Public Comments Summary
TKR/THR Bundle

We appreciate the many valuable and constructive comments by over 50 respondents during our public comment period, many of which were offered by the local and national community of orthopedic surgeons. We have made a number of substantive changes to the draft bundle as a result of public comments. We have also added citations to the evidence table and have completed final evidence appraisals.

While we anticipate that some provisions of the bundle and warranty remain areas in which there are differences of opinion, each comment has been carefully reviewed by our committee and weighed against available evidence medical evidence. Finally, the bundle was approved by the provider, purchaser, health plan, and quality organizations that comprise the Bree Collaborative in November 2013.

Changes made to section two, Fitness for Surgery, include:

- Body mass index should be less than 40.
- The patient must complete an advance directive and designate a durable power of attorney.
- Evaluation for good dental hygiene may require dental consultation as necessary.

Changes made to section three, Repair of the Osteoarthritic Joint, include:

- Facilities in which surgery is performed must comply with the American College of Surgery statement on health industry representatives in the operating room.
- Substitution of a more general statement about using appropriate medication to limit blood loss.
- Substitution of a more general statement concerning appropriate measures to avoid deep venous thrombosis and pulmonary embolism.
- All implants must be registered using the American Joint Replacement Registry.

In addition, the Bree Collaborative retained the specification that surgeons perform at least 50 joint replacements a year.

Public Comment Survey for Draft Total Knee and Total Hip Replacement (TKR/THR) Bundle

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

		Response Percent	Response Count
Orthopedic surgeons		**48.0%**	**24**
Other health care providers (primary care physicians, physical therapists, nurses, etc.)		12.0%	6
Hospitals		8.0%	4
Government/Public Purchasers		2.0%	1
Employers		0.0%	0
Health Plans		2.0%	1
Consumers/Patients		14.0%	7
Self		0.0%	0
Other (please specify)		14.0%	7
		answered question	**50**
		skipped question	**0**

2. Do you support the concept of a bundled payment model for TKR/THR surgery?

		Response Percent	Response Count
Yes		**46.0%**	**23**
No		32.0%	16
Neutral/No Opinion		22.0%	11
		answered question	**50**
		skipped question	**0**

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

	Response Count
	31
answered question	**31**
skipped question	**19**

4. Do you agree with the proposed components of the first section (Disability due to osteoarthritis despite conservative therapy)?

		Response Percent	Response Count
Yes		**68.0%**	**34**
No		24.0%	12
Neutral/No Opinion		8.0%	4
		answered question	**50**
		skipped question	**0**

5. Any comments about the Disability section?

	Response Count
	24
answered question	**24**
skipped question	**26**

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

		Response Percent	Response Count
Yes		**54.0%**	**27**
No		38.0%	19
Neutral/No Opinion		8.0%	4
answered question			**50**
skipped question			**0**

7. Any comments about the Fitness section?

	Response Count
	30
answered question	**30**
skipped question	**20**

8. Do you agree with the proposed components of the third section (Repair of the osteoarthritic joint)?

		Response Percent	Response Count
Yes		**42.0%**	**21**
No		38.0%	19
Neutral/No Opinion		20.0%	10
		answered question	**50**
		skipped question	**0**

9. Any comments about the Repair section?

	Response Count
	24
answered question	**24**
skipped question	**26**

10. Do you agree with the proposed components of the fourth section (Post-operative care and return to function)?

		Response Percent	Response Count
Yes		**64.0%**	**32**
No		24.0%	12
Neutral/No Opinion		12.0%	6
		answered question	**50**
		skipped question	**0**

11. Any comments about the Post-operative Care section?

	Response Count
	18
answered question	18
skipped question	32

12. Do you agree with the proposed quality standards?

	Response Percent	Response Count
Yes	44.0%	22
No	24.0%	12
Neutral/No Opinion	32.0%	16
answered question		50
skipped question		0

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

	Response Count
	19
answered question	19
skipped question	31

14. Please provide any general comments about the draft bundle here:

	Response Count
	28
answered question	28
skipped question	22

15. Name:

	Response Count
	35
answered question	35
skipped question	15

16. Email address:

	Response Count
	34
answered question	34
skipped question	16

17. Organization:

	Response Count
	35
answered question	35
skipped question	15

Page 2, Q1. What sector do you represent? (Choose the option that is the best fit.)		
1	The Alliance for Orthopedic Solutions is a national organization that collaborates with leading clinical experts and researchers in orthopaedics and includes the leading developers and manufacturers of innovative orthopaedic devices and implants. The Alliance is dedicated to ensuring that issues impacting orthopaedics, especially innovative technology and orthopaedic treatments, are given appropriate consideration in the formation of federal health care and reimbursement policy.	Oct 25, 2013 10:53 AM
2	anesthesiologist	Oct 18, 2013 4:25 PM
3	PACU RN and DATA ABSTRACTOR	Oct 18, 2013 10:15 AM
4	Anesthesiologist	Oct 18, 2013 8:40 AM
5	Bundled payment expert	Oct 15, 2013 6:09 AM
6	Medical Transportation sector	Oct 11, 2013 5:40 PM
7	quality at group health	Oct 9, 2013 2:28 PM

Page 2, Q3. Do you have any comments about the bundled payment concept?		
1	Not in its current form as there is no mention of patient accountability and compliance. All the risk is placed on the facility/provider. Otherwise, I would support the concept.	Oct 25, 2013 4:49 PM
2	People and their medical problems rarely fit neatly into a "bundle'. The bundle concept makes it very difficult to cover the complexities of medical care.	Oct 25, 2013 2:15 PM
3	it's great if there is support to put every patient through the checklist. most systems do not have all of this in place currently.	Oct 25, 2013 1:41 PM
4	The Alliance for Orthopedic Solutions strongly supports initiatives to promote high-quality care for orthopedic patients. The draft bundle developed by the Bree Collaborative's Accountable Payment Model (APM) subgroup outlines many key clinical parameters intended to contribute to optimal outcomes for patients who are candidates for joint replacement therapy. It is imperative to ensure, however, that these treatment guidelines do not limit access to patients who could greatly benefit from surgery, nor should they prevent patients from accessing medical innovations that could reduce pain, drastically improve functional status, and positively impact health-related quality of life. We outline below our specific concerns related to the Bree Draft Total Knee and Total Hip Replacement Bundle, and we request that these issues be addressed before recommendations are submitted to the full Bree Collaborative and the Washington State Health Care Authority.	Oct 25, 2013 10:53 AM
5	We applaud the efforts of stakeholders in Washington State through the Bree Collaborative to meet together towards the mission of improving health care. Washington State, along with the rest of the country, is working to identify and promote strategies that improve patient outcomes and the quality of health care services while reducing costs. Achieving these goals requires collaboration, and the Bree Collaborative helps fill this need by providing a forum in which this collaboration can be successful. The Bree Collaborative identifies up to three areas, annually, where there is substantial variation in practice patterns and/or high utilization trends that do not produce better care outcomes. After the Bree Collaborative selects a topic area, it appoints an expert workgroup to develop evidence-based recommendations for improving quality and reducing waste in the health care system. We do believe the Proposed Components would be benefited by a statement of principles to underscore the objectives and purpose of the effort. Statements such as: (cited from a VHA Knee Replacement Bundled Payment Simulation Project) "The bundle definition should include services that can be clearly related to the trigger-event" "The bundle design should encourage the provider and payer to agree on the specific types/causes of readmissions to target for better control, rather than set a price based on a general reduction target for all-cause readmissions" "The bundle design should not create a financial disincentive to direct a patient into the best/appropriate treatment pathway" "The bundle design should create an incentive to improve the quality and efficiency of patient care delivery" "Quality metrics, reasonableness to administer, and appropriate assurance of medical decision making for the benefit of the individual patient are critical elements."	Oct 25, 2013 10:28 AM
6	The American Association of Hip and Knee Surgeons (AAHKS) is a national association of orthopaedic surgeons formed to provide leadership in advocacy, education and research to achieve excellence in hip and knee patient care. AAHKS is committed to quality and improving the care of our patients. We	Oct 25, 2013 7:57 AM

