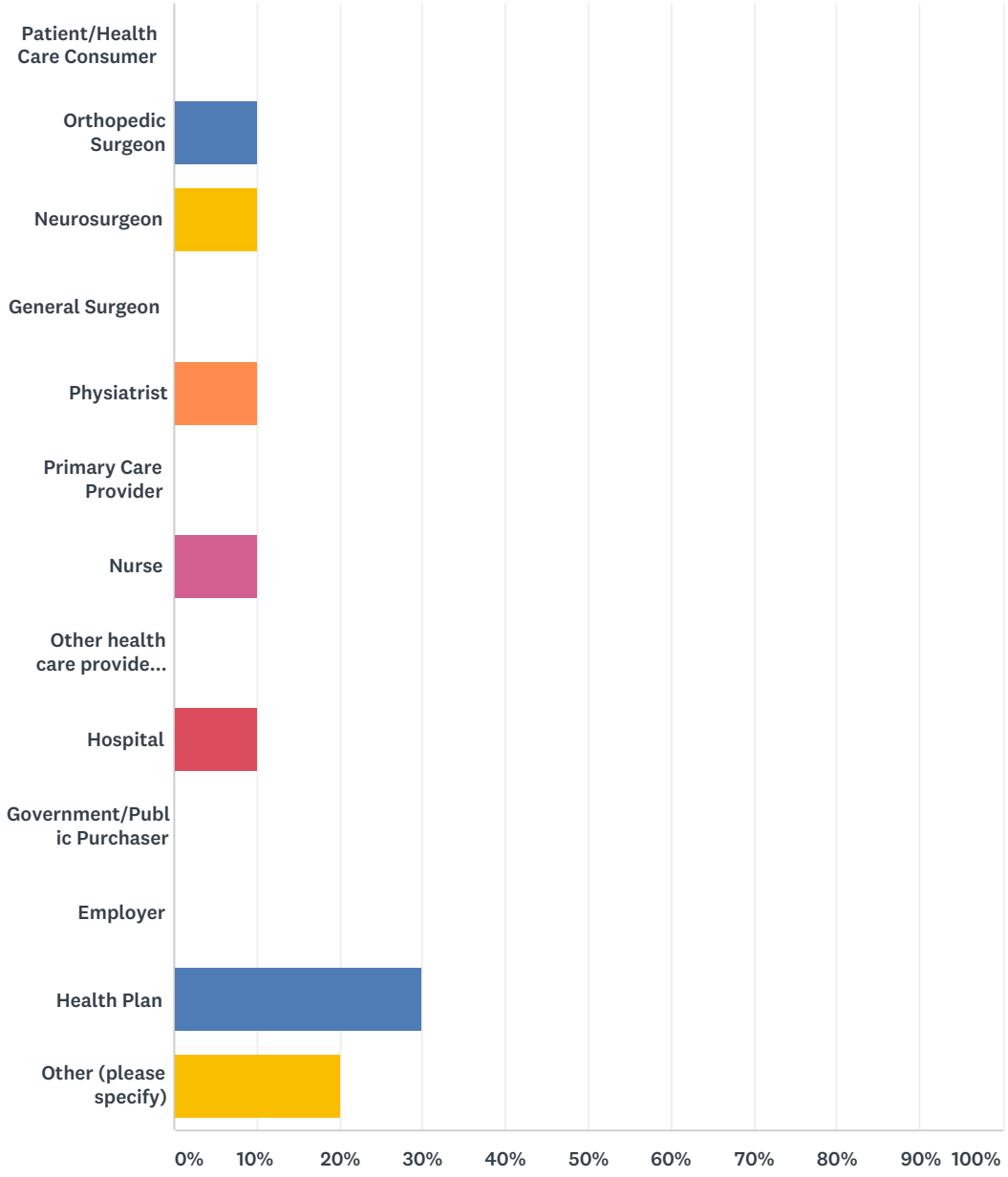
Q1 What sector do you represent? (Choose the option that is the best fit.)

Answered: 10 Skipped: 0



ANSWER CHOICES	RESPONSES	
Patient/Health Care Consumer	0.00%	0
Orthopedic Surgeon	10.00%	1
Neurosurgeon	10.00%	1
General Surgeon	0.00%	0
Physiatrist	10.00%	1
Primary Care Provider	0.00%	0

Nurse	10.00%	1
Other health care provider (nutritionist, physical therapist, etc.)	0.00%	0
Hospital	10.00%	1
Government/Public Purchaser	0.00%	0
Employer	0.00%	0
Health Plan	30.00%	3
Other (please specify)	20.00%	2
TOTAL		10

#	OTHER (PLEASE SPECIFY)	DATE
1	Please note, the comments provided are on behalf of the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) Joint Section on Disorders of the Spine and Peripheral Nerves (DSPN), American Academy of Orthopaedic Surgeons (AAOS) International Society for the Advancement of Spine Surgery (ISASS) and the Washington State Association of Neurological Surgeons (WSANS).	12/14/2018 3:45 PM
2	mid level spine	11/20/2018 4:56 PM

Q2 Please enter any general comments about the bundled payment concept below:

