

Measure Instrument Development and Support (MIDS) Task Order T0001

Subtask 3.1 MMS Form 8.3: Verbatim Public Comments for THA/TKA Readmission and Complications Measures

Submitted August 20, 2010 to:

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This material was prepared by Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE), under contract to the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy.

Date Posted	Measure Set	Text of Comments	Name, Credentials, and Organization of Commenter	Email address	Type of organization
7/29/2010	Complications Readmission	<p>H have read the QMs, complications and the summary. I am a [REDACTED] with TKR of the R knee in [REDACTED]. I have not had any of the complications listed and have not been hospitalized since the TKR. However I would be interested in any knowledge of a study of ADL function for persons in my age range after TKR.</p> <p>The TKR resolved the high level of pain I was experiences, however I continue to have low level pain</p> <p>I am unable to flex the knee past 100 degrees without significant pain and cramping.</p> <p>Therefore, maneuvering up and down stairs is a challenge ability to flex for dressing, bathing and grooming is limited.</p> <p>I was not prepared for the limitation in ADLs that I am experiencing. Please inform me if you are aware of any studies/stats post-op TKR related to function.</p> <p>DELORES L. GALIAS, RN RHIT STATEMENT OF --- On Thu, 7/29/10, CMS CMSProviderResource <CMSProviderResource@CMS.HHS.GOV> wrote:</p> <p>From: CMS CMSProviderResource <CMSProviderResource@CMS.HHS.GOV> Subject: CMS Seeks Public Comments on Hip and Knee Replacement Outcomes Measures To: ALL_FFS_PROVIDERS@LIST.NIH.GOV Date: Thursday, July 29, 2010, 2:11 PM</p> <p>CMS Seeks Public Comments on Hip and Knee Replacement Outcomes Measures</p> <p>Comments Accepted through Wednesday, August 11</p> <p>The Centers for Medicare & Medicaid Services (CMS) has contracted with Yale New Haven Health Services Corporation/Center for Outcomes Research</p>	Delores Galias	delores234@att.net	Individual

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		<p>and Evaluation (YNHHSC/CORE) to develop two quality outcomes measures for patients undergoing elective total hip and total knee replacement. Both measures are being developed using Medicare Part A inpatient administrative claims data and are designed for potential use in public reporting and Medicare's pay-for-reporting program.</p> <p>To date, CMS and YNHHSC/CORE has convened a Technical Expert Panel (TEP) and developed draft documents that define specifications for each measure.</p> <p>CMS now requests stakeholder review and public comment on the measure. Comments must be received by Wednesday, August 11, 2010. All measure comments are welcome, but we are particularly interested in feedback in the following areas:</p> <ul style="list-style-type: none"> • Definition of the outcomes • Risk adjustment • Technical Expert Panel (TEP) comments <p>To be considered, comments must be forwarded electronically via the website below or via email to hipknee@yale.edu. Please include your name, credentials, and email address in your message, and indicate whether you are commenting as an individual or as a representative on behalf of an organization. We also ask that you indicate whether your measure is general to all measures or specific to either measure.</p> <p>To review the measure in more detail, please visit CMS' Measures Management System online at: https://www.cms.gov/MMS/17_CallforPublicComment.asp.</p> <p>A summary of all the comments received will be posted on CMS' Measures Management System website about four weeks after the public comment period closes.</p> <p>Thank you for your support and participation.</p>			

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7/29/2010	Complications Readmission	<p>7/29/2010</p> <p>To: YNHHS/CORE Re: The Centers for Medicare & Medicaid Services (CMS) Hip and Knee Outcomes</p> <p>First I would like to clarify that I am writing this representing my own opinions and not of the institution for which I serve as Chairman of the Department of Orthopaedics. I would like consideration of a few points related to this hip and knee replacement project. The group has done an outstanding job of organizing and developing this program. The proper evaluation of quality measure in joint replacement surgery is important for public safety.</p> <p>1. I would like to question the reporting of complications where the surgery is done at Hospital A and then the complication occurs and the patient is admitted to Hospital B. This is a common occurrence especially when there are regional hip and knee referral centers. If the complications that arrive at the doorstep of community hospitals do not get reported back as complications from regional centers then the regional centers will have an inaccurate assessment of the complication rates. Patients very often seek their emergency care close to home and would not travel back to the regional hip and knee center. Operations done at the community level will probably see all their own complications. If not already taken into account, YNHHS/CORE needs to assure that the data collection follows patient unique identifiers through the collection period and do not depend upon the records of a single hospital for the data.</p> <p>2. The exclusion of SES as a covariant is a significant problem. As the Chairman of Orthopaedics of one of the most indigent congressional districts in the country I find it amazing to lump together the performance of surgeons who dedicate themselves to caring for this unfortunate population with all inherent social issues that can cause complications to surgeons who operate primarily on the wealthy and healthy. Excluding SES will further push hospitals to avoid taking on certain patients and widen the already rampant problem in access to quality healthcare.</p> <p>3. It is not clear how comorbidities will be stratified to compensate for</p>	Ira H. Kirschenbaum, MD Department of Orthopaedic Surgery, Bronx-Lebanon Hospital Center	ikirsch@bronxleb.org	Individual

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		<p>the surgeon performance of those who choose to operate on a higher comorbidity population. Clearly the comorbidity of liver disease increases multiple complications and changes in platelets and clotting factors may skew the results in favor of surgeons choosing a healthier population. May I suggest grouping the outcomes sections into results of surgeons in 3 different comorbidity groups- high, medium, and low. Comparison of a Group 1 population with a Group 3 population would be misleading.</p> <p>Ira H. Kirschenbaum, MD Chairman, Department of Orthopaedic Surgery Bronx-Lebanon Hospital Center Bronx, NY 10457</p>			
7/30/2010	Complications Readmission	<p>Complications following surgery: Will you be looking at all complications or selective complications such as DVT or blood utilization?</p> <p>30 Day all cause readmission seems to broad and should be limited to a readmission directly related to the surgery (DVT, PE, dislocation of hip, etc.</p> <p>Thank you. Lois Lois Yingling, RN, MSN, CPHQ Patient Safety Officer WPMHr</p>	Lois Yingling, RN, MSN, CPHQ, Patient Safety Officer, WPMHr	lois.yingling@flho sp.org	Individual
7/31/2010	Complications Readmission	<p>My [REDACTED] Father had severe arthritis of both knees and suffered with horrible pain and swelling for years. Last year he had a total knee replacement of his left knee with excellent results and he was performing his normal functions within weeks of the the surgery. He just recently had the right total knee replacement done and again had excellent results. His surgeon said that he is the 1 in 10 patients that follows all post operative instructions well enough to have both knee replacements done in less that one year of each other, and to have such great results. I myself cannot believe how well my Father recovered from both surgeries, although I believe part of it is because he is very active and is not the type of person to let anything keep him from going out and enjoying life.</p> <p>Patrice Steffee</p>	Patrice Steffee	pat.steffee@gmail.com	Individual
7/31/2010	Complications	Julia M. Diddell LPO, BOCPO, CPed Licensed Prosthetist/Orthotist, Board Certified Prosthetist/Orthotist	Julia M. Diddell LPO, BOCPO, CPed Licensed Prosthetist/Orthotist,	ortho-care@msn.com	Individual

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		<p>commenting as an individual practitioner on outcomes for both hip and knee replacements</p> <p>1). Many patients would benefit from the use of Hip-Thigh Orthoses to prevent the post op complications of hip-leg malalignment and post op dislocation, but the cost of items is not seperately billable to their Medicare Part B while they are in the hospital and Part A Skilled Nursing settings therefore, these items are not ordered by the physicians and the risk of complications rises. A less coslty item, hip abduction pillows are commonly prescribed but are uncomfortable for patients (which decreases compliance of use), can not be used in the act of ambulating or toileting so the complication rate risk rises. Solution: Hip-Thigh Orthoses should be carved out of hospital and SNF Part A payments and only allow Qualified Board Certified Orthotists to bill Medicare Part B for these items during the 100 days.</p> <p>2). Many post of Hip replacement patients are left with significant Leg Length differences after surgery. This does not resolve over time. Many are not treated for this surgical result early or even ever. They are at risk for gait disfunction, back pain and sound side knee and hip pain if the difference is not addressed in the form of shoe lift application. The rate of reimbursement for shoe lift application is below market costs. Solution:Medicare reimbursement rates should be increased and allow only Qualified, Board Certified Orthotists and Board Certified Pedorthotists to recieve this higher rate which should not only include the application of the shoe lift application, but the accurate measurement of the leg length difference. This rates should be boken into 0-1/2", 1/2-1", 1- 1/2-2", etc. Seperate reimbursement should be also made for the application of a replacement non-slip sole to the lifted shoe. This too, should be a carve out from the SNF Part A payment and the Orthotist/Pedorthotist should be allowed to bill Medicare Part B directly while the patient is still in their 100 days of SNF Part A.</p> <p>3). The application of knee orthoses is now being performed by a multitude of people such as techs, sales people, nurses, assistants, Physical Therapists. This leads to overuse abuses, malfitting devices which lead to skin breakdown and other complications. Solution: Fitting and billing for knee braces should be limited to Qualified, Board Certified Orthotists and written CMN's should be required which would reduce the utilization. If those changes are made, higher reimbursement rates to Orthotists should be put in place to offset the increased cost of obtaining CMNs.</p>	Board Certified Prosthetist/Orthotist		

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		<p>Thank you,</p> <p>Julia M. Diddell</p>			
8/1/2010	Complications	<p>my name is patricia a. baumann, do, faoao.</p> <p>individual who is the total joint surgeon in a multi-specialty group.</p> <p>I am a board certified orthopedic surgeon who specializes in total joint replacements - I completed my fellowship in july 2000 in adult reconstruction from the university of chicago. I have logged on and read the information for quality measures. There are no osteopathic physicians on your panel. periprosthetic fracture is not always related to the joint replacement - if a patient is involved in a MVC and fractures their femur or acetabulum - not a direct cause of the joint replacement - even if it occurred within 30 days of the surgery.</p> <p>bleeding complications related to anticoagulants - a problem when the cardiologist keeps putting a patient on plavix and ASA even though the patient is on a low molecular weight heparin for DVT prophylaxis. this creates bleeding issues, even for subdural hemorrhage.</p> <p>isn't this what the surgical site infection recommendations cover along with post operative complications?</p> <p>thanks.</p> <p>dr. baumann</p>	Patricia A. Baumann, DO, FAOAO	pabdtd@cfl.rr.com	Individual
8/2/2010	Complications	<p>I am commenting as a consumer of hip joint replacements. I've had bilateral hip replacements. The first one was done in [REDACTED] without any problems except my joint squeaks. I sound like the Tin Man from the Wizard of Oz. My Orthopedist cannot find a cause for the squeaking. I had the second hip done in October 2006 and ended up with permanent nerve damage to the sensory nerve in my thigh. As a result, I find myself falling down more frequently. My knee seems to give out. This hip joint also squeaks. Again, my Orthopedist cannot find a cause for the squeaking. I had no readmissions following my initial hospital surgical admissions.</p> <p>Thanks, Beverly Beverly Owens, RN, BSN, CCM, CPC Manager, Health Plans</p>	Beverly Owens, RN, BSN, CCM, CPC	BOwens@med.mia.mi.edu	Individual

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		University of Miami Health System bowens@med.miami.edu			
8/2/2010	Readmission	<p>Good Morning, My name is Jennifer Smith and I'm an advance practice RN who has extensive experience in both Orthopedics and Quality Measures. I'm commenting as an individual. I strongly believe when monitoring readmission rates following surgery we should only be counting readmission related to the surgery such as infection, DVT/PE, ect. Counting all unscheduled readmissions for 90 days regardless of reason can be misleading to public. For example you may have a patient with CHF or Diabetes who are readmitted 30 or more days after discharge as a result of noncompliance with their disease, the readmission would count against the center that did the joint replacement yet it has nothing to do with the quality of care received with the Joint Replacement.</p> <p>I'm asking that you strongly consider putting parameters around this measure. Thank You, Jennifer Smith RN, MSN, APN-C Manager of Clinical Development Surgical/Orthopedic Programs of Excellence</p>	Jennifer Smith RN, MSN, APN-C	jlsmith@virtua.org	Individual
8/2/2010	Complications Readmission	<p>I am commenting personally on my knee replacements. I had my first one [REDACTED] and my second on [REDACTED]. They were done by [REDACTED]. I am a [REDACTED] with osteoarthritis of nearly all my joints. I have had knee pain over 20 years. I went through Synvisc injections to each one twice. I got some relief, for about a year. My knees started bothering me much more the first of [REDACTED]. What caused me to have them done was my left knee got stuck, bent about 90 degrees while I bent it up to apply lotion to my leg. It released in my sleep so I immediately scheduled an appointment with my Nurse Practitioner. I saw [REDACTED] in 10 days. He looked at my xrays and says your knees are shot. I had bone on bone in both knees, the left being the worst. I was scheduled surgery in a month. I was given pre-op exercises, blood donation instruction, pre-surgery meeting with therapies and my nurse practitioner to clear me for surgery. I had surgery on Monday. I moved upstairs to inpatient rehabilitation on Friday and stayed there 7 days. It was 5 hrs of therapy a day and it was strenuous. I came home and had excellent home health physical therapy for 5-6 weeks. I returned to work for 10 days then felt so good I went to the beach</p>	Jane Duncan Murray RN BC, COS-C, CCA	jdmurray@arh.org	Individual

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		<p>for a week.</p> <p>I knew I was going to have my second knee done 3 months after the first. Same pre-op preparation, surgery on Wednesday. This time I got my blood back from the auto infuser. I think I had a hematoma where my drains were. It was quite swollen. I ran a temperature every day post op. I was scanned for clots, xrayed for pneumonia, the whole workup. Nothing was found to be the cause. It was during the Swine Flu peak so I remained on the post op floor instead of going upstairs to the rehab facility so I wouldn't be exposed to possible flu.</p> <p>I didn't get the intense physical therapy, but did walk a lot and did stairs. I came home on post op day 10 and again had excellent therapy from home health. I feel that my progress was behind about 3 weeks without the intense therapy I received at the rehab facility.</p> <p>I am thankful that I picked such a wonderful surgeon and had both my knees done, at my 'young' age. Prior to this, beside of my bones getting stuck, I had impaired ambulation. I waddled from side to side. I was in constant pain. I am allergic to all non-steroidal medications and didn't want serious pain medication because I have to work. I couldn't sleep, couldn't walk more than 30 feet. Grocery shopping wore me completely out.</p> <p>Now, I can walk anywhere, anytime. My gait is absolutely normal. I can ride in a car and get out without difficulty. I can now do stairs normally instead of one at a time up and down. I am still considerably obese but am trying to lose as I know that will be better for me.</p> <p>I have ZERO pain. As of today it's been 7 months since I have had to take anything for pain. I hope my replacements last 30 years, but if it becomes necessary for a re-do, I'm all for it. One thing I discovered, is that even though you may have help at home, inpatient rehabilitation for 5-7 days immediately after your operative stay is a must to improve the outcomes of your surgery.</p> <p>Thank you very much for allowing my comments.</p> <p>Jane Duncan Murray, RN BC, COS-C, CCA Clinical Analyst Information Systems</p>			

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		Appalachian Regional Healthcare jdmurray@arh.org			
8/2/2010	Complications Readmission	Lisa Grabert American Hospital Association lgrabert@aha.org Are comments on the measures due on 8/4 or 8/11?	Lisa Grabert American Hospital Association	lgrabert@aha.org	Hospital Association
8/2/2010	Readmission Complications	To whom it may concern: I am commenting as a representative of Bronson Home Health Care (a dept. of Bronson Methodist Hospital). Below are my comments which focus on the Care Setting. Home care should be part of the continuum of care to improvement patient's progress towards goals, reduce readmissions back to ACH, and improve patient safety. The "HOME CARE" service addresses areas of risk and outcomes. Key focus is on reducing infection, decreasing readmissions to ACH, improving functional status, and promoting patient safety in their home environment. There is a reduced chance of infection in the home environment. Safety issues can be addressed in the home setting where the patient will spend the majority of time recovering. Also, reduces cost of institutional transition of care during the recovery process. Discharge to home with home care services for physical therapy should be tracked as a desirable outcome. And encouraged as a best practice initiative. Thank you for the ability to comment on this initiative. AnnAnn Brissette RN, BSN, MBADirector Bronson Home Health Care brisseta@bronsonhg.org	Ann Brissette RN, BSN, MBADirector Bronson Home Health Care	BRISSETA@bronsonhg.org	Hospital
8/3/2010	Complications Readmission	To Whom it May Concern, I just recently disseminated the proposed measure specifications for comment with an 8/11 due date. Today I noted that in your (Yale) information, the comment period is listed as 8/4/10. I am assuming the period was changed and the 8/11 date is the current deadline date for comments? (see clips below) Michelle Horvath Michelle Horvath, MSN, RN, CPHQ Assistant Vice President, Quality Management Hospital for Special Surgery	Michelle Horvath, MSN, RN, CPHQ Assistant Vice President, Quality Management Hospital for Special Surgery	HorvathM@HSS.EDU	Individual
8/3/2010	Complications Readmission	I would suggest next time to also include a representative of a small health system on the panel to prevent selection bias (or the appearance there of) from the major Total Joint centers such as the Mayo Clinic and I hope that there is statistical stratification of the numbers i.e. when one surgeons does	Nancy M. Cummings, MD Chariman Pathways to Excellence in Orthopedics	ncummings@fchn.org	Health Care Association

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		<p>30 TJAs a year and has one complication vs another that does 100 and has one, what is the statistically significant cohort without this clearly the larger centers have an advantage.</p> <p>Sincerely, Nancy M. Cummings, MD Chariman of the Pathways to Excellence in Orthopedics Maine Health Management Coalition</p>	Maine Health Management Coalition		
8/3/2010	Readmission	<p>"All cause" readmission rates are misleading and may drive institutions and physicians to shun higher risk patients. These individuals at baseline have a greater risk of hospital admission irrespective of their having a hip or knee procedure. I understand that risk adjustment is done to account for this, but that misses the point. Whether risk adjusted or not, you should want relevant data. That is, the readmissions to be counted should be those that bear some relationship to the index hip or knee procedure. Joint problems are often not these patients' only problems, and tying all causes of readmission to the hip/knee procedures risks creating more noise than data.</p> <p>In contrast, the issues to be monitored for the post-arthroplasty complication measure seem much more rational.</p> <p>Thank you for the opportunity to comment. Donald R. Lurye, MD, MMM, CPE Chief Executive Officer Elmhurst Clinic, LLC dlurye@emhc.org</p>	Donald R. Lurye, MD, MMM, CPE Chief Executive Officer Elmhurst Clinic, LLC	dlurye@emhc.org	Individual
8/4/2010	Complications	<p>NYU Langone Medical Center NYU School of Medicine and Hospitals Center</p> <p>NYU Langone Medical Center and the NYU School of Medicine Department of Orthopaedic Surgery appreciate the opportunity to comment on the proposed outcomes measures pertaining to elective hip and knee surgery. We appreciate the care with which these measures have been developed, as well as the clarity of the documentation of both measures and analytic decisions. We have two suggestions to offer for your consideration:</p> <ol style="list-style-type: none"> 1. We suggest that the follow-up period for postoperative surgical site infection (SSI) be lengthened from 90 days to 180 days. It is not uncommon for the surgical procedure to treat the SSI to be performed more than 90 days after the index procedure. In addition, this would bring the national measure into better congruence with New York State and CMS reporting guidelines 	<p>Joseph A. Bosco III, MD, Associate Professor and Vice Chairman</p> <p>Joseph D. Zuckerman, MD, Professor and Chairman Department of Orthopaedic Surgery</p> <p>Martha J. Radford, MD Professor of Medicine, NYU School of Medicine Chief Quality Officer,</p>	Martha.Radford@NYUMC.ORG	Medical Center/Clinic

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		<p>which require reporting of SSI's in patients with surgical implants for up to one year post operatively.</p> <p>2. We suggest that diagnosis codes indicating deep venous thrombosis be added to the list for venous thromboembolism complications. We are concerned that by not including DVT events as complications, the measure will not present the full picture of complications. At NYULMC, we have found that a significant proportion of our VTE events are deep venous thrombosis without pulmonary embolus.</p> <p>Once again, thank you for the opportunity to comment on the proposed outcome measures. Please feel free to contact any of us if you have any questions.</p> <p>Joseph A. Bosco III, MD Associate Professor and Vice Chairman, Clinical Affairs Department of Orthopaedic Surgery, NYU School of Medicine NYU Hospital for Joint Diseases, NYU Langone Medical Center</p> <p>Joseph D. Zuckerman, MD Professor and Chairman Department of Orthopaedic Surgery, NYU School of Medicine NYU Hospital for Joint Diseases, NYU Langone Medical Center</p> <p>Martha J. Radford, MD Professor of Medicine, NYU School of Medicine Chief Quality Officer, NYU Langone Medical Center</p>	NYU Langone Medical Center		
8/4/2010	Complications Readmission	<p>In reference to your call for stakeholder review and public comment on measures currently in development, Masonicare would like to take this opportunity to share with you our willingness to participate in this therapy related initiative. Masonicare as a continuum provides inpatient, outpatient rehabilitation and home health services to communities throughout the state of Connecticut. We have provided continuum services to innumerable joint patients at home as well as in our rehabilitation settings. Our physical therapists would welcome the opportunity to participate with data in the following areas: Definition of the outcomes and/or serve on the Technical Expert Panel. We understand the importance of collaborating with our partners in the community and are preparing for success in the new health care environment.</p>	Mary T. Allegra RN, MSN, Vice President, Home Health & Hospice Masonicare	MAllegra@Masonicare.org	Medical Center/Clinic