Page 2, Q3. Do you have any comments about the bundled payment concept?		
	therefore support efforts to promote high-quality orthopaedic procedures. We are concerned that the draft policy as currently designed imposes unnecessary conditions that are not linked to quality of care and could have the unintended effect of hindering access to medically-necessary care for many patients.	
7	It is m belief that this system disadvantages providers- whether it is hospitals, surgeons or therapists into agreeing to provide potentially unlimited services for a fixed compensation.	Oct 25, 2013 1:38 AM
8	The bundled payment concept is essential for patient safety – it will assure patients that the best practices based on evidence are being used and will result in fewer complications.	Oct 24, 2013 4:01 PM
9	It is concise and avoids over payments for procedures	Oct 23, 2013 7:56 PM
10	It has to take into account the relative risk of patient health and complications	Oct 23, 2013 9:07 AM
11	Concerned about the structure for outcomes and models of payment	Oct 22, 2013 5:21 PM
12	Only if designed right.	Oct 22, 2013 3:41 PM
13	All factors can not be controlled by tne MD. warranty should be on controllable factors only	Oct 22, 2013 12:06 PM
14	Not at this time.	Oct 22, 2013 10:52 AM
15	The control of the bundle should be in the hands of the physician. Since they are performing the procedure, accepting the biggest liability, and care for the patient lifelong, it only makes sense for the doctor to be in control. Also factors that are based on cost and not on patient outcomes are given consideration greater than needed, to make recommendations.	Oct 21, 2013 12:07 PM
16	Bundled payments do not allow reflect the varying complexity of different patients with different co-morbidities and varying recovery issues.	Oct 20, 2013 7:45 AM
17	bundled payment going to the MDsmakes more sense than giving it to the hospitals	Oct 18, 2013 10:14 PM
18	I applaud the desire to control costs. As the more powerful entity, the hospital will have an inordinate control of the dollar over the orthopedist. (Mark up for the prosthetic implants is not justified and may be partially addressed by this model.)	Oct 18, 2013 5:01 PM
19	Bundled payment should include anesthesiologists.	Oct 18, 2013 4:25 PM
20	Bundled payments will help align incentives for financial efficiency, but must be 'secured' by robust performance metrics to guard against cutting corners.	Oct 18, 2013 9:29 AM
21	The challenge will be in the implementation ---more specifically the coordination of care to make it work. Then there is the challenge of dividing up the money	Oct 18, 2013 8:40 AM
22	will not be successful without proper involvement of experienced joint replacement surgeons	Oct 18, 2013 5:43 AM
23	appreciate and respect the detail and care which went into the work to bundle	Oct 17, 2013 9:53 PM

Page 2, Q3. Do you have any comments about the bundled payment concept?		
	best practice and desired patient outcomes. The bundle is specific, clearly defined and will be helpful in controlling costs while improving quality of care. That said, I believe that it will be necessary from the provider side and the patient end to review and revise the bundle on a routine basis to assure maximum benefit and compliance. The initial implementation could cover a three year span with assessment and revision to follow.	
24	Excellent method for patient safety and better health incomes	Oct 17, 2013 11:09 AM
25	It's effective at controlling the costs of episodes and should be used as a mechanism to inform consumers about the differences in total episode price by provider	Oct 15, 2013 6:09 AM
26	It really only works for employed orthopedic surgeons.	Oct 14, 2013 5:58 PM
27	Payment must be set at level which is fair to physicians.	Oct 14, 2013 12:23 PM
28	This model works from a one-size-fits all assumption. This can be highly prejudiced against individuals with conditions which could cause them to come in with a poor score in the overall ratings, yet individuals who could still have very successful outcomes and huge benefits from these procedures.	Oct 11, 2013 5:40 PM
29	This concept is amenable to relatively healthy patients. Those with higher risk, may still benefit from hip or knee replacement for pain relief, safety, and to promot independent living, however the bundled payment may not cover the added risk to include them in the bundle.	Oct 11, 2013 1:39 PM
30	Bundled pricing worked well before Medicare's "bright" idea to unbundled. That is when Tylenol in three hospital became $5 a pill.	Oct 10, 2013 11:09 PM
31	Excellent idea, and this work is well-researched and thought-out. Should help improve patient experiences and overall outcomes for these procedures.	Oct 9, 2013 2:34 PM

Page 2, Q5. Any comments about the Disability section?		
1	The concept is fine, but getting the baseline information into the facility EMR for reporting purposes may prove to be very difficult. Many surgeons have separate EMR's not connected to the facility so data mining will likely be manual at best.	Oct 25, 2013 4:49 PM
2	HOOS and KOOS are appropriate and may be a favored instrument for measuring functional status in patients with hip and knee arthritis and evaluating outcome following THA and/or TKA. Although this may be a favored instrument, it can be seen as onerous and unnecessary to re-measure a patient who has failed a 3-month course of conservative management. The value of these instruments happen when comparing initial function to post-operative function, or to function following a longer course of non-operative treatment (at least one year). I.C.1: Many of the conservative therapy/physical measures in I.C.1 can be beneficial, but the impact is very difficult to measure in just 3 months. For many patients, these measures do nto work or are not appropriate. These measures are a more appropriate strategy for longer time frames in a subset of patients (6-12 months), they should not be a pre-operative requirement for all patients. I.C.2: Trialing medications is appropriate, but there should be an option for "use is contra-indicated," which is the case in some patients (i.e. kidney disease).	Oct 25, 2013 4:34 PM
3	Although scores , such as KOOS, can be helpful in scientific studies to evaluate the effects of treatment, are not as helpful in routine clinical practice. Many scoring systems are available and not all physicians agree on the most valid scoring system. Also, their routine use on every patient would create yet another significant administrative burden for most offices.	Oct 25, 2013 2:15 PM
4	the scoring systems can be laborious and the data will need to be inputed to the registry	Oct 25, 2013 1:41 PM
5	The document endorses corticosteroid injection which have a known risk for increasing postoperative infections in total knee patients.	Oct 25, 2013 12:39 PM
6	We are concerned that the requirement of 3 months of conservative therapy unless “highly Disabling osteoarthritis is evident at the time the patient first seeks medical attention” is inappropriately clinically restrictive, and does not reflect standard of care and surgeon practice in decision-making processes. First, there are other medical conditions besides “highly disabling osteoarthritis” that could warrant surgery without conservative care, such as Rheumatoid arthritis, traumatic arthritis, malignancy involving the joint and osteonecrosis of the femoral condyle or femoral head, and traumatic fracture. More generally, however, no practice guideline can cover every patient scenario, so it is critical that surgeons retain their licensed autonomy to make the best treatment decisions based on sound clinical evidence and consideration of their individual patient’s needs. We therefore recommend that the guidelines acknowledge that there are situations in which conservative therapy is not appropriate for a particular patient, in which case the specific circumstances should be documented in the patient’s medical record. See for instance Palmetto GBA’s Medicare Local Coverage Determination (LCD) for Total Joint Arthroplasty (L33050), which specifies that unsuccessful conservative therapy should be addressed in the pre-procedure medical record if appropriate, and if conservative therapy is not appropriate, the medical record must clearly document why such approach is not reasonable.	Oct 25, 2013 10:53 AM