Answered: 9 Skipped: 1

#	RESPONSES	DATE
1	The bundled payment concept by itself has certain merit, especially if the bundled payment proposal clearly recognizes the potential heterogeneity of the patient's conditions and stratifies the payment based on the complexity of the needed treatments according to the complexity of the conditions. At the same time, the real world application of every aspect of the proposed model has the potential to be overly onerous and lead to limiting access to care. Furthermore, while certain comprehensive centers may incorporate elements of this model, private practioners, without access to physiatrists and mental health specialists face almost insurmountable barriers to adopting the rubric proposed.	12/14/2018 3:45 PM
2	Thoughtful design	12/10/2018 1:12 PM
3	Very well put together, easy to follow and understand	12/10/2018 11:33 AM
4	In the introduction, it is recognized that "lumbar fusion surgery is appropriate to mitigate the immediate threat of spinal instability from major trauma, tumor, infection or congenital anomalies". Further down in the introduction states the intention of the bundle is for patients without trauma, tumor or infection. There seems to be inconsistency in why and how the Bree has defined appropriate surgical candidate for the bundle.	11/23/2018 2:28 PM
5	The concept is reasonable. We will need to see if employers in this market adopt and steer their members. This has not been the case in the past for larger employers	11/20/2018 11:46 AM
6	Its a good idea, but I think too strict on some of the guidelines as well as on documentation. This will add many man-hours per patient to cover everything.	11/19/2018 7:12 PM
7	Appears to be a good way to bend the cost curve as well as involve specialists in value based care.	11/19/2018 11:32 AM
8	I think the concept is laudable. The implementation however will require administrative efforts far beyond what is feasible. The definition of the target patient group is not clear " patients with more than 12 weeks of back or lower extremity pain of confirmed spinal origin with neurologic symptoms or signs.". This is an absolutely insufficient description of patient pathology	11/17/2018 3:16 AM

9	It sounds overly restricted and will be difficult to navigate and will leading to loss of timely surgery even with obvious cases. There are clearly not enough Physiatrists in central and eastern Washington to provide these services. Additionally Physiatrists would provide most of the work and be reimbursed poorly compared to the surgeons.	11/16/2018 12:03 PM

Q3 Please enter your comments about Cycle I: Disability Despite Non-Surgical Therapy

Answered: 10 Skipped: 0

#	RESPONSES	DATE
1	B) 1. There is no clear literature supporting the definition of instability as 4mm of translation or 11 degrees of angulation. Both the SLIP Trial and the Swedish Lumbar Fusion study have confirmed this point.1,2 B) 3. It is appropriate to include decompressive surgery that will create instability, as this allows fusion for severe loss of disc height and severe foraminal stenosis, where the entire facet would need to be removed in order to adequately decompress the segment. C) The guidelines recommend three months of structured non-surgical therapy by a collaborative team, led by a physiatrist. We are concerned that this means that all patients who have a spondylolisthesis with instability, which is the most straightforward indication for fusion, must see a collaborative team led by a physiatrist “to validate that non-surgical care has occurred.” We are concerned that this requirement has the potential to lead to delays in care. It is not always feasible for a collaborative team to be headed by a physiatrist. Furthermore, it is not clear what were to happen if the patient simply cannot participate because of symptoms. What are the consequences of non-compliance? A patient that is highly motivated to improve may not always benefit from physical therapy. C) 1. d. This questions asks about behavioral therapies. We are concerned that access to providers who can perform behavior therapy described in the guidelines may be limited for many patients. This requirement will also lead to delays in care and restriction of the patient’s access to appropriate treatments if it is a requirement prior to surgery. D) 1. This question states, “A decision for lumbar fusion requires a meeting of all members of the [collaborative] team and a recommendation for fusion documented by the physician or physiatrist.” This requirement is especially problematic. Unless a practice had this element already developed and inherent to their practice, we anticipate that coordinating numerous “team” members’ schedules to have an in-person meeting would be difficult, time consuming and delay care in a patient with significant pain or neurological dysfunction with an obvious indication for surgery. The requirement that a physiatrist recommend a fusion procedure in writing is a significant issue. In doing so, it appears that the physiatrist is now in charge of determining the indication for surgical intervention, which is outside the scope of practice of a physiatrist. Physiatrists receive no formal training in decisions or criteria for surgery. Indications for surgery should always be at the judgement and discretion of the surgeon. Consultation with a spine surgeon should be the primary source for recommendations for operative treatment. An additional opinion from another spine surgeon would have greater value to the decision making process. 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’s recommendation factor into the informed consent process?	12/14/2018 3:45 PM
2	I would like to ask the workgroup if nutrition would factor into Cycle I, where there are indications of RA so far as non-surgical measures go	12/10/2018 1:12 PM
3	There are some that are not "fit" for surgery, this is a fact of life and must be stressed.	12/10/2018 11:33 AM
4	no comments	11/23/2018 2:28 PM
5	1. Will patients be willing to fill out these countless questionnaires? 2. It is not clear if the options of "all of the following" or "one or more of the following" is required on the outlines provided. 3. How will radiographic findings be verified...for example a surgeon can easily dictate motion and instability present on radiographs that is not actually there. Alternatively a radiologist may not read instability that is present.	11/20/2018 4:56 PM

6	1.B.2 re: "neural foraminal stenosis". This is not evidence based and in the literature is not an indication for fusion since does not represent instability. This should be removed as being a provider/surgeon opinion based recommendation only. #1 and #3 in the section are reasonable 1.C - the 3 month time frame, multi-disciplinary approach is good. However, requiring a specific specialist (e.g. physiatrist) to validate the fitness for surgery may be limiting in more rural locations. Certainly should not be a surgeon however.	11/20/2018 11:46 AM
7	There are not enough physiatrists available to manage the entire nonoperative side of treatment. In fact, most physiatrists don't want to manage this, they are usually seen for 1-2 visits then sent to the surgeon where the surgeon takes over. Great idea, unrealistic to expect all the physiatrists to take over. This can be adequately performed by the surgeon. What about in rural areas without many physiatrists? We have 3 in our county. One does LNI work. The other 2 do EMGs and ESIs and do not spend 3 months managing this. Also the depression and behavioral management? Where is this going to be covered if the next available psych appointment is 6 months away? Its like getting a patient into pain management - great idea, poor reality. Unless you are in a large city and a large multi specialty program this will not be done. Also, a non-surgeon does not have the training or expertise to decide surgery or not. They can suggest but ultimately the surgeon has the expertise and training.	11/19/2018 7:12 PM
8	Makes sense, all non-surgical options should be attempted before surgery.	11/19/2018 11:32 AM
9	Theoretically very interesting. Could I please get the resources to hire a collaborative team to help with this?	11/17/2018 3:16 AM
10	A	11/16/2018 12:03 PM