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8/4/2010	Complications Readmission	<p>the CMS webpage says the close of comments is Aug 11 but the Project pdf says it is Aug 4. Which is correct?</p> <p>Kay E. Jewell, MD President, Tara Center, LLC/Center for Consumers of Healthcare</p>	<p>Kay E. Jewell MD , President, Tara Center, LLC/Center for Consumers of Healthcare</p>	<p>kayjewellmd@yahoo.com</p>	<p>Individual</p>
8/5/2010	Complications	<p>Kay E. Jewell, MD President, Tara Center, LLC/Center for Consumers of Healthcare</p> <p>RE: Complications measure for hip/knee replacement Thank you for this opportunity to comment. The Complications measure should also include Deep Vein Thrombosis (DVT) in addition to PE. DVT is often considered just a surrogate for PE. While physicians may not consider DVTs to be as serious as a PE, DVTs are a significant clinical event when they occur alone. DVTs occur at a higher rate than PEs as primary and secondary diagnoses. (Spyropoulos 2007) They have a different rate of recurrence, hospitalization, readmission and cost of care. They occur more often than PE in most cases and specifically with TKR (Bjornara, 2006).</p> <p>DVTs require much the same approach as a PE and have the same impact on the patient in the diagnosis and management of the acute event ; first, they require diagnostic evaluation. Because more than 50% of them occur after hospitalization, there is an office visit/ED visit and often a readmission to the hospital. A DVT must also be treated for 3-6 months. That treatment, as with treatment for PE, usually with warfarin, carries with it its own risks of bleeding, falls, and readmission. It also requires weekly blood testing, dietary adjustment and alteration of habits to accommodate the increased risk of bleeding. DVT also has its own rate of recurrence and complications, e.g. post-thrombotic syndrome and regional pain syndrome.</p> <p>Spyropoulos et al reported that recurrent DVT cost was 21% greater than the cost of the initial VTE event (PE costs were the same for the initial and recurrent events). (Spyropoulos 2007)</p> <p>Nutescu (2008) specifically looked at the outpatient burden of DVT following orthopedic surgery. It was associated with a 22% and 74% increase in office and ED visits in the 6-months after discharge.</p>	<p>Kay E. Jewell MD , President, Tara Center LLC/Center for Consumers of Healthcare</p>	<p>kayjewellmd@yahoo.com</p>	<p>Individual</p>

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		<p>Recent studies have reported that the DVT associated with PE has a greater future impact on recurrence of VTE events.</p> <p>Other issues uncovered by the measure. There is a gap in care associated with the duration of prophylaxis after surgery to prevent VTE events. The hospital stay has been decreasing and patients have not been receiving the 7 day prophylaxis that is used and reported in the clinical studies, e.g. for enoxaparin. Most patients are receiving prophylaxis only during their hospital stay.</p> <ul style="list-style-type: none"> • 2003 – Ave LOS – hip – 5.8 days, knee – 6.3 days (White, 2003) • Huo (2009) – reports the trend to lower LOS for total hip and total knee, from 4.7/4.5 days respectively in 1996 to 3.7 days for both in 2001 • Spyropoulos 2009 data reported less than 40% of orthopedic patients received anticoagulants after the index hospital stay. • The SCIP-VTE 1 and 2 measures, which apply to high risk surgical procedures including major hip/knee procedures, do not apply if the hospital stay is less than 3 days. If clinicians use that as their guide, many patients may not even receive prophylaxis during their hospital stay. <p>Extended prophylaxis after 7 days: The ACCP and NICE guidelines address this with supportive literature cited – they recommend extended prophylaxis for major orthopedic surgery. The incidence of VTE is lowest with the longest duration of prophylaxis (Eriksson 2003). Rates of VTE ranged from 5.2% to 11.7% in patients treated for 9 to 11 days, from 6.7% to 13.4% in patients treated for 6 to 8 days, and from 8.7% to 17.0% in those treated for <=5 days.</p> <p>Repeated studies report that most of the VTE events are diagnosed after discharge from the hospital. White reported that 56% were diagnosed after discharged (all surgeries). Total or partial hip arthroplasty had the highest rate of diagnosis after discharge.</p> <p>Huo & Muntz summarized the literature on the need for extended prophylaxis (Huo 2009). They cited the following:</p> <ul style="list-style-type: none"> • White (2003) The diagnosis of VTE was made after hospital discharge in 76% of THRs and 47% of TKRs, and the median times to diagnosis were a respective 17 and 7 days. • Bjornara (2006) - 71% of symptomatic DVTs and 61.8% of symptomatic 			

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		<p>PEs occurred after discharge.</p> <ul style="list-style-type: none"> • Schelling (2005) median time to diagnosis after THR and TKR is 17 days and 7 days respectively. • Dahl (2000) – mean duration to VTE symptoms was 27 days for THR. 17 days for TKR and 36 days for hip fracture. <p>Bergqvist D, Joˆnsson B (1999) Cost-effectiveness of prolonged administration of a low molecular weight heparin for the prevention of deep venous thrombosis following total hip replacement. <i>Value Health</i> 2:288–294. doi:10.1046/j.1524-4733.1999.24003.x</p> <p>Bjornara BT, Gudmundsen TE, Dahl OE. Frequency and timing of clinical venous thromboembolism after major joint surgery. <i>J Bone Joint Surg Br.</i> Mar 2006; 88(3):386-391.</p> <p>Dahl OE, Gudmundsen TE, Haukeland L. Late occurring clinical deep vein thrombosis in joint-operated patients. <i>Acta Orthop Scand.</i> Feb 2000; 71(1):47-50.</p> <p>Huo MH, Muntz J. Extended thromboprophylaxis with low-molecular-weight heparins after hospital discharge in high-risk surgical and medical patients: a review. <i>Clin Ther.</i> Jun 2009; 31(6):1129-1141.</p> <p>Nutescu EA, Shorr AF, Farrelly E, Horblyuk R, Happe LE, Franklin M. Burden of deep vein thrombosis in the outpatient setting following major orthopedic surgery. <i>Ann Pharmacother.</i> 2008 Sep 2008; 42(9):1216-1221.</p> <p>Spyropoulos AC, Lin J. Direct medical costs of venous thromboembolism and subsequent hospital readmission rates: an administrative claims analysis from 30 managed care organizations. <i>J Manag Care Pharm.</i> Jul-Aug 2007; 13(6):475-486.</p> <p>White RH, Zhou H, Romano PS. Incidence of symptomatic venous thromboembolism after different elective or urgent surgical procedures. <i>Thromb Haemost.</i> Sep 2003; 90(3):446-455.</p>			
8/5/2010	Complications Readmission	<p>On behalf of the American Hospital Association, we are pleased to submit the attached comments on the hip/knee readmission/complication measures. If you have any additional questions or follow-up, please contact Lisa Grabert (lgrabert@aha.org).</p> <p>Lisa Grabert American Hospital Association lgrabert@aha.org</p>	Lisa Grabert American Hospital Association	lgrabert@aha.org	Hospital Association

Date Posted	Measure Set	Text of Comments	Name, Credentials, and Organization of Commenter	Email address	Type of organization
		<p>American Hospital Association (AHA) Comments 30-Risk Standardized Readmission Rate following the Elective Total Hip and Total Knee Arthroplasty and Risk-Standardized Complication Rate following Elective Total Hip and Total Knee Arthroplasty</p> <p>We thank CMS and the Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation for the opportunity to comment on these draft measures. Providing feedback through several stages of the measurement development process is critical to producing a reputable product. Today we are taking the opportunity to comment in the early stages of development and we are committed to providing feedback through further testing and possible endorsement phases as well. Our comments today cover the following areas: (1) measure development feedback process, (2) use of claims data in deriving quality measures and (3) ability to act.</p> <p>Measure Development Feedback Process Though we appreciate the ability to comment on these draft measures, we were not given sufficient time to make the detailed comments necessary in order to turn these measures into a reputable product. As such, we request the following next steps:</p> <ol style="list-style-type: none"> 1. Allow no less than 30-days for the public to respond to future draft measures; 2. Publish the notification for public comment and announcement for serving on a Technical Expert Panel (TEP) in the federal register; 3. Provide a detailed webinar presented by the measure developer on the basics of these measures that allows no less than 30-minutes for question and answers; 4. Willingness to work with the AHA to schedule an in-person face-to-face discussion with the measure developer to address detailed concerns regarding these measures. <p>Use of Claims Data to Populate Quality Measures In simply looking at available administrative claims data, it is not possible to distinguish between patients who have been readmitted due to factors largely within the control of the hospital and those who have been readmitted for other reasons. For example, there are no data that indicate whether an unplanned, related readmission was part of the natural course of the patient's disease or due to a missed step in hospital care. The science available to inform policy makers is scant. Very little is known about the causes for</p>			

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		<p>readmissions or potential ways to prevent readmissions among patients with other conditions. Before pursuing development any further development of this readmission measures or any other readmission measures, we strongly recommend that CMS introduce a new data element into the claims processing system that allows hospitals to indicate whether a readmission is planned or unplanned.</p> <p>Further, we note that there are several other aspects of claims data that provide important information that were overlooked in the development of these measures. The present on admission (POA) indicator has been an important data element of claims data since October 1, 2007. Rather than arbitrarily assuming a complication is related to a previous admission, the measure developer should use the data that is available and rely on the POA indicator for a more quantitative assessment of relatedness. We strongly recommend that the measure development build the POA indicator into the complications measure(s).</p> <p>In addition to the POA indicator, the measure developer should also add key major diagnostic categories to the exclusion list for the readmission measure(s). We strongly recommend that the measure contain exclusions for patients whose original discharge was associated with a primary or secondary diagnosis or procedure code for transplants, End Stage Renal Disease, burn, trauma, psychosis and substance abuse.</p> <p>Ability to Act Readmissions occur for a variety of reasons, including patient characteristics, home environments, lifestyle choices, access to primary care, patient non-compliance and complications. With these two measures, the developer is attempting to make a direct correlation between complications and readmissions. The evidence and science base that is currently available simply does not support this conclusion. We strongly recommend that the developer concentrate only on the complication measure and NOT the readmission measure around these surgical procedures. The complication measure is far more actionable than the all-cause readmission measure. The complication measure would allow hospitals to focus on targeted, specific areas for improvement.</p> <p>Further, it is unclear why the developer is targeting a single 30-day all-cause readmission measure when they provide much stronger evidence that there</p>			

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		<p>may be a need for three separate targeted complication measures of 7, 30, and 90 days.</p> <p>Concluding Remarks We would like to reiterate our gratitude for the opportunity to weigh-in early in the measure development process. These draft measures target a very important area and we are encouraged to see progress around measurement for these surgical conditions. We have only provided our high-level remarks in these comments and we look forward to scheduling a follow-up meeting with the measure developer to provide our detailed remarks in the very near future.</p>			
8/6/2010	Complications Readmission	<p>Gentlemen: It was my impression that the standard comment period in these instances are 90 days. I am surprised at the brief period (i.e., response by 8/11/10) given the 7/29/10 5 PM notification and during a heavy vacation month for a very lengthy set of documents.</p> <p>Sincerely, Tim McClung Timothy McClung, MPH, FACHE, CPHQ Director, Quality Operations Quality Department Norwalk Hospital</p>	Tim McClung Norwalk Hospital	Tim.McClung@Norwalkhealth.org	Individual
8/6/2010	Complications Readmission	<p>My name is Donna Stone and I am a CPC with an orthopaedic group. I also have had a total knee replacement. I want to comment on the Definitions of outcome. The first thing I have to say is *I can walk again*. This was life changing for me and I want to recommend that CMS continues to allow this surgery and therapy afterwards. It was not an easy recovery but with the help of a good therapist I was able to regain most of the lifestyle I was accustomed to before I was debilitated with arthritis. My therapist was very hard on me and I feel that this is the secret to my successful recovery and return to a active life. I was ■ when I had the surgery but now know many people older than I who have success stories to tell from the replacement of both the knee and hip joints. These people are now active and productive members of society that the replacement allows them to be. This is just my story that I felt compelled to share with you. I am not sure if it really falls into the realm of your study but when I saw this call for public comments I wanted to contribute mine. Thank you for allowing me to a venue for my opinion and story.</p> <p>Donna Stone CPC</p>	Donna Stone	ray-donna@nc.rr.com	Individual

Date Posted	Measure Set	Text of Comments	Name, Credentials, and Organization of Commenter	Email address	Type of organization
8/9/2010	Complications	<p>ray-donna@nc.rr.com</p> <p>Dear Sir/Madame:</p> <p>I read with interest the proposed guidelines. My comments are on two specific clinical assumptions.</p> <p>1. My understanding from reading the proposed guidelines is that same day/admission bilateral and unilateral total knee outcomes will be reported together and, apparently carry the same weight. My colleagues and I presented a paper at the AAOS this past year which is in line with several other articles. We note that the complication rates for bilateral total knee replacements are higher than unilateral procedures. However, for the patient who has bilateral disease, the cumulative risk of any complication within 90 days when staging surgery is exactly the same as that incurred when undergoing same day, bilateral surgery. We noted this in our registry data, currently 100,000 implants strong, and with high volume surgeons in diverse clinical practices. Thus reporting bilateral TKA alongside unilateral TKA will inadvertently make high volume centers that do bilateral TKA appear to have more complications when in reality, this is not the case. While I support collecting data for unilateral and multilateral procedures done during the same admission, I urge you to consider reporting unilateral and bilateral procedures separately.</p> <p>2. Surface replacement is currently an excluded procedure. The procedure, however, is nearly identical to a routine THA in all the elements that are related to the measures being reported with the same if not higher complication rates reported in the literature. There is no clinical reason to exclude it and the arguments presented for doing so are simply not supported by any factual evidence. The particular rationale seems to have been written by a non-clinician with only a passing understanding of the procedure. I suggest you consider NOT excluding Surface Replacement from data collection.</p> <p>Sincerely, Stefano Bini, MD Chief, Department of Orthopaedic Surgery and Podiatry Kaiser Oakland AAOS International Committee</p>	Stefano Bini, MD, Chief, Department of Orthopaedic Surgery and Podiatry Kaiser Oakland AAOS International Committee	Stefano.Bini@kp.org	Individual
8/9/2010	Complications Readmission	<p>Based on the two CMS proposed measures and invitation to comment:</p> <p>1. Complications of elective hip and knee replacement- include any related</p>	David E. Attarian, M.D., F.A.C.S.	breec001@mc.duke.edu	Individual

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		<p>event within the 90 day global period, but divided into major and minor categories. Listing aggravated pre-existing comorbidities versus newly acquired problems will be important. Perhaps some way to measure whether or not pre-existing comorbidities were optimized preoperatively. Also, correlate with evidenced based practices/ PQRI measures, i.e. were perioperative antibiotics and dvt prophylaxis measures followed per protocol, or not.</p> <p>2. 30 day all cause readmission- should differentiate causes directly related to surgery, e.g. deep infection, acute mechanical failure, versus other indirectly related causes, e.g. myocardial infarction, pulmonary embolus, versus completely unrelated- car accident, brain tumor, etc.</p> <p>David E. Attarian, M.D., F.A.C.S. Associate Professor and Vice Chairman Department of Orthopaedic Surgery Medical Director, Musculoskeletal CSU Duke University Health System</p>	<p>Associate Professor and Vice Chairman Department of Orthopaedic Surgery</p> <p>Medical Director, Musculoskeletal CSU Duke University Health System</p>		
8/9/2010	Complications Readmission	<p>Hospital risk-standardized complications rate following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA).</p> <p>Overall the document is well written, and the expert panel commentary/feedback section is very good. Overall the panel seems very credible and experienced. The summary of evidence of high impact and the business case documentation is credible. Specifically, I note that preliminary data analysis shows a substantial variation in RSCR (Risk-standardized complication rate) across hospitals using HGLM (hierarchical generalized linear models) from 1.9-15.9% with a mean of 6.7%.</p> <p>The tiered time windows for classification of complications seem appropriate. I am curious as to how the 90 day post admit date was chosen for joint infection and mechanical complications. It would seem that this number could properly be extended to 180 days.</p> <p>The denominator exclusions seem in general appropriate. Exclusion of patients undergoing resurfacing procedures does not seem necessary, in my opinion I would include them. For purposes of this measure are conversions</p>	<p>Timothy Brox, MD UCSF Fresno Orthopaedic Residency Program</p>	TBrox@fresno.ucsf.edu	Individual

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		<p>of a hip bipolar hemi-arthroplasty to a total hip arthroplasty a conversion or a revision? I would suggest that they should be classified as revision surgery for purposes of this measure.</p> <p>The outcome measures chosen are intermediate outcomes. It would seem appropriate to have a plan to correlate / validate the RSCR rates against standardized patient reported functional outcomes.</p> <p>I have several comments.</p> <p>1) Risk Stratification I am concerned about the overall risk stratification process. The concept of using an expected complication model that combines patient and hospital factors seems sound. The list of patient factors as listed seems reasonable. The additional factors of patients who have had recent pelvic or femoral shaft fractures would be seem an important co-morbidity increasing the potential problems for complication after a total hip arthroplasty. The hospital specific intercepts are not documented. If Socio-economic factors are not properly built into the model (i.e. not accounted for), the inevitable complications associated with Socio-economic patient factors may become a barrier to patient care.</p> <p>2) Acute myocardial infarction Although I understand the rationale for including acute myocardial infarction as a complication, I am concerned that the inclusion of this complication may result in access to care problems.</p> <p>3) Measure validation The document makes reference to measure validation. The measure notes that the decision to publicly report this measure and the approach has not been determined. It would seem likely however that there will plans to publicly report the hospital performance measures. Based on a preliminary analysis of 2008 Medicare Part A inpatient claims there is a substantial variation in unadjusted hospital complication rates. The aim of this measure is to reduce this complication rate. Public disclosure of this data will have a likely potential for changing patient preferences regarding hospitals. It is important that this patient preference be based on sound data. For all these reasons the approach to validation is very important. I have seen previous data suggesting that there are definite problems associated with administrative claims data</p>			

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		<p>such as will be used for this measure². I would hope that validation process would include opportunities for hospitals to see raw data associated with this measure and for hospitals to have an opportunity to both improve their processes of care and also their reporting of administrative data.</p> <p>4) Complications in spite of compliance with process of care quality measures Although not mentioned it would be my opinion that complications such as pulmonary embolism or infection complications that occur when the hospital/surgeon is fully in compliance with process of care quality measures are different than complications that occur when the hospital/surgeon is in noncompliance with process of care measures.</p> <p>1. Sharkey PF, Hozack WJ, Rothman RH, Shastri S, Jacoby SM. Why Are Total Knee Arthroplasties Failing Today? Clinical Orthopaedics and Related Research 2002;404:7-13.</p> <p>2. Bozic KJ, Chiu VW, Takemoto SK, et al. The Validity of Using Administrative Claims Data in Total Joint Arthroplasty Outcomes Research. J Arthroplasty 2010.</p> <p>Timothy Brox, MD UCSF Fresno Orthopaedic Residency Program Reply tbrox@fresno.ucsf.edu</p>			
8/9/2010	Complications	<p>CMS: Thank you for the opportunity to respond to the proposed quality outcome measures for Hip or Knee Arthroplasty procedures. This response is on behalf of the University of Minnesota Medical Center. Definition of the outcomes: Pneumonia (outcomes) includes viral pneumonias (480-480.9) as a complication of hip/knee procedures. This would seem to be more likely not related to the orthopedic surgery. Question having aspiration pneumonia (507.0) included.</p> <p>Bacteremia (790.7) is coded if a patient has a positive BC even if they have no other symptoms. Presence of this code does not always mean sepsis happened.</p>	<p>Constance M. Young, BSN, MS Department of Quality and Patient Safety</p> <p>Senior Data Analyst University of Minnesota Medical Center</p>	CYOUNG6@fairview.org	Medical Center/Clinic

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		<p>Other Post-Op infection (998.59) is what coders call a “junk code” and is not specific enough to be linked to the surgery.</p> <p>Hemorrhagic disorder due to intrinsic circulation anticoagulants (286.5) with incision/drainage is considered a complication in this evaluation. Coagulation defects are not caused from surgery.</p> <p>Will patients that are transferred for “continuation of care” to Behavioral, ACU or LTAC be counted as readmissions?</p> <p>Risk adjustment Will POA (present on admission) indicators be considered? Risk adjustment for SES would seem necessary, as wound infections and poor after care are often a result of SES. Hospitals with more patients of lower SES should be risk adjusted.</p> <p>Technical Expert Panel (TEP) comments: Complication-specific follow up periods: Death within 30 days would more likely to be attributed to other factors. Consider moving “death” into the 7 day follow up period to more accurately connect it with the orthopedic surgery.</p> <p>Constance M. Young, BSN, MS Department of Quality and Patient Safety Senior Data Analyst MB University of Minnesota Medical Center</p> <p>I would appreciate being added to the list-serve. Connie I would appreciate being added to the list-serve.</p>			
8/92010	Readmission Complications	<p>The American Association of Orthopaedic Surgeons (AAOS) appreciates the opportunity to comment on the quality measures developed for patients undergoing elective total hip and total knee replacement. We represent nearly 18,000 board-certified orthopaedic surgeons and have been a committed partner to the Centers for Medicare and Medicaid Services (CMS) in patient safety and quality health care. We look forward to providing input on measures being actionable, aligned, and risk adjusted.</p> <p>See attachment for full comment. Please let me know if you have any</p>	<p>John J. Callaghan, MD President Sent by Jacque Buschmann American Association of Orthopaedic Surgeons (AAOS)</p>	roche@aaos.org	Orthopedic Society

Date Posted	Measure Set	Text of Comments	Name, Credentials, and Organization of Commenter	Email address	Type of organization
		<p>questions. Thank you,</p> <p>Jacque Buschmann Jacqueline Buschmann, MPH Federal Policy Analyst American Association of Orthopaedic Surgeons roche@aaos.org</p> <p>August 11, 2010 Lein Han, Ph.D Government Task Leader Centers for Medicare & Medicaid Services</p> <p>Laura Grosso, Ph.D Associate Research Scientist Yale/Yale New Haven Hospital Center for Outcomes Research and Evaluation (CORE)</p> <p>Dear Dr. Han and Dr. Grosso: The American Association of Orthopaedic Surgeons (AAOS) appreciates the opportunity to comment on the quality measures developed for patients undergoing elective total hip and total knee replacement. We represent nearly 18,000 board-certified orthopaedic surgeons and have been a committed partner to the Centers for Medicare and Medicaid Services (CMS) in patient safety and quality health care. We look forward to providing input on measures being actionable, aligned, and risk adjusted. The AAOS appreciates the immense stakeholder input that CMS and Yale has obtained from the musculoskeletal community. We look forward to continued partnerships with both CMS and Yale for any and all musculoskeletal quality and patient safety initiatives. The AAOS is dedicated to committing considerable human and financial resources to developing and analyzing evidence-based process and outcome measures and encouraging the adoption of evidence-based practice guidelines for the prevention, diagnosis, and management of musculoskeletal disease. We invite CMS and Yale to call on us as a partner and expert in performance and quality measurement in musculoskeletal care.</p> <p>General Comments. As a general comment, the AAOS supports quality</p>			

