National Quality Forum

Comments on Draft Report: National Voluntary Consensus Standards for Patient Outcomes (Phases I and II)
2nd Report

Discussed by Patient Outcomes Steering Committee on July 27, 2010 conference call

Cmnt ID#	Member Council/ Public	Organization Contact	Comment	Response	Topic
5	P	John Allen, Minnesota Gastroenterology	I would support this approach strongly. I have worked on developing the PAC definitions for several conditions in gastroenterology. The methodology is intuitive and can separate quality of care thru the use of administrative data. In each condition there has been careful consideration about what constitutes a potentially avoidable complication - this includes both medical complications and excess resource use. As such this methodology addresses concerns about overuse and miss-use. The fundamental infrastructure is translatable to multiple conditions - this means that educational efforts will become easier with more implementation.	Thank you for your comment.	General Comments
7	P	Regina Herzlinger, Harvard Business School	The national voluntary consensus standards for patient outcomes phases 1 and 2 are extremely important and salubrious .They will force system accountability because they measure potentially avoidable complications across the care continuum .The data are also completely consumer-centric because they provide the sort of outcome ,relevant information which consumers want ,rather than the process data which is what they currently have available . My book ,Who Killed Health Care?, discussed the fragmented, insular old boys network which is killing health care systems around the world. The status quo feels it simply cannot be held accountable for what a colleague in another organization does and that the consumer is incapable of interpreting correctly the measures of their work . Since 1997,I have advocated transparency and the formation of integrated health care systems—I call them focused factories --as two of the key cures . I am so very pleased that this set of measures goes a long way to producing it.	Thank you for your comment.	General Comments

16	M, Health Professionals	Rita Munley Gallagher, PhD, RN, American Nurses Association	The American Nurses Association (ANA) concurs that the results or outcomes of an episode of health care are inherently important because they reflect the reason consumers seek health care (e.g., to improve function, decrease pain, or survive) as well as the result healthcare providers are trying to achieve. ANA applauds NQF's efforts to fill gaps in its measure portfolio for use in evaluating the outcome of episodes of care. NQF's efforts in that regard are laudable. However, ANA believes that a reformed system of care will call for measurement of different outcomes than those currently being operationalized which are primarily siloed and based on location of patient. These measures will likely not be of value in the future. Population management outcomes will be required. In addition, ANA recommends that NQF encourage developers of those measures not advanced to continue to refine their measures to meet NQF endorsement criteria so as to continue to advance the field. Finally, there is a clear need for emphasis to be placed on the development of measures focused on the outcomes of patient transitions in care.	Thank you for your comment.	General Comments
45	M, Health Plan	Sheree Chin Ledwell, Aetna	Aetna applauds NQF's continuing efforts to endorse outcome measures—particularly cross-cutting measures that get at system performance. In the near future, we recommend that there be a focus on functional status and quality of life measures as well.	Thank you for your comment. An additional report from the Patient Outcomes project with recommendations for needed outcome measures will be released later. Functional status and quality of life measures figure largely in these recommendations.	General Comments
60	M, QMRI	Linda Keegan, Kidney Care Partners	Kidney Care Partners has submitted its comments via e-mail and pasted them below. Kidney Care Partners (KCP), a coalition of patient advocates, dialysis professionals, care providers, and manufacturers working together to improve the quality of care for individuals with Chronic Kidney Disease (CKD), appreciates the opportunity to review and provide comments for the National Quality Forum's (NQF), National Voluntary Consensus Standards for Patient Outcomes, Second Draft Report for Phases 1 and 2. As an NQF Member, we commend you for focusing on outcome measures and congratulate you on the release of a thoughtful and well informed draft report.	Thank you for your comment.	General Comments

61	M, QMRI	Linda Keegan, Kidney Care Partners	As the report notes, patient outcomes are inherently important because they reflect the reason consumers seek healthcare and the results providers are attempting to achieve, as well as provide an integrative assessment of quality reflective of multiple care processes across the continuum of care. As KCP continuously strives to ensure that CKD and ESRD patients achieve optimal outcomes, we recognize the tremendous importance of this work. For instance, in 2009 KCP launched Performance Excellence and Accountability in Kidney Care (PEAK), a voluntary national quality improvement campaign undertaken by the kidney community to reduce mortality among first-year dialysis patients by 20 percent by the end of 2012—an effort to extend, even save, 10,000 lives. The PEAK Campaign is focusing on increasing the importance of patient education and key clinical care activities to achieve its goal, and through the identification and sharing 'breakthrough' practices, will equip healthcare providers with tools to help first-year dialysis patients better transition, to improve the health and survival of first year dialysis patients, and to reduce hospitalizations.	Thank you for your comment.	General Comments
62	M, QMRI	Linda Keegan, Kidney Care Partners	Although we recognize that NQF can only consider measures it receives, we want to register our disappointment that no CKD measures have been recommended under this project. We note that the report does not acknowledge that, in fact, NQF did seek CKD outcome measures during the Call for Measures in August/September 2009, but that none were received.	Thank you for your comment. Another report from the Patient Outcomes project will focus on the gaps in current measures. The lack of CKD measures will be discussed. We will add a note to this report that measures for CKD were solicited but none were received.	General Comments

63	M, QMRI	Linda Keegan, Kidney Care Partners	KCP recommends that the report reflect the broader scope of the intended project and note—perhaps in the section "Gaps in Desirable Outcome Measures"—the urgent need for developers to address the lack of CKD measures. Additionally, we strongly encourage NQF to, in the future, give high priority to the evaluation and endorsement of CKD measures. Noting the dearth of CKD measures in the NQF report and an emphasis on prioritizing the development/endorsement of them in the future would be an accurate and appropriate reflection of CKD's staggering personal, fiscal, and societal burden and its disproportionate impact on minorities: Approximately 26 million Americans—1 in 9 adults—are stricken with CKD and in 2007, the adjusted rates of prevalent and incident end-stage renal disease (ESRD) cases that had progressed from CKD reached 1,665 and 354 per million population, respectively. The disease burden of CKD and ESRD disproportionately affects minority populations, in particular African American and Latino populations: The rate of ESRD in minority patients ranges from 1.5 to 4 times those of age-adjusted Caucasian patients. Risk of hospitalization is 1.25 times greater in patients with CKD than in patients without, and adjusted hospital admission rates for dialysis patients have fallen only 1.5% since 1993. Risk of death is 1.72 times greater for patients with CKD and adjusted all-cause mortality rates are 6.7 to 8.5 times higher for dialysis patients.	Another report of the Patient Outcomes project will detail the gaps identified during this project. This report will be released for public comment later this summer.	General Comments
64	M, QMRI	Linda Keegan, Kidney Care Partners	While we are disappointed that no CKD measures were submitted for endorsement consideration, we would like to voice our general support of the two measures pertaining to diabetes mellitus—Proportion of patients with chronic conditions that have a potentially avoidable complication (PAC) during a calendar year, submitted by Bridges to Excellence, and the Diabetes Composite measure submitted by NCQA. As the most common cause of renal failure, diabetes accounts for 44 percent of all new ESRD cases.3 Nearly 24 million people in the United States have been diagnosed with diabetes,4 and in 2005 approximately 180,000 people were living with kidney failure as a result of the disease.3 KCP thus recognizes that improvement of diabetes outcomes through optimal disease management will concurrently reduce the number of patients developing CKD and progressing to ESRD.	Thank you for your comment.	General Comments

65	M, QMRI	Linda Keegan, Kidney Care Partners	Again, thank you for this opportunity to respond to NQF's National Voluntary Consensus Standards for Patient Outcomes, Second Draft Report for Phases 1 and 2. We look forward to continuing to work with you on the development of an appropriate measure set for ensuring the highest quality of care for patients with CKD. Sincerely, Linda Keegan Executive Director Kidney Care Partners	Thank you for your comment.	General Comments
67	M, QMRI	Bernard M. Rosof, MD, MACP, Physician Consortium for Performance Improvement®	The Physician Consortium for Performance Improvement(R) (PCPI) appreciates the opportunity to comment on the National Quality Forum's (NQF) National Voluntary Consensus Standards for Patient Outcomes, Second Report for Phases 1 and 2: A Consensus Report. As noted in our response to the First Report, we are pleased that NQF has taken up the difficult task of continuing to review and recommend the endorsement of outcomes measures. We continue to believe that by assessing the outcomes of medical care, these measures can help healthcare providers of all types provide better quality and safer care. While the PCPI supports aspects of this report, we have concerns regarding the following: levels of measurement for five measures; how Potential Avoidable Complications (PACs) were determined for four of the measures; questions about the reliability of four measures; as well as a point of clarification (included in comments sections for individual measures).	Thank you for your comment.	General Comments
76	M, QMRI	Nancy H. Nielsen, MD, PhD, American Medical Association	The American Medical Association (AMA) appreciates the opportunity to comment on the National Quality Forum's (NQF) National Voluntary Consensus Standards for Patient Outcomes, Second Report for Phases 1 and 2: A Consensus Report. As noted in our response to the First Report, we are pleased that NQF has taken up the difficult task of continuing to review and recommend the endorsement of outcomes measures. We continue to believe that by assessing the outcomes of medical care, these measures can help healthcare providers of all types provide better quality and safer care. While the AMA supports aspects of this report, we have concerns regarding the following: levels of measurement for five measures; how Potential Avoidable Complications (PACs) were determined for four of the measures; as well as a point of clarification (included in comments sections for individual measures).	Thank you for your comment.	General Comments