Q4 Please enter your comments about Cycle II: Fitness for Surgery

Answered: 10 Skipped: 0

#	RESPONSES	DATE
1	This section essentially limits the access of certain patients, such as patients with obesity, to appropriate surgical care, despite abundant literature supporting the efficacy of appropriate spine surgery in these patient populations. A) 1. a. This section concerns the recommendation that surgery be limited to patients with a BMI less than 40. While there is evidence that higher BMI increases certain complication rate, to withhold lumbar fusion for an obvious indication in patients with high BMI would be inappropriate, and is not supported by the literature. 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 BMI, numerous spine papers show no relation of BMI to outcome. A) 1. e, f, i, j, k. We would like to have greater clarity regarding who will be doing the screening for alcohol abuse, depression, psychiatric disorder, dementia, nutrition and liver function. Is that burden being placed on the surgeon, or is that part of the “collaborative team?” Particularly for patients being treated by a spine surgeon in a private practice setting, we would ask who is responsible for assembling this collaborative team? If it is the hospital or hospital system, this would seem to lead to the need to hire more practitioners or add to the workload of practitioners, in order to provide the needed “screening.” We are concerned that surgeons in the community setting without access to the resources of large hospital groups will not be able to comply and as a result will be disproportionately affected. This will cause an access problem to excellent care being provided by surgeons in private practice. B) 1. We question whether there is literature that supports the requirement for patient to have a “personal care partner.” We are concerned about patients who cannot provide one. We feel this proposal and those regarding obese patients would discriminate against certain patient populations and limit their access to appropriate treatments if they are overweight or live alone. Surgeons typically assess these factors in consultation with their patients when reviewing the risks and benefits of surgery and they should not be a blanket contraindication for surgery. C) 2, 3, 4, 6a: Is the surgeon responsible for treatment of nasal passages for staph, checking A1c, screening for delirium or checking nutrition and dentition? Again, this would be outside of the scope of most spine surgeons’ practices.	12/14/2018 3:45 PM
2	Is it relevant whether the care companion is a carrier for Staphylococcus? Is testing the care companion for same beneficial?	12/10/2018 1:12 PM
3	Very comprehensive list	12/10/2018 11:33 AM

4	B.1.c. : Is the Bree recommending/requiring a pre-surgical class, or is the language there to support providers in patient engagement within provider specific pre-surgical requirements? Would recommend editing language. C.3: Is this repetitive to A.1.d? Does the documented time period of stability below in A.1?	11/23/2018 2:28 PM
5	"Adequate" bone density is listed but there are no given guidelines for what is considered adequate? What if a patient has osteoporosis but is currently being treated? What if a patient has history of fragility fracture but DEXA scores do not reflect risk as reliably as FRAX? What is specifically "adequate" nutritional status? Do home evaluations have to be done pre-op on ALL patients? Did not see sleep apnea screening?	11/20/2018 4:56 PM
6	no comments	11/20/2018 11:46 AM
7	I agree. But what do you do with a person with neurologic deficit (foot drop, myelopathy, etc) that needs surgery but is a smoker or obese? Do you deny surgery and risk permanent neurologic damage?	11/19/2018 7:12 PM
8	The requirement for a "care partner" may be helpful, but will be impractical in many situations.	11/19/2018 11:32 AM
9	Smoking cessation has been routine. Weight loss is always attempted but if patient fails, there are currently no options. Many patients are able to loose weight after successful spine surgeries. Happy to provide references.	11/17/2018 3:16 AM
10	B	11/16/2018 12:03 PM

Q5 Please enter your comments about Cycle III: Spinal Fusion Procedure

Answered: 10 Skipped: 0

#	RESPONSES	DATE
1	We agree that it is reasonable to suggest general standards for teams performing spine fusion surgery, ways to optimize surgical processes and to discuss of registries and their potential utility. In fact, we urge the Bree Collaborative to review organized neurosurgery's NeuroPoint Alliance Spine Quality Outcomes Database (QOD), North America's largest surgical spine registry. While we agree that these sections are relevant in spine fusion surgery, there are several points that may not be generalizable to all spine fusion procedures. As such, some guideline may need to be amended. A) 6. In a busy surgery center, it may not be possible for all elective spine surgery to begin before 5 PM. If a delay in the operating schedule occurs, would the patient need to be cancelled and rescheduled? 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. Furthermore, we are not familiar with any literature that correlates the time of the start of surgery with outcome. B) 6. We agree with most of the recommendations regarding rh-BMP-2 use from the Washington Health Technology Program policy. This policy focuses on rh-BMP-2 use in revision cases and in anterior lumbar fusions. We strongly agree with these recommendations, however there are many other situations where rh-BMP-2 may be reasonable. In patients with osteopenia or osteoporosis, we feel that -rhBMP-2 is reasonable to use during initial spine fusion. D) Participation in Registries: As stated above, organize neurosurgery urges the Bree Collaborative to review and recommend the NeuroPoint Alliance QOD for spine surgery. However, we would like to have a greater understanding of who will be providing the funding for the surgeon and/or facility to participate in a registry. In addition, registries require time and intensive labor for data entry. Is the surgeon (if not hospital employed) responsible for doing this, or paying/hiring additional office staff to participate in the registry? Is the hospital required to provide labor to participate in the registry? Who determines which registry will be appropriate? This would be a significant hindrance to small practices, or providers who are not hospital employed.	12/14/2018 3:45 PM
2	No comments, appear to be reasonable	12/10/2018 1:12 PM
3	Very comprehensive	12/10/2018 11:33 AM
4	B.3 & B.5 vague.	11/23/2018 2:28 PM
5	Unless universally accepted, how do you prevent patients who refuse to participate in Spine COAP from just going to a facility not participating?	11/20/2018 4:56 PM

