle of services is a potentially promising payment approach which has gained attention by both commercial and public sectors. The unnecessary overuse of lumbar fusion surgery is a serious issue and WSHA fully supports efforts to improve care and reduce costs. We are also aware that recent reports illustrate issues in developing and successfully operationalizing a bundle payment (Health Affairs, 2014). Coordinating payment across different systems and across different provider types will be challenging. Adoption in integrated systems may be simpler than in those with independent physicians and facilities. If purchasers move forward with these approaches, they may be providing additional incentives to accelerate the move to integration and consolidation.

     Given some of the challenges, WSHA suggests Bree consider a one to two year pilot test of the bundle before major policy and payment reforms are adopted. A one to two year pilot period would allow stakeholders to disseminate and gain comfort with best practices, develop the appropriate technical infrastructure and links between providers while providing useful data on challenges or opportunities with the bundle. The information gained from the pilot period would aid the Bree Implementation Team in their efforts gain adoption of the bundle across Washington State.

     WSHA also would suggest Bree consider if there can be amendments to the specific proposed bundle that would still meet the state's objectives, if a system or payer adopts a similar but not identical model. Is there a process to review alternative configurations?

     We have specific comments on each of the sections as well. We look forward to having Bree consider and address these overall implementation issues as well as some of the specific concerns provided in sections below.

4. **Do you agree with the proposed components of the first section (Disability despite Non-Surgical Therapy)?**

- WSHA supports many of the concepts identified in the first section. We have specific concerns and questions with some components as they relate to access to care and assessment tools. These are noted in the subsequent section of the survey.

5. Any comments about the first section?

- WSHA supports the concept of a collaborative care team model, but we do not understand the statement that, "The physiatrist is accountable for leading the team…" How does a purchaser or payer determine this is occurring and is it critical in order to determine if a provider system is offering the appropriate bundle of care? How is a physiatrist 'accountable' and for all services offered across different systems? WSHA encourages the Bree Collaborative to refine section one to reflect greater flexibility and collaboration across providers and the patient.

  Requiring a physiatrist to be "accountable for leading the team…" may impact access, especially in rural areas. A query of the American Academy of Physical Medicine and Rehabilitation database for practicing physiatrist members in Washington State shows a high concentration of physiatrists along the I-5 corridor.

  The rigidity of the bundle, coupled with the potential lack of available physiatrist in rural communities might require a patient who is experiencing back pain to travel a considerable distance over "at least [a] three month" period to a facility that could meet the model established in the bundle. WSHA encourages the Bree Collaborative to consider the potential unintended impact of the bundle on access to care and determine if there can be greater flexibility in the collaborative care team model.

- The requirement of "at least three months of structured non-surgical therapy" and "active physical therapy" appears to be premised on: 1) those services being readily available within a patient's immediate community, 2) providers ability to accept Medicaid patients, and 3) those services being covered benefits, as offered by the payer/purchaser. It is unclear what access to physical therapy services is across Washington State, especially in rural communities. Additionally, if the payer/purchaser does not offer a full range of coverage for the appropriate services, then a patient could be faced with the prospect of paying for those therapy services out-of-pocket. This represents a barrier to care and could impact patient health and well-being.

  WSHA recommends the Bree Collaborative consider the effect of these recommendations on Medicaid patients and those in rural areas. We are still gathering data on the geographic distribution of physical therapists and Medicaid reimbursement for physical therapy services and will share information when we know more.

- Section I.A.3 "Document standardized baseline physical function by physical therapist using the Therapeutic Associates Outcome Score." Having spoken with representatives from Therapeutic Associates, Inc. (the copy write owner of the above mentioned tool) it is WSHA's understanding that the functional assessment tool is a proprietary product, and as such, would impose added operating expense on the provider. WSHA recommends the Bree Collaborative determine if alternative non-proprietary reporting options can be used. Also, it appears as if the 'Therapeutic Associates Outcome Score' has been changed to 'CareConnections Outcome System.'

6. **Do you agree with the proposed components of the second section (Fitness for Surgery)?**
    - Yes. WSHA has an additional general comment in the subsequent section of the survey.

7. **Any comments about the second section?**
    - The second section identifies a range of requirements and screening tools to assess 'fitness for surgery'. Some of the requirements are specific while others are intentionally not defined or specified. This flexibility allows for different approaches to alcohol abuse management, depression screening and treatment or other evidence-based interventions deemed appropriate by the care team. We appreciate the current flexibility in the bundle and believe it will allow for greater adoption and innovation.