Page 2, Q5. Any comments about the Disability section?		
7	After patients have osteoarthritic changes on x-rays and pain, benefit of “conservative therapy” of bracing, strengthening may not give any benefit. Reports on oral glucosamine do not support its use. The use of the KOOS or HOOS are supported. There is cost to gather this data and reporting of this and other data called for in this paper that are not mentioned.	Oct 25, 2013 10:28 AM
8	The draft would require a three-month trial of conservative therapy “unless highly disabling osteoarthritis is evident at the time the patient first seeks medical attention.” We believe that this standard is far too rigid to address the range of conditions that could merit surgery without an extended course of conservative therapy. We recommend explicitly recognizing that there may be situations in which conservative therapy is not appropriate for a particular patient. For example a patient may initially present late in disease progression (bone on bone) and be beyond the point where conservative therapy can be beneficial. The specific circumstances that warrant forgoing conservative care would need to be documented in the patient’s medical record. In addition, while the draft recognizes osteoarthritis, this provision also should recognize that surgery without the specified conservative treatments may be appropriate for other type of arthritis, including Rheumatoid arthritis, traumatic arthritis, along with malignancy, osteonecrosis, or traumatic fracture. The draft also references documenting the disability according to Knee Osteoarthritis Outcome Score (KOOS) or Hip Osteoarthritis Outcome Score (HOOS), and then redocumenting failure of conservative care on the KOOS/HOOS. We would point out that these steps can impose administrative burdens and costs that are not addressed by the draft.	Oct 25, 2013 7:57 AM
9	If you are going to consider a scoring system, you will need to define the acceptable KOOS score etc to qualify for replacement. I think activity of daily living disabilities should also be adequate documentation	Oct 25, 2013 1:38 AM
10	Not appropriate in most cases	Oct 24, 2013 4:12 PM
11	Several reasons that this is important: to ensure that people are not getting unnecessary surgery; to ensure that less invasive alternatives are explored before joint replacements; to ensure patients understand the level of disability that warrants implants. We question why the only condition included in the bundle is osteoarthritis. We recommend that the bundle apply to all conditions under which patients are getting hip or knee replacements, such as traumatic injuries or rheumatoid arthritis, so each patient would get the benefit of the applicable components of the bundle.	Oct 24, 2013 4:01 PM
12	Please specify the conservative therapy involved should be Physical Therapy. In addition to the strengthening, this should include normalization of joint (patho)mechanics and gait abnormalities. Why was viscosupplementation injection not included under 1C(2)?	Oct 22, 2013 5:21 PM
13	Even if we adopt KOOS/HOOS, please explain how the State will support a functional workflow and data collection. Seems to create more work, more paper if done haphazardly. Is the State willing to license, on behalf of the doctors, an outcomes measurements tool that is integrated with our EHR? Also, how do you document self reported productivity? Where is the tool for that?	Oct 22, 2013 3:41 PM
14	No	Oct 22, 2013 10:52 AM

Page 2, Q5. Any comments about the Disability section?		
15	Excellent in concept. Documentation of disability should not require universal use of KOOS or HOOS score assessment. K-L scale may be just gr 2 in some (eg RA) cases and still be an appropriate candidate.	Oct 18, 2013 5:01 PM
16	No	Oct 18, 2013 4:25 PM
17	HOOS/KOOS are research tools, not substitutes for clinical decision making.	Oct 18, 2013 5:43 AM
18	Sometimes xrays do not reveal the full extent of damage, yet surgical findings support the Grade 3-4 scale. Is there flexibility or other measures that can be used if an xray is deficient in meeting the standard, but the patient reports high disability or pain? The AAOS just recommended that patients not use glucosamine products due to insufficient scientific evidence of value and effectiveness. See link for more information: http://www.choosingwisely.org/doctor-patient-lists/american-academy-of-orthopaedic-surgeons/ - This appears to address only osteoarthritis diagnosis. While OA is undoubtedly the most common precipitator of hip/knee replacements, there may be other underlying diagnosis. How does the bundle address this reality?	Oct 17, 2013 9:53 PM
19	Of course there are other disability factors due to injury	Oct 17, 2013 11:09 AM
20	1. First, it appears that conservative care would be more appropriately called "nonoperative care". The use of xrays with Kellgren--Lawrence grade 3 or 4 changes can confirm the presence of OA of the knee, but some knee and hip patients have severe symptoms with less radiographic changes, and still may not be responsive to nonoperative treatment. Often the DJD may be more localized, so that the xrays UNDER DIAGNOSE the degree of OA present. In those cases the DJD may be documented by means of MRI, CT scan, response to diagnostic injection or by documentation of cartilage loss by arthroscopy. These patient if properly diagnosed can have marked improvement in function by partial or total joint replacement. The documentation of the need for surgery should allow for the alternate imaging to confirm the presence of OA, if conventional xrays do not confirm OA	Oct 15, 2013 10:29 PM
21	I am not clear why you selected the tools to measure disability out of all the tools available. I don't think the evidence you cited is particularly powerful.	Oct 14, 2013 5:58 PM
22	Depends on what you mean by "conservative therapy". If there's no cartiledge left in the hip and the joint is crumbling, then I suspect all the conservative therapy in the world will only delay the inevitable and end up adding cost to the procedure and delaying the individual's return to a productive lifestyle.	Oct 11, 2013 5:40 PM
23	Shoe modifications (specifically lateral heel wedges) have been identified by the choosing wisely priorities of AAOM as something that should not be recommended but is on the document as a recommended conservative approach. It should probably be removed.	Oct 11, 2013 11:31 AM
24	3 months is short, but probably fair. Most patients will have tried medical management for far longer.	Oct 9, 2013 2:34 PM

Page 2, Q7. Any comments about the Fitness section?		
1	Think BMI of 35 is too low. Would make it at least 40	Oct 25, 2013 4:55 PM
2	There is no definition for "adequate"peripheral circulation or nutritional status. Asking a surgeon to comment on a patient's sufficient lifespan needed to benefit from the surgery is inappropriate. This will be the first step of establishing an upper age limit for qualifying for the procedure. Age has nothing to do with quality of life. Arranging autologous blood donation is a terrible recommendation and sets people up for needing a post-op transfusion. There is no justification for this requirement.	Oct 25, 2013 4:49 PM
3	II.A.1: This section reads, "Adequate nutritional status to ensure healing," but it does not specify how nutritional status is measured or the acceptable parameters. In addition it reads, "Lifespan sufficient to realize benefits from surgery;" however, it does not specify how lifespan is estimated or provide parameters. Lifespan can be a contentious issue adn it may be more appropriate to exclude it from the list, especially since it is rarely a pertinent issue for elective TJA. II.B.1: What is the WA State approved Decision Aid? II.B.4: This section reads, "Patient must participate in end of life planning." Plese define end-of life planning.	Oct 25, 2013 4:34 PM
4	There are several issues here. Although it would be great to have all of my patients have a BMI under 35, the reality is that this is impossible. In today's world with it's rapid increase in obesity, a significant percentage of patients requiring joint replacement have a BMI greater than 35. They cannot lose weight due to dietary choices and their arthritic joints. Patients with a BMI >35 are also the most likely to develop DJD and cannot lose weight. Under this plan the overweight will be denied the huge lifestyle benefits that can be received from replacing an arthritic joint. Also, requiring dental/anesthesia consults in every patient, whether it is indicated or not is a huge inconvenience for our patients and a massive cost to the healthcare system. Consults are often appropriate, but not in every patient. I fully engage in shared decision making with all of my patients. It is insulting and unnecessary to place another administrative burden on us and force us to use a pre-approved Decision Aid, as if we are children and need our hands held. End of life planning is great, but this is not a discussion my healthy TJR patients want to have at this time.	Oct 25, 2013 2:15 PM
5	PCP support of the "fitness" has always been a challenge	Oct 25, 2013 1:41 PM
6	We do have a concern about addressing the difficulty of losing weight whilst disabled from knee or hip OA. This issue should be addressed.	Oct 25, 2013 1:40 PM
7	The evidence presented is weak on obesity. Obese patients with arthrosis have low success rates for significant weight loss and many of the patients undergoing successfull arthroplasty have BMI's greater than 35. You are dooming a significant percentage of the populate to a life of disability and pain with this recomendation.	Oct 25, 2013 12:39 PM
8	The Alliance is concerned that certain provisions in this section would unnecessarily and inappropriately restrict patient access to medically-necessary total joint replacement surgery. In particular, we recommend that the criteria be amended to remove the reference to “Body Mass Index less than 35” and “Lifespan sufficient to realize benefits from surgery,” as discussed below. Body Mass Index (BMI) less than 35 It is inappropriate to restrict obese patient	Oct 25, 2013 10:53 AM

Page 2, Q7. Any comments about the Fitness section?