6	III A. 3. - orthopedic surgeons must be board certified as are neurosurgeons in III.A. 2 in addition to a spine fellowship. I would prefer to see higher minimums for surgeons and facilities but there is no clear evidence to support specific levels. These are reasonable.	11/20/2018 11:46 AM
7	I agree, but who is going to pay for all of the data collection? If you want more data and outcomes, this will require more staff and expenses.	11/19/2018 7:12 PM
8	Definition of "multimodal pain management" unclear.	11/19/2018 11:32 AM
9	Case start before 5PM would be great but unrealistic at the extremely inefficient university system.	11/17/2018 3:16 AM
10	C	11/16/2018 12:03 PM

Q6 Please enter your comments about Cycle IV: Post-Operative Care and Return to Function

Answered: 10 Skipped: 0

#	RESPONSES	DATE
1	We agree that it is reasonable to have a standardized process for postoperative care as well as for patient discharge.	12/14/2018 3:45 PM
2	No comments, appear to be reasonable	12/10/2018 1:12 PM
3	I wish there was more focus on home health, it has shown to be very beneficial. Also who will be the caregiver. Often patients are sent home with a caregiver who is disabled or has psychiatric issues, this is a set up for failure.	12/10/2018 11:33 AM
4	D.2. : We recommend, and believe most appropriate, post-operative patient reported outcomes should be collected at 6 months.	11/23/2018 2:28 PM
5	Discharge summaries are not required for the less than 24 hour stay of a minimally invasive fusion.	11/20/2018 4:56 PM
6	No comment	11/20/2018 11:46 AM
7	I agree	11/19/2018 7:12 PM
8	No additional comments.	11/19/2018 11:32 AM
9	We would need a tremendous team effort to make this work	11/17/2018 3:16 AM
10	D	11/16/2018 12:03 PM

Q7 Please enter any comments on the proposed quality standards below including any measures that should be included

Answered: 10 Skipped: 0

#	RESPONSES	DATE

1	The Bree document indicates that, “The provider group performing surgery must maintain or participate in a registry of all patients having first-time, single level lumbar fusion.” As we’ve mentioned, we are supportive of voluntary registry participation but do recommend that the financial and labor burden of gathering data in the private practice setting be considered. c. There are numerous existing patient registries and we recommend that providers have the option of participation in the NeuroPoint Alliance Spine QOD. 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? Standards for appropriateness: 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 specifically for 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. 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 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? Standards for patient safety and affordability 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?	12/14/2018 3:45 PM
2	Nothing to add	12/10/2018 1:12 PM
3	Very comprehensive	12/10/2018 11:33 AM
4	The introduction to the section all of the sudden limits the denominator. The defined denominator, reported quarter, will not provide a sufficient denominator for statistic reliability for any hospital or provider in the state. Additional, in the second paragraph there is the first mention of "contract". I believe this whole paragraph should be deleted, it should be up to the purchaser and the provider to determine contractual language and reporting requirements. The proposed quality standards add a good template for purchasers to use and for providers to be working towards and/or reporting on, but contracting provisions do not belong. 2.c & 2.e should be removed as there is no clear definition used to report on these standards and the Bree document does not provide. 3.a. Recommend 6 month measurement 3.b. Recommend adding the work "only" between including and responses.	11/23/2018 2:28 PM
5	How do facilities accommodate for the increased number of staff such as physiatrists and psychologist needed to fulfill the pre-operative requirements?	11/20/2018 4:56 PM
6	There is no warranty for patient outcomes - return to work, return to function, pain free, etc. Since fusion is only effective in 50% or so, we should only be paying for those cases that work and not for those that do not. this would create MUCH better patient selection. You should not get $80K for a failure. Rather than just reporting 3, 6, 12 month patient disability and QOL improvement, those levels should be tied to the bundle	11/20/2018 11:46 AM
7	I agree. Who is paying for the data collection?	11/19/2018 7:12 PM
8	Number 5: Standards for Patient Safety and Affordability. The "affordability" part of this is unclear and confusing.	11/19/2018 11:32 AM
9	Who will do this work?	11/17/2018 3:16 AM
10	E	11/16/2018 12:03 PM

Q8 Please enter any comments on the surgical warranty

Answered: 9 Skipped: 1

#	RESPONSES	DATE
1	8. Please enter any comments on the surgical warranty 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. The operating 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, 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 and will not minimize complications. It is, however, a paradigm shift that may 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, 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. The proposed lumbar fusion warranty in its current form does not increase patient safety and does not minimize complications. The implementation of the purposed lumbar fusion warranty may compromise access to care for our patients.	12/14/2018 3:45 PM
2	Nothing to add, this appears reasonable	12/10/2018 1:12 PM
3	Concise	12/10/2018 11:33 AM
4	no comment	11/23/2018 2:28 PM
5	Is there exclusion for unknown pre-existing clotting disorders contributing to post-op complications or intraoperative bleeding?	11/20/2018 4:56 PM
6	The warranty is fairly standard post-surgical outcomes but NOT related to the proposed surgical benefit. There should/must be a warranty on the response to surgery in addition to standard complications of surgery/anesthesia	11/20/2018 11:46 AM

7	There are preventable complications (wrong site) and ways to mitigate known complications (infection, etc) but there is a know risk inherent with any surgery (infection, death, PE, etc). There are statistics in the literature with outcomes even in best case scenarios. There will be complications. If these are considered under warranty, then there has to be increased compensation to cover the cost of KNOWN, unpreventable complications that occur even using best practices.	11/19/2018 7:12 PM
8	No additional comments.	11/19/2018 11:32 AM
9	F	11/16/2018 12:03 PM