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		<p>measures that are actionable and help align and coordinate care in all settings by all providers. We obviously support the measurement and reduction of complications and readmissions. However, we have concerns with the ability of the overall performance rate to inform a hospital of its specific needs for quality and patient safety improvement. We understand that measuring quality in the hospital and physician community differs in many ways but we strive and advocate for alignment when possible.</p> <p>The AAOS is also looking for clarification on the selection of the readmission measure as both an efficiency/cost and outcomes measure. This designation essentially results in two different measurements without any specifications for the calculation of the efficiency/cost component.</p> <p>Risk-Adjustment. The AAOS would like to take the opportunity to express our support for a movement toward developing clinically relevant quality measures which recognize the importance of measuring both process and outcome. We cannot stress the importance of risk adjustment when outcome measures are publicly reported and/or used in future value based-purchasing programs enough. Both of these quality tools rely on accurate, valid, and reliable data to inform stakeholders and improve quality. Without risk adjustment, comparisons are not equitable.</p> <p>The AAOS appreciates the extensive work on ensuring a robust risk-adjustment model for both the readmission and complications quality measure. The AAOS has specific concerns with the lack of inclusion of socio-economic status (SES). However, we understand this decision based on the measure development criteria of the National Quality Forum (NQF). The AAOS also has concerns with obesity as a variable not included in the risk adjustment methodology. Obesity places patients at a higher risk for complications, particularly infection and venous thromboembolism, and readmissions.</p> <p>The AAOS appreciates this opportunity to provide input on the quality measures developed for patients undergoing elective total hip and total knee replacement. We look forward to working with CMS and Yale on future musculoskeletal issues. Please contact Jacque Buschmann at roche@aaos.org with any questions on the AAOS' comments.</p> <p>Sincerely,</p>			

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		<p>John J. Callaghan, MD President, American Association of Orthopaedic Surgeons</p>			
8/10/2010	Complications Readmission	<p>I did not see a Physical Therapist on the panel. I did not have time to read the measure details completely due to time constraints, but upon briefly reviewing the details I noticed there were many doctors but not therapists.</p> <p>There has been much research showing that outcomes for total joint arthroplasties are directly related to the therapy that they receive and to the extent in which they participate. Research also shows that there are less complications associated with these procedures when the patient is compliant and follows the therapist's exercise program and recommendations.</p> <p>It is also very important to take into account the patient's motivation and cooperation with their therapy program in preventing or decreasing the severity of any complications. If the therapy regiment for the patient while in the acute hospital stay and post-acute stay has already been considered for your outcome measure, then please disregard my comments and I apologize for taking up your time.</p> <p>Sincerely, Shehla C. Rooney Physical Therapist</p>	Shehla C. Rooney	shehlarooney@yahoo.com	Individual
8/10/2010	Complications Readmission	<p>Thank you for the opportunity to provide comment on this very important matter. My comments and recommendation are included in the attached word document. Regards,Jackie</p> <p>To: Laura M. Grosso, Ph.D. Yale New Haven Health Services Corporation/ Center for Outcomes Research and Evaluation (YNHHSC/CORE) Submitted via email to:hipknee@yale.edu.</p> <p>From: Jackie Birmingham, RN, BSN, MS VP Clinical Leadership Date: August 10, 2010 Re: Call for comments: outcomes measures for patients undergoing elective total hip and total knee replacement https://www.cms.gov/MMS/17_CallforPublicComment.asp.</p>	Jackie Birmingham, RN, BSN, MS, VP Clinical Leadership Curaspan Health Group	jbirmingham@curaspan.com	Private Company

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		<p>NB: These comments are related to the ‘risk adjustment’ portion and apply to all measures including patient safety and readmissions:</p> <p>Recommendation: The comments focus on discharge planning, patient transition and the discharge disposition status of patients.</p> <p>In order to measure the impact of all factors involved in patient safety and readmissions another risk factor must be added the published list of clinical risk factors: this risk factor is:</p> <ul style="list-style-type: none"> • Patients discharged without a referral to post-acute care and are readmitted within 30 days. <p>Background:</p> <p>1. Patients undergoing total joint replacement are at high risk for adverse outcome if there is not adequate discharge planning. The mere interruption of their functional status based on the nature of the procedure puts them at high risk for unintended outcomes.</p> <p>a. The published risk factors in the call for comments show great detail about the patients possible clinical conditions, but do not address the risk factor of the patient’s discharge disposition status.</p> <p>b. A factor that must be reviewed for impact on safety and readmission is whether or not the patient was referred for post-acute care such as Inpatient Rehabilitation Facility, Skilled Nursing Facility or Home Health Care.</p> <p>c. The Centers for Medicare and Medicaid (CMS) discharge disposition status codes required for billing indicates whether or not a patient was referred for medically necessary post-acute service.</p> <p>d. The listing of the discharge status codes can be found in this Special Edition of Medicare Learning Matters SE0801 at this website.</p> <p>i. http://www.cms.gov/MLN MattersArticles/downloads/SE0801.pdf</p> <p>ii. For example, patient’s with a discharge disposition status code of 01, would indicate that no-follow up care was arranged.</p> <p>e. The CMS also requires that hospitals provide discharge planning services as part of the Social Security Act. The requirement clearly indicates that patient’s discharge planning addresses avoiding a risk for an adverse health</p>			

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		<p>consequence by providing adequate discharge planning.</p> <p>i. http://www.ssa.gov/OP_Home/ssact/title18/1861.htm</p> <p>ii. Readmission is an adverse health consequence that can be avoided by adequate discharge planning, and in particular for patients whose functional status has been compromised by a total hip or knee replacement.</p> <p>Recommendation submitted by: This call for comments is submitted on behalf of Curaspan Health Group, a privately held software as a service (SaaS) provider based in Newton, MA.</p> <p>Curaspan Health Group builds secure patient-transition networks for hospitals, post-acute providers and suppliers to optimize patient care. Our hospital and post-acute care clients use the discharge planning software to manage patient transition and collect data. Collectable Data includes readmission rates based on the patient's discharge disposition status. The trending of readmissions based on where the patient went after discharge has had significant impact on hospital practices to assure patient safety at the time of discharge.</p> <p>In March 2010 a press release was distributed that showed the relationship to transition management, discharge status and readmissions. This report is available at http://connect.curaspan.com/content/readmissions</p> <p>We believe strongly in the value of transition management on patient safety, preventing avoidable readmissions and overall quality of life for patients.</p> <p>If you would like additional information, please contact me at: Jackie Birmingham, RN, BSN, MS Curaspan Health Group jbirmingham@curaspan.com</p>			
8/10/2010	Readmission Complications	<p>To Whom It May Concern:</p> <p>As a medical professional, I first want to say that for joint replacement patients with any risk factors, there should not be a penalty for readmission. Since joint replacements are rarely allowed on Acute Rehab units now, they are discharged much earlier than in previous years. A 4 day stay in the hospital for patients with medical comorbidities is not enough time to ensure that all underlying medical issues are stable.</p>	Lori Michel, Director of Rehab Services	lmichel@petersonrmc.com	Individual

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		<p>I think risk factors include: age over 85, obese patients, diabetics, patients with dementia, patients with compromised pulmonary functioning, patients that smoke, patients with sedentary lifestyles and patients who live alone. Our experience is that these patients are rarely ready to return home within the DRG LOS for joint replacements. Many times they are sent to nursing homes where there is less oversight by medical personnel, and greater exposure to infection.</p> <p>Complications that we see are infection—both UTI's and wound infections that do not show up during the acute stay, but become evident within the first 10 days; significant effects from pain meds, causing confusion and decreased alertness so they are unable to participate in therapy as early as necessary, patients with history of AF that have complications with PE's and are sent back to the acute floor, low blood pressure from pain meds or prolonged effects of anesthesia, infection of hardware that may not be evident for several weeks.</p> <p>Thank you, Lori Michel Director of Rehab Services</p>			
8/10/2010	Readmission	<p>I am writing on behalf of SeniorMetrix Inc. We are a privately held health care technology company with nearly 100,000 records of TKR and TKR replacement episodes in various combinations of acute, skilled nursing and home health settings. Our records are distinct from claims data and contain patient demographics and clinical characteristics that are significantly related to both outcome and hospital re-admission. Our purpose in this commentary is point out the potential shortcomings of a measure based primarily on claims data and vaguely defined chart review.</p> <p>Functional Outcome and Hospital Re-Admission Outcomes in this study do not address the functional level (ADL/IADL, work and recreational mobility) of the patient either prior to or at follow-up from surgery. Thus the proposed model assumes that factors relating to physical/cognitive disability and manifestations of same (e.g, falls) are not related to the study dependent variables: death and/or hospital readmission. We would argue that any consideration of hospital re-admissions for these elective procedures must include a pre-post measure of function.</p>	Reg Warren PhD Chief Science Officer, Director of Rehab Services SeniorMetrix, Inc.	warren@seniormetrix.com	Private Company

Date Posted	Measure Set	Text of Comments	Name, Credentials, and Organization of Commenter	Email address	Type of organization
		<p>Predicting Hospital Re-Admission</p> <p>Recently we studied hospital re-admissions during skilled episodes of care out to 30 days post hospital discharge on 45,000 SeniorMetrix skilled records from the Medicare Advantage 2008-2009; 16% re-admitted to hospital. Logistic regression models were used to estimate the likelihood of re-admission. Using only ICD-9 data, the model correctly predicted hospital re-admission 42% of the time. However, when we added functional status, concurrent conditions (e.g., IV, tube feedings, wound status, obesity) and usual living setting prior to hospitalization (e.g. home vs assisted living), the model's predictive accuracy rose to 75%. Our comment here is that claims data should be augmented with other measures in order to explain hospital re-admission. Perhaps the "chart review" portion of the study should be further defined to include such information.</p> <p>I would appreciate the opportunity to discuss our comments with study representatives.</p> <p>Reg Warren PhD Chief Science Officer SeniorMetrix, Inc.</p>			
8/10/2010	Complications Readmission	<p>Although this email is being written at my desk at work, it is on my lunch hour and has nothing to do with my firm. Please treat this email in that light.</p> <p>My home email address is mchair@embarqmail.com.</p> <p>When considering hip and knee replacements, there is a major missing component in the discussions with the elderly, their families, and in planning the follow-up care for weak and vulnerable adults. How can I ensure a quality of life after the surgery? I speak from experience with my mother.</p> <p>My mother had both of her knees replaced during her eighties. The first surgery went OK, but there were huge issues with sundowners syndrome after the surgery and her release to home. She did all her therapy at home and there was a huge difference in her hospital care once they understood she would not go to rehab. We found her basically laying in a wheelchair (aftermath of pain medicine that just didn't help her mentally) and being run through the motions of therapy but no real participation. Once we made it clear she was going home, the pain medicine was changed, her alertness</p>	Connie Morrill-Hair Senior Metrix, Inc.	cmhair@sek.com	Individual

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		<p>improved and they got her up and moving before releasing her. The sundowner's kicked in a few days later, but with the help of my then alive dad, our overnight stays and some care takers that we had hired—not paid for by Medicare, we got her through it and I would classify that surgery as a success.</p> <p>After my father passed, she was scheduled for a second knee replacement. We spoke to the surgeon about the sundowners and he tried something different—but we didn't successfully impress the hospital to avoid overmedication. All of the same things happened. In fact on the day of discharge I was with Mom and couldn't believe her condition and shared with the hospital my sister was on her way to take mom home. What not to rehab? No—home therapy—well wouldn't you know it, they had to scurry about and do real rehab and held her all day until she 'sobbered up'. We made it through that episode of sundowners as well. Again I would call that surgery successful—but without family involvement, I think the outcome would have been different.</p> <p>When my mother was ■ she fell, jammed her hip and a hip surgery was recommended. We took her to two physicians and both said why wouldn't you do this? Our fear was the aftermath and the quality of life. We weren't equipped to give her the home care she needed so this time we agreed to rehab. We had orders written—no prescription pain medicine. The anesthesiologist worked with us to use locals, and when she came to her room we thought yes, we found the magic bullet. But on day two, while we weren't there, the hospitalists asked mom if she was in pain—she said yes—and she was given prescription pain medicine. In the morning I found a zombie—they struggled to get her in a wheelchair, literally drug her to therapy—I sat there in therapy and watch as they blasted orders to her and she was totally unresponsive—did that matter—no—they could say they gave her therapy. Then the physician came in to do her exam—sitting in the wheelchair—a nothing exam (but Medicare was billed for it). He and I had words about the exam and the pain medicine. He was not happy, but pain medicine stopped and mom improved. But the damage had been done. Off she went to rehab—and guess what—more pain medicine, more useless therapy, and she developed C-diff. It was a terrible experience for her and as I looked around the rehab center, I could see several old people in the same boat as my Mom. But statistically, the doctors were following protocol, and Medicare paid the bill.</p>			

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		<p>We finally got Mom home and she spent the next six months in and out of doctor's offices and the hospital—all because of the ancillary treatments associated with the hip replacement. Was the hip replacement a success statistically—sure—but did the associated treatment really help my Mom—no way. She died seven months after the surgery in our home. She never had a really good day after her surgery—not because of the hip replacement, but because of all the associated treatments.</p> <p>So when you ask about hip and knee replacement—it won't surprise me if statistics say yep it works. But where in the survey will it say what was the quality of the patient's life before the surgery and three months after the surgery? Was the patient's mental competence compromised by the pain medicine? Was the therapy offered at the hospital really of value? Was the medical treatment during rehab by the book or based on the patient's personal history and needs?</p> <p>How do we separate getting the job done with x dollars versus restoring people to a quality life? How do we tack onto the cost of the surgery all the other conditions, including sundowners, that is a byproduct from putting old people through such a stressful time? And for the C-diff—how do we get hospitals and doctors to step up and understand that antibiotic treatment for some infections makes patients vulnerable to other infections—so don't just treat the urinary tract infection, but treat the bodies need for good bacteria in order to be restored.</p> <p>In closing I'd like to say that I am scared to turn 65 because I will become a patient in the Medicare system—where drug treatments are preferred over natural and/or over the counter treatments, where drug treatment is used rather than lifestyle adjustments, and where rewards are in place to treat conditions based on statistics rather than the person's individual needs. I'd also like to say I am please someone is asking for feedback.</p> <p>I am a baby boomer, Connie</p>			
8/10/2010	Complications Readmission	Attached please find comments from Dr. Edward Cheng and Dr. Patrick Morgan regarding the: YNHHS/CORE has issued a call for public comment on the two measures currently in development:	Edward Y. Cheng, MD Adult Reconstructive Service, Adult	borgs013@umn.edu	Individuals

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		<p>1. Complications following Elective Total Hip or Knee Replacement 2. 30-Day All-Cause Readmission following Elective Total Hip or Knee Replacement I understand that the due date was extended to tomorrow 8/11 at 12N. Thank you.</p> <p>UNIVERSITY OF MINNESOTA August 10, 2010 TO: hipknee@yale.edu FROM: Edward Y. Cheng, MD Adult Reconstructive Service, Adult Reconstructive Fellowship Director Mairs Family Professor, University of Minnesota, Department of Orthopaedic Surgery Editorial Board, The Journal of Bone and Joint Surgery-American</p> <p>Patrick M. Morgan, MD Assistant Professor, University of Minnesota, Department of Orthopaedic Surgery</p> <p>RE: Comment on YNHHS/CORE development initiative (https://www.cms.gov/MMS/17_CallforPublicComment.asp)</p> <p>1. Complications following Elective Total Hip or Knee Replacement 2. 30-Day All-Cause Readmission following Elective Total Hip or Knee Replacement</p> <ul style="list-style-type: none"> • Definition of the outcomes • Risk adjustment • Technical Expert Panel (TEP) comments <p>Dear CMS: We applaud your initiative to determine risk-standardized complications for THA and TKA. Thank you for the opportunity to provide comment. We would have the following comments on the documents posted for evaluation.</p> <p>Definition of the outcomes 1. The most glaring issue is that assessment of the quality and adequacy of care after a surgical procedure involves and includes much more than only looking at the incidence of complications. Therefore, while this data is important, it offers an incomplete and potentially inaccurate assessment of the quality of care. The data could also be misinterpreted, misconstrued and lead to unintended consequences or at worst, absurd practices in an effort to avoid</p>	<p>Reconstructive Fellowship Director</p> <p>Mairs Family Professor, University of Minnesota, Department of Orthopaedic Surgery</p> <p>Editorial Board, The Journal of Bone and Joint Surgery-American</p> <p>Patrick M. Morgan, MD Assistant Professor, University of Minnesota, Department of Orthopaedic Surgery</p>		

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		<p>complications. Some examples would be: a) the risk of pulmonary embolism could be reduced or eliminated by placing vena cava filters in all patients but nearly all physicians and surgeons would oppose the routine implementation of this treatment, b) the risk of hip dislocation and knee joint instability could be eliminated in the short term by routine usage of constrained cups and knee implants, respectively. However, clearly the routine usage of these implant designs is inappropriate and not in the best interest of patients. We would strongly encourage CMS to look at more issues other than only complications. While this is</p> <p>Twin Cities Campus Department of Orthopaedic Surgery Web: www.ortho.umn.edu CMS August 10, 2010 Page 2</p> <p>admittedly a much more difficult task, assessment of surgical indications, functional benefit or improvement over baseline (not necessarily the absolute functional outcome score), radiographic evaluation, are some metrics that would offer a more complete look at the quality of care.</p> <p>2. Form 9.1, page 2. "Complications are counted in the measure only if they occur during a hospital admission." All complications should be counted regardless of whether or not they occur or result in hospital admission. For example, a superficial wound infection, a knee manipulation for contracture and, a deep venous thrombosis all are complications that should be counted but routinely are treated on an out-patient basis.</p> <p>3. Complications identified during an admission to a hospital other than where the original surgery was performed should be captured and also attributed to the original hospital and surgeon.</p> <p>4. As the complications are identified from ICD-9 coding, the sensitivity for picking up a complications is wholly dependent upon the accuracy and completeness of coding. What evidence is there to document that hospitals are uniform in their self reporting, accuracy, usage and interpretation of diagnoses? There will be a strong bias against reporting or using different ICD-9 codes. As an example, a major criticism of the CMS pay for performance measure of antibiotic timing before joint replacement surgery was that hospitals were prevaricating in their reporting of this data.</p> <p>5. Form 9.1, page 3. Why do multiple complications count only once toward the numerator?</p> <p>6. Form 9.1, page 3. We would include the codes for a post-operative</p>			

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		<p>cerebrovascular accident.</p> <p>7. Form 9.1, page 3. An excellent assessment of the outcome of a THA or TJA is the functional outcome measurement of the operated joint specifically (excluding metrics dependent upon other joints) at the timepoint of 1 year post-operative.</p> <p>8. The proposed outcomes do not include other important parameters known to impact both the short-term and long-term function and long term durability of the implant. These parameters also would assess the technical skill of the surgeon as well. These parameters would include: peri-prosthetic fracture, subsidence, implant alignment and position, hip dislocation, knee ligament laxity resulting in clinical instability, patellofemoral imbalance.</p> <p>Unfortunately, most of these parameters cannot be abstracted from ICD-9 codes (except perhaps hip dislocation) and some can only be determined on post-operative xrays. As hip dislocation usually results in an emergency room outpatient, and some in patient, contact with the hospital, it should be possible to capture this complication.</p> <p>9. We would advise including measurement of postoperative hyperglycemia. It has been shown that surgical outcomes are related to excessive elevation in serum glucose. Failure to properly control glucose post-operatively impacts the incidence of wound infection.</p> <p>CMS August 10, 2010 Page 3</p> <p>10. Denominator exclusions. We would also exclude patients with an underlying tumor, benign or malignant; either related to the joint replacement or in the patient's medical history within the past 5 years as this impacts the likelihood of some of the outcome measures (eg, cancer and venous thrombosis). This has such profound and variable implications that we think it would be difficult or impossible to fairly control for this risk factor by inclusion of patients merely by identifying the risk factor of cancer (CC 8-12). For example, an AJCC stage III sarcoma of the buttock or a radiated pelvis due to gynecologic cancer would have dramatically different impact on risk of complications as compared to a localized cervical cancer cured by prior hysterectomy or a nonaggressive form of prostate carcinoma.</p> <p>11. It is not clear whether or not a urinary tract infection is considered a complication.</p> <p>12. Page 13. Some superficial wound infections (eg, stitch abscess at distal</p>			

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		<p>end of TKA incision may initially be considered minor and not result in a procedure code thus evading inclusion as a complication, yet they are at high risk of eventually leading to a deeper infection that may not be diagnosed for months. Unfortunately, while the requirement of a procedure code improves the feasibility of doing this project, it does not reliably differentiate between a clinically significant and insignificant infection.</p> <p>Risk Adjustment</p> <p>1. Determination of clinical covariates, page 6. The methodology for determining the medical co-morbidities (clinical covariates) is insensitive and therefore completely inadequate. Merely abstracting Medicare claims during the previous 12 months is insufficient for many reasons including but not limited to: patient not eligible for Medicare coverage due to age or other reasons during prior 12 months, some co-morbidities may not result in a Medicare claim (eg morbid obesity, heart failure, transient ischemic attacks, dyspnea, COPD, etc). This is especially true as more care is rendered in the outpatient, instead of inpatient, setting.</p> <p>2. We would use the preoperative physical examination to abstract the clinical covariates in addition to the history of Medicare claims data. Understandably this is much more difficult but having a complete evaluation of co-morbidities is critical to fairly assessing the risk and performing risk adjustment.</p> <p>3. Many additional co-morbidities that impact the risk of complications but were not clearly included are:</p> <ul style="list-style-type: none"> a. Ethanol abuse b. Drug abuse c. Tobacco abuse d. History of radiation treatment or exposure e. Immunosuppression f. Organ transplantation g. Bone marrow transplantation (sometimes done for non-malignant conditions) h. Osteoporosis i. Metabolic bone disease, eg renal osteodystrophy j. Joint contracture preoperatively k. Bony deformity 			

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		<p>l. Bony deficiency m. Neurologic conditions not listed (eg, Parkinson’s disease, other movement disorders) n. Ankylosing spondylitis o. Hemophilia p. Coagulopathies q. Prior ipsilateral or contralateral amputation r. Patient’s preoperative functional status s. Patient’s preoperative activity level 4. We would only consider and control for those co-morbidities that are know to be associated with the outcome or complication be analyzed. If the co-morbidity does not influence the outcome, it should not be considered in the analysis for that outcome.</p>			
8/10/2010	Complications Readmission	<p>Please assure that the postings are confidential--no names, no email addresses Connie Morrill-Hair, MBA, AVA Smith Elliott Kearns & Company, LLC E-mail: cmhair@sek.com</p> <p>-----Original Message----- From: CMS Hip/Knee Arthroplasty Outcomes Measures [mailto:hipknee@yale.edu] Sent: Tuesday, August 10, 2010 12:45 PM To: Connie Morrill-Hair Subject: Thank you for your comments</p> <p>Thank you for your interest and participation in CMS' Hip/Knee Arthroplasty Outcomes Measures public comment period. All comments will be publicly posted once the public comment period has ended. You will be notified once they are available for viewing.</p> <p>Help Us Serve You Better. We invite you to take 5-10 minutes to complete our client survey at www.sek.com. Your input and comments are very important to us and will assist us in responding to your current and future needs.</p> <p>For copies of IRS forms, handy financial calculators or the latest in tax tips check our website at www.sek.com.</p>	Connie Morrill-Hair	cmhair@sek.com	Individual