	access to total joint replacement surgery, since they are more likely to need total joint replacement than individuals with lower BMI levels. Bourne et al.1 showed that the need for Total Knee Replacement (TKR) and Total Hip Replacement (THR) increased with BMI. Specifically, the need for TKR was more than 18 times greater and need for THR was more than 5 times greater for patients with a BMI of 35-40 compared to patients with a BMI of less than 25. Patients with a BMI over 40 were almost 33 times more likely to need TKR and were almost 9 times more likely to need THR. Limiting total joint replace based on BMI criteria will prevent numerous patients from receiving the care they need. In addition, total joint replacement has been shown to result in significant improvements in patient functioning, pain, and satisfaction for obese and morbidly obese patients. Multiple studies have shown little to no difference in patient outcomes between obese and non-obese patients.2-7 While obesity may increase the risk of complications, steps can be taken to decrease this risk.8 Efforts should be made to reduce complication rates in obese patients rather than limiting access for a patient group that can substantially benefit from total joint replacement. Lifespan sufficient to realize benefits from surgery This factor is deeply personal and highly subjective, and should be determined solely by the patient in consultation with his or her family, physician, and surgeon. The clinical practice of medicine is the scope of practice of licensed physicians. As such, no lifespan criteria should be included in the treatment guideline as it presents a very dangerous precedent in the established, independent clinical decision-making practices of licensed physicians. References: 1. Rajgopal V, Bourne RB, Chesworth BM, et al: The impact of morbid obesity on patient outcomes after total knee arthroplasty. J Arthroplasty 23:795-800, 2008. 2. Krushell RJ, Fingeroth RJ: Primary Total Knee Arthroplasty in Morbidly Obese Patients: A 5- to 14-year follow-up study. J Arthroplasty 22 suppl 2:77-80, 2007. 3. Dowsey MM, Choong PFM. Early outcomes and complications following joint arthroplasty in obese patients: A review of the published reports. ANZ J Surg. 2008; 78:439-444. 4. Amin AK, Patton JT, Cook RE, Brenkel IJ. Does obesity influence the clinical outcome at five years following total knee replacement for osteoarthritis? J. Bone Joint Surg. Br. 2006; 88: 335–40. 5. Deshmukh RG, Hayes JH, Pinder IM. Does body weight influence outcome after total knee arthroplasty? A 1-year analysis. J. Arthroplasty 2002; 17: 315–19. 6. Moran M, Walmsley P, Gray A, Brenkel IJ. Does body mass index affect the early outcome of primary total hip arthroplasty? J. Arthroplasty 2005; 20: 866–9. 7. Stickles B, Phillips L, Brox WT, Owens B, Lanzer WL. Defining the relationship between obesity and total joint arthroplasty. Obes. Res. 2001; 9: 219–23. 8. Hamlin BR. Treatment of Knee Arthrosis in the Morbidly Obese Patient. Orthop Clin N Am 42 (2011) 107–113.	
9	A Body Mass Index of 35 in a tall, muscular, and athletic patient should not preclude surgery on an otherwise qualifying patient. An absolute single number is not a “minimum requirement.” The requirement for a patient to participate in end of life planning seems like an unwarranted requirement. Autologous blood donation on a routine basis is not cost effective, leads to unnecessary transfusion with their inherent risks, and has not been proven to be more safe than tested blood bank blood, should in fact a post-operative transfusion be necessary. This is a dated practice. Patient reported measures are to be supported. What level of dementia is acceptable? How do we judge lifespan? It is unclear whether this must be line-itemed or generally acknowledged, either way assessing some of the parameters will increase cost if objective documentation is required.	Oct 25, 2013 10:28 AM

Page 2, Q7. Any comments about the Fitness section?		
10	Inflexible criteria relating to Body Mass Index (BMI), blood donation, end-of-life planning, and dental screening are inappropriate and would result in major barriers to care for many patients. For example, a strict Body Mass Index cutoff of 35 could disqualify patients who are otherwise in excellent health and who have a medical need for the surgery. It appears from the evidence table that this recommendation is based on two low-grade studies, while other literature indicates favorable outcomes for obese patients. We recommend that this factor be removed from the policy. In addition, while we believe there is value in end-of-life planning, we believe that this is a personal, subjective, individual matter. Orthopaedic surgeons should not be tasked with assessing life expectancy or counseling patients on whether their lifespan is “sufficient to realize benefits from surgery.” With regard to autologous blood donation, this is not generally considered an “optimal” practice, since blood transfusions also can be safe should a post-operative transfusion become necessary. In general, while we support measures intended to ensure patient safety, engagement and preparation for surgery, the final draft should ensure that the requirements do not exceed the orthopaedic surgeon’s specialty, such as assessing a patient’s lifespan or level of delirium or dementia, or deciding which patients should be referred for dental screening (especially if lack of dental insurance became a barrier to needed orthopaedic surgery). Ideally, a system wherein patients could report on relevant measures is preferred. Finally, additional information should be provided regarding the expectations of surgeon interaction with Care Partners to ensure that it does not result in duplicative visits and paperwork.	Oct 25, 2013 7:57 AM
11	Your BMI requirements are unrealistic for the US population. I agree that patients with a BMI of less than 35 are better candidates. However, there are many patients whos quality of life are much improved with replacement. Second thought is that if you are going to require patients to have completed all the preop clearances identified- dental, good diabetic control, etc, insurance providers must be required to pay for all of these things.	Oct 25, 2013 1:38 AM
12	Will dramatically increase cost. BMI > 35 not shown to adversely affect outcomes	Oct 24, 2013 4:12 PM
13	This component of the bundle is essential to helping patients understand their characteristics that can reduce surgical complications and to ensure that they are getting the optimal pre-surgery preparations. We strongly support the inclusion of nasal cultures to identify staphylococcal carrier status as this is a key prevention strategy for avoiding dangerous MRSA infections. The documentation of patient engagement is of utmost importance to ensure shared decision making and so that patients will think clearly about the kind of support they will need from a loved one or friend throughout the process. While informed consent is not mentioned here, it is definitely a part of this section of the bundle – people must be advised of the risks of surgery and implants, alternative treatments and what their future will look like once their implant is in place.	Oct 24, 2013 4:01 PM
14	Who decides "lifespace sufficient to realize benefits from surgery?" Sounds like you are asking the physicians to place value on someone's remaining life. There are drug addicts who get hip replacements who have only temporary control of drug dependence. How do you value their life over an active 90 year old? Would these individuals still get TKR or THR and just not be paid for via a bundle? How will the physician have to document all of the items in the patient engagement section? What happens if the patient fails to actively participate?	Oct 22, 2013 3:41 PM

Page 2, Q7. Any comments about the Fitness section?		
	Sounds like you need to hire case managers to make sure the patients do all of their part - you cannot rely on the physicians to massively increase their work given the low rate of payment.	
15	Our practice, based on recent studies, is to build up the patient's blood prior to surgery vs. autologous blood donation.	Oct 22, 2013 10:52 AM
16	A patient may have dementia and yet still need/qualify for knee/hip surgery due to pain and immobility.	Oct 20, 2013 7:45 AM
17	Not all patients have access to a decision aid counselor. Some do not have a personal care provider (ie NH residents, independent persons w/o close relatives). ProTime is not always indicated. Dental consult does not need to be done routinely. Anesthesia, PT consults are nice but not always necessary. Universal reporting measures not uniformly necessary.	Oct 18, 2013 5:01 PM
18	No	Oct 18, 2013 4:25 PM
19	I wonder about the BMI requirement. There is a Catch-22: obese patients may need the TKR in order to be mobile enough to lose weight. But since these patients do consume more resources, perhaps they should be left out of the bundle.	Oct 18, 2013 9:29 AM
20	These are very stringent limits on fitness. At my hospital almost no-one would qualify for a TKR. The BMI limit of 35 is suprisingly low. However as an anesthesiologist I fully agree that if we limited our surgical candidates to these paragons of wellness our outcomes would be outstanding. The Preop preparation are all in agreement with American Society of Anesthesiologist recommendations	Oct 18, 2013 8:40 AM
21	weight, life span discussions are ethically complicated and do not lend themselves to "guidelines"	Oct 18, 2013 5:43 AM
22	Required participation in a shared decision making process is excellent. My concern is that doctors classically speed over the finer points only to state in surgical reports that the patient was informed of and consented to proceed in spite of a stated risk or possible outcome without actually telling the patient. This happened to me every surgery, so when participating in a bundle and warranty as complex and specific as this, it will take very careful planning to execute the process well. I suggest a checklist similar to that used in the OR which requires the nurse or doctor initial on each line item with the patient signature required for each section. Another model would be to use a before surgery educational class in addition to time with the doctor to explain the bundle and warranty as specific to the patient. A combination of both pathways to shared decision making would provide the strongest assurances that the patient is informed, on board and engaged. I question the requirement that the patient participate in end of life planning. While I generally agree that advance planning is the most helpful position to take, to insist that as part of TKR/THR a patient must deal with end of life issues seems out of place. It may also be viewed by some as a violation of religious freedom. Section II C - arrange blood donation Is this still standard practice? Having had 5 hip replacement surgeries in the last 6 years, I never once backed a blood donation. WI was told by my physician that planning for transfusion by advance donation of blood was correlated with a higher need for	Oct 17, 2013 9:53 PM