Q9 Please enter any comments on the contracting guidance to providers and employers as described in Appendix C

Answered: 6 Skipped: 4

#	RESPONSES	DATE
1	This appears reasonable. The COE "bundle" administrator may be different than the Plan TPA/Administrator, and require data sharing and related security measures to protect PHI. Also Participant Communications should be added. Informational pieces for prospective participants and those entering the Care Journey are pivotal to build engagement, understanding and shared decision-making.	12/10/2018 1:12 PM
2	Very comprehensive and well explained	12/10/2018 11:33 AM
3	no comment	11/23/2018 2:28 PM
4	no additional comment	11/20/2018 11:46 AM
5	Capacity to maintain access with increasing volume may be a challenge.	11/19/2018 11:32 AM
6	G	11/16/2018 12:03 PM

Q10 Please enter any comments on the code sets as described in Appendix E

Answered: 6 Skipped: 4

#	RESPONSES	DATE
1	No additional comments	12/10/2018 1:12 PM
2	Very well done	12/10/2018 11:33 AM
3	Diagnosis codes: This is a confusing section. The codes provided are not all encompassing of the diagnostic codes for patients that would qualify for the bundle and warranty. Example (M47.26, M48.06, M48.07). It would be more helpful to define that diagnosis that would exclude a patient from a warranty. Procedural codes: The Warranty specifies single lumbar, so why provide additional level codes? Confusing to the customer. Procedural code notes: This is unnecessary and confusing. Stating CPT codes may include, calls out a few CPT codes of many that could be on a patient's claim. It would be more helpful to call out codes that would exclude a patient. Complication Codes: These do not match what is specified in the warranty section of the document. Addition of Wound infection and other complications, was this supposed to be the surgical site infection that is defined by the CDC? Complications of other internal prosthetic devices, implants and grafts added and not in the warranty section. Complications of other transplanted organs and tissues not in the warranty section. Recommend removing and cleaning up this appendix.	11/23/2018 2:28 PM
4	no additional comment	11/20/2018 11:46 AM
5	No additional comments.	11/19/2018 11:32 AM

6	H	11/16/2018 12:03 PM

Q11 Please enter any comments about the evidence table below including any articles to add

Answered: 7 Skipped: 3

#	RESPONSES	DATE

1	The draft states that, “We have intended that this bundle be used for patients with more than 12 weeks of back or lower extremity pain of confirmed spinal origin with neurological symptoms or signs … in the presence of spinal instability.” Yet most of the references listed are for the patients with general low back pain, therefore, not suitable to be applied for the designed patient population. When referencing for articles that influence surgical vs nonsurgical treatment decisions, the authors are confusing the patient population with “low back pain” with the bundle-intended target patient population that has “more than 12 weeks of back or lower extremity pain of confirmed spinal origin with neurological symptoms or signs … in the presence of spinal instability.” The example of such references that are only applicable for the general “low back pain” population, instead of the proposed bundle targeted patient population are reference numbers 1, 2, 15, 17, 18, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 43, 45, 46, 47, 48, 49, 50, 51. The authors cited a NASS guideline in reference number 32 for treatment of degenerative lumbar spine stenosis, while completely ignoring the appropriate NASS guideline for the bundle intended patient population, “Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care Diagnosis and Treatment of Degenerative Lumbar Spondylolisthesis 2nd Edition” published in 2014, which supported the surgery, including lumbar fusion surgery for the stated patient population. In fact, of all the reference articles listed in the evidence table that relate to the appropriateness of spine fusion surgery, only reference number 16 is somewhat related to the bundle-intended target patient population. Reference number 16, which is somewhat flawed by including patients with both stable and unstable spine conditions, states “In the nonrandomized as-treated comparisons of symptomatic patients with degenerative spondylolisthesis and spinal stenosis treated surgically showed substantially greater improvement in pain and function during a period of 2 years than patients treated non-surgically (but with high complication rates). “ Appropriate references omitted from the evidence table for the intended patient population are listed below: Ghogawala Z, Dziura J, Butler WE, Dai F, Terrin N, Magge SN, Coumans JV, Harrington JF, Amin-Hanjani S, Schwartz JS, Sonntag VK, Barker FG 2nd, Benzel EC. Laminectomy plus Fusion versus Laminectomy Alone for Lumbar Spondylolisthesis. N Engl J Med. 2016 Apr 14;374(15):1424-34. 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 In the cycle 2: “Fitness for surgery” Section, the authors listed references of certain conditions, such as obesity, smoking, opioid, high sugar level, alcohol, depression, psychiatric disorders, osteoporosis, anemia, dementia, low albumin and cirrhosis, would likely increase the risk of complications of surgery. We certainly agree that those conditions make the surgery more complex and are potentially associated with more complications. However, excluding those patients from getting the appropriate treatments is ethically questionable, especially for the conditions that are not easily reversible. The authors confuse the potential increased risk with the ultimate appropriateness of the interventions. The right approach to patients with certain complicated conditions, is a thorough assessment by the operating surgeon as to whether a certain treatment is the best option for the particular patient. For example, for an obese patient with severe low back, leg pain, with clear evidence of spinal instability and failed conservative treatments, the question should be whether a lumbar fusion surgery is the appropriate treatment for that particular patient, despite the increased risks compared to the same surgery done in a non-obese patient. Using the authors’ logic, any medical interventions should only be permitted for the healthiest patient population as those are the groups with the least potential complications. Clearly, this does not reflect the real world practice of medicine. References omitted from the Bree Guidelines but related to this topic are below: Lingutla KK, Pollock R, Benomran E, Purushothaman B, Kasis A, Bhatia CK, Krishna M, Friesem T. Outcome of lumbar spinal fusion surgery in obese patients: a systematic review and meta-analysis. Bone Joint J. 2015 Oct;97-B(10):1395-404. Adogwa O, Carr K, Thompson P, Hoang K, Darlington T, Perez E, Fatemi P, Gottfried O, Cheng J, Isaacs RE. A prospective, multi-institutional comparative effectiveness study of lumbar spine surgery in morbidly obese patients: does minimally invasive transforaminal lumbar interbody fusion result in superior outcomes? World Neurosurg. 2015 May;83(5):860-6.	12/14/2018 3:45 PM
2	No additional comments	12/10/2018 1:12 PM
3	Very concise and complete	12/10/2018 11:33 AM
4	no comment	11/23/2018 2:28 PM
5	no additional comment	11/20/2018 11:46 AM
6	No additional comments	11/19/2018 11:32 AM
7	I	11/16/2018 12:03 PM