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		<p>To ensure compliance with U.S. Treasury rules, unless expressly stated otherwise, any U.S. Tax advice contained in this communication (including attachments) is not intended or written to be used, and cannot be used, by the recipient for the purpose of 1) avoiding penalties that may be imposed under the Internal Revenue Code, or 2) promoting, marketing or recommending to another party any tax-related matters addressed in this communication.</p>			
8/10/2010	Complications Readmission	<p>Please accept the attached comments on behalf of Bacharach Institute for Rehabilitation with regard to the Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation project to develop quality outcomes measures for patients undergoing elective total hip and total knee replacement. We appreciate the opportunity to share our suggestions. Overall, we believe the project we well developed and should result in process improvement and positive patient outcomes.</p> <p>The attached comments are general to all measures. Thank you for your consideration. Richard Kathrins</p> <p>Summary of Technical Expert Panel (TEP) Evaluation of Measures 1. Table 2: Risk Adjustment Methodology: consistent with NQF guidelines, the model does not adjust for patient admission source and their disposition, as these factors are associated with structure of the health system. Comment: While I agree that the patient source and their disposition may be associated with the structure of the health system we know that the availability of medical supervision is variable within the various post-acute care (PAC) setting. Level of medical supervision, nurse to patient ratios, hours of therapy and access to medical testing all vary by PAC setting.</p> <p>If this is not calculated in the risk adjustment methodology we should at a minimum understand the incidence of complications as defined by the project, either death, surgical and medical complications categorized by PAC location. In addition, the incidence of complication should minimally define if the complications occurred within 7 or 90 days as outlined in the project.</p> <p>2. Mechanical Complications (page 16): Comment: Patients are re-admitted for surgical manipulation within 90 days due to a loss or inability to fully mobilize the joint. This may be considered a planned admission but clearly the re-admission may be due to a failure of the</p>	Richard Kathrins, Ph.D. President/CEO Bacharach Institute for Rehabilitation	rkathrins@bacharach.org	Medical Clinic/Center

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		<p>PAC to mobilize the joint, co-morbidities or other care or patient issues. This type of re-admission should be tracked as it presents a negative outcome.</p> <p>3. Determination of Follow-up Period for Complications (page 9): Comment: Work by Morley, Gage, Smith, et al. (November 2009): Post Acute Care Episodes – Final Report, defined episodes of care differently for the Department of Health and Human Services. Could some consideration be given to being consistent with the definitions of episodes of care?</p> <p>FORM 9.1 – Measure Information Form</p> <p>4. Risk Adjusted Methodology/Variables (page 6): Comment: Could consideration be given to including pre-morbid level of functional independence or mobility as a clinical risk factor?</p>			
8/10/2010	General	<p>The problem I have with the concept, as I understand it...is, I can not improve complication or readmission rates based on a percentage. If the idea is to improve the quality then you need information/data. Telling me that our readmission rate for Total Joints is 6.7% doesn't tell me anything, unless you tell me what the readmission is for, i.e. an infection, coronary artery disease, flare up of their CHF, adverse effects of their pain medications, etc. –that would be helpful. If you really want to figure out the disparities, then you need more detail. And, risk-adjustments don't necessarily help. But, CMS id going to do what CMS wants.</p>	<p>Ramona Frazier RN Quality Services Director Delta County Memorial Hospital</p>	<p>rfrazier@deltahospital.org</p>	<p>Hospital</p>
8/10/2010	Complications Readmission	<p>Received: Aug 10, 2010 04:46:26 PM Expires: Sep 09, 2010 04:46:26 PM From: makosd@mlhs.org To: hipknee@yale.edu Cc: Subject: hip and knee project Attachments: htmlBody.html</p> <p>Dear YNHHSC/CORE members, I can personally speak to this topic as my [REDACTED] totally independent mother had an elective right total hip replacement for severe DJD done [REDACTED]. She has returned twice to the hospital since surgery. Once to the ED on [REDACTED] for hematoma evaluation and then admitted [REDACTED] for hematoma evacuation. In between these admission she has been to a rehabilitation hospital and currently returned to a SNF. I am not responding for my health system.</p>	<p>Doreen Makos, RN, BS, CPHQ Main Line Health System Medical Peer Review Nurse</p>	<p>makosd@mlhs.org</p>	<p>Individual</p>

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		<p>As a former Director of Utilization, Case Management and Discharge Planning, I have seen my share of these cases. Age should not be a criteria to having an elective procedure such as a hip replacement. Ability to follow directions if going plan is live alone is necessary because of the initial post-operative limitations. Post-operative Outcomes data collection is a must. Post-operative hematoma formation or post-operative infections not only impact a patient quality of care, but there pos-operative mortality, not to mention the financial drain on Medicare and the family. As of today, [REDACTED], my mother has incurred six additional wheel chair van trips (at \$65 a trip) to either the hospital or doctors office for treatment of the hematoma. In some cases surgeons insert the prosthesis and have their PA close for them while they go on to another patient and the scenario repeats itself. Tracking Supervised health professionals e.g. CRNP and PA's is imperative. I would also recommend checking the infection rate of staples versus sutures. Regards,</p> <p>Doreen Makos Doreen Z. Makos, RN, BS, CPHQ Main Line Health System Medical Peer Review Nurse</p>			
8/10/2010	Complications Readmission	<p>Dear Dr. Grosso, Attached is our response to your invitation for public comment regarding the proposed CMS inpatient quality measures. Please confirm that you have received. Thank you. Mary I. O'Connor, MD President American Association of Hip and Knee Surgeons AA S American Association of Hip and Knee Surgeons</p> <p>E-mail: helpdesk@aahks.org August 11,2010</p> <p>Lein Han, Ph.D. Government Task Leader Centers for Medicare and Medicaid Services Laura Grosso, Ph.D.</p>	Mary I. O'Connor MD President American Association of Hip and Knee Surgeons	OConnor.Mary@m ayo.edu	Orthopedic Society

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		<p>Associate Research Scientist Yale/Yale New Haven Hospital Center for Outcomes Research and Evaluation (CORE) E-mail (hipknee@yale.edu)</p> <p>Dear Dr. Han and Dr. Grosso, The American Association of Hip and Knee Surgeons (AAHKS) appreciates this opportunity to comment on the two measures currently in development by the Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHSC/CORE): (1) Complications following Elective Total Hip or Knee Replacement (the Complications Measure); and (2) 30-Day All-Cause Readmission following Elective Total Hip or Knee Replacement (the Readmission Measure).</p> <p>AAHKS is a national association of orthopedic 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. Our organization has recently decided to commit significant resources to the development of outpatient quality measures for arthroplasty patients. AAHKS also recognizes the need for quality measures regarding inpatient care and acknowledges the significant resources and effort which CMS has devoted to these proposed inpatient measures. Furthermore we appreciate the complexities of data collection and risk adjustment and understand the complexities of data collection. We support the concept of this project and want to partner with eMS to improve inpatient care for our arthroplasty patients.</p> <p>We do have a variety of concerns with the two proposed measures which will be delineated in this document. Of greatest concern is that these measures would have the unintended consequences of decreased patient access to arthroplasty for those at higher risk of complications and readmission.</p> <p>US_ACTIVE-I04274825.1-PSHEIVES 8/10/10 11 :40 AM I. Comments on Complications following Elective Total Hip or Knee Replacement AAHKS has significant concerns regarding the risk adjustment proposed in the Complications Measure. Based on our understanding of the information presented in the Complication Measure, the risk adjustment in the draft would be best suited for determining risk of medical complications. The Complication Measure lists nine inclusion complications, including 1) acute</p>			

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		<p>myocardial infarction; 2) pneumonia; 3) sepsis/septicemia; 4) pulmonary embolism; 5) wound infection; 6) surgical site bleeding; 7) death; 8) periprosthetic joint infection; and 9) mechanical complication. We are also under the impression that using the proposed risk adjustment would account for less than 50% of variance seen in these complications and 30-day readmission rates. Among these complications, half are directly related to the procedure (i. e., surgical site bleeding, wound infection, periprosthetic joint infection, mechanical complications). However, there is no risk adjustment to capture patient variance relating to these surgical complications (e.g., obesity, preoperative deformity, functional status, quality of bone). In particular obesity and preoperative deformity are risk factors well known to orthopedic surgeons. Arthroplasty on patients with significant hip or knee deformity is a more complex surgical procedure (more release of soft tissues; possible need for specialized implants and augments) and such patients are at higher risk of surgical complications. Furthermore, we know of no surgeon who prefers to operate on an obese patient as compared to a thin patient. Surgeons are well aware of the increased risk of wound healing problems, infection, thromboembolic complications and readmission in the obese patient. Without more robust risk adjustment access to arthroplasty for such patients will decrease. AAHKS believes that such patient and limb specific factors need to be included in the risk adjustment for these Complications Measures.</p> <p>Although it is critical that risk adjustment consider patient-specific measures that influence surgical complications, there are currently no risk adjustment administrative codes. related to surgical factors that influence outcome. AAHKS recognizes the difficulty of using non-administrative claims data to develop quality measures. Accordingly, we urge CMS to develop ICD-9 codes that would capture the very meaningful data relating to the complexity of the patient's orthopedic issues and deformity. AAHKS would like to help CMS develop ICD-9 codes to address these risk factors and believe such codes could be developed in a time-efficient manner. Although we agree that the measures currently listed in the Complication Measure could be immediately reported, we strongly recommend holding the more direct surgical complications measurements until the significance of obesity and limb specific factors is understood and taken into account for risk adjustment. In addition to the risk adjustment factors discussed above, studies demonstrate that socioeconomic status is an independent predictor of outcomes. I AAHKS recognizes that</p>			

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		<p>SooHoo NF, Lieberman JR, Ko CY, Zingmond DS. Factors predicting complication rates following total knee replacement. J Bone Joint Surg Am. 2006. 88(3):480-5.;</p> <p>SooHoo NF, Farnig E, Lieberman JR, Chambers L, Zingmond DS. Factors That Predict Short-term Complication Rates After Total Hip Arthroplasty. Clin Orthop Rel Res (2010) 468:2363-2371.</p> <p>-2-</p> <p>CORE group agreed to perform subsequent additional analysis to determine the potential impact of socioeconomic status on the hospital's risk standardized outcome rates' and, if necessary, to consider adjusting the measure by social economic status. We strongly believe that risk adjustment should account for the patient's socioeconomic status and measures should not be released without such inclusion. In particular, we are concerned by contradictory nature of the statement in the Complication Measure that: "Preliminary analyses demonstrated that although [socioeconomic status] is a significant predictor of adverse outcomes at the patient level, it does not affect overall hospital performance in the risk-adjustment complications model... Given our preliminary findings, we do not expect to stratify by such factors." We respectfully ask that if a factor (i.e., socioeconomic status) is "a significant predictor of adverse outcomes," what is the rationale demonstrating that it does not affect the Complication Measure model? If it has an affect on adverse outcom.es, necessarily, it must be accounted for in the model. AAHKS requests a detailed explanation of the CORE group's rationale for this exclusion. We understand that the National Quality Forum (NQF) does not allow for risk adjustment for quality measures based on disparities in care. However the reality is that socioeconomic factors do influence the outcomes of elective THA/TKA. We have significant concerns that without proper risk adjustment of socioeconomic status, those patients with poor socioeconomic risk will have less access to care as the incentive will be for hospitals and surgeons to not perform elective surgery on these patients.</p> <p>Lastly, AAHKS is concerned that variability in coding among providers will confound this data and inaccurately disadvantage certain providers based on factors not related to the quality of the care received by the patient. The</p>			

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		<p>variability in coding among providers has been documented in the medical literature.² While AAHKS recognizes that a certain degree of variability in coding among providers is inevitable, if CMS endeavors to use this data in public reporting and Medicare's pay-for-reporting program, it is critical that this variability be accounted for in some manner. This could range from provider outreach and education to studying the variability more closely for coding these complications and using this information to inform whether differences observed via the Complication Measure accurately reflect the quality of care.</p> <p>II. Comments on 30-Day All-Cause Readmission following Elective Total Hip or Knee Replacement AAHKS is concerned that the Readmission Measure endeavors to take too broad a sweep of data to produce meaningful results. We understand that the measure will look to "all cause" readmissions. However, it is entirely unclear how such a broad metric bears any real nexus to a specific population of patients receiving a particular treatment (i. e., elective total hip 2 Sony T, Skinner Jet al. Regional Variations in Diagnostic Practices; N Engl J Med. 2010 Jul 1;363(1):45-53. Epub 2010 May 12.</p> <p>-3- or knee replacement). Much of the hospital care that could affect readmission rates is generic to any type of elective surgery. By narrowing the population to those patients receiving elective total hip and knee replacement, the Readmission Measure unnecessarily introduces population-specific bias into the data. If YNHHS/CORE is interested in the quality of care for patients receiving elective total hip and knee replacement, it should endeavor to study readmissions that are related to the specific procedure. If YNHHS/CORE is interested in the overall quality of care received by a patient following elective surgery, the patient population should be substantially broadened to include large groups of like procedures to contribute to the measure. While an "all cause" approach presents a relatively easy way to approach the development of a quality measure, it does a disservice to the ultimate goal of the project; that is, to produce a real snapshot of the quality of care received by the patient. There must be some nexus between the readmission and the care received at the hospital for the particular procedure. In addition to introducing unnecessary confounders into the project, AAHKS also questions the utility of the data proposed by the Readmission Measure. Even if the data were reflective of quality of care, the failure to collect specific information that are</p>			

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		<p>related to hip and knee arthroplasty results in hospitals not receiving feedback sufficiently specific to improve practices. Improvement of the quality of care is the goal vis-a.-vis quality measures, and we have concerns that this generic approach does not further that goal. In either case, we request that CMS carefully study and account for the influence of such confounding factors such as obesity, preoperative limb deformity and socioeconomic status on the rate of readmission, and consider developing some exclusionary criteria for injuries clearly unrelated to the prior care (e.g., automobile accidents).</p> <p>III. American Joint Replacement Registry AAHKA strongly recommends that CMS specify that participation in the American Joint Replacement Registry (AJRR) be a quality measure for THA/TKA. The AJRR was recently founded and is an independent board formed to operate the joint registry. Provider participation in this registry is critical to improving outcomes, because the joint registry will allow the tracking of implant performance and identify problems, if any exist, with specific products. The correct time to enter a patient in the joint registry is after the index procedure; therefore, including participation in the joint registry as a hospital quality metric is appropriate. AAHKS has been a supporter of AJRR from its onset, and feels very strongly the joint registry is essential to decreasing the revision burden. A quality measure directed to participation in the AJRR would greatly enhance the data on suboptimal clinical outcomes, and further CMS' goal to enhance the quality of care for Medicare beneficiaries. We urge CMS to consider this; data from countries with joint registries show a decrease in the revision burden. This would have a significant impact on quality of care for Americans and decrease healthcare costs.</p> <p>-4-</p> <p>IV. Closing Thoughts AAHKS expresses its appreciation to YNHHS/CORE and CMS for its full consideration of these comments. AAHKS looks forward to working with YNHHS/CORE and CMS to further refine these measures and develop additional ICD-9 codes to help make the data more robust and the measures more meaningful. Finally, we would be pleased to discuss these comments with you in greater detail. Please feel free contact me at oconnor.mary@mayo.edu or 904-953-0713. Sincerely,</p>			

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		<p>Mary I. O'Connor MD President American Association of Hip and Knee Surgeons cc: Robert A. Hall, MEd, CAE, Executive Director, AAHKS AAHKS Board of Directors John J. Callaghan MD, President, American Academy of Orthopedic Surgeons William Robert Martin, III,MD, Medical Director, American Academy of Orthopaedic Surgeons Chitranjan S. Ranawat, MD, President, Hip Society Arlen Hanssen, MD, President, Knee Society David Lewallen, MD, Chair, American Joint Replacement Registry</p> <p>-5-</p>			
8/10/2010	Complication General	<p>My name is David Bindelglass I am an orthopaedic surgeon and joint replacement specialist. Ironically I am one of the busiest joint replacement surgeons in the Yale system working at Bridgeport Hospital. As a reference I would give Marna Borgstrom. I have also sat on the health policy committee of the American Association of Hip and Knee Surgeons. In Febuary I published a paper in Ct. Medicine about a patient driven tool to measure outcomes in Total Knee Arthroplasty.</p> <p>The major comment I would make is that every discussion about outcomes measurement in arthroplasty surgery among clinicians always comes down to risk stratification. There is little argument about your outcome measure as stated. Every clinician believes that if their results are inferior, it is because their patients are somehow sicker. The medicare data is so dependent on coding at the hospital level that the results are always suspect. Historically, it is perceived that our ability to risk stratify has made very little progress in decades and it is important to confront this apparent fact. That is the major observation that needs to be made.</p> <p>Personally I believe that effective risk stratification may not be possible, and so for at least high volume centers or providers it may be better to actually give up trying to do it and just accept that large enough sample sizes may obviate the need to risk stratify all together. That is a minority opinion and somewhat on the fringe but perhaps worthy of consideration.</p>	David Bindelglass Bridgeport Hospital	dbindelglass@osgp c.com	Individual

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		<p>The second point I would make refers to viewing pulmonary embolism as a complication of arthroplasty. The AAOS has debated this point strenuously, but it is important to realize that which pulmonary emboli are significant is still controversial. The diagnosis especially by CT angiogram is evolving as is its treatment. This makes it difficult to look at this complication as an outcome measure at this point in time. Thank you for your consideration, David Bindelglass, MD</p>			
8/10/2010	Readmission Complications	<p>TO: The Yale-New Haven Health Services Corporation/Center for Outcomes Research and Evaluation FROM: Federation of American Hospitals DATE: August 10, 2010 SUBJECT: Development of Two Measures related to Elective Total Hip and Total Knee Replacement</p> <p>The Federation of American Hospitals (FAH) is the national representative of investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching, short-stay rehabilitation, and long-term care hospitals in urban and rural America, and provide a wide range of acute, post-acute and ambulatory services.</p> <p>The FAH is pleased to have the opportunity to comment on the development of two Hip and Knee measures being developed for CMS by the Yale-New Haven Health Services Corporation/Center for Outcomes Research and Evaluation. The measures, Complications following Elective Total Hip or Knee Replacement and 30-Day All-Cause Readmission following Elective Total Hip or Knee Replacement, could play a critical role in improving patient care. We were pleased to be a part of this public comment process and also appreciate the workgroup taking these comments into consideration during the development phase and prior to a final measure being submitted to the National Quality Forum for consideration for endorsement. However, we did find the limited comment period to be challenging and would encourage that future comment periods be longer to afford time for detailed review.</p> <p>In general, the FAH member companies believe the topics addressed in these measures are important to measure and that measurement will help hospitals to improve patient care. We have several technical questions and comments for your consideration.</p>	Jayne Hart Chambers Senior Vice President, Strategic Policy and Corporate Secretary The Federation of American Hospitals (FAH)	JChambers@FAH. org	Hospital Association

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		<p>In reviewing the All-Cause Readmission following Elective Total Hip or Knee Replacement, the data seem to suggest there are specific complications that can be related to readmissions at varying time frames of 7-days, 30-days and 90-days. If this is the case, then why are there not three distinct measures? Such specificity would be more actionable for clinicians than the broader 30-day measure.</p> <p>The measures provide for specific exclusions, with which we agree. However, as we have commented previously on other readmission measures, the FAH believes that additional exclusions for transplants, End Stage Renal Disease, burn, trauma, psychosis and substance abuse should also be added to the measures. In addition, the use of claims data as the data source has limitations. The ability to identify the exclusions is limited. Therefore, we request that CMS develop additional codes that can be used with claims measures to capture the exclusions.</p> <p>The FAH supports the Complications measure, and finds this measure to be the most actionable of the measures under consideration. We would urge CMS and Yale-New Haven Health Services Corporation/Center for Outcomes Research and Evaluation to focus its attention on this one in an effort to drive improvement in patient care.</p> <p>We look forward to seeing the final report and the specifications for the measures before they are submitted to the Centers for Medicare and Medicaid Services and the National Quality Forum.</p> <p>If you have any questions about our comments, please contact Jayne Hart Chambers, Senior Vice President Strategic Policy and Corporate Secretary, at jchambers@fah.org</p>			
8/10/2010	Complications Readmission	<p>August 11, 2010 Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE) Submitted electronically as directed to: hipknee@yale.edu RE: Elective Total Hip or Knee Replacement Quality Outcomes Measures</p> <p>Dear Administrator, Edwards Lifesciences (“Edwards”) partners with clinicians that primarily</p>	Dirksen Lehman Vice President, Government Affairs and Reimbursement Edwards Lifesciences	Betsy_Gross@edwards.com	Private Company

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		<p>treat patients in the hospital inpatient setting to develop innovative technologies in a number of areas including critical care monitoring. Edwards' focus is on improving patient quality of care. Therefore, we appreciate the opportunity to submit the following comments in response to the two proposed quality outcomes measures for patients undergoing elective total hip and total knee replacement.</p> <p>Stakeholder Feedback via the Working Group and the Technical Expert Panel</p> <p>Based on the background information provided, a number of stakeholders were consulted in the initial proposed measure development process. This included the formation of a working group and a Technical Expert Panel (TEP) that convened regularly to provide input and feedback from a "diversity of perspectives and backgrounds". Representatives of these two groups consisted of clinicians, professional societies, payers, and consumers. It is important, however, to note that representatives from the medical technology manufacturing industry were omitted from this process. Organizations that design and develop prosthetic joint technologies, patient hemodynamic monitoring systems, and other technologies that are essential in performing these procedures have a tremendous amount of knowledge through years of clinical studies, physician and hospital collaboration, and patient safety monitoring. We strongly encourage CMS to formally integrate and consider the value of the contributions of the medical technology manufacturing industry as the measure development process continues.</p> <p>Complications following Elective Total Hip or Knee Replacement</p> <p>Edwards supports the proposed measuring of complications following elective total hip or knee replacement. As indicated by the preliminary analyses using 2008 Medicare inpatient claims data, patients undergoing elective total hip and knee replacement procedures have a relatively high complication rate of 6.7%.</p> <p>Several complications included in the measure are associated with significant incremental costs to the hospital and the healthcare system. Edwards especially supports the inclusion of sepsis in this list. In a report of patient safety indicators issued by the Agency for Healthcare Research and Quality (AHRQ), postoperative sepsis was associated with 21.9% excess mortality, 10.9 excess length of stay days and \$57,727 incremental costs when analyzed</p>			