      Given the existing flexibility in the bundle, we think the Bree Collaborative should develop a process to vet and allow for alternative evidenced-based bundles which reduce unnecessary fusion surgery. The above process would allow hospitals to innovate and adapt to local community/patient needs while still reducing unnecessary lumbar fusions. A bundle that is too prescriptive may face development delays as the 'right' components are negotiated or as payers and providers experience challenges in broad implementation.

8. **Do you agree with the proposed components of the third section (Spinal Fusion Procedure)?**
    - WSHA broadly agrees with the elements of an optimal surgical process, but has strong concerns regarding the volume standard. Our concerns are noted in the subsequent section of the survey.
9. **Any comments about the third section?**
    - The report recommends a minimum volume standard (twenty) for spine surgeons to perform spinal fusions. It is unclear how the volume standard was developed and what data was used to establish the threshold. Has analysis been done on how many spine surgeons are currently meeting this standard and how it would impact access to care?

      Based on hospital discharge data for 2013, approximately 150 providers and ten out of 43 hospitals would NOT have met the volume requirement. Are there additional variables that need to be considered? For example, do pediatric surgeons also need to meet the same standard as adults and are there pediatric surgeons in the state doing more than the minimum number? Given the low volume of pediatric lumbar fusions across the state an exemption from the volume requirement may be warranted. Are there other factors that also should be considered as well for other patient populations? From available data, there is no difference in length of stay (a quality proxy) for patients whose providers or hospitals had fewer than the minimum volume threshold when compared to those who performed more than 20 fusions in a year.

      In terms of the general concept, a volume standard may not prevent poor quality and may have the unintended impact of encouraging some low volume providers to do more cases. We would prefer the bundle use quality standards to assess eligibility as opposed to a volume standard, potentially a standard developed from a one or two year pilot as suggested earlier.

10. **Do you agree with the proposed components of the fourth section (Post-Operative Care and Return to Function)?**
    - Yes.
11. **Any comments about the fourth section?**

- No

12. Do you agree with the proposed quality standards?

- Yes, however, please see our comment in the subsequent section of the survey.

13. Any comments about the standards (or other measures that you believe should be included)?

- The Washington Health Alliance and the Foundation for Health Care Quality are specifically named in the bundle as 'quality organizations' who will have access to registry data. On what basis is access to the data permitted? While WSHA was not explicitly named, the association has a large number of quality improvement project underway across Washington State. WSHA would like to be granted access to the registry data in an effort to support collaboration on quality improvement efforts.

14. Do you support the concept of a warranty for lumbar fusion?

- We hope a warranty drives more attention to the issue of consistently providing appropriate care. WSHA would ask the Bree Collaborative to consider if some hospitals or systems are more likely to be unable to deliver a warranty than others. For example, is warranty risk higher for lower volume providers and/or those providers that treat more complicated patients?

15. Do you have any comments about lumbar fusion warranty?

- Per our discussions with Bree staff, thank you for updating the warranty code set.

16. Do you have any comments about the evidence table?

- No

Please provide any general comments about the documents here:

- Along with our comments to pilot test before implementation and to allow for appropriate variations in the bundle, we also think there should be future evaluation and reconsideration. WSHA recommends that the Bree Collaborative adopt an appropriate assessment process and revisit the recommendation at a specified interval to gauge the impact of the policy, track quality and assess for any unintended outcomes on access or quality. The Bree Collaborative should make changes to the bundle based on data or changes to evidence-based practice.

Dear Bree Collaborative,


Vickers MacPherson
2012 Meta analysis ‹acupuncture trials fc


Haake 2007 German

Thank you for the opportunity to comment on the Bundle, Warranty, and Evidence Table for Lumbar Fusion.
We note that in the sections on Non-surgical treatment, and Post-surgical Care and Return to Function, acupuncture and East Asian medicine were not considered thoroughly.
Although acupuncture is mentioned in item #16 of the Evidence Table, the article by Chou is a review from 2007, and more recent and specific evidence is available.
For example, two articles are attached.
We believe that acupuncture and East Asian medicine present useful treatments for this condition and would ask that the committee consider this option.
Thank you.

Respectfully,

Iman Majd, MD, EAMP

Mercy Yule, EAMP

Washington East Asian Medicine Association, Research Committee

The Bree Collaborative proposal for a bundled model with regards to lumbar fusions poses several challenges to the field of spinal surgery, particularly from the perspective of providing the best patient care at reasonable cost. A main fault of the proposal is its assumption all spine patients can be grouped similarly, and thus treated in the equivalent manner. Unfortunately, this stereotyping is impractical when analyzing spine surgery, as patient conditions, history, and demographics are individualized. General standardization of spine fusion surgery is reasonable with regards to optimization of care, as well as documentation/registry/outcomes collection, but it is not practical to constrain spine fusion surgery in a pathway without regards to the heterogeneity of the patient population. Particularly with multitudes of conditions warranting spinal fusion, each patient will require personalized examination and treatment.