Q12 Please provide any general comments about the documents here

Answered: 7 Skipped: 3

#	RESPONSES	DATE
1	Despite the claim the bundled payment is for “patient-centered care,” we are concerned that the recommendations will limit some patients’ access to appropriate care and increase the cost, time and logistical challenges for patients and their surgeons. The proposal in this draft ignores the abundant evidence supporting the appropriateness of lumbar fusion surgery in treating patients with clear evidence of instability who failed appropriate conservative treatments. The proposal would lead to significantly diminished patient access to appropriate surgical care, diminish the surgeon’s role to mere “technician” and add extreme hurdles for the surgeons to provide appropriate care to the patients. This proposed bundled payment concept, without considering the vast variety of patient’s conditions and their real needs, would only lead to the penalization of the providers who are willing to help the patients that are sicker, more complicated and in more desperate need for the appropriate treatments. The authors cited the “disproportionate rise in lumbar fusion compared to other spine surgeries” as the reason for the need for increasing regulation and hinted the inappropriateness of the rising volume of lumbar fusion surgery, ignoring the possibility that the increasing popularity of the surgery could be due to the clear efficacy of such a surgery in alleviating the patient’s pain and disability, in the appropriate group of patients. This is as if to say the disproportionate rise in the smart phone usage compared to other phones is the reason for limiting the smart phone usage, ignoring the convenience and increased productivity the smart phone brought over the traditional landlines. The draft cited the “evidence that for many patients considered candidates for lumbar fusion, there was no clear benefit of surgery compared to non-surgical care” without listing any real supporting evidence for the bundle-intended patient population and ignoring the evidence supporting surgery over non-surgical care in such patient populations. The draft claimed “2) a growing national and international support among spine surgeons for the application of such standards, and 3) when the bundle is used as a basis for value-based purchasing, with direct contracting between provider and employer, quality and affordability improve and satisfaction is high among patients, providers, and the employer. “However, no evidence for these claims for the bundle-intended patient population is provided. We remain concerned that the proposed model will increase costs and delay care, while not providing more “warranty” against potential complications than what we already provide with the 90 day global period. There will be more providers involved in the pre-operative evaluation process including physiatrists gatekeepers and increased costs incurred with additional medical screening related to psychiatric disorders, delirium, nutrition, etc. There will be delays in care with more practitioners needing to see, evaluate and “sign off” on surgical intervention, as well as “collaborative team meetings” prior to any surgical procedure. The decision making for surgery will be removed from the judgement of the surgeon, and given to a “collaborative team” and a physiatrist, for whom the indications for surgery are outside of their scope of practice. While we urge the Bree Collaborative to include the NeuroPoint Alliance Spine QOD as an option to fulfill the recommendation for participation in a registry, we feel it is important to consider the cost of registry participation and the labor involved with these registries.	12/14/2018 3:45 PM
2	Rigorous, well thought out.	12/10/2018 1:12 PM
3	Wonderfully done, very easy to understand. Complete and concise	12/10/2018 11:33 AM
4	no comment	11/23/2018 2:28 PM
5	Bundles have yet to be definitively proven to reduce costs and improve quality. therefore, this should still be considered experimental and measured rigorously.	11/20/2018 11:46 AM
6	No additional comments	11/19/2018 11:32 AM
7	J	11/16/2018 12:03 PM

Q13 Do you have any comments or suggestions to help these recommendations be adopted across Washington State?

Answered: 10 Skipped: 0

#	RESPONSES	DATE
1	Again, please note that these comments provided are on behalf of the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) Joint Section on Disorders of the Spine and Peripheral Nerves (DSPN), American Academy of Orthopaedic Surgeons, International Society for the Advancement of Spine Surgery (ISASS) and Washington State Association of Neurological Surgeons (WSANS). Questions may be directed to Catherine Jeakle Hill, AANS/CNS Washington Office, Senior Manager for Regulatory Affairs at chill@neurosurgery.org. References Noted in Question 3 B) 1. Are listed below: 1. Ghogawala Z, Dziura J, Butler WE, et al. Laminectomy plus Fusion versus Laminectomy Alone for Lumbar Spondylolisthesis. N Engl J Med. 2016;374(15):1424-1434. 2. Forsth P, Olafsson G, Carlsson T, et al. A Randomized, Controlled Trial of Fusion Surgery for Lumbar Spinal Stenosis. N Engl J Med. 2016;374(15):1413-1423.	12/14/2018 3:45 PM
2	Not at this time.	12/10/2018 1:12 PM
3	Very useful and well presented document	12/10/2018 11:33 AM
4	no comment	11/23/2018 2:28 PM
5	Organize all the barriers to being fit for surgery with specific guidelines and recommendations in a flow sheet allowing a MA or nurse to screen.	11/20/2018 4:56 PM
6	Bundles should not be required or adopted as many providers are already in value based arrangements. The bundle may limit these VBA contracts and benefits. The guidelines themselves are very reasonable however.	11/20/2018 11:46 AM
7	Currently we have multiple insurance carriers and plans, all with different guidelines for surgery (that also routinely change their guidelines). We never know which data needs to be documented. If there is a standard to follow that every insurance company mandates, then this will be easier.	11/19/2018 7:12 PM
8	Must be more emphasis on interoperability within the state for employers/hospitals/providers to rapidly and consistently share data.	11/19/2018 11:32 AM
9	Generally good and well-intended recommendation. Unrealistic to implement.	11/17/2018 3:16 AM
10	K	11/16/2018 12:03 PM