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		<p>in 7.45 million hospital discharge abstracts from 994 acute-care hospitals across 28 states in 2000.</p> <p>Recent estimates suggest that over 750,000 cases of severe sepsis and 2.26 cases per 100 hospital discharges, are diagnosed in the U.S. every year, of which half may be hospital acquired. This represents a dramatic increase from the late 1970s, when it was estimated that there were 164,000 cases annually. In a 2007 study of 8,403,766 patients during the years 1993-2003, it was reported that the percentage of severe sepsis cases among all sepsis cases grew continuously from 25.6 percent in 1993 to 43.8 percent in 2003, an increase of 18.2%.</p> <p>Studies indicate that the incidence of sepsis increases with age, rising most dramatically in the elderly, in part due to impaired immunologic response to infection, co-morbidities, and/or increased exposure to potentially resistant bacterial pathogens in nursing homes. The incidence of post-operative sepsis in patients aged 45-64 is estimated at 9.08 per 1,000 hospital discharges and 11.16 per 1,000 discharges for ages 65 and older. In a study of 1,276,451 surgery discharges in the state of New Jersey, it was reported that the incidence of severe sepsis following surgery after elective cases increased from 32.9 percent to 64.6 percent within a sixteen-year time frame (1990-2006). Surgical patients account for 30 percent of patients with sepsis, and were significantly greater for non-elective surgery patients than for elective.</p> <p>Edwards believes that inclusion of sepsis in this measure will greatly increase awareness of the incidence of this complication and will propel clinicians to adopt diagnostic and treatment protocols which will decrease its incidence and the economic burden sepsis represents in an increasingly overburdened healthcare economy.</p> <p>Perioperative Fluid Optimization for Surgical Patients</p> <p>Edwards applauds CMS and the Yale New Haven Health Services Corporation for identifying the need to address the variations in practice patterns that lead to high complication rates in this patient population. This will ultimately lead to the consistent and wide-spread adoption of best practices, some of which are proven and endorsed in other regions around the world, including the practice of perioperative fluid optimization.</p>			

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		<p>Inadequate fluid management may increase cardiac complications from either poor perfusion as a result of hypovolemia or heart failure from volume overload. Known complications from inadequate fluid status include pulmonary edema, congestive heart failure, myocardial infarction, acute renal failure and hypotensive crises. These complications can arise either intra-operatively or post-operatively and can greatly impact morbidity and overall costs.</p> <p>Orthopedic surgery patients are frequently hypovolemic on admission for a variety of reasons including inadequate fluid intake related to immobility, chronic pain associated with the underlying surgical condition, a reluctance to drink because of an anxiety over incontinence, and/or the use of concomitant therapies (e.g., diuretics). Hypovolemia can lead to tissue hypoperfusion during the surgical procedure with potential organ dysfunction in the perioperative period, manifesting into postoperative morbidity, increased duration of hospital stay and resource utilization, and mortality.</p> <p>It has also been shown that “traditional” vital signs alone, such as heart rate and arterial pressure, are insufficient indicators of hypovolemia despite actual reduced blood flow to certain organs. As a result, these forms of monitoring are insensitive to identifying hypovolemia at an early and critical stage. Intraoperative hypoperfusion has previously been identified in 63% of major surgery patients and was associated with increased morbidity and duration of hospital stay.</p> <p>Impressive improvements in patient outcome have been demonstrated where fluid therapy has been targeted at optimizing oxygen delivery to tissues and avoiding hypovolemia. , , This understanding of the importance of fluid optimization led to the development of the 2008 British Consensus Guidelines on Intravenous Fluid Therapy for Adult Surgical Patients by the Association of Surgeons of Great Britain and Ireland, the Society of Academic and Research Surgery, the Renal Association, the Intensive Care Society, the British Association for Parenteral and Enteral Nutrition (BAPEN), and the Association for Clinical Biochemistry. As stated by the guidelines, “In patients undergoing some forms of orthopaedic and abdominal surgery, intra-operative treatment with intravenous fluid to achieve an optimal value of stroke volume should be used where possible as this may reduce postoperative complication rates and duration of hospital stay.”</p>			

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		<p>Edwards appreciates the opportunity to comment on the proposed quality measures, and applauds CMS' continued responsiveness to the need for refining existing programs with the goal of providing high quality and efficient care to its beneficiaries.</p> <p>Sincerely,</p> <p>Dirksen Lehman Vice President, Government Affairs and Reimbursement</p> <p>Zhan C, et al., "Excess Length of Stay, Charges & Mortality Attributable to Medical Injuries During Hospitalization," JAMA, 2003, 290: 1868-1874.</p> <p>Eber MR, Laxminarayam R, et al. Clinical and economic outcomes attributable to health care-associated sepsis and pneumonia. Arch Intern Med 2010; 170(4):347-355.</p> <p>Dombrovskiy VY, Martin AA, Sunderram J, Paz HL. Rapid increase in hospitalization and mortality rates for severe sepsis in the United States: A trend analysis from 1193 to 2003. Crit Care Medicine 2007; 35:1244.</p> <p>Ducel G, Fabry J, Nicoll CL, eds. Prevention of hospital-acquired infections: A practical guide. World Health Organization 2002.</p> <p>McDonald K, Romano P, Davies S, et al. Postoperative sepsis: rate per 1000 eligible admissions. National Quality Measures Clearinghouse 2006.</p> <p>Vogel TR, Dombrovskiy VY, Lowry SF. Trends in postoperative sepsis: are we improving outcomes? Surg Infect 2009; 10(1),71.</p> <p>Barash, et al, Clinical Anesthesia 2009, p. 285.</p> <p>Basilico F, et al., "Risk factors for cardiovascular complications following total joint replacement surgery." Arthritis and Rheumatism, Volume 58, Issue 7. June 24, 2008.</p> <p>Venn R, et al., Randomized controlled trial to investigate influence of the fluid challenge on duration of hospital stay and perioperative morbidity in patients with hip fractures. British J of Anaesthesia 2002, 65-71</p> <p>Mythen MG, Webb AR. Intra-operative gut mucosal hypoperfusion is associated with increased post-operative complications and cost. Intensive Care Med 1994, 99-104</p> <p>Shoemaker WC, et al., Prospective trial of supranormal values of survivors as therapeutic goals in high risk surgical patients. Chest 1988, 1176-85</p> <p>Wilson J, et al., Reducing the risk of major elective surgery: randomized controlled trial of preoperative optimization of oxygen delivery. Br Med J</p>			

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		<p>1999, 1099–103 Boyd O, et al., A randomized clinical trial of the effect of deliberate perioperative increase of oxygen delivery on mortality in high risk surgical patients. J Am Med Assoc 1993, 2699–707 NHS Evidence. British consensus guidelines on intravenous fluid therapy for adult surgical patients. 2008. www.ics.ac.uk/downloads/2008112340_GIFTASUP%20FINAL_31-10-08.pdf.</p>			
8/11/2010	Complications Readmission	<p>Please consider risk-adjusting for SES as it clearly impacts outcomes and complications as you point out from your preliminary data. This will negatively impact those hospitals that care for many low SES patients and may result in an access barrier for those patients. Additionally, I am not sure of the basis for concluding that measuring and reporting these measures will not provide a barrier to access. Hospitals and physicians may well refer higher risk patients to other centers or simply refuse to perform the procedures in high risk patients is an effort to protect the local hospitals quality outcomes.</p> <p>Charles Davis</p> <p>Charles M. Davis Assoc. Professor of Orthopaedics and Rehabilitation Visit us at www.pennstateorthopaedics.com</p>	Charles M. Davis Assoc. Professor of Orthopaedics and Rehabilitation	cdavis2@hmc.psu.edu	Individual
8/11/2010	Complications Readmission	<p>Mercy Medical Center would like to submit the following recommendations for the proposed Hip & Knee quality measures. Please let me know if you have any questions or need additional information.</p> <p>Measure 1: Risk-standardized complications rate following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA): The exclusion population for this measure did not include patients who developed infection; however it was noted the data will be risk-adjusted for infection Recommend: Provide details on how data will be risk-adjusted for infection</p> <p>Measure 2: Hospital 30-day risk-standardized all-cause readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) : The numerator population for the 30-day risk standardized readmission</p>	Jamie Chew Q.I. Manager Quality Improvement Department Mercy Medical Center	jchew@mdmercy.com	Medical Clinic/Center

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		<p>measure includes patients readmitted to any acute care hospital for any reason within 30 days of the discharge date of the index hospitalization. Recommend: Numerator population should include patients admitted to any acute care hospital for complications related to the procedures of interest (THA and TKA) and included in the criteria they've defined as complications for their risk-standardized complication measure: AMI, PN, Sepsis/Septicemia, Pulmonary Embolism, Wound Infection, Surgical Site Bleeding, Periprosthetic Joint Infection; Mechanical Complication</p> <p>Thank you, Jamie Chew</p> <p>Jamie Chew Q.I. Manager Quality Improvement Department Mercy Medical Center</p>			
8/11/2010	Complications Readmission	<p>Hi, I was wondering if you are excluding patients in the numerator that have coded complications that are present-on-admission (POA). Thank you! Michael Michael Ellison Inova Health System Performance Improvement and Outcomes Division Research Analyst</p>	<p>Michael Ellison Inova Health System Performance Improvement and Outcomes Division Research Analyst</p>	<p>Michael.Ellison@inova.org</p>	Individual
8/11/2010	Complications Readmission	<p>Hello,</p> <p>My company has worked with over 100 U.S. hospitals to implement Destination Joint Replacement Centers. As part of that implementation, we build each hospital a joint replacement specific performance management dashboard to internally track, trend, and benchmark their outcomes. The dashboard includes clinical metrics like complications and re-admissions (30 day). In discussing these two metrics with hospitals and affiliated surgeons, two questions typically come up. They are:</p> <ul style="list-style-type: none"> · How do you adjust complication and re-admission rates for lower volume facilities? · How do you account for complications or re-admits that were unrelated to the joint replacement surgery? 	<p>David Steele, M.D., M.B.A. Vice President, Performance Management Marshall Steele & Associates</p>	<p>dstele@marshallsteele.com</p>	Individual

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		<p>Although you mention risk adjusting based on volume, it wasn't clear how you intended to do so. Similarly, you discuss risk adjusting for patient demographics/co-morbidities but it wasn't clear how you plan to adjust for new onset of an unrelated condition. When we review these metrics with our hospital clients, we only look at a subset of complications that are most likely to be related to the surgery (scrubbing out all conditions present on admission). We also ask a quality nurse in the hospital to review the charts of the 30 day re-admits (there typically are only a few each quarter) to determine if any were unrelated, which we would then remove on an exception basis. If your methodology will more accurately adjust for these situations, I would be very interested to learn more. Thanks.</p> <p>David</p> <p>David Steele, M.D., M.B.A. Vice President, Performance Management Marshall Steele & Associates dsteele@marshallsteele.com</p>			
8/11/2010	Complications Readmission	<p>Lein Han, Ph.D. Centers for Medicare and Medicaid Services</p> <p>Laura Grosso, Ph.D. Yale New Haven Hospital Center for Outcomes Research and Evaluation (CORE)</p> <p>Re: Call for Comment for Elective Total Hip or Knee Replacement Quality Measures</p> <p>Dear Researchers:</p> <p>The Alliance for Orthopedic Solutions (the Alliance) appreciates the opportunity to comment on the two measures currently in development by the Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE): 1) Complications following Elective Total Hip or Knee Replacement (the Complications Measure); and 2) 30-Day All-Cause Readmission following Elective Total Hip or Knee Replacement (the Readmissions Measure).</p>	Eric Rugo Executive Director, Alliance	PSheives@ReedSmith.com	Orthopedic Device Manufacturing Alliance

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		<p>The Alliance 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 appreciates and supports the development of meaningful quality measures relating to elective total hip and total knee replacement (TH/TK replacement), and looks forward to working with YNHHS/CORE to optimize the collection of useful data to inform the treatment of patients.</p> <p>We appreciate the efforts of the YNHHS/CORE and CMS to develop these proposed hospital inpatient quality measures for total hips and total knees. That said, the Alliance has substantial concerns about the methodology used for this project, and ultimately, with the utility of the data following collection. For this reason, we encourage YNHHS/CORE to consider our recommendations and reevaluate the methodology for this project, and consider whether the current proposal will provide accurate representations of the quality of patient care for patients undergoing TH/TK replacement and whether this measure will contribute to improving the quality of care. As proposed, we share the concerns of the American Association of Hip and Knee Surgeons (AAHKS) that these measures could have unintended consequences and negatively impact specific patients' access to total joint procedures.</p> <p>I. CONCERNS WITH PROPOSED QUALITY MEASURES</p> <p>The Alliance has considerable concerns with several methodological issues proposed in the design of each quality measure. We are concerned because these issues could create roadblocks to the development of useful evaluation measures for complication and readmission rates for TH/TK replacement.</p> <p>A. Design of the Quality Measure for Total Hip/Total Knee Replacement</p> <p>Based on similarities in methodology, it is apparent that the hip and knee quality measure proposals are modeled from NQF Quality Measure #0330 for Hospital Specific 30-day Risk Standardized Readmission Rate following Percutaneous Coronary Intervention (PCI). Of note, NQF #0330 established a methodology for translating prospectively collected data from Medicare administrative claims files using data prospectively supplied to the National Cardiovascular Data Registry, CathPCI. Specifically, data from the PCI registry was systematically analyzed to evaluate if information from Medicare</p>			

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		<p>administrative claims data were reliable enough to isolate care process issues, which correlate to readmission within 30 days of discharge of an indexed PCI procedure. With regard to NQF#0330, special care was taken to link Medicare Part A claims and enrollment data to registry data. This linking had the effect of indentifying expected re-admission from PCI indexed procedures to administrative claims data. Importantly, the CathPCI registry collects level 4 data that is not available in claims information. The key here is that the risk stratification was then measured from registry data and not claims data.</p> <p>The Alliance supports the concept of using a very large and rich data registry to stratify or risk adjust. The Alliance also believes that the methodology used for NQF #0330 logically can be used to model other QF quality measures, provided that the process and outcome measures are similarly situated. However, because the quality measures for elective total hip and knee replacement are entirely dependent on physician documentation and subsequent coding translation for accuracy the Alliance believes that applying this methodology to elective total hip and knee replacement is problematic unless –</p> <ul style="list-style-type: none"> Ø Hospitals also report data to a joint registry and Ø Additional ICD-9 codes are adopted to describe certain surgical risk factors. <p>Accordingly, we believe that the use of registry data, just like the PCI data, is critical to validating the hip/knee measures as discussed below and hip and knee quality measures should also be registry-based.</p> <p>For this reason, we support the recommendations of the American Association of Hip and Knee Surgeons (AAHKS) and believe that CMS should require hospital participation in an orthopedic joint registry which then can be relied upon to stratify and make risk adjustments on a national level. Until such time as the registry can be used, we recommend that CMS delay moving forward with the proposed methodology. Alternately, it may be feasible to move forward and implement only the “medical” complications discussed in the Complication Measure.</p> <p>B. The Proposed Quality Measures Should Include Additional Diagnoses/Procedures to Capture all Relevant Information</p>			

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		<p>Looking ahead, if a registry is adopted and used to validate a method for stratifying and conducting risk adjustments with administrative claims data, the Alliance believes that it will also be necessary to use and develop much more information from claims data. As proposed, using only the primary and secondary diagnosis on subsequent, non-indexed admissions may be completely inadequate to capture all the necessary and relevant data.</p> <p>According to health economic researchers, all information on the claim related to the patients diagnosis and inpatient procedures should be considered in order to “find” complications related to indexed procedures. Among other things, we support the recommendations to develop and refine codes that can be used to report obesity, preoperative deformities, functional status and bone quality. For this reason, the Alliance strongly recommends that the diagnosis and procedure codes be expanded to include at least ten different conditions/procedures to capture such important measures as obesity and osseous defects.</p> <p>C. SES and BMI - Additional Factors to Consider Relating to Methodology</p> <p>The Alliance appreciates the difficulty in capturing, documenting and analyzing data to determine patient variance and readmissions for the assessment of quality of care. However, the Alliance is concerned that many of the risks directly related to readmission and complications may not be captured during the index admission in claims data under these proposals. The Alliance believes that certain conditions specific to patients are notably absent from collection. These factors include body mass index (BMI) and socioeconomic status (SES), presumably due to the difficulty of collection in an electronic format from administrative claims data. While we understand that NQF has not traditionally included SES data in quality measures, most researchers agree that SES is highly correlated to readmission for a number of reasons, including English language proficiency. It is well documented that when SES affects literacy and patient understanding, SES has a very distinct and negative impact on the process of care, including compliance with medical instructions and rehabilitation. Therefore, although SES data may be difficult to collect, it should not be omitted from the measures due to its significant impact and the health care communities need to better understand and deal with its impact. The Alliance is also concerned that if SES data is not taken into account, there could be unintended consequences. Specifically,</p>			

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		<p>physicians and hospitals may decline to care for these patients so as to avoid negative ratings and potentially Medicare payment cuts.</p> <p>D. Additional Data and Strategic Concerns</p> <p>On a more detailed level, our concerns with some very specific aspects of the proposals are detailed below.</p> <ul style="list-style-type: none"> • Clinical Documentation. Assuming a high degree of accuracy in clinical documentation, the proposed model had a Receiver Operating Curve (ROC) value of only 0.64. ROC scores are valued from 1.00 (best) to 0.50 (fair). In fact, the fair range for a ROC score is from 0.50 to 0.75. The ROC curve plots the false positive rate on the X axis and the false negative rate on the Y axis. Interpretively, this shows the trade-off between the two rates. If the area under the ROC curve is close to 1, you have a very good test. If the area is close to 0.5, you a questionable test. Thus, the Alliance hopes that a score of 0.64 places the hip/knee measure in the range of a meaningful rather than a “questionable/fair” test and strongly supports measures to improve this value. • The Alliance recommends that if the ICD-9 codes need to be refined, CMS should work with AAHKS and the Alliance and other interested parties to establish the appropriate codes as quickly as possible. • Effective Date. We believe that the effective date should be discharge, rather than admission in the indexed procedure. • Denominator. Please note that the rationale for Denominator exclusion #4 is not valid. Total hip resurfacing procedures are never performed after a previous total hip arthroplasty. • Data Sources. Data sources should include Pharmacy Data, as well as electronic administrative claims data in order to accurately and better account for co-morbidities. <p>II. AMERICAN JOINT REPLACEMENT REGISTRY</p> <p>As mentioned above, the Alliance also strongly recommends that CMS support hospital participation in the American Joint Replacement Registry (AJRR). We believe that such participation is vital to advance the development of quality measures related to patient care in those undergoing</p>			

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		<p>THA/TKA.</p> <p>The Alliance believes that hospital participation in the AJRR registry as an alternative for meeting quality reporting requirements would greatly facilitate the goal of improving patient outcomes. The joint registry will allow the tracking of implant performance from the time of implant (index procedure) until the patient dies in addition to tracking performance of providers. Finally, the robust nature of this registry data will enable complete assessment and analysis and validation of administrative claims data and stratification of risk (see discussion above re NQF#0330).</p> <p>III. INDUSTRY EXPERTISE AND ASSIST</p> <p>We were pleased that many participants on the TEP had an official connection to orthopedic specialty societies and thus very familiar with the total joint procedures. Looking ahead to refinement of these Quality Measures, the Alliance stands willing to be more actively engaged in the process. Industry, specifically the Alliance, appreciates this collaboration, and is always eager to work with CMS on issues involving quality and orthopaedic procedures. We believe that industry experts can provide valuable information on implants and procedures and look forward to working with the TEP and CMS going forward.</p> <p>IV. CONCLUSION</p> <p>The Alliance believes that these proposals present concerns related to data, methodology and process development. Significant changes must be considered to ensure the production of accurate measurement results are used to inform the public about hospital specific outcome measures generated from administrative claims data alone.</p> <p>The Alliance is pleased to work further with YNHHS/CORE to address these methodological and data issues. Again, and in closing, we applaud your efforts and believe with further refinements these measures will contribute to better patient outcomes.</p> <p>Sincerely, Eric Rugo Executive Director, Alliance</p>			

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		<p>cc: Bob Hall, AAHKS (via email) Mary O'Connor, President AAHKS (via email) Alliance members (via email)</p>			
8/11/2010	Complications	<p>I am commenting as an individual regarding the proposed THA/TKA outcome measures to be included as part of Medicare Part A recipients and posted to hospital compare.</p> <p>Upon review of the outcome measures and in regards to the complication measures, PE is listed as a complication outcome. I was unable to determine if DVT/VTE was also an inclusionary or additional specific outcome measure? Given the discussions surrounding recommendations/guidelines for clinical practice, it would appear to be important to identify if the provider had a process measure in place to address anticoagulant medication prophylaxis or other VTE prophylactic strategies as part of a treatment algorithm? This in turn could potential provide best practice or evidenced based treatment recommendations if specific DVT/VTE/PE process measures were stratified and outcomes identified.</p> <p>Secondly, there appears to be no patient specific measures. Pain mitigation strategies and multimodal pain measures have been highly discussed in the literature and have been shown to be an essential component of outcome success. It would be important to identify providers that monitor a patient's pain self-report in regards to differing treatment and/or mitigating strategies and how a patient's pain rating is represented over time. In addition, cases represented from patient's as intractable pain may lead to rehospitalization.</p> <p>Thanks for the opportunity to comment on this initiative.</p> <p>Matt Janes, PT, DPT, MHS, OCS, CSCS National Orthopedic Specialist http://www.gentiva.com</p>	<p>Matt Janes, PT, DPT, MHS, OCS, CSCS ; National Orthopedic Specialist</p>	<p>Matt.Janes@gentiva.com</p>	Individual
8/11/2010	Complications Readmission	<p>Unable to open file on hip/knee criteria for comment from the CMS website:</p> <p>Kandi Moore, RN, CNOR Chief Executive Officer Specialists Hospital Shreveport</p>	<p>Kandi Moore, RN, CNOR Chief Executive Officer Specialists Hospital Shreveport</p>	<p>kmoore@msil.md</p>	Individual
8/11/2010	Complications	<p>August 11, 2010</p>	<p>Vi Naylor</p>	<p>vnaylor@gha.org</p>	Hospital