85	M, Health Plan	Rebecca Zimmerman, AHIP	AHIP appreciates the opportunity to comment on the National Quality Forum's National Consensus Standards for Patient Outcomes. Outcomes measures are important indicators of the care patients receive and this project is an important step forward in endorsing measures that will provide meaningful information to consumers and other stakeholders.	Thank you for your comment.	General Comments
93	M, Provider	Samantha Burch, Federation of American Hospitals	The Federation of American Hospitals appreciates the opportunity to comment on the National Voluntary Consensus Standards for Patient Outcomes, Second Report for Phases 1 and 2. Improving our ability to measure outcomes using methodologies that draw a strong link to the performance of the provider is critical and we strongly support NQF's work in this area. We are pleased to offer several comments related to the specific measures recommended for endorsement, however, our comments only relate to the measures that are applicable to hospitals. We appreciate that this report includes an explanation of how the recommended measures align with the NPP Priorities.	Thank you for your comment.	General Comments
100	M, Health Professionals	Janet Leiker, on behalf of the AAFP Commission on Quality and Practice, American Academy of Family Physicians	Would like to see level of evidence/strength of recommendation documented for each specific measure.	NQF's measure evaluation criteria requests documentation of the process-outcome linkage for outcome measures. This information is included in the measures submission forms posted on the project web site.	General Comments

101	M, Consumer	Debra Ness, National Partnership for Women & Families	As with the first phase of the Patient Outcomes project, the National Partnership for Women & Families strongly commends the National Quality Forum for overseeing this vitally important work on patient outcomes measures. The National Partnership has been a strong advocate for the development, endorsement, and implementation of quality measures that will be useful and meaningful to consumers, and having data on the outcomes of procedures related to diabetes, surgery, cardiovascular care, and other conditions is in line with our efforts. While we support the work being done by NQF in this area, we would like to note our concern with the lack of functional status measures available for evaluation and potential endorsement. We understand that measures of functional status are complex to develop (and of course, that NQF is not a measure developer), but we hope that by raising our concern, we can push for resources to be put toward this critical topic. We also want to raise the point that as these measures become implemented and publicly reported, it is critical that they be stratified by race, ethnicity, language and gender. This is always an important factor in measure implementation, but particularly so for outcome measures. What better way can the field assess -- and address solutions to – health care disparities than by knowing the outcomes of care for different demographics.	Thank you for your comment. The Steering Committee was also concerned with the lack of functional status measures. The development of functional status and quality of life measures as performance measures has lagged behind. The forthcoming report from the Patient Outcomes project outlining the gaps in outcome measures specifically notes the lack in these areas. The Patient Outcomes Steering Committee was particularly focused on how measures addressed disparities. The Committee provided much feedback to the developers on the importance of collecting the necessary data fields to allow for stratification.	General Comments

114	M, Provider	Nancy Foster, American Hospital Association	The AHA appreciates the opportunity to comment on this report. We have both general comments about the report and specific comments about some of the measures proposed for endorsement. First, it is critically important that the health care field have more well crafted outcomes measures by which to judge our success of our efforts to improve the care delivered to patients. We strongly support NQF's efforts to identify such measures. Among those that are recommended in this report, two are identified as composite measures, and yet there is no reference to the work NQF has undertaken to identify the criteria by which composite measures should be judged. We suggest that such information be included in the introductory materials to the report and that the Committee make specific reference to how they assessed the composites against the criteria for composite measures. This is both an important consideration for these particular measures and for educating all interested stakeholders on what constitutes a good composite measure. Further, we note that in the section on NQF strategic directions, there is a recognition that composites are easier for consumers to understand. While this may be true, they may be less actionable of providers in actually improving care, and it would be worth noting in this section that there needs to be some balance in assessing composite measures given these competing interests.	NQF's Composite Measure Evaluation Framework describes the criteria for evaluating composite measures - see http://www.qualityforum.org/Publications/2009/08/Composite_Measure_Evaluation_Framework_and_National_Voluntary_Consensus_Standards_for_Mortality_and_Safety—Composite_Measures.aspx Information on NQF's composite measures evaluation framework will be added to the report. The composite criteria requires that the component measures be evaluated against the criteria but are not required to be sufficiently important as a stand alone measure.	General Comments
115	M, Provider	Nancy Foster, American Hospital Association	The introductory materials also include a reference to the work of the National Priority Partners and a listing of the priorities, but there seems to be no further reference to this work through the rest of the document. It would useful to know how the Committee believes these measures they are recommending contribute to the priorities. On a different issue, on line 50 of the document, the report states that readmissions are the result of a deterioration in health status. While this may be true for many readmissions, it is not universally true. Readmissions can be part of a planned course of treatment, for example for a cancer patient or a burn patient. More precision in this language would be important given the public policy issues surrounding readmissions. We suggest simply dropping the statement about readmissions since it is simply an example and not really needed to make the point that the Steering Committee was looking to make.	A refence to the National Priorities has been included at the end of the measure discussion. Not all measures fall into one of the NPP categories. The sentence on readmission will be deleted.	General Comments

116	M, Provider	Nancy Foster, American Hospital Association	There are several opportunities embedded in these measures for NQF to promote greater standardization in measures, and the Steering Committee address two of them explicitly --- the need for standardized statistical and standardized reporting methods. We strongly concur that this would be useful for the NQF to undertake. Others are not addressed. For example, the mortality and readmission measures currently endorsed by NQF cover the period of 30 days post admission to the hospital Several of these proposed measures cover the period of 30 days post discharge. It is unclear why there is this discrepancy in measure period, but greater consistency would be useful for a variety of analytic and data collection reasons. Additionally, even small items like standardizing nomenclature for measures will be useful as we move to embed more in EHRs. Therefore, the use of PNA for pneumonia in these measures and PNE in other NQF endorsed measures should be avoided. Please pick one abbreviation and stick with it.	The Harmonization project will provide greater guidance to Steering Committees on how to consider and resolve harmonization issues. The upcoming measaure maintenance work places a greater emphasis on measure harmonization and identifying "best in class". During the active phase of the project, the measure information is provided by the measure developer/owner. Once endorsed, NQF can standardize abbreviations in the database.	General Comments
145	P	Kay Jewell, Center for Consumers of	Support the remainder of the measures recommended. It is regretful that the measures for cancer did not meet criteria for endorsement. It was a good discussion and review and there's hope for future measure development.	Thank you for your comment.	General Comments
160	M, Health Professionals	Ralph Sacco, American Heart Association, American Stroke Association; Ralph W. Brindis, President, American College of Cardiology; Frederick A.	Finally, as noted in our letter to you regarding the first report for Phases 1 and 2 of the Patient Outcomes project, we are concerned about the NQF setting a precedent of endorsing composite measures that include component measures that are themselves not considered appropriate for public reporting. In general, the ACCF and AHA believe that composite measures should be comprised only of measures that are considered adequately valid on their own.	NQF's Composite Measure Evaluation Framework describes the criteria for evaluating composite measures - see http://www.qualityforum.org/Publications/2009/08/Composite_Measure_Evaluation_Framework_and_National_Voluntary_Consensus_Standards_for_Mortality_and_Safety—Composite_Measures.aspx Information on NQF's composite measures evaluation framework will be added to the report. The composite criteria requires that the component measures be evaluated against the criteria but are not required to be sufficiently important as a stand alone measure.	General Comments