With regards to nonsurgical management, physiatry treatment and evaluation does pose several benefits in the pre-operative period. However, this particular proposal does not account for the consequences, both patient care oriented and legally, for placing increased responsibility on the specialty. As the current practicing physiatrists are already limited in number, the suggested minimum three month requirement increases strain on the physicians as well as poses a delay of treatment with clinics becoming backlogged. Additionally, as stated above, it assumes all patients have similar conditions that warrant the same controlled care pathway. For severe anatomic problems, such as a spondylolisthesis with progressive myelopathy, a delay of care can result in permanent neurologic dysfunction and disability. If postponed for conservative care, what is the cost-benefits analysis of delaying surgical treatment for these patients while incurring the costs of non-surgical management? Lastly with regards to the non-surgical pre-operative time period, the suggestion a physiatrist could be responsible for the recommendation of the fusion not only requires an action outside of their scope of practice and training, but exposes an element of liability for the physiatrist. Does this bundle suggest additional education requirements for all physicians in the physiatrist specialty in order to provide appropriate training for this? Will they legally be held responsible for permanent nerve damage when the anatomic problem is delayed for completion of the three months of conservative treatment?

With regards to post-operative care and follow-up, the recommendation for follow-up within 48 hours is not practical or always feasible. Patient clinic appointments can pose challenges for patients who live a distance from the facility or those with challenging living arrangements. Again, bundling all patients into the same grouping does not allot for patients with special circumstances. However, a clinic phone call within three business days of discharge is reasonable and promotes a more thorough approach to patient care as well as continuity of care.

Lastly, the literature referenced in the collaborative statement included many studies not associated with the spine. Assuming non-spine research is applicable to the surgical spine field poses serious consequences to the patient population. Surgical spinal care cannot be generalized to other joints or extremity conditions. The conditions affecting the spine can cause different physiologic effects on the body as well as unique presentations of symptoms, each which should be treated on an individualized basis.

In conclusion, while the goal of the Bree Collaborative proposes several recommendations for the treatment of spinal conditions worthy of further consideration, standardization of care requires a collaborative approach involving both non-surgical and surgical providers examining each condition on a customized basis.

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Ginny,

This is to follow up on our phone call today and to provide some short notes for the record regarding our views on the report. As I mentioned, Providence opted not to use the Survey Monkey tool because we endorse the survey responses provided by the Washington State Hospital Association (WSHA) with some minor caveats and distinctions. Those are as follows:

- Providence does not endorse the idea of pilot testing the bundles. We believe the time to embark on this path is now.
- In the First Section – we support the requirement of at least three months of structured nonsurgical therapy. Additionally, we are interested in more discussion around documenting standardized baseline physical function by physical therapists using the "Therapeutic Associates Outcome Score."
- In the Third Section we support volume standards as well as warranties for lumbar fusion.

Please don't hesitate to contact us with any concerns or questions. Look forward to the next meeting and discussion.
Best,
Eileen Sullivan

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August 19, 2014

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Dr. Robert Bree Collaborative

Robert Mecklenburg, MD, Chair (robert.mecklenburg@vmmc.org)
Accountable Payment Models Workgroup

Foundation for Health Care Quality
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Re: Dr. Robert Bree Collaborative -
Lumbar Fusion Bundle
Lumbar Fusion Warranty

Dear Steve and Bob,

The Washington State Medical Association (WSMA) respectfully offers the following comments on these draft proposals.

The WSMA actively participates in the work of the Bree Collaborative, with a particular focus on the adoption of appropriate policies and processes. In contrast, for situations where clinical issues are to be addressed, the WSMA encourages practicing physicians and Washington state specialty society representatives to offer their expert commentary.

Lumbar Fusion Surgery Bundle

The WSMA acknowledges the considerable efforts by the Accountable Payment Models (APM) Workgroup in developing these latest proposals, seeking to create reasonable policy recommendations on lumbar fusion.

Page 4 –
Disability Despite Non-Surgical Therapy
I.C - Document at least three months of structured non-surgical therapy delivered by a collaborative team.
The WSMA supports the concept of a "collaborative care team", but has concerns with the component that states "The physiatrist is accountable for leading the team…" To be clear: the WSMA is not opposed to the participation of a physiatrist on the collaborative care team, however, the terms "accountable" and "leading" are unclear and potentially confusing as to how genuinely *collaborative* decision making would be accomplished among the members of that team. The WSMA therefore recommends that the workgroup further refine that language to achieve the formation of a truly collaborative care team model, as the name implies.