Date Posted	Measure Set	Text of Comments	Name, Credentials, and Organization of Commenter	Email address	Type of organization
	Readmissions	<p>Marilyn Tavenner Acting Administrator Centers for Medicare & Medicaid Services Hubert H. Humphrey Building 200 Independence Avenue, S.W., Room 445-G Washington, DC 20201</p> <p>Yale New Haven Health Services Corporation/ Center for Outcomes Research and Evaluation hipknee@yale.edu.</p> <p>Reference to 30-day Risk Standardized Readmission Rate following the Elective Total Hip and Total Knee Arthroplasty; and Risk-Standardized Complication Rate following Elective Total Hip and Knee Arthroplasty.</p> <p>Dear Colleagues:</p> <p>On behalf of the more than 170 member hospitals, the Georgia Hospital Association (GHA) welcomes the opportunity to share our comments on these draft measures.</p> <p>We support the comments and suggestions made on our behalf by the American Hospital Association (AHA) and as they indicated, GHA agrees that we did not have sufficient time to obtain detailed comments from our member hospitals for this initial comment period. We hope that future drafts comment periods will allow us more time to solicit this information from our association members so we can provide you with more frontline feedback.</p> <p>Measure Development and Feedback Process: As noted above, we support AHA's recommendations for the steps in the review process to:</p> <ol style="list-style-type: none"> 1. Allow no less than 30-days for the public to respond to future draft measures. 2. Publish the notification for public comment and announcement for serving on a Technical Expert Panel (TEP) in the federal register. 3. Provide a detailed webinar presented by the measure developer on the basics of these measures that allows no less than 30 minutes for questions and answers 	Executive Vice President Georgia Hospital Association (GHA)		Association

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		<p>4. Encourage you to work with AHA per their request to meet face-to-face with the measure developer to address detailed concerns that we do have concerning these measures.</p> <p>Use of Claims Data to Populate Quality Measures:</p> <p>1. GHA supports AHA’s recommendation for CMS to introduce a new data element into the claims processing system to allow hospitals to indicate whether a readmission is planned or unplanned.</p> <p>2. Definitions for planned or unplanned readmissions with need to be determined for consistency with the measure abstraction.</p> <p>3. GHA supports AHA’s recommendation for further develop the POA indicator into a complication measure(s).</p> <p>4. In addition to AHA’s recommendation that exclusions be made to the readmission measure(s) to include patients whose original discharge was associated a primary or secondary diagnosis or procedure code for transplants, ESRD, burn, trauma, psychosis and substance abuse. Please add to this category exclusion for patients with Hyperparathyroidism to the exclusions list for both readmission and complication measures.</p> <p>Ability to Act:</p> <p>1. GHA strongly supports looking at complication criteria versus readmission criteria. With the proposed definition for readmission; a readmission to any acute care hospital, for any reason occurring within 30 days of the discharge date of the index hospitalization, does not account for the many variables that affect the patient’s care in the outpatient environment which may be the underlying cause for the readmission.</p> <p>Closing:</p> <p>The Georgia Hospital Association and its member facilities are deeply committed to the provision of safe, effective, patient-centered, timely, efficient and equitable care to all patients. It is in this spirit that we appreciate this opportunity to offer our comments and look forward to commenting on future drafts and end products.</p> <p>If you have any questions, please contact me at 770-249-4500 or</p>			

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		<p>vnaylor@gha.org.</p> <p>Sincerely, Vi Naylor Executive Vice President</p>			
8/11/2010	Complications Readmissions	<p>Date: August 11, 2010 To: Centers for Medicare & Medicaid Services/Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation From: Jennifer Faerberg Association of American Medical Colleges</p> <p>Subject: AAMC Comments on Draft Hip and Knee Replacement Measures The Association of American Medical Colleges (AAMC), which represents all 130 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 68 Department of Veterans Affairs medical centers; and nearly 90 academic and scientific societies, appreciates the opportunity to provide comments on the draft measures, Risk-Standardized Complication Rates and 30-day Readmission Rate following Total Hip and Total Knee Arthroplasty.</p> <p>We strongly believe that any measure developed for use in a quality-reporting program should benefit from extensive public vetting and input. We are pleased to be given this opportunity for comment prior to the measures being submitted to the National Quality Forum (NQF). However, due to the short period-of-time to review the measures, we have done a cursory review and this memo contains our initial feedback. We would be happy to provide more specific comments at a later date or during the upcoming NQF process.</p> <p>Risk Adjustment Model The risk adjustment model used for these measures is the same model utilized in the current AMI, HF and Pneumonia mortality and readmission measures. As we have stated in prior comment letters, we still have concerns regarding the inability of this model to account for patient socio-economic status (SES) factors. These factors play a key role in the quality of patient outcomes and need to be addressed in these types of outcome measures. We are pleased to see that as a result of the Technical Expert Panel (TEP) review and concern regarding the lack of inclusion of SES factors, the measure developer will</p>	Jennifer Faerberg Association of American Medical Colleges	jfaerberg@aamc.org	Medical Association

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		<p>conduct further analysis to determine the potential impact of SES factors on the outcome rates and consider the possibility of stratifying results. We look forward to seeing the results of this additional analysis.</p> <p>We also remain concerned with the use of a model that is based on administrative claims and not clinical data. Administrative claims are unable to accurately capture a patient's severity of illness, which plays a significant role in determining patient complications and readmissions.</p> <p>30-day Readmission Rate Hospitals and their local health care community are only starting to understand how and why readmissions occur and implement appropriate interventions. The focus of any readmission measure should only be those readmissions that are unplanned but related to the index admission. All unrelated readmissions should be excluded.</p> <p>In addition, we believe that any readmission associated with a primary or secondary diagnosis of ESRD, transplant, trauma, psychosis or substance abuse should be excluded. While the occurrence of these readmissions may be low, we believe they should be removed from the denominator population.</p> <p>Risk Standardized Complication Rate In order to strengthen the clinical risk adjustment model we believe the list of condition categories utilized should be expanded to include obesity and sleep apnea. These medical conditions contribute to a patient's severity of illness and research has shown they have a major impact on patient outcomes especially related to hip and knee replacement surgeries.</p> <p>Medical, surgical and device-related complications are included in this measure with each type of complication having its own follow-up period. While we understand the reason for the different follow-up periods it becomes unclear as to how the three types of complications with multiple time periods would be handled within one measure. This raises the question if the measure should be stratified by type of complication.</p> <p>Thank you again for the opportunity to comment on these important draft measures and we look forward to future opportunities to comment. However, we would ask that in the future, more notice be given for providing comments and the window for comments be extended. It is difficult to provide a thorough review and gather expert opinion within a two-week timeframe.</p>			
8/11/2010	Complications	page 3 numerator details # 4: Might be better illustrated if expanded to	Vincent Barba, MD,	Barbavj@umdnj.ed	Individual

Date Posted	Measure Set	Text of Comments	Name, Credentials, and Organization of Commenter	Email address	Type of organization
		<p>"venous thromboembolism.</p> <p>page 4 denominator exclusions: should include patients with neoplastic disease [primary or metastatic lesions] that necessitated the THA/TKA. These patients often have extensive surgical resection and THA/TKA may be part of the reconstruction procedure. These patients may be at higher risk of complications and have had much more extensive surgery than a garden variety THA/TKA patient.</p> <p>Has the AOS and ACS been involved in this measure discussion?</p> <p>Thank you, Dr Barba</p> <p>Vincent Barba, MD, FACP, FHM Medical Director for Quality Improvement University Hospital & New Jersey Medical School</p> <p>Assistant Professor of Medicine Assistant Professor of Preventive Medicine & Community Health New Jersey Medical School</p> <p>Attending Physician, Medicine University Hospital barbavj@umdnj.edu</p>	<p>FACP, FHM Medical Director for Quality Improvement University Hospital & New Jersey Medical School</p> <p>Assistant Professor of Medicine Assistant Professor of Preventive Medicine & Community Health New Jersey Medical School</p> <p>Attending Physician, Medicine University Hospital</p>	u	
8/11/2010	Complications Readmission	<p>August 11, 2010 Centers for Medicare and Medicaid Services Yale New Haven Health Services Corporation /Center for Outcomes Research and Evaluation hipknee@yale.edu Re: APTA Comments regarding hip and knee replacement outcome measures</p> <p>Dear Sir or Madam: On behalf of our 74,000 member physical therapists, physical therapist assistants, and students of physical therapy, the American Physical Therapy Association (APTA) is pleased to submit comments on the two quality measures for patients undergoing elective total hip and total knee replacement. We support CMS' goal to improve the quality of health care</p>	R. Scott Ward, PT, PhD President American Physical Therapy Association	gaylelee@apta.org	Physical Therapy Association

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		<p>under the Medicare program. Physical therapists are committed to providing high-quality timely care, and to the promotion of evidence-based practice and patient-centered practice. APTA's goal is to foster advancements in physical therapy practice, research, and education. The mission of APTA is to further the profession's role in the prevention, diagnosis, and treatment of movement dysfunctions and the enhancement of the physical health and functional abilities of members of the public. We commend CMS and Yale New Haven Health Services on their work toward development of outcome measures for hip and knee replacements.</p> <p>Specifically, these measures relate to complications following elective total hip or knee replacement and 30-day all-cause readmission following elective total hip or knee replacement. When considering the likelihood of readmission to the hospital, it is essential to consider the impact of the care that the patient receives both during the hospital stay and post-hospital discharge. Nearly all patients who are discharged from a hospital after a total hip or knee replacement will go on to use other services. Most of these patients are discharged either to a skilled nursing facility, inpatient rehabilitation hospital, home health, or an outpatient therapy setting. It is important that the patient be discharged to the most appropriate setting based on their condition and other relevant factors and that the patient receives timely rehabilitation. In all of these settings physical therapists provide key components of the patient's care and can play an essential role in minimizing hospital readmissions for certain causes.</p> <p>Physical therapists' role in preventing hospital readmissions first occurs in the acute care setting by providing patients with education and functional training on mobility, ambulation, and assistive device(s). Physical therapists also play a critical role in providing training to caregivers and family members. In addition, physical therapists, in conjunction with other members of the hospital health care team, assist in discharge planning, including the determination of the most appropriate setting for a patient post discharge taking into account their medical status, functional status and other factors, such as their home environment.ⁱ The need for a coordinated effort for the continuum of care across settings for patient is imperative to good outcomes. In addition, the need for optimal access to healthcare, including physical therapist services in the post-hospital phase of care is critical, especially for individuals at high risk for re-admission.ⁱⁱ Information from the physical therapist's discharge summary should always be communicated to the post-</p>			

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		<p>acute care providers. Patients who have had a hip or knee replacement are at risk for falls, which can result in hospital readmission. Physical therapists can intervene to prevent falls by recommending the most appropriate ambulation assistive device, and the amount and type of caregiver assistance needed for ambulation, transfers and ADLs. If the patient is going to be discharged to their home, physical therapists facilitate a home visit/interview prior to discharge to assess the ability of the family members to provide care and to recommend necessary adaptations to the home prior to discharge. This home assessment could occur prior to admission to the hospital for the surgery as could other patient education and training that could improve outcomes in the post-surgical phase.</p> <p>Dislocations can occur in patients who have had hip replacement surgery and can result in hospital readmission. Physical therapists should be consulted to ensure patient understanding of post-operative instructions regarding positioning and supportive devices, if indicated. This involves instructing patient, caregivers and family members regarding these precautions and providing necessary home devices and equipment to comply with post-operative instructions and prevent dislocation. Prior to discharge physical therapists screen/monitor the patient for any signs of deep vein thrombosis and instruct the patient and family members/caregivers in signs and symptoms to watch for that might indicate thrombosis. Instructions are provided on action to take should these symptoms appear. Early and regular intervention by a physical therapist can help ensure that the patient is sufficiently active to reduce the risk of deep vein thrombosis.</p> <p>Physical therapists can play a significant role in pain management. They can also help identify problems patients may be having with the secondary effects of medications. Either of these problems can result in a patient either under medicating or over medicating to compensate. Once identified physical therapists facilitate communication with physicians and other care providers before problems escalate.</p> <p>Infection at the surgical site is a common reason for readmission after hip or knee replacement surgery. Throughout the patient's rehabilitation, physical therapists continually monitor the patient for signs of infection and instruct the patient and family members/caregivers in signs and symptoms to watch for that might indicate early signs of infection. Instructions are provided on</p>			

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		<p>action to take should symptoms of an infection appear.</p> <p>Even with appropriate care and precautions taken, there are times that medical complications will occur that will require readmission to the hospital. In addition to the surgical outcome and the post-operative care that the patient receives, the probability of readmission depends upon many other factors related to the patient's condition including patient severity and certain comorbidities. Any outcome measures used in a system must be risk adjusted to account for factors such as patient severity of illness, comorbidities, functional limitations, age, gender, cognitive status, availability of a caregiver, and prognosis that may influence the outcomes of care. Risk adjustment is essential to create a level playing field that takes into account patient differences. While considerable progress has been made, more work still needs to be done to identify a more effective risk adjustment model. It would be unfair to penalize a hospital that serves a patient population that is more complex than the typical patients who receive hip or knee replacements.</p> <p>We are pleased to see that the measure does include a risk adjustment model with 30 variables. Number 15 under clinical risk factors is "hemiplegia, paraplegia, paralysis, functional disability." Virtually all individuals undergoing total hip or total knee replacement have a functional disability. The data would be more refined and meaningful if "functional disability" is identified as a separate risk factor and the disability would need to be unrelated to the indication for a total hip or total knee replacement. In addition, we would recommend that two other risk factors be added, which are: history of prior fracture to the hip/knee and osteoporosis/osteopenia. Physical therapists are integrally involved with the patient's care after a hip replacement or knee replacement. In this and many other patient populations, physical therapists follow a patient closely and at regular intervals and therefore can identify subtle changes in a patient's status that can escalate. We encourage CMS to ensure that physical therapists have meaningful opportunities to participate in technical expert panels and other discussions related to these quality measures.</p> <p>Thank you for the opportunity to comment. We look forward to working with you to ensure good outcomes measures for hip and knee replacements as well as other conditions.</p> <p>If you need further information, please contact Gayle Lee, Director, Federal</p>			

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		<p>Payment Policy at gaylelee@apta.org or Mary Fran Delaune, Director, Practice atmaryfrandelaune@apta.org.</p> <p>Sincerely, R. Scott Ward, PT, PhD President</p> <p>i Kennedy, D., Stratford, P., Riddle, D., Hanna, S., & Gollish, J.. (2008). Assessing Recovery and Establishing Prognosis Following Total Knee Arthroplasty. Physical Therapy, 88(1), 22-32. Retrieved August 11, 2010, from ProQuest Health and Medical Complete. (Document ID: 1408636491).</p> <p>ii Nizar N Mahomed, Jane Barrett, Jeffrey N Katz, John A Baron, & et al. (2005). Epidemiology Of Total Knee Replacement In The United States Medicare Population. Journal of Bone and Joint Surgery, 87(6), 1222-8.</p>			
8/11/2010	Complications Readmission	<p>Comments for: Hip and Knee Replacement Outcomes Measures Date: August 7, 2010 From: Michelle Bianco, Vice President Accelero Health Partners sm Credentials: BS Physical Therapy Primary responsibility for developing, implementing and improving clinical outcomes service line intelligence tool for hospitals 2008-2010 Email: michelle.bianco@accelerohealth.com</p> <p>Thank you for the opportunity to respond to the total hip and total knee proposed outcomes measures. The focus of this feedback from Accelero Health Partners is related to ‘definition of outcomes’. The measures of complications being proposed are indicated below:</p> <p>Through our work at Accelero Health Partners, we provide our partner hospitals with a web based service line intelligence tool. Our database for 2009 alone contains over 20,000 total joint replacement cases. While this database contains the complications that are being proposed, it is also inclusive of many other complication indicators. Due to the volume of complications seen within the total joint replacement patient population, we could recommend the inclusion of the following complications:</p> <ol style="list-style-type: none"> 1. Renal failure (noted in 38 % of DRG 469 patients) 2. Urinary complications -consisting of both urinary tract infections and urinary retention (noted in 11.8% of DRG 469 and 2.7% of DRG 470 	Michelle Bianco, Vice President Accelero Health Partners, BS Physical Therapy Accelero Health Partners	michelle.bianco@accelerohealth.com	Private Company

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		<p>patients)</p> <p>It has been our experience that when hospitals are provided with a vehicle to measure clinical outcomes, improvements can be attained resulting in better patient outcomes.</p> <p>If further discussion is required, please do not hesitate to call me at</p>			
8/11/2010	Complications Readmissions	<p>Attached is a memo from Dr. James Weinstein in response to the request for comments on outcomes measures.</p> <p>Please contact us at if you have any questions.</p> <p>Thank you TO: The Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation FROM: Dr. James N. Weinstein, President, The Dartmouth-Hitchcock Clinic; Director, The Dartmouth Institute for Health Policy and Clinical Practice; And on behalf of the National Health Value Collaborative RE: CMS Quality Measures Public Comment: Elective Total Hip or Knee Replacement 1. Complications following Elective Total Hip or Knee Replacement 2. 30-Day All-Cause Readmission following Elective Total Hip or Knee Replacement DATE: August 11, 2010</p> <p>Thank you for the opportunity to provide comments on the CMS Proposed Measures for Total Hip or Knee Arthroplasty (TKA/THA). I write to you today on behalf of the National Health Value Collaborative, a voluntary group formed by our health systems to develop models for best clinical practices that demonstrably and measurably improve care and outcomes. The members of the Collaborative – all of whom have participated in drafting these comments – are: The Cleveland Clinic Dartmouth-Hitchcock Medical Center/Dartmouth-Hitchcock Health The Dartmouth Institute for Health Policy and Clinical Practice Geisinger Healthcare Intermountain Healthcare</p>	<p>Dr. James N. Weinstein,\n President, The Dartmouth-Hitchcock Clinic; Director, The Dartmouth Institute for Health Policy and Clinical Practice; And on behalf of the National Health Value Collaborative</p>	james.n.weinstein@dartmouth.edu	Hospital Health System Quality Collaborative

Date Posted	Measure Set	Text of Comments	Name, Credentials, and Organization of Commenter	Email address	Type of organization
		<p>The Mayo Clinic</p> <p>These measures are of particular relevance to us as our first combined project focuses on the clinical pathway for Total Knee Replacement. We will be sharing data on clinical processes and outcomes in an intensive effort to document, duplicate, and disseminate best practices for this increasingly common procedure.</p> <p>Following are our comments, summarized by category and key issues.</p> <p>OVERALL: Longitudinal Measurement of Health and Value We feel the primary goal of tracking TKA and THA populations should be to measure patient outcomes relative to the cost of services. To that end, we view the endpoint of 90 days as too short, given that complications (such as deep tissue infection) may not surface among major joint patients for up to 365 days.</p> <p>Additionally, measures of functional health after one and two years relative to baseline should be included as crucial measures of patient outcomes. AAOS has established definitional criteria for a joint registry, considered by many to be a gold standard, and should be used to guide future phases of measure development. The participation of AAOS on the TEP could be tapped to strengthen this aspect of measure development.</p> <p>We acknowledge that administrative data collected by CMS is limited. CMS could capture more meaningful data by encouraging submission of all joint replacements to a national joint replacement registry. Based on experience, most notably in Sweden, such a registry has been shown to improve care and reduce measurement burden.</p> <p>In the future, we also recommend defining the episode of care for joint replacement to include post-hospital costs for SNF and Acute Rehabilitation, especially as more care is shifted outside of the hospital setting.</p> <p>Stratification of Cohorts We noted no explicit criteria for patient stratification. It is our view that knees and hips should be addressed as separate patient cohorts due to distinct differences in patient presentation, criteria for performing the procedure, and surgical approach and recovery trajectory that are unlikely to be addressed in the severity adjustment model.</p> <p>Age would be another important consideration. A review of one health system's data found that 24% of hips and 16% of primary knees are replaced in patients age 80 or over.</p>			

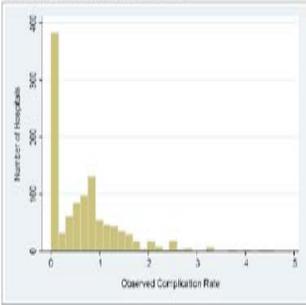
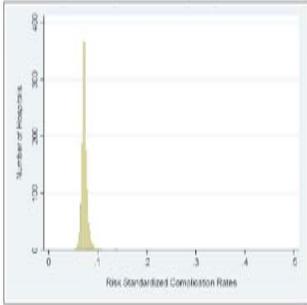
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		<p>DEFINITION OF OUTCOMES:</p> <p>Case Selection We had two comments here. There was no explicit statement of “primary” joint replacement or how bilateral knee replacements would be called out, nor were procedure codes of interest (81.51 and 81.54) stated in the TEP Summary. We suggest that additional and explicit exclusionary criteria should be stated that would disqualify certain primary TKA or THA procedures from the denominator such as procedures performed on the other knee during the same OR case (e.g., partial revisions) or those cases where resurfacing of the hip joint was performed at a point in time prior to electing a primary replacement. Bilateral primary knee replacements should be addressed as separate strata – bilateral joints may be performed during the same hospital admission, either sequentially or simultaneously on the same OR day (i.e., by two surgical teams).</p> <p>Complications Another point of consideration is that some short-term complications may not be identifiable with administrative data. Acute myocardial infarction, pneumonia and sepsis are restricted to only those instances which occur within 7 days of the index admission. For complications identified as secondary diagnoses on the index admission, the incidence date of the complication cannot be determined from administrative data. We ask for clarification on the assumptions you imply for index stays exceeding 7 days in length. Additionally, we recommend that joint infection be split into deep and superficial infection as they represent different degrees of severity and impact on value. VTE should be split into DVT and PE as they represent different degrees of severity and impact on value in the complications measure. We also suggest the addition of dislocation to the complications list unless 996.4x codes cover this. We suggest that iatrogenic infection and decubitus ulcer (NOT present on admission) should be considered complications of care.</p> <p>Readmissions For the readmission measure, decubitus ulcer (not present on admission) is a patient safety event so should not be part of risk adjustment, given that it is stated “we do not risk-adjust for CCs that are possible adverse events of care that are only recorded in the index admission.” For both the Readmissions and Complications measures, we recommend risk-</p>			