18	P	Kay Jewell, Center for Consumers of Healthcare	HbA1c control for a selected population (OT1-028-09) NCQA. I attended both the Diabetes TAP and the SC meeting. I do not believe this measure received the analysis it deserves, that the data supports Patients need a measure for good control to begin to close the gap between the evidence that <7% improve outcomes and the current rates being achieved. We need a measure for good control, one that can stand on its own as a publicly reported measure. Is there a way for NQF to work with the developer to address concerns that would allow it to be recommended for endorsement as a stand-alone measure this year? This is the year for Diabetes measures according to the draft plan. That means diabetes would not come up again until 2014. There is no recommendation for Measure OT1-009-09 pending additional review by ICSI. Could a similar position be taken for this measure, if it's ok with the NCQA timeline for its next meeting of its Diabetes group? There were 2 issues raised 1) hypoglycemia as an exclusion and 2) the exclusion of those >65 who do not have evidence of significant micro-or macrovascular complications. Given the population data, it is a major public health issue that we develop a quality measure for good control of <7% that is applied to all those who do not have exclusions, for their benefit in the short-term and the long-term and to try to control healthcare costs by preventing or slowing down the rate of complications in ALL people with diabetes.	The SC reviewed comments 18-19, 128-139 and 14 and the measure developer response which addressed the Hgb A1c <7%. The Committee reviewed the findings of the recent ACCORD trial that prompted concerns about hypoglycemia with aggressive management. The Committee reaffirmed their decision not to reocmmend the measure. Measure developer response: Thank you for your comment. Although we recognize your concern regarding the A1c <7% measure, the recommendation to include the measure is closely tied to the most recent clinical trials from ACCORD, ADVANCE, and VADT on diabetes and expert consensus on the implications of these studies on HbA1c measurement. Therefore, it was the decision of NCQA that the evidence suggests that the benefit for control of HbA1c under 7% is for microvascular rather than macrovascular complications and the group with the most benefit and least risk are younger and earlier in the stage of their diabetes. Also, the benefit from avoiding microvascular progression requires 10-20 years to begin to be manifest with respect to important patient outcomes. Therefore, the safest control level across the vast majority of persons with diabetes is somewhere between 7-8%. NCQA has submitted a separate measure of good control for HbA1c <7% (with some exclusionary criteria) for endorsement by NQF.	Measures Not Recommended

19	P	Kay Jewell, Center for Consumers of Healthcare	A1c<7% - We are concerned about causing harm (hypoglycemia) without benefit of the data and harm that has only been defined as CV risk over the next 10-20 years. This is a narrow perspective that is not consistent with the NQF national agenda or CMS's needs. We have to address the whole patient & all the diabetes complications within the first 5-10 years. These complications have significant impact on lives, function, and healthcare costs; people go to the doctor to try to treat what could have been avoided, delayed or lessened with good glycemic control early on. Those doctor visits, tests and medications add up for the Medicare patient and the budget. They contribute to functional disability - vision loss, gait, falls, memory and decreased QoL. Those with chronic illness with functional impairment (14%) spend 46% of the healthcare dollars - diabetes ranked 5th. Of those, 14% get help with ADLs/IADLS; they represent 5% of the population and 23% of the spending, diabetes ranked 2nd. Diabetes ranked 3rd in the most common chronic condition among the top 5% of spenders over 65. (Lewin Group, aspe2010). We need to prevent/delay functional impairment whenever/wherever possible. 26% of nursing home patients have DM, they are one of the most heavy care groups:, based on their level of functional disability, the presence of heart and circulatory problems, cognitive impairment, & depression. More than 1/2 are in pain on admission. (Travuss 2004)	See response to comment #18.Measure developer response: Thank you for your comment. This measure has been collected as part of the Comprehensive Diabetes Care composite measure set for the HEDIS population for two years. The data collected indicates that there is significant variation among regions and room for improvement. According to the evidence, lowering A1c to below or around 7% has been shown to reduce microvascular and neuropathic complications of type 1 and type 2 diabetes	Measures Not Recommended

128	P	Kay Jewell, Center for Consumers of Healthcare	OT1-028-09: SA1c<7%- Severe hypoglycemia or hypoglycemia unawareness – these are reasons supported in the guidelines for not striving for <7%. There were 2 issues – how to code for this exclusion and what the data says about hypoglycemia as an age-related issue. RE: codes. The measure does not include ICD-9 codes to report these two exclusions. Is the developer is open to and able to add codes for this exclusion? E.G. 201.0, 251.1 AND 251.2 as a suggestion because they include hypoglycemia in the definition. The data on hypoglycemia was briefly discussed at the TAP. Dr. Hellman pointed out that hypoglycemic episodes are related to frequency of testing (and attention to results). Cox (2007) reported that imminent (within 24 hours) episodes could be predicted in 60% of type 2 DM when 3 serum blood glucose readings were available in the 24 hour before an episode. If 5 readings were available, the detection increased to 75%. The concern is that hypoglycemia can become a vicious cycle – based on the autonomic failure theory, episodes of hypoglycemia cause a defect in the regulation and awareness cycle. Avoiding hypoglycemia for 2 weeks is recommended to reset the regulation. (Cryer 2003) The rate is skewed – a few patients have more of the episodes – (Akram 2006b) The rate of impaired awareness of hypoglycemia is lower in T2 vs T1 (Akram 2006b)	See response to comments #18-19.	Measures Not Recommended
129	P	Kay Jewell, Center for Consumers of Healthcare	OT1-028-09) Clinical guidelines, evidence-base to exclude >65 without complications: National guidelines, ADA and AACE/ACE have reviewed the 2008 studies and more recent studies. They continue to recommend <7% and do NOT impose an age limit. The American Geriatric Society/California Health Plan recommendations are consistent with the ADA and ACE. In their guidelines, the American Geriatric Society supported a goal of < 7% unless the person's life expectancy was < 5 years. All 3 recommend excluding those >65 who have complications. This measure does that with the exclusions. Zarowitz 2006 recommend good control of diabetes even in the nursing home, starting with a target of 8% and titrating down. They do recommend the target of 7%, with careful titration. New analysis of the ACCORD data does NOT support the exclusion of this population.	See response to comments #18-19.	Measures Not Recommended

130	P	Kay Jewell, Center for Consumers of Healthcare	OT1-028-09) Assumption: people over 65 are not achieving A1cs < 7% and it is the elderly who will be the problem getting better control if we do not exclude them. It is those >65 that physicians would be putting at unnecessary risk trying to meet this measure. The elderly are already doing a better job getting to <7% and we are not seeing a huge increase in hypoglycemia. The evidence is just the opposite – hypoglycemia is more of an issue for those in poor control. NCQA data (p5) –National mean for A1c<7% was 28.68% for commercial and 32.87% for Medicaid. This is lower than the NHANES data- where 48% <65 had an A1c<7%. Medicare had the highest performance of either group - mean 45% in one region (highest in Commercial- 40%). This is consistent with NHANES data for A1c<7% - >65 – 68%; <65 yo – 48%. (Hoerger 2008) Studies of management care members report that more people over 65 have an A1c<7%. (Shetty 2005,Gilmer 2005, Menzin 2010) Healthcare costs including hospitalizations increase when the A1c is over 7.5% - supporting the need for this measure to move toward better glycemic control for all patients (with the exceptions for <8%).	See response to comments #18-19.	Measures Not Recommended

131	P	Kay Jewell, Center for Consumers of Healthcare	OT1-028-09) Myth: age is the biggest risk factor for death and hypoglycemia – The data from the first articles on ACCORD and other studies pointed out a risk and speculated that control to 6.5% would put the elderly at unnecessary risk – therefore, they should all be excluded. Additional analysis have better defined the populations at risk for death in those studies – it was not related to age, duration of diabetes or the presence of complications. (Calles-Escandon 2010). The baseline characteristics that defined the subgroups with an effect on mortality were: self-reported neuropathy (numbness ad absent sensation), use of aspirin and higher A1c >8.5% Riddle 2010 – identified "persisting higher A1c levels" as likely contributors to increased mortality in the intensive arm. Bonds 2010 -Severe symptomatic hypoglycemia does not appear to account for the difference in mortality.." the risk of death was lower in the intensive arm than the standard arm. Other literature: Risk of severe episodes of hypoglycemia. Potential risk factors – impaired hypoglycemic awareness is the most important (Akram 2006) Incidence rate in T2 is 1/3 that of T1 DM. (Akram 2006, 10% Cryer 2003)rate of about 0.35 episodes per patient year Self-estimated hypogly6cemia unawawerenss was the most significant risk factor for any event – risk was 3 fold. (Akram 2006 – cross-sectional)	See response to comments #18-19.	Measures Not Recommended
132	P	Kay Jewell, Center for Consumers of Healthcare	OT1-028-09) Menzin 2010 – Managed care - mean age was 66.6 yr; 63% of the sample was over 65 (n=6203) and 3841 had an A1c<7%). Those over 65 made up 65% of the patients with an A1c<7%. They looked at the top 5 diabetes-related hospitalizations by mean A1c; for hypoglycemia, the 10 hospitalizations were in those with an A1c>10%. The adjusted hospitalization rate was significantly higher for patients with worse A1c – 13 /100 for mean A1c<7% and 30/100 patient-years for mean A1c>=10.0% The data from these studies would support the additional analysis of ACCORD ; that it is not age or A1c of 7% that is the concern for significant hypoglycemia.	See response to comments #18-19.	Measures Not Recommended