A related concern is the potential for limited access to physiatrists across the state, especially in rural areas. If a physiatrist is not available locally, the proposed model does not offer any latitude for adapting the care team model. Absent that adaptability, a patient in a rural area might be required to frequently travel a considerable round trip distance over the "at least three months" period to a facility that could offer that rigid model of structured non-surgical therapy. The WSMA therefore recommends that the workgroup introduce greater flexibility in this requirement so that the proposed collaborative care team model can be adapted to local needs, particularly in rural areas.

Also, the condition of requiring "at least three months of structured non-surgical therapy" appears to be premised on those services being covered benefits, as offered by the payer/purchaser. If the payer/purchaser does not offer that full range of coverage, then the patient could be faced with the prospect of paying for those therapy services out of pocket, which in reality is unlikely to occur. The patient is thereby thwarted from receiving potentially necessary services. The WSMA therefore recommends that the workgroup revisit this criterion, acknowledging the potential impact of benefit design on the course of care, and to consider amending the criterion to allow some flexibility to accommodate those limitations.

In addition, regarding the requirement found in I.A.3 "Document standardized baseline physical function by physical therapist using the Therapeutic Associates Outcome Score", our understanding is that process involves the use of a proprietary product, and as such, could impose added operating expense on the provider. The WSMA therefore recommends that the workgroup revisit this process requirement to determine if alternative non-proprietary reporting options can be used.

Page 7 –
Spinal Fusion Procedure
III.A – General Standards for a surgical team performing surgery
The WSMA has concerns regarding the volume based standard in A.1: "The spine surgeon must perform a minimum of twenty lumbar fusion surgeries in the previous twelve months." It is unclear as to how this threshold was identified, and it appears to be an arbitrary standard rather than evidence driven, based on comments the WSMA has received.

While the underlying concept of having surgeons achieve a threshold of clinical proficiency is sound, once this criterion is a component of a reimbursement policy, it will thwart the ability of surgeons to achieve competency. That is, once adopted as a policy, only those surgeons who already meet that criterion would be authorized for payment for that service, essentially locking out any opportunity for other surgeons to achieve that arbitrary threshold.

A related factor is that as the overall number of lumbar fusions performed annually decreases, it would be increasingly difficult for a surgeon to achieve that annual threshold.

Also, the requirement for orthopedic surgeons to have "successfully completed a spine fellowship" appears to be an arbitrary standard rather than evidence driven, based on comments the WSMA has received.

Furthermore, how would verification of a physician having met that threshold be accomplished? Absent an All Payer Claims Database as a centralized source for identifying the occurrence of particular treatment events, each health insurer would only have access to those claims it processed, not a widespread sample across all insurers.

For these reasons, the WSMA therefore recommends that this policy component be revisited, replacing the volume based standard with more reasonable and achievable measures of clinical proficiency.

General Comments

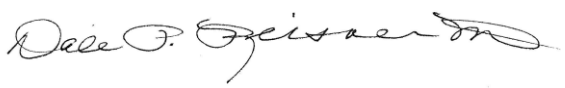
Reasonable Access to Care
The stringent criteria articulated in the proposal likely would constrain access to lumbar fusion surgery, which appears to be a goal of the proposal. However, absent any data offering projected impacts on access to care once such a policy was adopted, it is unclear as to whether those criteria might adversely limit the overall availability of this surgery. For example, might too few surgeons be available to reasonably meet the statewide care needs of those patients whose clinical status does warrant the procedure? The WSMA therefore recommends that the workgroup gather data that would offer projections on the impact of this proposal on statewide access to care.

Furthermore, the WSMA recommends that the workgroup include a component within this proposal that would encourage payers and purchasers to pilot this proposal on a limited basis as a safeguard against the potential adverse impact of impairing access to needed services.

Potential for Successful Adoption
The WSMA notes that the August 2014 issue of Health Affairs includes an article "Bundled Payment Fails To Gain A Foothold In California", reporting on the problems encountered in that state in attempting to implement the bundled payment model. The WSMA therefore recommends that the workgroup avail itself of these late breaking findings to ascertain if any vicarious learning could be incorporated into the Bree Collaborative's proposal.

In closing, the WSMA respectfully provides these comments for consideration. Should you have any questions in this regard, please contact Bob Perna by phone at 206.441.9762 or via email: rjp@wsma.org.

Sincerely,



Dale Reisner, MD
President

cc: Ginny Weir, Program Director (gweir@qualityhealth.org)