Q14 Name:

Answered: 8 Skipped: 2

#	RESPONSES	DATE
1		12/14/2018 3:47 PM
2		12/10/2018 1:12 PM
3		12/10/2018 11:34 AM
4		11/23/2018 2:28 PM
5		11/19/2018 7:12 PM
6		11/19/2018 11:33 AM
7		11/17/2018 3:16 AM
8		11/16/2018 12:04 PM

From:
To: Ginny Weir; Robert.Mecklenburg@virginiamason.org
Subject: RE: Standards for Implantable Hardware
Date: Tuesday, November 27, 2018 12:04:55 PM

Ginny, would you also please add the following:

Due to increasing pressure, the FDA is now talking about revamping the 510(k) process to be more current with today's technology. They will rename the 510(k), but the proposed plan will still use substantial equivalence as the measure. Until devices are held to gold standard for testing safety and effectiveness, the device market will not be safe for patients. Performance measures based on lab tested benchmarks do not provide simulation of use in the human body. Using real world evidence as a performance measure makes guinea pigs out of patients. Changing the name of the pathway, removing predicate devices that are more than 10 years old does not create a safer device market. A rat by any other name is still a rat.

Registry data provides another challenge, because the data is not transparent, includes very little in the way of patient reported outcomes, and suffers from severe under-reporting. The FDA MAUDE database is unwieldy for most uses. There still are major problems with the use of UDI in tracking devices. The ICIJ, in recent investigative reports have stared an international device registry. I would suggest this is a good resource for transparent data. I also recommend that the star find a way to make the data available through Device Events available to all providers - surgeons, purchasers, insurers and payors.

We cannot rely on FDA standards and industry claims. Providers, payers, and patients alike need to proceed with great caution when considering the use of any medical device. The Bree is charged by the State to provide recommendations of best practice for common medical procedures so as to optimize outcomes while minimizing costs. If patient outcomes are indeed the priority, then strong language regarding the realities of medical device selection must be included in this bundle.

Thanks Ginny!
Linda

Sent from Xfinity Connect Application

Dear Meck,

I am sure you remember the concerns I expressed about device selection standards during the re-review of the Hip and Knee Bundle Warranty. We would have had that conversation again with the Spinal/Lumbar Fusion workgroup had I been able to be present at the meeting during which this should have been discussed. This is an area of grave concern for me, as you know, and I have come across some information that I believe is critical to moving forward with this issue.

Ginny's email stated the following:

4. Standards for implantable hardware

The lumbar fusion bundle is silent on the issue of accountability of the manufacturer or provider for selection of implantable hardware. Bree has included such language in the bundle for total joint replacement. I've included this below with URLs

****

Selection of the surgical implant (from the bundle on total joint replacement)

*1. Select an implant that has a <5% failure rate at ten years.**For more recently introduced implants registry data should demonstrate a failure rate of less than 1% per year for the first 5 years and then never > 5% between years 6-10.*

2. All hospitals and facilities must report level I data to the American Joint Replacement Registry

3. Surgical teams are encouraged to select implants from suppliers that offer warranties against defects

http://www.titanspine.com/article/titan-spine-announces-guarantee-its-spinal-interbody-fusion-devices

https://www.ecnmag.com/2017/04/aesculap-launches-device-warranty-plasmaporexp-surface-enhancing-technology-portfolio-spinal-fusion

https://www.spinalelements.com/TI_PR_ENO_080116.pdf

https://www.nuvasive.com/news/nuvasive-unveils-newest-additions-to-early-onset-scoliosis-portfolio-at-posna-annual-meeting/

If anything,the situation with device safety has continued to deteriorate as the FDA has repeatedly failed to fulfill its responsibility to protect the health of the American public by insisting on pushing more and more devices through to market using the 510(k) pathway. As you will recall, the 510(k) was established by Congress in 1976, and should have been phased out by now according to the legal parameters within which it was created. However, the FDA not only continues to advance devices to market, but has further truncated the process repeatedly, so that devices are allowed to be used in patients without any checking for falsification of bench testing, prior study data, risk/benefit profile, or even mislabelled with untested uses.

Recently several studies have been published which verify the harm being done due to FDA failure in pre-market processes and severely delayed response to post-market medical device reports of adverse events. Though the studies are focused on the cervical spine and related devices, the data points to the difficulty in setting standards for the use of devices in any surgical procedure. Spinal surgeries involving polymer-based (PEEK) implants have been a huge boom. Surgeons paid tens of millions to promote/teach/develop & implant them are now saying the devices fail at a rate 5x higher than the long held gold standard products made of bone.

This all points to the underlying question - how did these defectively designed, mislabeled devices that conceal known harms get to market? Industry routinely games the FDA 510(k) pathway by introducing these type of devices into U.S. operating rooms by routinely omitting material facts and safety information about the actual device-use risk profile. Designed for one unproven/untested use, they easily dupe the FDA by submitting false declaration of conformity statements and bench-testing with erroneous data associated with a completely different use. It's all too easy to dupe the FDA CDRH which seemingly is asleep on the job. As a result, millions of Americans have undergone

cervical spinal fusion surgeries that left them with catastrophic injuries, disabled, dependent on opioids or dead. None of the patients were informed that the devices were mislabeled or of the actual device-use risk profile. Private and public insurance benefits programs paid out billions over the last decade. Blue Shield of California and Cigna have changed their policy coverage to "investigational and experimental" and the "subject of likely abuse." In addition, Stanford, OHSU, and University of Texas, Austin are all investigating at the highest levels, the use of these devices.