133	P	Kay Jewell, Center for Consumers of Healthcare	The only important benefit is cardiovascular which takes 10-20 years to realize: This is a given -it does take 10-20 years to realize the benefit of good control on CV complications. Actuarial tables report a life expectancy of a person aged 65 in the year 2005 is 18.7 more years; and the presence of diabetes increases mortality two-fold. It is age-bias to believe there is no value to a person over 65 if they cannot live 15-20 years.	See response to comments #18-19.	Measures Not Recommended
134	P	Kay Jewell, Center for Consumers of Healthcare	OT1-028-09: Other critical issues overshadowing physician support for a measure of good control: It's time to separate the other issues from the issue of the quality measure for good control of diabetes. Achieving better control is a major public health issue but it is physicians who will be held accountable through this measure. There are many issues or barriers from the physician's perspective to achieving the goals: can this be accomplished, will patients go along with it, what will it take to do it, do physicians have the skills or resources to achieve the goals; who will have the time for all that patient education for all the people who will be needing it, most these patients will require insulin at some point – that takes even more time to educate and monitor, who will pay for the time it will take, and who will help the healthcare system work with patients to achieve these goals. It is physicians who are expected to find the resources and dollars to provide the education and counseling needed to achieve the goals when their reimbursement continues to be threatened for Medicare patients. Many will delay the addition of insulin as long as possible to avoid what can be a major issue/barrier for the patient and the physician. Who will help work with patients on that? Who will find the time needed to educate and care for all these patients? If the NCQA data is correct – only 30% of the commercial population is achieving <7%.	See response to comments #18-19.	Measures Not Recommended

135	P	Kay Jewell, Center for Consumers of Healthcare	It is physicians and diabetic educators whose hands are tied by insurance restrictions on insulin pens; insulin administered through pens has been shown to increase patient compliance with insulin use (not as painful to inject, can be carried with and used outside the home); reduces waste (of vial at end of 4 weeks – or patients continuing to use outdated insulin with problems with glucose control and increased dosing), reduces skipped doses, reduce hypoglycemic events and ED visits, reduce time needed for education compared to education and demonstrations of use of vials and syringes, reduce patient errors, reduce drug wastage and reduce overall costs and increase compliance in those in lower socioeconomic and educational levels. The rest of the world has recognized the value and uses insulin pens - 86% vs 14% for vials/syringes; in the US, it is around 10%. It is physicians who will be accountable and be penalized for low numbers in the pay-for-performance environment if patients do not achieve <7%. This is the loudest argument I hear when this subject comes up – it is real and it is interfering with getting the right measure for good control of diabetes. Someone needs to address it – but it is not NQF.	See response to comments #18-19.	Measures Not Recommended

136	P	Kay Jewell, Center for Consumers of Healthcare	OT1-028-09: there are no benefits to good control that appear in less than 10-20 years to be considered. Good glycemic control is associated with a reduced rate of microvascular complications within 5 years, this is supported by the UKDPS studies and ADVANCE. These events have a major impact on a person's quality of life – change in vision, pain, need for medication and healthcare utilization. They are very significant and should not be overlooked. Retinopathy and increased risk for cataracts – lead to poor vision. In addition to the impact on a person's quality of life, it contributes to decreased independent function. The UKPDS results were significant for the impact on progression of DR, even when the median difference in A1c between the study groups was 0.9%. • There was a 31% lower risk of retinopathy for a 1% decrease in A1c. This was thought to occur regardless of the initial level of retinopathy. • There was also a 19% reduced risk of cataract extraction for each 1% decrement in A1c. For those who had evidence of retinopathy at baseline, progression was associated with older age, male sex and higher A1c. • BP control also has an impact on progression of DR. A 10 mm Hg decrease in systolic blood pressure equated to an 11% reduction in photocoagulation or vitreous hemorrhage. Without treatment, it is expected that ½ of the people with VTR would reach the legal blindness level within 3 years. If appropriate photocoagulation or other current treatment is applied, only ½ to 1/10 would progress to legal blindness.	See response to comments #18-19.	Measures Not Recommended

137	P	Kay Jewell, Center for Consumers of Healthcare	OT1-028-09: Shea studied DR in the Medicare population, specifically Diabetic Macular edema, because it is the most common cause of vision loss in patients with DR. Resources used for DME include fluorescein angiography, laser photocoagulation, and optical coherence tomography and intravitreal injection. Treatment has changed; rates of photocoagulation are decreasing while intravitreal injection is increasing. When just the population with diabetes is considered, DME is associated with a 7% increased 1-year cost and 8% higher 3-year costs. 1-year direct medical cost: Those with DME: $ 11,290 Control: $ 8,398 3 year direct medical costs Those with DME: $ 33,620 Control:$ 11, 436	See response to comments #18-19.	Measures Not Recommended
138	P	Kay Jewell, Center for Consumers of Healthcare	OT1-028-09: Neuropathy – there are many types of neuropathy that develop relatively quickly and are impacted by hyperglycemic control - better control, slower progression –it affects 60-70% of patients with diabetes. Cardiac Autonomic Neuropathy – evident within 5 years, associated with increased risk of sudden death and orthostatic hypotension. (Would create comorbidity and also contribute to drug interaction problems, especially management of hypertension). Erectile dysfunction – affects 20-85% of men with diabetes; DM increases risk 3-fold. Occurs earlier in men with diabetes; ~age 60, worsens with age, duration of diabetes and A1c levels, treatments are less than adequate and costly. Degree of dysfunction and progression is related to glycemic control (Khatana 2009, Meena 2009) Awad 2010). It's being considered a sentinel predictor of new onset macroangiopathic events (CV) disease) (Hermans 2009) GI- nocturnal diarrhea Delayed gastric emptying Fecal incontinence Peripheral neuropathy Gait instability, risk of falls and falls: Painful neuropathy Ulcerations/amputations	See response to comments #18-19.	Measures Not Recommended

139	P	Kay Jewell, Center for Consumers of Healthcare	OT1-028-09: Bladder instability and incontinence; (neurogenic bladder); atrophic vaginitis, vaginal candidiasis and UTI Fecal impaction Memory/cognitive problems – associated with hyperglycemic control Other: Delayed wound healing Increased susceptibly to infection Hyperosmolar nonketotic coma	See response to comments #18-19.	Measures Not Recommended
14	M, Provider	Tammy Czarnecki, Department of Veterans Affairs	Concerns over the diabetes measure set: <7% measure: 1)Evidence: a.Benefit: The UKPDS trial, which is the evidence base for the recommendations, could not maintain <7% for the entire course of the trial (it was 7.3% at the end), and increased to ~ 8% after the trial was closed. b.Patients with longer onset diabetes (about 10 years) did not incur a major benefit from intensive therapy in the ACCORD or VADT trials. The benefit in VADT and ADVANCE was limited to progression of proteinuria and retinopathy. Harms: The NCQA measure excludes patients with dementia and CV disease but doesn't address other potential excluding conditions such as chronic complex illness such as mental illness or substance abuse. There are no exclusion criteria for prior serious hypoglycemia. c.Measurement issues: A single A1c test may not be accurate enough, even if performed in a laboratory using National Glycosylated Standardization Program methodology, to guide therapy. (http://www.ngsp.org/CAC2009.asp). The NCQA permits point of contact A1c testing to be used to assess "quality". These are CLIA waivered and the accuracy cannot be ascertained. Other guidelines: The VHA_DOD Diabetes Guidelines and the American College of Physicians recommend individualization of targets for patients with diabetes. Conclusion: We believe the current <7% measure as specified for patients who have longer duration may have limited benefit (especially for patients marginally above 7%) and could incur harms if physicians were motivated to over treat patients to "meet a measure	The SC discussed this measure again and noted the concerns highlighted in this comment. The Committee reaffirmed their decision not to recommend the measure. Measure developer response: Thank you for your comment. Although we recognize your concern regarding the A1c <7% measure, the recommendation to include the measure is closely tied to the most recent clinical trials from ACCORD, ADVANCE, and VADT on diabetes and expert consensus on the implications of these studies on HbA1c measurement. Therefore, it was the decision of NCQA that the evidence suggests that the benefit for control of HbA1c under 7% is for microvascular rather than macrovascular complications and the group with the most benefit and least risk are younger and earlier in the stage of their diabetes. Also, the benefit from avoiding microvascular progression requires 10-20 years to begin to be manifest with respect to important patient outcomes. Therefore, the safest control level across the vast majority of persons with diabetes is somewhere between 7-8%.	Measures Not Recommended