Page 2, Q7. Any comments about the Fitness section?		
	that transfusion - a kind of self-fulfilling prophecy - unless the donation was made months in advance rather than the typical 4-6 weeks. hen I asked the surgeon about it I was told by my physician that planning for transfusion by advance donation of blood was correlated with a higher need for that transfusion - a kind of self-fulfilling prophecy - unless the donation was made months in advance rather than 4-6 weeks before surgery.	
23	Body mass index of 35 or less should not be a criteria for surgery. These patient also have severe pain with OA, and with special care (such as coordinating hospital care with the medical team, can be safely operated on). these patients are usually the most grateful and appreciate patients. With a similar mind set, although we RECOMMEND, all patients stop smoking, to require them to stop prior to surgery is to put a burden on the patient that very few can accomplish. This would change the surgical outcome in very few patients and would be a cruelty to most, as despite efforts the nicotine dependency is extremely difficult to overcome. Although most patients can find a personal care partner, many single patients, particularly if living alone do not have this resource. This barrier can be overcome with use of an extended care setting. I recommend that each hospital offer a joint class, and it is recommended to patients but not required. AUTOLOGOUS BLOOD DONATION IS NO LONGER RECOMMENDED DUE TO THE HIGH LEVEL OF WASTAGE. PLEASE REVIEW THIS WITH HEMATOLOGIST. THEY WILL NOT AGREE WITH THAT RECOMMENDATION.	Oct 15, 2013 10:29 PM
24	I'm not sure it matters. Ultimately, the bundle acts as a regulating mechanism because surgeons should be dissuaded from operating on patients who might have very long recovery times. And if you emphasize fitness too much, you can encourage significant cherry picking	Oct 15, 2013 6:09 AM
25	The BMI and medical requirements are ideal; however, weight loss is exceptionally difficult when physical activity is impossible. Multiple studies have shown benefit for less than ideal patients from joint replacement even though they have increased surgical risks. These guidelines may well deprive people of beneficial treatment.	Oct 14, 2013 5:58 PM
26	BMI >35 will exclude a substantial proportion of patients who would otherwise benefit. Will there be an option for these patients?	Oct 14, 2013 12:23 PM
27	I think this is a key ingredient for patients to have success, without their buy-in, I don't think this will be successful.	Oct 14, 2013 10:18 AM
28	I believe this is arbitrary. I know a nurse who has a genetic condition that causes her to be above the BMI proposed through no fault of her own. She is active none-the-less and certainly if she were to develop severe osteoarthritis, it would be a crying shame to deny her a procedure that could return her to a productive lifestyle.	Oct 11, 2013 5:40 PM
29	No point in surgery on someone who can't recover full function or has severe medical issues.	Oct 10, 2013 11:09 PM
30	Excellent. The patient has responsibility to prepare him or herself for best outcome as well. Plus all the health measures listed will be good for patient's overall health regardless of surgery.	Oct 9, 2013 2:34 PM

Page 2, Q9. Any comments about the Repair section?		
1	B2.3 states cephalosporin AND vancomycin should be used. This should only be done in those cases where the patient tests positive for MRSA. VTE prophylaxis section is poorly defined. Acceptable pharmacological agents should be identified and standardized. Hyperglycemia should also be monitored and managed in non-diabetics as well. This shouldn't only apply to patients with diabetes. C1 should be changed to: Do not select implants that have a >5% failure rate at 10 years. Otherwise, new products can't be used since there is no failure rate available.	Oct 25, 2013 4:49 PM
2	III.B.1: Spinal anesthesia is preferred, but sometimes general anesthesia is required. Adductor canal block is an option that is not widely practiced or standard of care at this time. III.C.1: According to this section, "Providers must select an implant that has a <5% failure rate at 10 years." This is an unreasnoable requirement. Many of the implants used in contemporary arthroplasty surgery do not have a ten (10) year track record in peer-reviewed literature or in a foreign country registry. III.C.2: This section reads, "When alternate implants are used, document informed consent and ensure a publicly reported national joint registry is in place to track outcomes." Special informed consent should not be required for FDA-approved implants that do not meet the criteria in Sec III.C.1. A national joint registry is currently under development and is not yet fully subscribed to by all institutions.	Oct 25, 2013 4:34 PM
3	I would love to have a consistent surgical team during all of my cases, but getting hospitals to implement this seems like a fantasy. Many OR's run specific days for total joints and efficiently get many cases done. To arbitrarily not allow cases to start after 5pm is silly and an over reach of authority.	Oct 25, 2013 2:15 PM
4	many surgeons do not do 50 cases a year.	Oct 25, 2013 1:41 PM
5	These are ideal world situations for selecting a surgical team. How will this work when the patient is not near a high-volume facility? What will the process be for selecting newer joint hardware types? (Balancing long term evidence with innovative solutions for problems with older models.)	Oct 25, 2013 1:40 PM
6	The Alliance recommends changes to both the standards for the surgical team performing TKR/THR and the selection of the surgical implant. Standards for a surgical team performing TKR and THR The evidence presented by the APM subgroup does not support an arbitrary criterion mandating a surgeon volume of 50 joint replacements per year, which could unnecessarily restrict patient access, particularly in rural areas. While the study by Lau et al. cited in the draft evidence table suggests a correlation between surgeon volume and patient outcomes, the study's authors warn that their results should be interpreted with caution. (Lau RL, Perruccio AV, Gandhi R, Mahomed NN. The role of surgeon volume on patient outcome in total knee arthroplasty: a systematic review of the literature. BMC Musculoskeletal Dis, 2012 Dec 14; 13(): 250). In addition, the draft evidence table characterizes Lau et al. as a systematic review that is of "lower quality"; we therefore recommend against using this study as the basis for restricting access to surgeons. The draft bundle states that the "roster of the surgical team must be consistent." Evidence of the relationship between surgical outcomes and surgical team consistency has not been provided, and would be necessary for review before such a requirement is imposed. In addition, a more specific definition regarding the term "consistent" would be required for this criterion to be applied. Selection of the surgical implant We agree that the use	Oct 25, 2013 10:53 AM