This directly contradicts the article listed above as a warranty product, but uses PEEK supposedly covered in titanium.

The NASS President Study showing the high failure rate is below:

https://web.archive.org/save/https://www.spineuniverse.com/professional/news/pseudarthrosis-found-half-patients-peek-implants-anterior-cervical-discectomy?fbclid=IwAR2TNwaPP1ZxeTJTMuB5b8xyWAj7MFnqFmZA0pfObTSNk5-vT2VwPkE49J0

OHSU also co-authored the study and published their own findings here below:

https://thejns.org/spine/view/journals/j-neurosurg-spine/aop/article-10.3171-2018.7.SPINE18531.xml

Registry data is severely limited by under-reporting and a lack of patient reported outcomes.

Regarding Nuvasive's Publication of Warranty:

This orthopedic journal reveals that the Nuvasive Magec system which was redesigned to include RELINE for pediatric patients was cleared for market through the 510(k). It has not been tested outside the lab.
https://www.odtmag.com/contents/view_breaking-news/2017-09-06/fda-clears-nuvasives-redesigned-magec-system

The cited article from Ginny's email states:

In addition, as part of the Company's Surgical Intelligence™ platform, LessRay offers the surgeon and hospital system the opportunity to use significantly reduced radiation imaging in the operating room. *Following a recent procedure using LessRay, Dr. Amer Samdani, Chief of Surgery at Shriners Hospital for Children — Philadelphia, remarked, "I was amazed that the NuVasive LessRay technology allowed us to take less shots and reduce the radiation emission with every shot, which has significant impact for staff and patients of all ages."* *This practice of using opinion leaders who are being paid by the industry is rampant.*

Dr. Amer Samdani received $440,00 from industry from 2013-2016

All Payments: At a Glance

2016

144 PAYMENTS

$197,671 PAYMENT TOTAL

9 COMPANIES PAID THIS DOCTOR

2015

59 PAYMENTS

$79,450 PAYMENT TOTAL

3 COMPANIES PAID THIS DOCTOR

2014

125 PAYMENTS

$121,019 PAYMENT TOTAL

6 COMPANIES PAID THIS DOCTOR

2013

41 PAYMENTS

$41,979 PAYMENT TOTAL

5 COMPANIES PAID THIS DOCTOR

https://projects.propublica.org/docdollars/doctors/pid/170269

I am gravely concerned that we are facing a nearly impossible situation for setting standards. Let me know how I can help.

Linda Radach

Washington Advocates for Patient Safety

Patient Safety Action Network

USA Patient Network

From:
To: Ginny Weir
Subject: Indirect decompression in spinal surgery - ScienceDirect
Date: Thursday, November 29, 2018 5:09:44 PM

Hi Ginny,

Attached is a recent summary article describing a number of lumbar fusion techniques to provide indirect nerve root (or foraminal stenosis) decompression. This foraminal stenosis is what we've referred to in this bundle as "up/down" stenosis or nerve impingement. The bibliography gives several good articles that show clinical support for performing a single or two level lumbar fusion to treat the radiculopathy that arises from this condition.

https://www.sciencedirect.com/science/article/pii/S0967586817309815

As to the issue of spine surgeon board certification, I have never heard of this separate board certification body for spine surgeons. I believe that the widely held community standard is board certification in one's area of residency (post-graduate medical education). I do not support different definitions for neurosurgeons and orthopedic surgeons.

See you soon,

From:
To: Ginny Weir
Subject: RE: Bree lumbar fusion bundle
Date: Monday, December 17, 2018 5:04:42 PM

Not likely I can come to Olympia, but here is my response.
Thanks!

Dear Ms. Weir,
I write on the behalf of the Washington state orthopedic Association which represents the interests of orthopedic surgeons and their patients across the state of Washington. Thank you for the opportunity to comment on the Bree collaborative lumbar spine fusion bundle.
We have had an opportunity to review the documents provided regarding the bundle. The intent of the bundle appears to be a reduction in of spinal fusions performed, with the presumption being that this procedure is being offered too frequently for non-evidence based indications. It would also appear that there is a significant effort to optimize the outcomes of those procedures which are performed. We applaud those efforts and are impressed with the scientific diligence that has validated the recommendations included in the bundle.

We do have some concerns, however.
Overall, the bundle seems to be highly proscriptive. In many cases it appears that community spine surgeons will be unable to meet the requirements necessary to comply with the bundles' recommendations. I will give you several examples.
Example #1 "Collaborative Team". Orthopedic spine surgeons in private practice in many communities have tried to work with or hire Physical medicine and rehab physicians to work with them. This has largely been unsuccessful from a financial point of view. A collaborative team led by a PM&R physician, we agree, is desirable but is often not available to surgeons practicing in community environments.
Example #2. Patient reported outcome measures are seemingly a requirement before proceeding with spinal fusion. The PROMIS–10 and Owestry disability indices are offered as possible methods of measurement of disability, but these are time-consuming to apply and most private practice simply cannot afford to pay the staff necessary to complete those studies.
Example #3, operating room team. In the environment in which most of us work, we cannot have two surgeons available to perform these procedures and are not in control of who our operating team is each day. We therefore cannot guarantee a consistent "spine team" in the operating room.

While the intent of the "bundle" is admirable, our concern is that many spine surgeons will simply "give up" on the idea of performing spinal fusion surgery or even to be involved in the care of patients covered by state run insurance plans. This may be beneficial to those groups do manage to meet the requirements of the bundle, but will be will significantly limit access for those patients not living and an area where those institutions exist.
Perhaps some leeway in applying the bundle needs to be granted to community spine surgeons, or perhaps some "gradual phase-in" process would be helpful.

Nicholas Rajacich, MD
President, Washington State Orthopaedic Association