113	M, Health Plan	Tom James, National Network Operations	Humana would encourage reconsideration of the following two measures, which are strong measures that could have their concerns resolved. Both represent common complications that represent significant variation in occurrence: a.)OT1-011-09—Post-operative stroke or death in asymptomatic patients undergoing carotid endarterectomy b.) OT1-012-09—Coronary artery bypass graft (CABG) procedure and postoperative stroke during the hospitalization or within 7 days of discharge.	The SC reviewed this measure again. No further changes to the measure have been offered by the developer. OT1-011-09 was not recommended due to several technical concerns: lack of systematic evaluation to identify stroke; short average length of stay; and not addressing appropriateness of the procedure The SC reviewed measure OT1-012-09 again, The Committee did not believe that this candidate measure provided see any added value since NQF has endorsed a risk-adjusted 30-day stroke after CABG measure from STS. This candidate measure is not risk-adjusted and includes a shorter observation period.	Measures Not Recommended
174	M, Health Professionals	Rachel Groman, American Association of Neurological Surgeons	The AANS agrees with the Committee's decision and thinks this measure needs to be re-worked.	Thank you for your comment.	Measures Not Recommended
15	M, Provider	Tammy Czarnecki, Department of Veterans Affairs	<8% measure: 1.There are no exclusion criteria for decreased life expectancy, serious hypoglycemia, or conditions that would increase the risk of serious hypoglycemia, especially for patients on insulin. This would include dementia or cognitive impairment. 2.This is of special importance in the Medicare population 65-75 years of age given a higher prevalence of severe conditions. In the VADT there was no significant benefit in any outcome-other than progression of proteinuria, over 5.6 years in the intensive group (6.9% A1c) vs the treatment group 8.4%. 3.Measurement: Seniors without diabetes have higher A1c levels for any degree of glycemia than younger individuals; the absolute difference is about 0.4% (Pani et alDiabetes Care 2008;31:1991–6). The clinical significance is not known. We are concerned about the failure to include any exclusion criteria in the Medicare population for chronic complex illness, especially for patients on insulin. There are similar issues regarding the A1c measurement issue.	Measure developer response: Thank you for your comment. In general, the trial data from the ACCORD, ADVANCE, and VADT studies showed that the safest control level across the population of nearly all patients with diabetes is <8% (noting that for a substantial portion of the younger population of persons with diabetes, a level below is beneficial). Given the gap in care, it was the decision by NCQA that the most net benefit can be gained by focusing on reducing HbA1c levels below 8% (the gain under 7 may be small compared with reductions at higher levels). Hence, the reason NCQA did not add exclusion criteria to the <8% measure for any segment of the population.	OT1-009: Optimal Diabetes Care

43	M, Provider	Rae Williams, HealthPartners	HealthPartners medical group strongly supports this diabetes composite measure and patient level composite measures in general because they represent the best care and outcomes for the patient. Diabetic patients are less likely to suffer long term complications of renal failure, cardiovascular and peripheral vascular disease if all of their modifiable risk factors are in control. This all-or-none intermediate outcome measure supports these goals. This measure, originally developed by HealthPartners, is now collected state-wide and current scores represent over 135,000 diabetic patients. We believe that focused efforts, which include transparency of results, has led to significantly improved care and outcomes for diabetics. Rates of control have improved at the state and individual clinic level. Rates within our own medical group of 28 clinics have steadily increased from 19%(2007) to 36% (2010)patients achieving all targets.	Thank you for your comment.	OT1-009: Optimal Diabetes Care
44	M, Provider	Rae Williams, HealthPartners	It is our hope that NQF reconsiders this measure for endorsement. MN Community Measurement (MNCM) annually reviews ICSI and ADA guidelines to insure that the targets of the composite are in alignment with current guideline recommendations. When evidence and guidelines have changed MNCM convenes an expert workgroup to review the evidence and make recommendations for changes to the measure. The measure was criticized for its current blood pressure target of < 130/80, which is consistent with current ICSI and ADA guidelines, but incongruent with the 3/14/2010 ACCORD study results recommending a systolic blood pressure no lower than 135 to 140 for higher risk patients. ICSI diabetes guidelines are currently in revision and the measure developers plan to adjust the blood pressure target to align with ICSI when this guideline is released in early August 2010.	This measure has not been given a final recommendation pending the anticipated review of the ICSI guidelines in August 2010. After the guidelines and measure specifications are revised, the Steering Committee will make a final recommendation.	OT1-009: Optimal Diabetes Care
109	M, Consumer	Debra Ness, National Partnership for Women & Families	We support this measure, noting of course the concerns regarding the change in evidence base that recently were released. We look forward to seeing the review and evaluation of that measure when it is resubmitted, following the updates that will be made to reflect new evidence that pertains to that measure.	Thank you for your comment.	OT1-009: Optimal Diabetes Care

141	P	Kay Jewell, Center for Consumers of Healthcare	Should stick with <7% with exclusions. BP article that raised concern - was for 120- not 130 which is what the current recommendation is. Good to have ICSI review and recommend.	Measure Developer Response: Thank you for your comments. We understand your viewpoint about leaving the target at < 7.0 because many diabetics are better managed at this level, but applying the appropriate exclusions proved to be very burdensome in terms of data collection. In December 2008, following ACCORD study results and changes to both the ICSI Diabetes Guidelines and the American Diabetes Association Standards of care, we convened an expert workgroup to determine what the A1c component should be, at that time it was < 7.0. Initially the workgroups set out to define using available data to identify patients who were more appropriate for an A1c goal of < 7.0 and those patients who were more appropriately managed at < 8.0 due to co-morbid conditions. Some of the co-morbid conditions could be defined by ICD-9 code very reliably, like cardiovascular disease and heart failure, but other significant co-morbids like history of hypoglycemia or limited life expectancy could not be reliable captured unless resource intensive chart abstraction was undertaken for each patient. Due to the inability to define what the group felt was the most important co-morbid, history of hypoglycemia, that for measurement purposes mindful of patient safety, the A1c target for all patients was set at < 8.0. Systolic blood pressure < 130 versus < 140: Agree that the ACCORD study results were based on intensive hypertension control to a systolic BP of 120 and that our current measurement target of < 130/80 is not promoting a blood pressure target as low as the intensive arm of the ACCORD study. ICSI Diabetes guidelines are currently undergoing revision with a planned release in August 2010 and one of the areas of focus is blood pressure management. Also, recently finalized (7/13/10) Meaningful Use Measures have a measure for diabetes blood pressure control set at less than 140/90. We are most likely to align with the national measure, but need to formalize the measure change with our diabetes technical advisory group to gain consensus over the next weeks.	OT1-009: Optimal Diabetes Care

167	P	Hemal Shah, Boehringer Ingelheim Pharmaceuticals, Inc.	BI supports certain elements of the composite but would like to raise some other important issues for your consideration. Therefore, we agree with NQF's decision to withhold a final recommendation pending further evidence and deliberation. The "all-or-none" approach taken by this measure (in which practices achieve credit only if they meet all of its components) has been supported by key stakeholders in the quality measurement community. Purported benefits of this model include reflecting patient interests, fostering a system outlook, and providing a sensitive scale for performance assessment. The Optimal diabetes care measure in particular has had success in Minnesota; the statewide practice average of diabetes patients with diabetes (Type I and Type II) ages 18 to 75 who reached all of the D5 treatment goals has increased from 4 percent in 2004 to nearly 19 percent in 2009. The measure emphasizes each outcome as equally crucial in diabetes care and shows how measures can more holistically quantify best practices with respect to a disease. While "all-or-none" measures are emerging as a valuable route for performance evaluation, this model can also be burdensome to providers and may not adequately recognize whether select outcomes within the measure were achieved. Further, for certain therapeutic areas there may not be consensus as to which measures should comprise an "all-or-none" approach. We encourage NQF to carefully consider these complex issues as it considers endorsing similar measures.	The Diabetes TAP and Steering Committee discussed the pros and cons of "all or none" measures at length including the issues you have raised. The Steering Committee supported the measure concept as identifying "optimal" care and not merely adequate performance. Measure Developer Response: Thank you for your comments. As more practices move towards electronic health records (EHRs) the burden for data collection is reduced. Approximately 67% of the clinics in MN have implemented an EHR system. EHRs also allow for full population reporting, providing powerful outcome results beyond that achieved with sampling. Results for the individual components are available to providers to better understand their patient population and may be used for quality improvement purposes. Individual component results are also available on our public website www.mnhealthscores.org. Many medical groups provide patient educational material geared towards the individual goals within the all or none composite. We have a companion consumer centered website for viewing and understanding diabetes results at www.theD5.org.	OT1-009: Optimal Diabetes Care