Page 2, Q9. Any comments about the Repair section?		
	of the highest quality product that supports the patient's medical need should be promoted. Implant survivorship is an important factor in product selection, but it is just one consideration in determining the most suitable product for any particular patient. For instance, there is evidence showing that implant performance is not a predominant factor of knee failure (see Schroer WC, Berend KR, Lombardi AV, et al. Why Are total knees failing today? Etiology of total knee revision in 2010 and 2011. The Journal of Arthroplasty 28 Suppl. 1 (2013) 116–119). Limiting access to only implants that meet the stated survivorship criteria will decrease a surgeon's ability to match implant characteristics to the needs of the specific patient, which could lead to higher revision rates, reductions in patient satisfaction resulting in decreases in quality of life and/or activities of daily living, and increased costs over time. There are also practical questions associated with the draft standard, including: How will survivorship be defined? What data sources (study, registry, institution) would be used to establish survivorship rates? How would the decision criteria be applied if there are inconsistent results among multiple data sources? Since the cause of implant failure is multi-factorial, how would patient- and surgeon-specific factors be accounted for in examining failure rates? How will national statistics be translated to Washington state patients? How would patients access the most advanced new technologies that do not have 10-year performance data? Limiting implant selection based on failure rate could block patient access to new technologies that have been designed specifically to address unique patient conditions, to improve patient function, OR efficiency, and implant survivorship with pre-clinical results that are superior to products introduced decades ago, would ultimately result in increased costs and poor outcomes over time for all stakeholders. We recognize that the Draft Bundle makes provision for implants to be used that do not meet the stated criteria via patient informed consent and registry data collection. However, investigation at the hospital/surgeon level as to how these provisions would be established and implemented should be completed and carefully considered prior to mandating these requirements in a treatment guideline. Otherwise, should the requirements be found to be overly burdensome, the impact could be that Washington state total joint patients would not have access to innovative implants.	
7	Standards for TJA and "optimal surgical process" continue to evolve as our knowledge grows. Codifying current practice in this draft proposal will definitely affect innovation and deployment of lessons learned. Trained and certified surgeons should not be excluded by payers on a single annual volume basis. Bundles can be used to describe what would be included in a payment for an episode of care but should not be used to define who can provide specific care – that is for the certifying specialty boards. Who should receive care is a matter for medical and surgeon judgment and guidelines should not be hurdles for either patients or their surgeons. Spinal anesthesia may or may not be the best anesthetic care plan for an individual patient depending on the specifics of the patient and the planned surgical procedure. Adductor canal block is not necessarily indicated in each patient. This may be contraindicated in patients with a very high risk of falling and local bleeding. Implants that have a well-documented, accepted, and reproducible 10 year failure rate are limited.	Oct 25, 2013 10:28 AM
8	We recommend that surgical qualifications be established by certifying specialty boards, rather than through payer guidelines. The payment bundle or other coverage criteria should not exclude trained and certified surgeons based on	Oct 25, 2013 7:57 AM

Page 2, Q9. Any comments about the Repair section?		
	minimum numbers of surgeries performed annually, given the unnecessary negative impact it could have on patient access to care. Anesthesia techniques should be tailored to the individual patient based on the physician's assessment of the patient. For example, spinal anesthesia may be the best anesthetic care plan for an individual patient depending on the specifics of the patient and the planned surgical procedure. With regard to implants, the policy should ensure the flexibility for a surgeon to choose the best product for the specific patient, including newer technologies that may not have had time to demonstrate a 10-year performance profile.	
9	The number of required joints per year is too high. Realistically, I do 40-50 knees a year which would not qualify. In my career of 9 years and residency, I have performed over 500 knee replacements. That cumulative experience should suffice. I would propose a lower threshold of 30 annually for both knee and hip OR a career minimum of 500.	Oct 25, 2013 1:38 AM
10	No evidence that performance of > 50 replacements per year improves outcome	Oct 24, 2013 4:12 PM
11	We strongly support (A) the general standards for a surgical team to have documented credentials. We do not believe it is appropriate to have device company representatives in the operating room. If they are present, patients should be fully informed of the identity and the role of the person present. Under (B) we would recommend changing the statement about urinary catheters: "Only use urinary catheters when necessary for that particular patient and restrict use to less than 48 hours." Under (C) the "Selection of the surgical implant" section, there is a note to document informed consent. Informed consent should include specific information to the patient about the exact device that is being implanted. In a Consumers Union survey of more than 700 people with hip or knee implants, two-thirds said they wished they had been given more information and more than half did not know the name of the company that made their implant. Further, patients should be given copies of any inserts from the implant packaging that describe their device. Too many patients lose touch with their surgeons and later find they do not have the detailed information they need about what has been implanted in their bodies. This is especially important when problems with the implant arise.	Oct 24, 2013 4:01 PM
12	This is a clinical question and will defer to the physicians.	Oct 22, 2013 3:41 PM
13	No	Oct 22, 2013 10:52 AM
14	Evidence for a true benefit of "more than 50 joints per year" is lacking. Some studies used "3 per year" as a standard. Any benefit not found significant. (If you include that, you should lnly allow hospitals that have LOW volumes of TJA to perform them as they had a better outcome than the high volume "mills" JBJS this past summer). Excellent multi-modal pain control can be obtained w/o adductor blocks. SECOND generation cephalosporins AND Vanco should not be used routinely.	Oct 18, 2013 5:01 PM
15	1. what if the patient is contraindicated for spinal anesthesia? what other choice does anesthesiologist have? 2. In the Avoiding bleeding section: "Use standardized IV fluid protocols implemented by RN's". It should be said "by anesthesiologist"	Oct 18, 2013 4:25 PM

Page 2, Q9. Any comments about the Repair section?		
16	Why spinal and not epidural? Seems overly proscriptive regarding anesthesia techniques. While I agree that regional is generally better, there will be some patients who need combined GA in order to tolerate the anxiety of the OR and surgery, or pain when regional blockade is incomplete or ineffective.	Oct 18, 2013 9:29 AM
17	The Perioperative pain management is in line with current evidence. Spinal anesthesia has a good evidence base but there is only weak evidence that spinal is superior to general anesthesia. Patient choice of GA or even Epidural seems reasonable Adductor Canal block is certainly the "block de jour" but femoral nerve block is easier in many cases.	Oct 18, 2013 8:40 AM
18	implant choices should not be governed	Oct 18, 2013 5:43 AM
19	Section III - A - 1) Setting a baseline of minimal number of procedures done by a physician is essential in establishing skill and proficiency in dealing with TKY/THR. However, some types of approaches and devices have a much steeper learning curve than 50/year. 2) Setting credentials for surgical team members is critical. I assume these conditions would exclude the device reps from being present in surgery. They should not be allowed in the OR. Section III - C 1) YES!!! to the recommendation for selecting a device with <5% failure rate at 10 years. However, I think there is a possible unintended impact which is a huge negative for the patient. Surgeons are familiar with the devices they use. The hospitals are likely going to press for the use of a tried and true device. lW@hen a surgeon is unfamiliar with a device and has not had sufficient training and use, the patient is put in harms way. How will the effective training of surgeons be accomplished and tracked in these circumstances? Also, as a patient, I want to be informed if my physician is training on a device. Section III - A - 1) Setting a baseline of minimal number of procedures done by a physician is essential in establishing skill and proficiency in dealing with TKY/THR. However, some types of approaches and devices have a much steeper learning curve than 50/year. 2) Setting credentials for surgical team members is critical. I assume these conditions would exclude the device reps from being present in surgery. They should not be allowed in the OR. Section III - C 1) YES!!! to the recommendation for selecting a device with <5% failure rate at 10 years. However, I think there is a possible unintended impact which is a huge negative for the patient. Surgeons are familiar with the devices they use. The hospitals are likely going to press for the use of a tried and true device. lW@hen a surgeon is unfamiliar with a device and has not had sufficient training and use, the patient is put in harms way. How will the effective training of surgeons be accomplished and tracked in these circumstances? Also, as a patient, I want to be informed if my physician is training on a device.	Oct 17, 2013 9:53 PM
20	Many surgeries are preformed in the evening and if hospital schedules are tight, this requirement should be left to the surgeon and hospital. Specific blocks such as adductor canal blocks are usually performed by only a few anesthesiologist. There are many more successful anesthetic techinique being developed all the time that are safer, quicker, less costly. Optizmiation of pain control is appropriate. Sections 2, 3, 4 generally are OK recommendations, but are too specific, as specific techniques and medicines are changing rapidly. AS examble, transexamic acid is just now becoming available, and does have some specific risks. Surgeons should not be required to select an implant that has a failure rate of less than 5% at 10 years, because if so, no new implants could be tried. Instead recommend that the hospital has at least on implant system on	Oct 15, 2013 10:29 PM

Page 2, Q9. Any comments about the Repair section?		
	formulary that meets that requirement.	
21	There is no national data base to provide information on survival of prosthetics in the United States, and virtually all commercially available prostheses meet these standards. The FDA determines safety and utility. I think that requiremnent for 50 replacements per year is really arbitrary. The Norwegian registry reporte a 2 % difference in failure between < 50 and greater than 150 joints per year. The guidelines should mandate a maximum operative time of 90 minutes if they are going to mandate space suit wear. (0 minutes has been demonstrated for over 50 years to be the break point for increased post-operative infection rates.	Oct 14, 2013 5:58 PM
22	Mandating spinal and adductor block is inappropriate. Not all patients want/can have a spinal; use of adductor block is not standard of care and is unnecessary, Similarly, mandated use of tranexamic acid is inappropriate; although there is slight reduction in blood loss, this is of minimal clinial benefit.	Oct 14, 2013 12:23 PM
23	no	Oct 11, 2013 5:40 PM
24	Not everyone needs repair first. With MRi's details may make it clear repair is hassles	Oct 10, 2013 11:09 PM