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		<p>adjustment for race and ethnicity. There is a national disparity report calling for a need to understand these factors. This is emphasized in a recent AHA initiative – AHA surveying hospitals on use of race/ethnicity data to end health disparities (8/5/10).</p> <p>The AHA is surveying hospitals through Sept. 1 to identify "best practices" for collecting and using race, ethnicity and primary language data to eliminate health disparities. A summary of the survey results will be shared with hospitals and others in the field. “ This survey is especially timely in light of health reform implementation and our national goal to eliminate health care disparities," AHA President and CEO Rich Umbdenstock and Senior Vice President of Research Maulik Joshi said in a letter e-mailed to hospital CEOs yesterday. "Now more than ever, hospitals need to have access to meaningful and complete data about their patients and outcomes and effective evidence-based methodologies for addressing health care disparities."</p> <p>RISK ADJUSTMENT: Patient Characteristics We are concerned that the co-morbidity risk factor weighting is not provided. We suggest that access to the research that was conducted by Yale New Haven would provide a basis for viewing the preliminary weights that are being considered in the adjustment model.</p> <p>While co-morbidities are included in the clinical risk factors, they should be weighted individually as certain co-morbid factors (obesity, rheumatoid arthritis, diabetes, COPD, CAD, PVD) may present higher risk to outcomes than others and may also present a potential perverse impact on patient selection among providers.</p> <p>Given the standard practice of measuring height and weight, we believe BMI should be included in the list of clinical risk factors.</p> <p>Risk adjustment should expand beyond age, sex and co-morbidities. There is currently no risk adjustment for surgical factors including reason for surgery. Administrative codes related to surgical factors that influence outcome are not well defined. ICD-9 codes relating to the complexity of patient’s orthopedic issues and deformity should be developed to more accurately reflect risk.</p> <p>The current CMS Complication Measure excludes socioeconomic status although it has been shown to be a significant predictor of adverse outcomes at the patient level. Given that these outcome measures will be used for payment, suggest use of SES in risk model as it would penalize institutions managing under-served populations and disparity populations. Even if SES</p>			

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		<p>does not add to the statistical explanation of the model, socioeconomic status should be included in the model to improve face validity. Further, it is not clear why type of Medicare plan was not considered for risk adjustment.</p> <p>Anesthesia Type Anesthesia type was not addressed in the documentation. We recommend the choice of spinal anesthesia be included as a factor in risk for pulmonary embolism.</p> <p>TEP COMMENTS: We agree with the TEP that more study is needed on disparities; nevertheless, it is important information that outweighs our limited understanding, which can be informed by the data. Again, thank you for the opportunity to comment. Should you have questions or wish to discuss or clarify any of these points, please do not hesitate to contact me by email at: james.n.weinstein@dartmouth.edu</p>			
8/11/2010	Complications Readmission	<p>I never had any of them. A lot of friends are very happy with the outcome of hip replacement. As of knee replacement I have a couple of friends were things went wrong and they have not recovered, mainly due to infection or otherwise. They were very intelligent, active people in their community, helping others. They are now in wheel chairs. I do hope if I need one in the future that things would improve in the area of knee replacements. I would hold out as long as I can, till things would improve. Otherwise, joint replacements are necessary.</p> <p>Doris Giger Retired: Mechanical Designer, GE Nuclear Division.</p>	Doris Giger Retired: Mechanical Designer, GE Nuclear Division.	RomainGR@aol.com	Individual
8/11/2010	Complications Readmission	<p>August 11, 2010 Lein Han Government Task Leader Centers for Medicare & Medicaid Services Susannah Bernheim and Laura Grosso Yale New Haven Health Services Corporation Center for Outcomes Research and Evaluation (YNHHSC/CORE) RE: Quality outcomes measures for patients undergoing elective total hip and total knee replacement and ischemic stroke hospitalization The Consumer-Purchaser Disclosure Project is an initiative that is improving health care quality and affordability by advancing public reporting of</p>	Christine Chen, MPP Policy Analyst Consumer-Purchaser Disclosure Project	CChen@pbgh.org	Consumer Group

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		<p>provider performance information so it can be used for improvement, consumer choice, and payment. We are a collaboration of over sixty leading national and local employer, consumer, and labor organizations. We appreciate the opportunity to comment on YNHHS/CORE's two elective total hip or knee replacement measures and two ischemic stroke measures. We wholeheartedly applaud the development of measures to address outcomes, in particular the procedure-specific measures, and the intention of using these measures for public reporting as well as internal quality improvement. This is particularly of importance when it comes to hip and knee replacement procedures, given not only their volume, but the fact that they are the types of procedures for which consumers often do have the opportunity research the provider and setting where they would like to receive care. We also encourage CMS to add measures of patient-reported outcomes for knee and hip replacement, which are becoming more common and are most amenable to this form of measurement. While the total hip or knee replacement and ischemic stroke measures are directionally appropriate, we caution against the use of risk adjustment methods that obscure variation in the data results, such as the hierarchical generalized linear model (HGLM). This analytical technique can wash away nearly all of the variation observed in the raw data because it shrinks performance data towards the mean.^{1,2} The result is that most providers (i.e., individual hospitals) being profiled will be labeled as "average," regardless of the level of statistical significance imposed. This thereby limits the value of such measures for public reporting and quality improvement. For example, across the 25th to 75th percentiles, YNHHS/CORE notes that unadjusted hospital-level mortality rates for ischemic stroke range from 9.4% to 21.4%. This range, after applying HGLM, was reduced to 14.2%-16.3%. Given this compression of results, we are uncertain about the claim made by YNHHS/CORE that "the results of the risk-standardized rates show continued meaningful difference even after risk adjustments." At the end of this document we provide a powerful visual of how drastically HGLM shrank the range of values for a hospital outcome measure related to complications from ICDs for heart patients.</p> <p>1 Racz, M. J. and J. Sedransk, "Bayesian and Frequentist Methods for Provider Profiling Using Risk-Adjusted Assessments of Medical Outcomes," J. of the American Statistical Association, 105:489 (March 2010), 48-58. 2 Kipnis, P., G. J. Escobar, and D. Draper, "Effect of Choice of Estimation Method on Inter-Hospital Mortality Rate</p>			

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		<p>Comparisons,” Medical Care, 48:5 (May 2010), 458-465. Consumer-Purchaser Disclosure Project Comments on Knee, Hip, and Ischemic Stroke Hospital Outcome Measures</p> <p>Page 2 of 3 August 11, 2010 HGLM is highly specific – meaning that those who are identified as outliers almost surely are outliers – but lacking in sensitivity – meaning that it does not identify as many outliers as there are. HGLM makes adjustments for sample size that result in providers being pulled towards the mean. The smaller a given provider’s volume the less weight is attached to their observed results and the more weight is given to the mean value. This results in fewer providers being designated as outliers and, depending on the statistical confidence level that is chosen, may not identify any low volume provider as different from average even when their observed result is quite different from the mean. There are other analytical approaches that give more equal weight to specificity and sensitivity so that the chances that a provider is identified as an outlier when they are not are more balanced against the chances that a provider is not identified as an outlier when they are. Also, others in the academically-based biostatistics community have confirmed that there is no agreement that HGLM is superior to other, more traditional techniques and, in fact, two separate articles that came out earlier this year point out that traditional methods yield better discrimination (Kipnis et al. 2010 and Racz et al. 2010).</p> <p>Inequitable and/or unreliable methods of risk adjustment may lead to profiling that subsequently results in severe consequences. One consequence is that providers who provide relatively good quality of care go unrecognized. More importantly, consumers may be mistakenly led to providers of relatively poor quality care who are displayed as being “no different than average.” We therefore recommend that any analytical approach for estimating risk-adjustment models should incorporate a reasonable balance between specificity and sensitivity in identifying performance that is higher or lower than the norm. On behalf of consumers and purchasers across the country, thank you for your consideration of our comments. If you have any questions, please don’t hesitate to contact David Hopkins (dhopkins@pbgh.org), who is a team member of the Disclosure Project. Consumer-Purchaser Disclosure Project</p>			

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		<p>Comments on Knee, Hip, and Ischemic Stroke Hospital Outcome Measures</p> <p>Page 3 of 3 August 11, 2010 Excerpted from Hospital Risk-Standardized Complication Rate following Implantation of Implantable Cardioverter-Defibrillator (ICD) Measure Methodology Report: Consumer-Purchaser Disclosure Project</p> <p>Comments on Knee, Hip, and Ischemic Stroke Hospital Outcome Measures Page 3 of 3 August 11, 2010 Excerpted from Hospital Risk-Standardized Complication Rate following Implantation:</p> <p>Figure 5 – Distribution of Hospital Unadjusted Complication Rates (2007 Development Sample; N=1,060 Hospitals)</p>  <p>Figure 6 – Distribution of Hospital Risk-Standardized Complication Rates (2007 Development Sample; N=1,000 Hospitals) – HGLM</p> 			

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8/11/2010	Complications	<p>August 11, 2010 Lein Han, Ph.D., Government Task Leader, Centers for Medicare & Medicaid Services [Submitted electronically via hipknee@yale.edu]</p> <p>Established in 1951, The Joint Commission is an independent, not-for-profit organization that evaluates and accredits approximately 17,000 health care programs and organizations in the United States. These include hospitals, laboratories, ambulatory care and office-based surgery centers, behavioral health, home care, hospice, and long term care organizations. Although accreditation is voluntary, a variety of federal and state government regulatory bodies recognize and rely upon Joint Commission decisions and findings for both Medicare and licensure purposes across all of the Joint Commission's accreditation programs.</p> <p>The Joint Commission appreciates the opportunity to review and comment on the proposed outcomes measures. We have reviewed the proposed measures and have provided two comments for your consideration.</p> <p>The first comment addresses Complications Rate Following Elective total Hip or Knee Replacement. CMS proposes to only capture complications if they occur during a hospital admission. Frequently complications occur following a procedure, but do not result in an inpatient admission. For example, an individual may present to an emergency department with a very serious complication and be transferred to another facility, or even expire during treatment. Therefore, The Joint Commission is concerned that the narrow focus of complications only during a hospital admission will miss very serious cases that occur following a procedure and must be included in an assessment of performance. We urge CMS to consider this and other scenarios under which surgical complications may occur that are proximal to the surgical procedure but not necessarily occurring during or resulting in an admission.</p> <p>We note that venous thromboembolism (VTE) is not included in the list of complications for this measure while pulmonary embolism (PE) is included. Since venous thromboembolism (VTE) includes deep vein thrombosis (DVT)</p>	Marco A. Villagrana Associate Director, Federal Relations The Joint Commission	mvillagrana@joint commission.org	Health Care Accreditation Organization

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		<p>and pulmonary embolism (PE) and DVT commonly occurs in the leg, we ask CMS to provide the rationale for omitting VTE as one of the complications for this measure.</p> <p>We appreciate the opportunity to comment on the proposed outcomes measures. If you have any questions or would like to discuss our comments, don't hesitate to contact me at</p> <p>Sincerely, Trisha Kurtz Director for Federal Relations</p> <p>2.</p>			
8/11/2010	Complications Readmissions	<p>On behalf of St. Tammany Parish Hospital in Covington, Louisiana, I would like to submit the following comments related to the proposed hip and knee replacement outcome measures for the physician quality reporting initiative. Complications, which are often avoidable, lead to an increase in the cost of care as well as an increase in the risk for mortality; therefore, St. Tammany Parish Hospital supports the inclusion of complications following elective total hip and knee replacements. Because elective hip and knee replacements are generally performed on medically stable individuals, the risk for readmission is decreased. The 30-day all cause readmission measure is also supported. It is agreed that, as stated in the proposed rule, elective readmissions should be excluded from the measure.</p> <p>Thanks,</p>	Ashley E. Rush, RN, MSN Quality Manager St. Tammany Parish Hospital in Covington, Louisiana,	Troy Rush <tkeyy514@yahoo.com>	Hospital
8/11/2010	Complications Readmission	<p>To Whom it May Concern,</p> <p>Thank you for the opportunity to comment on the proposed measures: 30-Day Risk-Standardized Readmission Rate following Elective Total Hip and Total Knee Arthroplasty and Risk-Standardized Complication Rate following Elective Total Hip and Total Knee Arthroplasty.</p> <p>We, at the Hospital for Special Surgery, feel it important to re-state the well-known limitations of using administrative data for the analysis of quality of care. The use of billing data depends on coding staff's ability to recognize events in the charts; accurately characterize these events and assign the relevant ICD-9 complication codes. This is quite challenging. It is reasonable to assume that there are substantial variations in the accuracy and integrity of medical record coding. Variations in coding are frequently encountered by researchers, necessitating arduous and thorough validation</p>	Michelle Horvath, MSN, RN, CPHQ Hospital for Special Surgery	HorvathM@HSS.EDU	Hospital

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		<p>before drawing valid conclusions about care and treatment. To date, although the limitations of relying on administrative data for quality data programs are consistently mentioned, there has been no prioritized, commitment to routine auditing and validating data at all hospitals in order to assure reliability of the data for clinical purposes (versus chart abstraction validation programs currently in place).</p> <p>Additionally, Hospitals that make a commitment to accurate coding will appear to have a higher rate of complications. We have seen this phenomenon in voluntary adverse event/complication reporting programs in NYS. Although regulatory bodies may attempt to footnote that higher rates of complications or events might not indicate poor quality of care; the impression left is otherwise.</p> <p>Using the ICD-9 code as the definition of some complications such as pulmonary embolism is problematic since, unlike myocardial infarction, there is no separate code designating this as an acute event.</p> <p>The TEP report notes that “In the coming years we will conduct a validation study using medical records to confirm the accuracy of this approach”, however this reference appears noncommittal and is only made in relation to one aspect of the readmission methodology. We urge a broader approach to confirming the accuracy, validity, and reliability of administrative data for use in this and other quality initiatives.</p> <p>In relation to “readmission within 30 days”, a potential area of bias exists where there is variation in hospital practice in sending patients to rehab after surgery. Readmission endpoint can potentially be biased as those hospitals that do not have rehab services nearby will be disadvantaged. They are more likely to send patients home and then readmit them if there are any complications. These hospitals will be classified as having worse outcomes even if they have lower occurrence of serious events leading to readmission.</p> <p>Additionally, comorbidities or disease conditions as defined by ICD-9 codes often lack validity and can be only be used on study by study basis. It is hard to define certain deformities or 'bone quality' and adjust for these important risk factors. Some specialized centers are concentrating on these patients as their niche in the orthopedics and are again likely to have 'worse outcomes' due to residual confounding.</p>			

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		<p>The use of procedure related complication codes (i.e. 996-999) in the setting of revision surgery is similarly a problem. Our experience with administrative databases used for research purposes demonstrates that in the case of a revision procedure it is often not possible to discern from coding alone whether the procedure-related complication code is a complication of the primary (index) procedure or if the complication is related to the revision procedure itself.</p> <p>Furthermore, while we appreciate the discussion regarding the decision to not use socioeconomic status (SES) in the risk adjustment methodology, we disagree with this decision. SES is clearly related to higher rates of complications/increased LOS etc. The proposal points out the fact that socioeconomic status and disparities going along with this variable cannot be accurately accounted for. It is very hard to create an accurate measure of overall comorbidity burden to account for the individual patients' medical status and their propensity for complications in general. The use of established measures like comorbidity indices such as the Charlson, Deyo or Elixhauser depend on accurate coding at the very least. Adjustment for demographics and these comorbidities might not be sufficient when looking at quality of care. SES has independent effect on outcomes (including readmission) and by not accounting for SES in the analysis, hospitals that care for lower SES patient populations may have results that appear inferior.</p> <p>The proposal does not specify the handling of bilateral procedures during an index admission in relation to risk-standardizing for complication rates. This is a higher risk procedure and if not specifically acknowledged, hospitals that perform an over proportional amount of these procedures will appear as if they erroneously have higher complication rates. We know that country-wide bilateral TKAs performed during the same hospitalization make up about 6.5% of all surgeries (Memtsoudis et al. Anesthesiology 2009; 111:1206-16). Hospitals, like us, will be penalized by not accounting for this in the risk-adjustment methodology.</p> <p>The proposal is inaccurate when referencing our paper in respect to codes used for bleeding. We did not use ICD 9 code 286.5 in our paper.</p> <p>(Memtsoudis S, Gonzalez Ella Valle A, Besculides M, Gaber L, Sculco T. (2008). In-hospital complications and mortality of unilateral, bilateral, and</p>			

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		<p>revision TKA. Clin Orthop Relat Res, 466:2617?2627.)</p> <p>We would like to participate in further discussion/testing of these measures. Please do not hesitate to call on us.</p> <p>Douglas Padgett, M.D. Chief, Adult Reconstruction and Joint Replacement Alejandro Gonzalez Della Valle, M.D., Department of Orthopedics Stavros Memtsoudis M.D., Department of Anesthesiology Art Sedrakyan, M.D., Ph.D., Research Department</p>			
8/11/2010	Complications Readmission	<p>August 11, 2010 Dr. Laura Grosso Dr. Jeptha Curtis Via. e-mail: hipknee@yale.edu Dr. Zhenqiu Lin YNHHSC/CORE New Measures Team</p> <p>Dear Hip/Knee Measures Team: I am writing to convey our comments on the proposed readmission and complication outcome measures for Hip and Knee replacement.</p> <p>Readmission Measures We agree that readmission rates for hip and knee replacements are partially controllable by providers through a combination of patient preparation, surgical/hospital procedures and techniques, effective rehabilitation, and coordination and follow-up post-discharge with both the patient and any post-acute-care providers. We agree that revision procedures should be excluded, and that risk adjustment should differentiate both type of procedure (hip or knee) and number of procedures performed based on our own analysis of all-cause readmissions in New York State SPARCS administrative data between 2006 and 2008:</p> <p>Complication Measures Selected and Follow-up Periods The recommended complications represent the major negative outcomes for initial total hip and knee replacement patients. Each can be reduced by provider actions to improve care delivery and coordination as outlined above. We also agree with the differential follow-up periods of 7, 30, and 90 days for various types of complications likely to be related to the index admission, including the changes recommended by the TEP.</p>	John D. Shaw President Next Wave	shawj@nextwave.info>	Private Company

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		<p>Risk Adjustment We strongly recommend that presence of a ;§Personal history of venous thrombosis and embolism; (ICD-9-CM code V12.51) be added as a risk factor. It is highly predictive for the development of subsequent Pulmonary Embolism, one of the major components of the complication measure. We note the discussion of race, ethnicity, and SES for consideration as risk adjusters. We support the intent to follow current National Quality Forum policy to: „h NOT include as a risk adjuster (to hold all hospitals to the same standards of care), but also Consider stratifying results by race, ethnicity, and SES (to acknowledge any significant and inversely associated adverse outcomes. This will enable any use in payment policy to recognize this more difficult to treat population and avoid perverse incentives for hospitals to avoid treatment of low SES patients).</p> <p>Complication Measures ;V Technical Specifications We do however have some concerns over how the complication measure specifications are stated. It appears from the way the measure is presented that complication diagnoses reported during the index admission as either primary diagnoses or secondary diagnoses that are present on admission will be considered a complication outcome for a procedure that has not even occurred at that point in time. By ICD-9-CM diagnosis code definition, primary diagnoses are the reason the patient was admitted, and are always present on admission. Secondary diagnoses can be either present on admission or develop during the stay. Only those diagnoses occurring after the procedure is performed (usually the day of admission) should be considered as complications of that procedure for inclusion in an outcome measure. Suggested language to clarify this (for ALL of the XXXXXXXX codes listed) would be: When to Count as Complication Index Admission „h Presence of any XXXXXXXX code listed above in secondary diagnosis field and NOT present on admission Readmission „h No change Follow-up Period for Complication Measure „h Arising during the index admission (after the index procedure is performed) or within ____ days from admission date In addition to incorporating present on admission (POA) concepts into the measure specifications, we also highly recommend additional validity testing of these measures in a more complete dataset than MEDPAR. Currently, hospitals</p>			

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		<p>report and Medicare and other payors collect 25 diagnoses and 25 procedures for each inpatient claim. However, due to constraints in CMS's legacy data systems, only 9 diagnoses and 6 procedures are kept in current MEDPAR data. CMS will be collecting the full 25/25 diagnoses/procedures starting in January, 2011 as part of their MEDPAR information technology update. In our analysis, we found that risk adjusted complication measures (e.g. the AHRQ PSIs) based on a limited 9/6 data set vary significantly when compared to full reporting. The order of magnitude of this variability is similar to that of POA refinements, and frequently greater than variability between hospitals. The magnitude and direction of this variation does depend on specific diagnosis codes utilized by the measure and the degree to which each of these codes are reported in the first 9 positions. We therefore recommend sensitivity validation be performed on a full dataset. The AHRQ All-Payor State Inpatient Datasets (SID) have a linking identifier available to support longitudinal analysis. Approximately 2/3 of the hospitals in these datasets report at least 15 diagnoses. Validation can be performed for just Medicare patients in this data vs. MEDPAR. All-payor versions of the measures could also be tested for the future. Thank you for the opportunity to comment on these proposed measures.</p> <div data-bbox="451 889 1003 1258" data-label="Figure"> <table border="1"> <caption>30 Day All Cause Readmission Rates</caption> <thead> <tr> <th>Category</th> <th>Readmission Rate (%)</th> </tr> </thead> <tbody> <tr> <td>1-Bi-Lateral Hip</td> <td>8.0%</td> </tr> <tr> <td>2-Bi-Lateral Knee</td> <td>7.9%</td> </tr> <tr> <td>3-Revision Hip</td> <td>17.2%</td> </tr> <tr> <td>4-Revision Knee</td> <td>12.9%</td> </tr> <tr> <td>5-Primary Hip</td> <td>12.2%</td> </tr> <tr> <td>6-Primary Knee</td> <td>10.4%</td> </tr> </tbody> </table> </div> <p>Sincerely, John D. Shaw President</p>	Category	Readmission Rate (%)	1-Bi-Lateral Hip	8.0%	2-Bi-Lateral Knee	7.9%	3-Revision Hip	17.2%	4-Revision Knee	12.9%	5-Primary Hip	12.2%	6-Primary Knee	10.4%			
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8/11/2010	Complications Readmissions	August 11, 2010 Yale New Haven Health Services Corporation/Center for Outcomes Research	Steven Brotman, M.D., J.D.	SBrotman@AdvaMed.org	Health Care Technology														

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		<p>and Evaluation (YNHHSC/CORE) Via e-mail to: hipknee@yale.edu RE: Elective Total Hip or Knee Replacement Quality Outcomes Measures Dear Administrator, The Advanced Medical Technology Association (AdvaMed) welcomes the opportunity to comment on two measures currently in development by the Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE): (1) Complications following Elective Total Hip or Knee Replacement; and (2) 30-Day All-Cause Readmission following Elective Total Hip or Knee Replacement.</p> <p>AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies, including orthopedic implantable device companies that supply the vast majority of hip and knee implants used worldwide AdvaMed supports the need to develop relevant quality measures related to inpatient care provided to patients undergoing these replacement procedures and understands the potential problems and complex issues involved in data collection/analysis. While we support this effort, we have several concerns with both proposed measures and several statements in the Summary of Technical Expert Panel (TEP) Evaluation of Measures. Our comments will address these issues below. I. Measure Regarding Complications Following Elective Total Hip or Knee Replacement</p> <p>a. Risk Stratification AdvaMed has serious concerns regarding various facets of the risk stratification method that is proposed in the Complications Measure. CMS is proposing to stratify risk based</p> <p>August 11, 2010 Page 2 of 6</p>	Senior Vice President, Payment and Health Care Delivery Policy The Advanced Medical Technology Association (AdvaMed)		Association