49	M, Health Plan	Sheree Chin Ledwell, Aetna	Importantly, the definition of AMI is harmonized with the already endorsed CMS 30-day mortality measure. Aetna is concerned, however, that including transfers in or out might make risk adjustment less accurate due to risk-shifting to academic centers. We believe that clear instructions (by incorporation or link) for risk adjustment should be included with the measure specifications and public readers should be made aware how—at an appropriate level of detail—the risk adjustment works. In addition, for inpatient mortality health plans would have to rely on the accuracy of the discharge disposition on the facility bill. Historically, health plans have felt that death is underreported. Death within 30 days after discharge is a bigger problem. Social security files would have to be used to identify deaths. There is also discussion about admission with the diagnosis of AMI vs. post hospitalization evidence of AMI. It would seem that this would also be a valuable population to include if we believe that mortality is a valid metric of quality.	Measure information, including the biostatitician's evaluation of the risk model are provided in the measure information document available at http://www.qualityforum.org/projects/Patient_Outcome_Measures_Phases1-2.aspx#t=2&s=&p=6%7C. Measure Developer Response: 1st comment: Including transfers in or out might make risk adjustment less accurate due to risk-shifting to academic centers. Clear instructions for risk adjustment should be included with the measure specifications. 1st response: "Transfer-in" status is a patient factor included in the risk-adjustment model. Patients with "transfer-out" status are excluded from the denominator so that an individual patient is not double-counted (that is, the patient is included in the denominator of the receiving hospital). Since we do not assume linked data, the "accountable" hospital is the last hospital of admission. Thus, transfers out are excluded. Transferred patients are not always high risk; the impact is not always in the same "direction". 2nd comment: For inpatient mortality, health plans would have to rely on the accuracy of the discharge disposition and health plans have felt that death is underreported. 2nd response: Studies using linked vital records data (death certificates) have generally confirmed the accuracy of the coding of "in-hospital death" for the discharge disposition data element. 3rd comment: Admission with the diagnosis of AMI and post hospitalization evidence of AMI would be valuable populations to include. 3rd response: Current work at AHRQ is based on the creation of a future version of the AHRQ QIs that will include enhanced administrative data, including laboratory values, that could be used to risk-adjust or confirm the principal diagnosis. The decision was made to limit the denominator to cases with a principal diagnosis of AMI to harmonize the denominator definition with the CMS 30 day AMI mortality measure.	OT1-010: AMI Mortality Rate
88	M, Health Plan	Rebecca Zimmermann, AHIP	Support. The measure relies on administrative data and should be easily implemented.	Thank you for your comment.	OT1-010: AMI Mortality Rate

103	M, Consumer	Debra Ness, National Partnership for Women & Families	We would like to see in the final report some clarification regarding how this measure would be implemented, given that an already-endorsed CMS AMI mortality rate measure is being used in the RHQDAPU program and reported on Hospital Compare. It does note in the report that this measure is harmonized with the CMS measure, but more detail and explanation would be helpful as to implementation opportunities. As for the measure itself, we are very supportive of this measure, for it covers a much broader swath of the population than the CMS mortality measure, and it also will account for the challenges faced by small hospitals in reporting AMI mortality rates, given how it counts transfers out of the hospital.	This measure is currently being reported by several states. Examples include New York: www.myHealthFinder.com; Kentucky: http://chfs.ky.gov/ohp/healthdata/IQI.htm; Oregon: www.oregon.gov/OHPPR/HQ/Hospital_Specific_Reports.shtml. Measure developer response: Users have access to public use software (on the AHRQ QI web site: qualityindicators.ahrq.gov) and may implement the measure using their own data.	OT1-010: AMI Mortality Rate
117	M, Provider	Nancy Foster, American Hospital Association	NQF already has an endorsed AMI mortality rate measure, and it incorporates the period of the hospitalization and 30 days post admission. That measure has a sophisticated risk adjustment method and is in broad use. The report offers no indication of why another AMI mortality measure is needed, whether the inpatient only measure time frame is clinically more or less significant than the 30 day post admission period, or whether how the two risk adjustment methods compare. We see no reason to have two AMI mortality measures and suggest the committee compare the two and make a recommendation to either keep the currently endorsed measure or replace it with the AHRQ measure.	Additional information will be added to the report describing the differences in the measures and the benefits of having both measures. Unlike the 30-day mortality measure which includes only patients $\geq$ 65 years, this measures includes all patients experiencing AMI as a primary diagnosis. The inpatient measures is more feasible for some implementers since tracking out of hospital deaths can be difficult. Members of the Steering Committee also felt that knowing the proportion of in-hospital deaths was also important as well as the 30-day mortality data. Measure developer response: The in-hospital and 30-day measures are complementary, rather than alternatives. An in-hospital measure is beneficial because all hospitals can compute the measure on readily available data and in "real-time", while a 30-day measure requires access to data on out-of-hospital death, which often takes time (e.g. 2-years) to collect and to link to discharge records. In the AHRQ 30-day mortality workgroup report, the two measures had a correlation of 0.814, meaning hospitals and consumers learn most of the information in the 30-day measure from the in-hospital measures.	OT1-010: AMI Mortality Rate

119	M, Health Plan	Catherine MacLean, WellPoint, Inc.	WellPoint supports this measure for endorsement. We would like to ask whether the measure has been considered for harmonization, as it is so similar to a previously-endorsed measure. Also, we have a larger question for developers of mortality measures - would it be appropriate to exclude patients with Do Not Resuscitate orders?	See response to comment #117. All measures will be reviewed for harmonization in the upcoming cardiovascular maintenance review later this year. Measure developer response: 1st comment: Is the measure being considered for harmonization? 1st response: The NQF measure maintenance process offers a mechanism to harmonize measure specifications. AHRQ has harmonized many of its measures with other developers through this process. 2nd comment: Would it be appropriate to exclude patients with Do Not Resuscitate orders? 2nd response: The research evidence suggests that a patients' DNR status is correlated with a hospitals' mortality rate, meaning that excluding patients based on DNR status would bias the rate. The field needs a better method of identifying patients admitted only for palliative care. There are current proposals to improve coding for palliative care.	OT1-010: AMI Mortality Rate

157	M, Health Professionals	Ralph Sacco, American Heart Association, American Stroke Association; Ralph W. Brindis, President, American College of Cardiology; Frederick A. Masoudi, Chair, ACCF/AHA Task Force on Performance Measures	The incremental value of this measure above existing NQF-endorsed measures for AMI mortality is not entirely clear. The statement that the CMS mortality measure requires manual medical record abstraction is inaccurate. Specifically, the CMS model uses administrative risk adjustment that has been shown in published validation to approximate closely the results of clinical risk adjustment when applied at the hospital level. Further, this measure's severity adjustment uses a proprietary system (specifically 3M). Risk adjustment methods for any approved NQF measure should be readily available in open-source format. Otherwise, measurement endorsement can become a high-stakes process for proprietary products like risk-adjustment software.	The comments in the reports refer to endorsed measure *161 AMI inpatient mortality (TJC)* and not measure *230-AMI 30 day mortality (CMS)*. This will be clarified in the report. Measure developer response to comment on proprietary risk-adjustment method. Measure developer response: 1st comment: A question in regard to incremental value of this measure above existing NQF-endorsed measures for AMI mortality. 1st response: The in-hospital and 30-day measures are complementary, rather than alternatives. An in-hospital measure is beneficial because all hospitals can compute the measure on readily available data and in "real-time", while a 30-day measure requires access to data on out-of-hospital death, which often takes time (e.g. 2-years) to collect and to link to discharge records. In the AHRQ 30-day mortality workgroup report, the two measures had a correlation of 0.814, meaning hospitals and consumers learn most of the information in the 30-day measure from the in-hospital measures. 2nd comment: The measure's severity adjustment uses a proprietary system (3M APR DRGs). Risk adjustment methods for any approved NQF measure should be readily available in open-source format. 2nd response: The AHRQ QI software includes a limited license 3M APR-DRG grouper software at no cost in order to implement the risk-adjustment. The logic behind the assignment of any particular case to the APR-DRG and risk-of-mortality subclass is open-source even if the software to implement that assignment is proprietary.	OT1-010: AMI Mortality Rate