Page 2, Q11. Any comments about the Post-operative Care section?		
1	Duration of anti-coagulation is very uncertain. The duration should be left to medical providers, not your group	Oct 25, 2013 4:55 PM
2	C1 should read: Instruct patient to perform home exercise program three times daily using exercises taught in the hospital. Ensuring home PT three times daily is poorly worded.	Oct 25, 2013 4:49 PM
3	Post-operative care and our care models with respect to discharge continue to evolve. This is not really part of a bundle, but part of a continuum of care without room for patient preference or patient-centered adaptations to the processes and care pathways. Admittedly, the goal in part is to reduce variation, but I am afraid this goes a step too far. For example, home physical therapy may not be indicated in a patient 3 times daily. Significant knee swelling, too, may be benefitted by rest, elevation, compression and ice. A predetermined number of daily exercises may not be reflective of an individual patient's condition.	Oct 25, 2013 10:28 AM
4	A one-size post-operative care model is inappropriate. Patient condition, abilities, life-style, and family circumstances all need to be factored into discharge planning and post-op treatment/rehab planning.	Oct 25, 2013 7:57 AM
5	It is our understanding that some surgeons do not offer regular follow up after an implant. The bundle includes return visits at 4-6 weeks, but does not address the need for patients to check in over the years. Even if they do not retain a relationship with their surgeon, it would help if surgeons would advise patients of when they should check in with a physician in later years to ensure there is no degradation or cracking or erosion of their implant.	Oct 24, 2013 4:01 PM
6	Providers outside of the hospital system should be included in the post-op communication process	Oct 22, 2013 5:21 PM
7	Home health is not a solution for all post-op patients. Some do outpatient PT. Post-op visits are not the same for all physicians.	Oct 22, 2013 3:41 PM
8	We have had better sucess with Outpatient PT vs. Home Health.	Oct 22, 2013 10:52 AM
9	Role of hospitalists/PCPs? How will they be paid for involvement in medical management of a patient?	Oct 20, 2013 7:45 AM
10	For the most part-- I agree. Universal use of the HOOS and KOOS scale would frustrate and anger our populace which is under-educated and find our basic questionnaires to already be overwhelming, let alone the burden of collating result by our staff with ever mounting cost of staffing.	Oct 18, 2013 5:01 PM
11	Hospitalists or appropriate medical consultants will be available for consultation to assist with complex or unstable medical problems in the post--operative period It is anesthesiologists who take care these problems. Provide accelerated physical therapy and mobilization if regional pain control is acceptable. they do not mention CPNB or epidural analgesia for postop pain, how can accelerated physical therapy be applied?	Oct 18, 2013 4:25 PM
12	rapid rehab is not feasible without being complemented by MIS techniques.	Oct 18, 2013 5:43 AM
13	Based on Best Practices of Orthopedic Hospitals like Swedish (Seattle) a post-	Oct 17, 2013 11:09 AM

Page 2, Q11. Any comments about the Post-operative Care section?		
	operative training orientation prior to surgery (2 hours) is provided by professional medical staff	
14	c1. who will ensure the patient does home PT 3 times a day? This is overkill. Instead recommend a post discharge rehab program address home exercises as well as supervised PT., OK with D.	Oct 15, 2013 10:29 PM
15	While these are suitable guidelines none of the recommendations have sufficient scientific support to warrant universal adoption.	Oct 14, 2013 5:58 PM
16	no	Oct 11, 2013 5:40 PM
17	Absolutely needed - good follow through and excellent PT	Oct 10, 2013 11:09 PM
18	Extremely important to include rehab and to try to avoid post-op infections, bleeding and clots. Also great to include this in bundle.	Oct 9, 2013 2:34 PM

Page 2, Q13. Any comments about the standards (or other measures that you believe should be included)?		
1	IV.D.1: Different physicians and programs have different recommendations for follow-up visits. The guideline should be more flexible to accomodate different practice patterns. For instance, at Swedish, one or more of our doctors see patients 2-4 weeks post-discharge and often the last post-op visit is 2 months if the patient is recovering well. Then all patients are seen at 1-year post-op.	Oct 25, 2013 4:34 PM
2	Quality care is very important, but the degree of documentaion required in this draft appears excessive and onerous.	Oct 25, 2013 2:15 PM
3	Consider pre-operative PT/exercise regimen recommendations.	Oct 25, 2013 1:40 PM
4	We believe support for the financial cost of registry participation must be shared. Additionally, we do not believe many of the standards listed are truly ‘quality standards’. While these may be ideals, they do not necessarily map to health outcomes.	Oct 25, 2013 10:28 AM
5	Radiographic evidence of a well aligned prosthesis is the only objective here. Patient outcomes are significantly impacted by individual effort, which is not represented in any measure here.	Oct 25, 2013 1:38 AM
6	The administrative burden and costs associated with this data collection and analysis is unrealistic in this era of diminishing resources.	Oct 24, 2013 4:12 PM
7	We strongly support the Quality standards and recommend that the Collaborative or the state unify information from the provider group registries to provide a richer resource for all clinicians and patients/public in the state. Perhaps the state would not run the registry but bring the data together. Registries should include statistics such as the number of procedures done and should offer patients the opportunity to have their information included. They should enable tracking of outcomes beyond the warranty period for hospital-acquired infections and failures of devices. This information is very important to enable the Collaborative to assess the effectiveness of the bundle.	Oct 24, 2013 4:01 PM
8	Who is providing the "registry" mentioned in this section?	Oct 22, 2013 3:41 PM
9	Let the Orthopedic surgeons make the decisions. Not politicians, business leaders, etc. If they want to be doctors/surgeons and make policy, attend four years of medical school, 5 years of residency, and 1-2 years of fellowship training.	Oct 22, 2013 11:58 AM
10	No.	Oct 22, 2013 10:52 AM
11	The studies suggesting surgeons performing less than 50 joints per year have less than optimal outcomes are flawed. While volume can improve outcomes, it is not the only factor. Many high quality surgeons perform a low volume practice with success. Because these surgeons do not publish their results, the data is skewed. If we limit what can be offered my the local community, we are hurting our patients and the quality care they can recieve. Lets encourge low volume surgeons to publish their outcomes, then make an informed decsion.	Oct 21, 2013 12:07 PM
12	Conceptually good. High administrative burden. Concerns as outlined above.	Oct 18, 2013 5:01 PM
13	These will need to be fleshed out more. I hope that engagement with specialty	Oct 18, 2013 9:29 AM

Page 2, Q13. Any comments about the standards (or other measures that you believe should be included)?		
	organizations will be forthcoming.	
14	These standards look like they will work for the patients--but there are going to be many patients that would have traditionally received a joint replacement but that will not qualify for this bundle. Where will they receive their care?	Oct 18, 2013 8:40 AM
15	quality standards that are selected need to be vetted by literature before they are implemented	Oct 18, 2013 5:43 AM
16	The draft states that each provider group will maintain a registry of first time TKR/THR procedures and that the information must "be available for reporting to current or prospective purchasers and their health plan. It will be made available to quality organizations such as the Puget Sound Health Alliance and the Foundation for Health Care Quality." While there may be simplicity in starting out with single provider registries, unless those registries can be linked to one another, important overall trends may be missed. At minimum, I suggest that the provider registries be uniform so that collating the data is done more easily. The best choice would be for a central registry which all providers used. Secondly, the data from these registries needs to be fully accessible to the general public. Third, recovery from TKR/THR varies based upon the procedural approach (minimally invasive vs. traditional). The recovery period can take up to one year, so for the bundle to set recovery visits at 4-6 weeks and three months may be insufficient for some patients who will need care over the first year.	Oct 17, 2013 9:53 PM
17	Based on Best Practices of Orthopedic Hospitals like Swedish (Seattle) suggest a pre-operative training orientation prior to surgery (say one hours) regarding Device Warranty provisions with checklist to help Patients/Advocates' clarity about risks and failure modes, symptoms of problems for the particular device they will receive plus warranty provisions provided by manufacturer should be provided by professional medical staff (education notebook suggested) pre-surgery. Contact me with any questions.	Oct 17, 2013 11:09 AM
18	Must include improvement in pain levels with surgery as opposed to no surgery. Total cost to perform surgery and return person to mobility vs. government providing full and complete care for immobile person no longer able to care for themselves.	Oct 11, 2013 5:40 PM
19	Except the step to require repair first in all cases	Oct 10, 2013 11:09 PM