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		<p>on Medicare administrative claims information. Risk adjustment is a key element that must be valid, reproducible, sensitive and specific. Any flaws that may be present in the methodology to examine risk adjustment can potentially lead to flawed conclusions and therefore compromise the validity of the resultant conclusions. Thus it is important to consider as many relevant variables as possible in developing this model.</p> <p>In addition to age, sex and clinical covariates, socioeconomic status (see discussion below), other concurrent treatments/interventions and sources of co-morbidity should also be considered. Notably absent from the discussion on determination of risk stratification factors are individual patient measures in the orthopedic context such as functional/range of motion status, presence or absence of specific orthopedic preoperative deformities, bone mineral density and other indicators and/or disorders involving variability of bone quality, including osteoporosis, osteo/rheumatoid arthritis, metabolic diseases/disorders affecting bone growth/functions and medications affecting mineral absorption and bone quality. AdvaMed strongly believes that these patient-specific factors should be included in the risk stratification for the measure, as they vary from patient to patient and can play a very significant role in the post-surgical complication rate. Additionally, CMS might consider the significance and development of ICD-9 (or ICD-10) codes in the future that could capture these same patient-specific orthopedic variations and which could be included in the risk adjustment model.</p> <p>b. Socio-Economic Status (SES) AdvaMed shares the concerns with several of the TEP members that the SES was not included as a covariate in the risk-standardized models, as it may be potentially inversely associated with adverse outcomes post THA and TKA. AdvaMed is especially perplexed concerning the stance of the following statement appearing in the section “Summary of Data on Disparities by Population Group” in the measure information forms of both measures: “Preliminary analyses demonstrated that although SES is a significant predictor of adverse outcomes at the patient level, it does not affect overall hospital performance in the riskadjustment complications model...Given our preliminary findings, we do not expect to stratify by such factors.” This statement is contradictory; it identifies socioeconomic status as a “significant predictor of adverse outcome” but then negates its role in the proposed model. The rationale of this statement needs further detailed clarification and reasoning for this exclusion.</p>			

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		<p>August 11, 2010 Page 3 of 6</p> <p>AdvaMed strongly believes that risk stratification should take into account a patient's socioeconomic status. AdvaMed recognizes that SES-based information, for example, educational level, literacy and language skills/abilities, can potentially alter the process of care of patients undergoing joint replacement and thus confound the results and conclusions in these measure sets. For example, some patients, while they may be literate, may not understand the complexity of their health condition and their care and treatment. This will influence their compliance and ultimately can significantly impact the quality of care that they receive which, in turn, will affect the outcome data. Additionally, there may be some hospitals where SES would have a significantly different impact on complication or readmission rates (e.g., hospitals in regions for which patient SES is incongruent with the average of all U.S. hospital regions). We believe that while this information may be difficult to elicit and collect, its omission could have a significant impact on the validity of these measures. AdvaMed is, however, pleased that the YNHHS/CORE has agreed to perform additional analyses to determine the potential impact of SES status on hospitals' risk standardized outcome rates – both for readmission and complications – and consider stratifying the measure by SES.</p> <p>c. Measure Complication: Pulmonary Embolism The complications included in this measure include pulmonary embolism (PE), presumably related to a deep vein thrombosis (DVT), however, DVT is omitted from the list of complications. AdvaMed believes that the complication listing for PE should include the occurrence of DVT, as DVT is one of the most likely precursors of PEs. The addition of DVT to the complication list would be consistent with the past and most recent Hospital Inpatient Prospective Payment Rule (IPPS). As final policy for FY 2011, the IPPS lists deep vein thrombosis and pulmonary embolism following certain orthopedic procedures – including total hip and total knee arthroplasties -- as conditions that will continue to be subject to the Hospital-Acquired Condition (HAC) payment provision. Therefore, we strongly suggest that DVT be included in the list of complications in the measure. Further, although the data presented in the TEP report indicates that the appropriate follow-up period for PE should be limited to within 30 days from the admission date, we suggest</p>			

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		<p>that the combined DVT/PE timeframe be extended beyond 30 days, as a longer follow-up period may be consistent with various standard anticoagulant use following surgery.</p> <p>II. Measure Regarding 30-Day All-Cause Readmission Rate Following Elective Total Hip or Knee Replacement AdvaMed has serious concerns regarding the development of a measure using an “allcause” readmission rate. As noted in the readmission specification document, the YNHHS/CORE workgroup noted that “using all-cause readmission will, however, undoubtedly include a mix of unavoidable and avoidable readmission.” AdvaMed believes that all-cause reporting has limited usefulness since many unrelated conditions</p> <p>August 11, 2010 Page 4 of 6 are responsible for a patient’s return to the hospital. Thus, this increases the possibility of introducing needless confounding factors and bias into the measurement and thus obscures the utility of such measure. Interestingly, the workgroup also discussed an alternative approach which would exclusively count readmissions for procedure-specific complications (e.g., mechanical complications, revision, wound infection, surgical site bleeding). The workgroup unfortunately rejects this approach with minimal detailed analysis of the advantages/disadvantages of each approach for this instance. AdvaMed believes that the measure should focus on studying readmissions that are related to the specific procedure in order to provide more meaningful data and advance the quality of care for those patients that undergo elective total hip and knee arthroplasty.</p> <p>AdvaMed wishes to note that several of the risks that could be directly attributed to both readmissions and complications are not captured in the proposed claims data. Notably absent are Body Mass Index (BMI) and SES (see discussion on SES, above). AdvaMed believes that (BMI), or a similar measurement, should be considered as a risk factor in the statistical models affecting the complication and readmission rates. Although we recognize BMI is not captured in claims data, we suggest the possibility of including it as a surrogate measure.</p> <p>III. Administrative Claims Data These measures identify complications from administrative claims data as</p>			

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		<p>well as use the claims variables for risk adjustment. AdvaMed has serious concerns regarding the use of administrative claims data in setting these quality measures. Administrative claims data lacks robust clinical information and other pertinent patient data—such as those contained in medical records — which are necessary to assess details related to patient complications and other variables that are used in determinations of these measures.</p> <p>Although the YNHHS/CORE group states that administrative claims data has been used to develop risk-adjusted outcomes measures for mortality following admission for certain cardiac-related events (myocardial infarction, heart failure and death) -- and that these models produce estimates of risk-standardized mortality rates (RSMRs) that are very similar to rates estimated by models based on chart data -- it is unclear that this extrapolation truly applies to the measured outcomes involving THA/TKA. Secondly, aside from variability in reporting of intra-hospital data, there are compounded sources of variability when administrative data is used to compare rates across hospitals. Romano et al. reported that ICD-9-CM complications were underreported among a subset of orthopedic surgery patients, especially at hospitals with low risk-adjusted complication</p> <p>August 11, 2010 Page 5 of 6 rates and concluded that the validity of using coded complications to compare provider performance is questionable, even with careful efforts to identify serious events.¹ These limitations of using administrative claims data to measure clinical quality outcomes become increasingly evident when this data is applied to claims for total joint arthroplasty. Most recently, Bozic et al. examined the validity of using administrative claims data in total joint arthroplasty research.² This study concluded that for revision total hip arthroplasty, concordance between clinical diagnoses and administrative claims was very good for dislocation, mechanical loosening, and periprosthetic joint infection, but considerably lower for prosthetic implant failure/breakage and other mechanical complication. Similarly, for revision total knee arthroplasty diagnoses, concordance was very good for periprosthetic fracture, periprosthetic joint infection, mechanical loosening, and osteolysis, but much lower for implant failure/breakage and other mechanical complication. Losina et al. analyzed</p>			

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		<p>whether Medicare claims accurately document underlying rheumatologic diagnoses in total hip replacement recipients and concluded that inaccuracies in claims coding of diagnoses are frequent, providing potential sources of bias.³</p> <p>IV. Joint Registry Data AdvaMed recommends that CMS strongly and proactively support hospital participation in the American Joint Replacement Registry (AJRR) in order to advance the development of quality measures related to patient care in those undergoing THA/TKA. Supporting the AJRR registry as an alternative for meeting quality reporting requirements would provide an invaluable resource in furtherance of the goal of improving patient outcomes. The joint registry will allow the tracking of implant performance from the time of the index procedure and the identification of any complications or issues that may be related to the care of the patient with that device. Additionally, robust registry data could be extremely useful in the analysis/validation of administrative claims data and stratification of risk, as evidenced by its use in the recent NQF approved quality measure on readmission rates following percutaneous coronary intervention.⁴</p> <p>¹ Romano, Patrick S. MD, MPH; Chan, Benjamin K. MS; Schembri, Michael E.; Rainwater, & Julie A. PhD, Can Administrative Data Be Used to Compare Postoperative Complication Rates Across Hospitals? Medical Care Volume 40. Issue 10. Pages 856-867 (October 2002).</p> <p>² Bozic KJ, Chiu VW, Takemoto SK, Greenbaum JN, Smith TM, Jerabek SA, & Berry DJ. The Validity of Using Administrative Claims Data in Total Joint Arthroplasty Outcomes Research. The Journal of Arthroplasty, Article in Press, June 2010.</p> <p>³ Elena Losina, Jane Barrett, John A Baron, & Jeffrey N Katz. Accuracy of Medicare claims data for rheumatologic diagnoses in total hip replacement recipients. Journal of Clinical Epidemiology, Volume 56, Issue 6, Pages 515-519 (June 2003).</p> <p>⁴ 30-Day All-Cause Risk Standardized Readmission Rate Following Heart Failure Hospitalization (risk adjusted) (NQF # 0330; endorsed 5/15/2008).</p> <p>August 11, 2010</p>			

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		<p>Page 6 of 6</p> <p>Finally, it is noteworthy that the Technical Expert Panel (TEP) does not contain representation from the joint manufacturing industry. CWe believe that having an industry member serve on the TEP would enhance the overall measure development process by bringing a body of essential unique perspectives and providing invaluable input and feedback.</p> <p>AdvaMed greatly appreciates the opportunity to provide these comments to CMS. We would be pleased to answer any questions regarding these comments. Please contact Steven Brotman, MD, JD, Senior Vice President, Payment and Health Care Delivery Policy, at SBrotman@AdvaMed.org, if we can be of further assistance.</p> <p>Sincerely, //ss// Steven Brotman, M.D., J.D. Senior Vice President, Payment and Health Care Delivery Policy The Advanced Medical Technology Association (AdvaMed)</p>			
8/12/2010	Complications Readmissions	<p>Minor revision made to last night's submission. Thank You. Michelle Horvath, MSN, RN, CPHQ</p> <p>To Whom it May Concern,</p> <p>Thank you for the opportunity to comment on the proposed measures: 30-Day Risk-Standardized Readmission Rate following Elective Total Hip and Total Knee Arthroplasty and Risk-Standardized Complication Rate following Elective Total Hip and Total Knee Arthroplasty.</p> <p>We, at the Hospital for Special Surgery, feel it important to re-state the well-known limitations of using administrative data for the analysis of quality of care. The use of billing data depends on coding staff's ability to recognize events in the charts; accurately characterize these events and assign the relevant ICD-9 complication codes. This is quite challenging. It is reasonable to assume that there are substantial variations in the accuracy and integrity of medical record coding. Variations in coding are frequently encountered by researchers, necessitating arduous and thorough validation before drawing valid conclusions about care and treatment. To date, although the limitations of relying on administrative data for quality data programs are consistently mentioned, there has been no prioritized, commitment to routine auditing and validating data at all hospitals in order to assure reliability of the data for clinical purposes (versus chart abstraction validation programs</p>	Michelle Horvath, MSN, RN, CPHQ Hospital for Special Surgery	HorvathM@HSS.EDU	Hospital

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		<p>currently in place).</p> <p>Additionally, Hospitals that make a commitment to accurate coding will appear to have a higher rate of complications. We have seen this phenomenon in voluntary adverse event/complication reporting programs in NYS. Although regulatory bodies may attempt to footnote that higher rates of complications or events might not indicate poor quality of care; the impression left is otherwise.</p> <p>Using the ICD-9 code as the definition of some complications such as pulmonary embolism is problematic since, unlike myocardial infarction, there is no separate code designating this as an acute event.</p> <p>The TEP report notes that “In the coming years we will conduct a validation study using medical records to confirm the accuracy of this approach”, however this reference appears noncommittal and is only made in relation to one aspect of the readmission methodology. We urge a broader approach to confirming the accuracy, validity, and reliability of administrative data for use in this and other quality initiatives.</p> <p>In relation to “readmission within 30 days”, a potential area of bias exists where there is variation in hospital practice in sending patients to rehab after surgery. Readmission endpoint can potentially be biased as those hospitals that do not have rehab services nearby will be disadvantaged. They are more likely to send patients home and then readmit them if there are any complications. These hospitals will be classified as having worse outcomes even if they have lower occurrence of serious events leading to readmission.</p> <p>Additionally, comorbidities or disease conditions as defined by ICD-9 codes often lack validity and can be only be used on study by study basis. It is hard to define certain deformities or 'bone quality' and adjust for these important risk factors. Some specialized centers are concentrating on these patients as their niche in the orthopedics and are again likely to have 'worse outcomes' due to residual confounding.</p> <p>The use of procedure related complication codes (i.e. 996-999) in the setting of revision surgery is similarly a problem. Our experience with administrative databases used for research purposes demonstrates that in the case of a revision procedure it is often not possible to discern from coding alone whether the procedure-related complication code is a complication of the primary (index) procedure or if the complication is related to the revision procedure itself.</p> <p>Furthermore, while we appreciate the discussion regarding the decision to <i>not</i> use socioeconomic status (SES) in the risk adjustment methodology, we disagree with this decision. SES is clearly related to higher rates of</p>			

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		<p>complications/increased LOS etc. The proposal points out the fact that socioeconomic status and disparities going along with this variable cannot be accurately accounted for. It is very hard to create an accurate measure of overall comorbidity burden to account for the individual patients' medical status and their propensity for complications in general. The use of established measures like comorbidity indices such as the Charlson, Deyo or Elixhauser depend on accurate coding at the very least. Adjustment for demographics and these comorbidities might not be sufficient when looking at <u>quality of care</u>. SES has independent effect on outcomes (including readmission) and by not accounting for SES in the analysis, hospitals that care for lower SES patient populations may have results that appear inferior. The proposal does not specify the handling of bilateral procedures during an index admission in relation to risk-standardizing for complication rates. This is a higher risk procedure and if not specifically acknowledged, hospitals that perform an over proportional amount of these procedures will appear as if they erroneously have higher complication rates. We know that country-wide bilateral TKAs performed during the same hospitalization make up about 6.5% of all surgeries (Memtsoudis et al. <i>Anesthesiology</i> 2009; 111:1206–16). Hospitals which perform many bilateral simultaneous TKR (like Hospital for Special Surgery) will be penalized by not accounting for this in the risk-adjustment methodology.</p> <p>The proposal is inaccurate when referencing our paper in respect to codes used for bleeding. We did not use ICD 9 code 286.5 in our paper. (Memtsoudis S, Gonzalez Ella Valle A, Besculides M, Gaber L, Sculco T. (2008). In hospital complications and mortality of unilateral, bilateral, and revision TKA. <i>Clin Orthop Relat Res</i>, 466:2617-2627.)</p> <p>We would like to participate in further discussion/testing of these measures. Please do not hesitate to call on us.</p> <p>Douglas Padgett, M.D. Chief, Adult Reconstruction and Joint Replacement Alejandro Gonzalez Della Valle, M.D., Department of Orthopedics Stavros Memtsoudis M.D., Department of Anesthesiology Art Sedrakyan, M.D., Ph.D., Research Department</p> <p>Submitted by: Michelle Horvath, MSN, RN, CPHQ Hospital for Special Surgery</p> <p>horvathm@hss.edu</p>			

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8/12/2010	Complications Readmissions	<p>There needs to be a stratification of outcomes in terms of primary, conversion & revision surgeries Among primary cases there should be development of risk categories (low/medium/high) to account for patients with morbid obesity, diabetes, immune deficiency & malignancy.</p> <p>Regards- Mary Drake</p> <p>Manager, Quality The Ohio State University Hospital East E-mail: Mary.Drake@osumc.edu</p>	<p>Mary Drake Manager, Quality The Ohio State University Hospital</p>	<p>Mary.Drake@osu mc.edu</p>	<p>Hospital</p>
8/13/2010	Complications Readmissions	<p>Good Morning.</p> <p>I respectfully request that you enter this final, complete version of our comments, originally made prior to the deadline, on this important quality initiative.</p> <p>Please feel free to contact me. Michelle Michelle Horvath, MSN, RN, CPHQ Assistant Vice President, Quality Management Hospital for Special Surgery 535 East 70th Street New York, N.Y. 10021 phone 212-606-1123</p> <p>8/13/10 To Whom it May Concern, Thank you for the opportunity to comment on the proposed measures: 30-Day Risk-Standardized Readmission Rate following Elective Total Hip and Total Knee Arthroplasty and Risk-Standardized Complication Rate following Elective Total Hip and Total Knee Arthroplasty.</p> <p>We, at the Hospital for Special Surgery, feel it important to re-state the well-known limitations of using administrative data for the analysis of quality of care. The use of billing data depends on coding staff's ability to recognize events in the charts; accurately characterize these events and assign the</p>	<p>Thomas P. Sculco, M.D., Surgeon-in-Chief</p> <p>Douglas Padgett, M.D. Chief, Adult Reconstruction and Joint Replacement</p> <p>Alejandro Gonzalez Della Valle, M.D., Department of Orthopedics</p> <p>Stavros Memtsoudis M.D., Department of Anesthesiology</p> <p>Art Sedrakyan, M.D., Ph.D., Research Department</p> <p>Hospital for Special Surgery</p>	<p>HorvathM@HSS.E DU</p>	<p>Hospital</p>

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		<p>relevant ICD-9 complication codes. This is quite challenging. It is reasonable to assume that there are substantial variations in the accuracy and integrity of medical record coding. Variations in coding are frequently encountered by researchers, necessitating arduous and thorough validation before drawing valid conclusions about care and treatment. To date, although the limitations of relying on administrative data for quality data programs are consistently mentioned, there has been no prioritized commitment to routine auditing and validating data at all hospitals in order to assure reliability of the data for clinical purposes (versus chart abstraction validation programs currently in place).</p> <p>Additionally, Hospitals that make a commitment to accurate coding will appear to have a higher rate of complications. We have seen this phenomenon in voluntary adverse event/complication reporting programs in NYS. Although regulatory bodies may attempt to footnote that higher rates of complications or events might not indicate poor quality of care; the impression left is otherwise.</p> <p>Using the ICD-9 code as the definition of some complications such as pulmonary embolism is problematic since, unlike myocardial infarction, there is no separate code designating this as an acute event. Additionally, we would characterize pulmonary embolus as a medical complication and not a surgical complication. It has been shown in multiple studies that prevention of PE, fatal PE, and all cause mortality is no better with the use of guideline-supported potent anticoagulants for prophylaxis; and that these events cannot be avoided in every case (Ref: Sharrock NE, González Della Valle A, Go G, Salvati EA. Potent anticoagulants increase all-cause mortality and symptomatic pulmonary embolism after total joint arthroplasty. Reply to a Letter to the Editor. Clin Orthop 2008;466(3):714-21. Poultsides L, Gonzalez Della Valle A, Memtsoudis S, Roberts T, Sharrock N, Salvati E. Systematic review of cause of death following elective THR and TKR performed with different thromboprophylaxis regimens. European Hip Society Meeting, Athens, Greece, September 8 to 11, 2010). Consequently, classifying PE as a surgical complication may erroneously imply that the surgeons and the hospitals are directly responsible for it.</p> <p>The TEP report notes that “In the coming years we will conduct a validation study using medical records to confirm the accuracy of this approach”, however this reference appears noncommittal and is only made in relation to</p>			

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		<p>one aspect of the readmission methodology. We urge a broader approach to confirming the accuracy, validity, and reliability of administrative data for use in this and other quality initiatives.</p> <p>In relation to “readmission within 30 days”, a potential area of bias exists where there is variation in hospital practice in sending patients to rehab after surgery. Readmission endpoint can potentially be biased as those hospitals that do not have rehab services nearby will be disadvantaged. They are more likely to send patients home and then readmit them if there are any complications. These hospitals will be classified as having worse outcomes even if they have lower occurrence of serious events leading to readmission.</p> <p>Additionally, comorbidities or disease conditions as defined by ICD-9 codes often lack validity and can be only be used on study by study basis. It is hard to define certain deformities or 'bone quality' and adjust for these important risk factors. Some specialized centers are concentrating on these patients as their niche in the orthopedics and are again likely to have 'worse outcomes' due to residual confounding.</p> <p>The use of procedure related complication codes (i.e. 996-999) in the setting of revision surgery is similarly a problem. Our experience with administrative databases used for research purposes demonstrates that in the case of a revision procedure it is often not possible to discern from coding alone whether the procedure-related complication code is a complication of the primary (index) procedure or if the complication is related to the revision procedure itself.</p> <p>Furthermore, while we appreciate the discussion regarding the decision to not use socioeconomic status (SES) in the risk adjustment methodology, we disagree with this decision. SES is clearly related to higher rates of complications/increased LOS etc.</p> <p>The proposal points out the fact that socioeconomic status and disparities going along with this variable cannot be accurately accounted for. It is very hard to create an accurate measure of overall comorbidity burden to account for the individual patients’ medical status and their propensity for complications in general. The use of established measures like comorbidity indices such as the Charlson, Deyo or Elixhauser depend on accurate coding at the very least. Adjustment for demographics and these comorbidities might not be sufficient when looking at quality of care. SES has independent</p>			

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8/13/2010	Complications Readmissions	What time period are you currently looking at? Will our readmission data for this be available to download?	Jamie E. Matt, RHIA Clinical Quality Analyst	Jamie.Matt@Carle.com	Hospital

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		Thanks, Jamie Jamie E. Matt, RHIA Clinical Quality Analyst Quality Management Services Carle Foundation Hospital Jamie.Matt@Carle.com	Quality Management Services Carle Foundation Hospital		