50	M, Health Plan	Sheeree Chin Ledwell, Aetna	A minor concern is that component 2 is an all or none measure and therefore can obscure whether improvements are occurring in individual components. The main concerns are with the star reporting system: (a) the 98% confidence intervals are unconventional and place virtually all performers in the middle—not very useful for consumer comparisons; (b) the 1-2-3 stars are not intuitive (or used in other circumstances) and would require very clear explanations. We concur with the Steering Committee that the measure is important to report (and for program improvement) but that the star system not be a required part of the report and that the default report mode is results and confidence interval. Lastly, this measure is defined and is based on abstracted data that comes from the STS database. Health plans would have to acquire this data or rely on STS metrics and results.	Measure Developer Response: (a)The 99% Bayesian probabilities used in our quality rating system are not the same as confidence intervals generated by frequents approaches. Our approach provides consumers with a simple and intuitive statement: "There is at least a 99% probability that this provider has better (worse) performance than average." This is how most people incorrectly interpret traditional confidence intervals, whose actual interpretation is much more complicated and non-intuitive. Regardless of the statistical approach used to classify outliers, there is no gold standard for the specific numerical criterion. This decision always involves a tradeoff between sensitivity for detection of outliers and specificity to avoid false outlier determination. For example, nearly a century of statistical control chart theory supports the use of 3 SD (99.7%) control limits to identify special cause variation, with 2 SD (95%) as alert or warning signals. This approach was applied to cardiac surgery over 15 years ago {1}. For the STS CABG composite, we used STS data to explore multiple different probability levels for 1 and 3 star ratings before deciding on 99%. The comment that our approach "places virtually all performers in the middle" is completely incorrect and confuses our Bayesian probability criterion with the tails of a normal distribution. In fact, using our criterion, approximately 20-30% of providers have been classified as either 1 or 3 stars each reporting period. This is a substantially higher proportion of high and low outliers than any public report card of which we are aware, including the New York CABG report card and the Hospital Compare myocardial infarction and heart failure public reports. The STS CABG composite consists of 11 individual measures, and even with a 99% criterion it is much more discriminating of performance outliers than any single measure. With our rating system, consumers are actually better informed about differences in performance, but at the same time our 99% Bayesian probability criterion protects providers from misclassification. (b) The use of this specific three-star rating system is modeled exactly on work by the leading academic expert in the area of enhancing consumer understanding of report cards, Professor Judith Hibbard {2, 3}. For a variety of reasons, we do not want to dissociate this star rating system from the numerical	OT1-013: STS CABG

89	M, Health Plan	Rebecca Zimmerman, AHIP	This measure is a composite of several individual measures that are NQF-endorsed. We are unsure if hospitals will be willing to publicly report their performance based on the STS registry data without reliability and validity testing comparing hospitals' claims data with the self-reported data from the registry. Additionally, it is unclear from the supporting materials if the data from the registry is open for users to assess what adjustments are applied.	Measure Developer Response: STS data is independently audited by the Iowa Foundation for Medical Care annually, and data quality has been high. Our risk models have been published in peer-reviewed journals, including every aspect of their development and testing, as well as all intercepts and coefficients {4-7} References: (4) O'Brien SM, Shahian DM, Filardo G, Ferraris VA, Haan CK, Rich JB, et al. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 2--isolated valve surgery. Ann Thorac Surg 2009 Jul;88(1 Suppl):S23-S42. (5) Shahian DM, O'Brien SM, Filardo G, Ferraris VA, Haan CK, Rich JB, et al. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 3--valve plus coronary artery bypass grafting surgery. Ann Thorac Surg 2009 Jul;88(1 Suppl):S43-S62. (6) Shahian DM, O'Brien SM, Filardo G, Ferraris VA, Haan CK, Rich JB, et al. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 1--coronary artery bypass grafting surgery. Ann Thorac Surg 2009 Jul;88(1 Suppl):S2-22. (7) Shahian DM, Edwards FH. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: introduction. Ann Thorac Surg 2009 Jul;88(1 Suppl):S1.	OT1-013: STS CABG

96	M, Provider	Samantha Burch, Federation of American Hospitals	The FAH continues to have concerns related to the use of registry-based measures and hospitals' ability to replicate the measure for internal quality improvement purposes. Related to implementation, we are concerned that given that the steering committee did not endorse the confidence interval or the associated star rating system, the measure could be reported one way by STS and a different way by CMS if this measure were to be adopted into the national pay-for-reporting program. We believe this could be confusing for consumers and make meaningful national comparisons difficult.	NQF has endorsed registry based measures previously from STS, NSQIP and ANA. Removing the star system and specified confidence interval from the recommendation puts this measure in the same place for implementation as all other recommended measures. No other NQF-endorsed measures have embedded reporting specifications. Measure developer response: STS data is independently audited by the Iowa Foundation for Medical Care annually, and data quality has been high. Our risk models have been published in peer-reviewed journals, including every aspect of their development and testing, as well as all intercepts and coefficients {4-7} References: (4) O'Brien SM, Shahian DM, Filardo G, Ferraris VA, Haan CK, Rich JB, et al. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 2--isolated valve surgery. Ann Thorac Surg 2009 Jul;88(1 Suppl):S23-S42. (5) Shahian DM, O'Brien SM, Filardo G, Ferraris VA, Haan CK, Rich JB, et al. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 3--valve plus coronary artery bypass grafting surgery. Ann Thorac Surg 2009 Jul;88(1 Suppl):S43-S62. (6) Shahian DM, O'Brien SM, Filardo G, Ferraris VA, Haan CK, Rich JB, et al. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 1--coronary artery bypass grafting surgery. Ann Thorac Surg 2009 Jul;88(1 Suppl):S2-22. (7) Shahian DM, Edwards FH. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: introduction. Ann Thorac Surg 2009 Jul;88(1 Suppl):S1.	OT1-013: STS CABG

104	M, Consumer	Debra Ness, National Partnership for Women & Families	We support the recommendation to endorse this measure based on its specifications, and the fact that the measures (and underlying data) that make up this composite are sound. Our concerns with this measure relate to the specification of the composite and the measure developer's assertion that it be reported at the 99% confidence interval, using a star system that is at best confusing and at worst misleading to consumers. We would appreciate receiving more information on whether this measure could be reported in a way that is consistent with other quality measures, and without a proscribed star system.	The Steering Committee recommends the measure with its numerical result similar to all other endorsed measures. The CSAC will consider the policy implications of specifying non-standard confidence intervals (98%) and embedded reporting (star) systems as part of measure specifications at the August 12 conference call. Measure developer response (also see previous response): The use of this specific three-star rating system is modeled exactly on work by the leading academic expert in the area of enhancing consumer understanding of report cards, Professor Judith Hibbard {2, 3}. For a variety of reasons, we do not want to dissociate this star rating system from the numerical score. Based on over three years of experience with using this system for a majority of US cardiac surgery programs, we understand its operational characteristics. It has been well-accepted by consumers, purchasers and providers. We do not wish to have others take our numerical scores and misuse them--for example, taking a group of hospitals that are statistically indistinguishable and subdividing them in attempt to create rank orders. References: (2) Hibbard JH, Peters E. Supporting informed consumer health care decisions: data presentation approaches that facilitate the use of information in choice. Annu Rev Public Health 2003;24:413-33. (3) Hibbard JH, Peters E, Slovic P, Finucane ML, Tusler M. Making health care quality reports easier to use. Jt Comm J Qual Improv 2001 Nov;27(11):591-604.	OT1-013: STS CABG
120	M, Health Plan	Catherine MacLean, WellPoint, Inc.	WellPoint is concerned that STS may not be able to gather enough support from hospitals to publicly report results in a meaningful way. For this measure to be useful, it will need to be publicly reported, and before it can be publicly reported, STS needs to garner support from all hospitals, not just those who are scoring well on this measure. WellPoint would also ask for STS to clarify what will be reported – is it just the composite score or will STS also provide subcomponent scores? Hospitals will need to receive subcomponent scores in order for the measure to be actionable. Lastly, since this is a very resource-intensive measure, there may be an undue burden placed on hospitals, especially those with less or no experience with STS-reporting. These issues should be addressed in order for this measure to be successful.	Measure Developer Response: STS will publish overall composite scores as well as scores for the component domains. Over 90% of programs in the US currently participate in the STS Adult Cardiac Surgery Database. Public reporting will entail no additional resource expenditure for these programs.	OT1-013: STS CABG