Page 2, Q14. Please provide any general comments about the draft bundle here:		
1	Insitution of physical pre-operatively for everyone is going to raise the cost of treating these people across the board..	Oct 25, 2013 4:55 PM
2	Good intentions, but the the mandated, cookie cutter appraoch to patent care will increase health care cost in multiple ways and create more busy work for already over-worked surgeons.	Oct 25, 2013 2:15 PM
3	it won't work well if there are too many variables imposed too fast. the roll out plan over time would work best to ensure compliance.	Oct 25, 2013 1:41 PM
4	The decision to perform joint arthroplasty should be made by the patient and physician, not by the state. I agree with the quality standards to minimize infection and VTE but realize some of the evidence is poor. Our hospital uses clorhexidine wipes because compliance is better because of the ease of use and they are easier on the patient's skin.	Oct 25, 2013 12:39 PM
5	We recommend greater outreach to and inclusion of the American Academy of Orthopaedic Surgeons (AAOS), the American Association of Hip and Knee Surgeons (AAHKS), and joint reconstruction manufacturers through the Advanced Medical Technology Association (AdvaMed) with regard to the Bree Collaborative's current initiative and future total joint replacement guideline development efforts.	Oct 25, 2013 10:53 AM
6	The draft calls for providers to "install methods to measure appropriateness, evidence-based surgery, return to function, and the patient care experience. We recommend that this be administered with flexibility to enable the use of existing outcome measurement tools already adopted by surgeons and those being developed by the American Joint Replacement Registry (AJRR). A timeline of 6-12 months for outcome measurement should be considered.	Oct 25, 2013 7:57 AM
7	The proposal as structured will exclude many patients from getting a replacement due to what I would consider excessive requirements. As written, it will also severely limit access to sugeons who are capable and competent to perform the procedure. I recommend toning the requirements for both I would also remove the word warranty when referring to surgery- my experience is that in the best hands and in the best circumstances and in fit patients complications happen- No warranty about outcomes or longevity should be implied	Oct 25, 2013 1:38 AM
8	I consider myself a proficient, skilled orthopedic surgeon. If the Bree initiative is implemented I will immediately stop performing joint rereplacements. Perhaps this is what is hoped for. It will lead to long waits and patient and provider dissatisfaction.	Oct 24, 2013 4:12 PM
9	We recommend that the warranty and the bundle be revisited in three years for updating and modifications if necessary. These bundles should be required to be used with the previously adopted warranty; they should not be separated. Due to the short duration of the bundle, there needs to be a clear educational outreach component for patients regarding the bundle and the warranty terms. Consumers Union would be willing to help with such outreach.	Oct 24, 2013 4:01 PM
10	Bundles are great in the motivated client base. They eill fail in the "unmotivated" client base	Oct 22, 2013 12:06 PM

Page 2, Q14. Please provide any general comments about the draft bundle here:		
11	Will not participate in this program if any type of warranty is involved.	Oct 22, 2013 11:58 AM
12	We are using a Marshallm Steele Joint Center, with great sucess. This aligns well with that structure.	Oct 22, 2013 10:52 AM
13	Enormous administrative burden to carry out each of the measures described, some of which are unnecessary, and in some cases are, or will soon be found to be incorrect. It would be far better to provide a CME bearing educational forum that educates and actually PROVIDES the practitioner with the tools to carry out these measures in an expedient manner which does not increase the cost to us and to our health care system.	Oct 18, 2013 5:01 PM
14	1. anesthesiologists play a very important role in the surgery suite. 2. anesthesiologists improve early patient engagement, intraoperative efficiency, clinical outcomes, post procedural initiatives, and care coordination.	Oct 18, 2013 4:25 PM
15	Who contributed to this? Why not be transparent about the participants in the process? I would be reassured, for example, if I knew the Washington State Society of Anesthesiologists had contributed.	Oct 18, 2013 9:29 AM
16	The apparent marginalization of the role of preoperative anesthesia assessment, intraoperative anesthesia care and post operative pain management by anesthesiologists is distressing. Especially when so much of the entire document has already been the subject of decades of research recorded in the anesthesia literature.	Oct 18, 2013 8:40 AM
17	Many of the standards and recommendations are poorly vetted, outdated, unnecessary, expensive, and inappropriate for today's joint replacement patients. Autologous donations have repeatedly been shown to be costly, dangerous, and ineffective. This is just one example. I reviewed the panel members involved with this initiative as well as the references identified as "evidence-based" medicine. The intention of this effort is to be applauded, but this product fall far short.	Oct 18, 2013 5:43 AM
18	Thank you for your thorough work in assembling this bundle as well as the warranty. The warranty only extends to 90 days for mechanical trouble with a device. The reality is that the majority of devices fail well after the first 3 months, with most mechanical failures coming sometime between 2-5 years from implant. It is unreasonable, I think, as a protection for the patient, to limit the bundle/warranty to 90 days. This is especially true when the surgeon has selected a device with <5% failure rate in 10 years. If a different device is used and consented to while knowing the failure rate was higher, then that was the patient's choice. Then and only then should the bundle be void after 90 days.	Oct 17, 2013 9:53 PM
19	Excellent methodology. Suggest re-visiting and updating on a 3-year cycle for continuous improvements. Very thorough evaluation of success factors, quality standards and details of actions included. Bundle will greatly benefit patient outcomes on a consistent/reliable basis when thoroughly implemented. Thank you for opportunity to input from Patient/Advocate perspective.	Oct 17, 2013 11:09 AM
20	Be careful about too specific recommendations about medicines, as these change every few months. Also leave room for surgeon discretion with regards to initiation of surgical care, as unnecessarily burdening patients with directives	Oct 15, 2013 10:29 PM

Page 2, Q14. Please provide any general comments about the draft bundle here:		
	about time, when surgical care is inevitable in a short time, only frustrates the patient and leads to futile costs.	
21	It's important to fix the time window for the bundle, usually covering 30 days pre-op and up to 90 days post discharge, including all post-acute care.	Oct 15, 2013 6:09 AM
22	The draft bundle samples an incredibly small cross section of the appropriate literature, uses guidelines with absolutely no scientific validation (The L&I pain management guidelines) and appears to be a thinly veiled attempt at racketeering and restraint of trade while at the same time deprives patients with legitimate disability of their right to medical treatment.	Oct 14, 2013 5:58 PM
23	Unless price point is adequate to insure fair reimbursement of physician, a bundled plan will fail. I speak as one of the few orthopaedic surgeons who perform THA/TKA in Medicaid patients: if my reimbursement goes below where it is now, it is simply not worth performing these procedures, since I lose money on each one.	Oct 14, 2013 12:23 PM
24	It would be nice to have some financial conversations about how practical application can be set up and acheived. Costing, etc.	Oct 14, 2013 10:18 AM
25	There simply must be options or a review process to consider exceptions for people who are in severe pain from their deteriorated joints. Also exceptions and/ or review for Individuals with rare genetic or other medical disorders that cause them to fail the means test yet could return to productive lifes if granted this surgery. To fail to consider the benefits of an exception to an individual is unconscionable.	Oct 11, 2013 5:40 PM
26	See above. I'm a big fan of defendable guidelines. Downside can be that innovation may be stifled	Oct 10, 2013 11:09 PM
27	Well done! Thank you for all your work on this!	Oct 9, 2013 2:34 PM
28	I would recommend that the pt engagement requirement for use of an approved decision aid be called out and highlighted. It is a big change for the community	Oct 9, 2013 2:28 PM

Pages 38-46 include the names and contact information for respondents and have therefore been removed from the publicly posted version.