158	M, Health Professionals	Ralph Sacco, American Heart Association, American Stroke Association; Ralph W. Brindis, President, American College of Cardiology; Frederick A. Masoudi,	The argument used against implementing the proposed “star” system, namely that the public may have difficulty understanding the approach, seems paradoxical. Some NQF-endorsed measures require consumers to understand risk-adjusted outcome rates, which are substantially more complex than the proposed rating system. Indeed, many consumer-rating agencies use approaches like that proposed by STS specifically because they are more understandable. It is difficult to believe that consumers cannot be appropriately educated to understand that one star means less than average, two stars means average, and three stars means better than average. The ACCF and AHA urge the NQF to reconsider the decision not to endorse this consumer-friendly component of the STS measure.	Consumer members of the Steering Committee did not agree that the star system is "consumer friendly" but rather misleading as 1-2-3 stars should mean "good-better-best" when in fact, one star means "below STS average ".	OT1-013: STS CABG
53	M, Health Plan	Sheree Chin Ledwell, Aetna	The calculation of this measure would require medical record abstraction. For health plans this would be an intensive use of resources. For those using this measure, Aetna suggests that reporting should be stratified to take account of disparities.	The SC discussed this comment in detail. The Committee acknowledged the data burden but felt the burden was offset by the usefulness of the measure. There are no similar measures and the required data elements are few. Measure Developer Response: We do recognize that there is a burden of data abstraction, which we specifically estimate and comment upon in our submitted measure materials. Given the relatively low requirement for number of cases reported (~180) and the very limited data set specified by the measure, we believe the burden would actually be less than the burden currently associated with other quality measures which might be retired. The risk adjustment variables are just three: preoperative functional status (as defined), ASA Class at surgery (assessed in every surgery), and the CPT code of the procedure itself. The outcomes monitored are 16 defined outcomes. As stated in our submitted materials, we believe the measure can easily be carried out with approximately 0.125 FTE. The measure is not currently stratified by race or ethnicity. The measure is risk-adjusted, without inclusion of race or ethnicity, as per NQF guidelines. However, as stated in our submitted materials, post hoc stratification by race or ethnicity could be performed for the purpose of identifying disparities if race/ethnicity variables are collected.	OT1-015: Elderly Outcome

59	M, Provider	Kenneth Henriksen, Advocate Physician Partners	The observation about the burden of reporting in the absence of NSQIP participation applies to this proposed measure for endorsement as well. The Appendix A: Measure Specifications makes reference to a separate list of ACS NSQIP CPT Codes for evaluating the surgical procedures comprising this measure. We could not locate this separate list in the report materials limiting our ability to comment on this measure proposed for endorsement.	The list of CPT codes are located in the OT1-015-09 PDF file on the project page under the Public and Member Comment-2nd Report tab. Measure developer response: We have commented on the burden of data collection in our submitted materials and in response to other comments above. The list of CPT codes was submitted to the NQF along with all other measure materials, and was evaluated by the technical advisory panel.	OT1-015: Elderly Outcome
98	M, Provider	Samantha Burch, Federation of American Hospitals	While we believe it is extremely important to build a portfolio of measures to address the elderly population, we echo our concerns raised in our comments on the colorectal surgery outcomes measure related to the burden on hospitals of collecting the required data from numerous sources.	See response to comment #53. The Steering Committee and TAP discussed the burden of data collection during their deliberations. The developer has minimized the number of data elements to an essential few and felt the importance of the information justified the data collection burden. Measure developer response: We understand there is a natural concern about compliance burden. We have estimated and commented on that burden in our submitted materials. We have also restated those points and clarified issues about the burden in response to other comments above.	OT1-015: Elderly Outcome
108	M, Consumer	Debra Ness, National Partnership for Women & Families	We support this measure.	Thank you for your comment.	OT1-015: Elderly Outcome

123	M, Health Plan	Catherine MacLean, WellPoint, Inc.	WellPoint believes that many hospitals will not have the capacity to report this measure, since it relies on medical record review, and will require matching of administrative data (used to capture 30-day events) with medical record data. Hospitals that have been involved with NSQIP may be better able to capture and report this data, but hospitals that have not been involved with NSQIP may have significantly less reliable or valid results, as they adjust to the NSQIP reporting methodology.	See response to comment #53. Measure Developer Response: Please see the response to Aetna comment above regarding the burden associated with the measure. There is no matching to administrative data as outcomes are not captured by that mechanism. The outcomes for the measure are not defined in terms of ICD9 codes. We believe the simplicity of the measure specification and required data fields will enable any hospital to comply, and estimate that perhaps 90% of hospitals, performing more than 95% of cases in the country, will have adequate volumes to do so (as per submitted materials). It is true that hospitals already participating in NSQIP will find the measure specifications familiar, but we do not believe that this represents any performance advantage. In any actual implementation of the measure, it is likely that the implementing organization would propose an associated auditing mechanism.	OT1-015: Elderly Outcome
173	M, Health Professionals	Rachel Groman, American Association of Neurological Surgeons	The information that could be derived from this measure could be helpful in guiding decisions regarding surgery for the elderly. However, the NSQIP methodology has not been applied to neurosurgery in an extensive way (NSQIPs still working to develop a neurosurgical-focused module). According to the O/E data provided, there are significant variations among hospitals. There is a difference of greater than 25% between hospitals using specific quartile cutoffs and the 10th percentile and the 90th percentile O/E ratios showed a difference of 64%. "These statistics demonstrate the significance of the performance gap in mortality and serious morbidity outcomes in the elderly across hospital providers." As the reviewer points out, "It would be useful to have more information about the protocol for insuring consistent and reliable 30-day endpoint ascertainment. Observed differences in mortality and morbidity could conceivably reflect differences in protocols for following patients post discharge during the 30 day window. Are patients who are lost to follow up excluded from the calculations? Or, are they included and assumed not to have an event?"	Measure developer response: The measure is not limited to neurosurgery and excludes major trauma. The measure includes a CPT code risk adjustment to otherwise standardize across procedure types as described in the submission materials. We agree that a performance differential is demonstrated in our submitted data. The ACS NSQIP takes a rigorous approach to ascertaining outcomes at the 30 day postop time point, and that approach would be maintained in this measure. Institutions are encouraged to, and guided in, obtaining 30 day outcomes and the data set would include only cases with 30 day outcome information.	OT1-015: Elderly Outcome

17	P	Kay Jewell, Center for Consumers of Healthcare	This is a good composite and very valuable however, it is hard to support a composite measure when the individual measure's within are not considered solid enough to stand on their own, e.g. the A1c<7%.	NQF's Composite Measure Evaluation Framework describes the criteria for evaluating composite measures - see http://www.qualityforum.org/Publications/2009/08/Composite_Measure_Evaluation_Framework_and_National_Voluntary_Consensus_Standards_for_Mortality_and_Safety—Composite_Measures.aspx Information on NQF's composite measures evaluation framework will be added to the report. NQF's composite measure evaluation criteria does not require a measure to be endorsed as a stands alone measure to be included in a composite. After further discussion of the Hgb A1c <7 measures, the Committee will be re-evaluating this measure at the same time as the final evaluation and reocmmendation of OT1-009: Optimal Diabetes Care. Measure developer response: Thank you for your comment. Although we recognize your concern regarding the A1c <7% measure, the recommendation to include the measure is closely tied to the most recent clinical trials from ACCORD, ADVANCE, and VADT on diabetes and expert consensus on the implications of these studies on HbA1c measurement. Therefore, it was the decision of NCQA that the evidence suggests that the benefit for control of HbA1c under 7% is for microvascular rather than macrovascular complications and the group with the most benefit and least risk are younger and earlier in the stage of their diabetes. Also, the benefit from avoiding microvascular progression requires 10-20 years to begin to be manifest with respect to important patient outcomes. Therefore, the safest control level across the vast majority of persons with diabetes is somewhere between 7-8%. NCQA has submitted a separate measure of good control for HbA1c <7% (with some exclusionary criteria) for endorsement by NQF.	OT1-029: Comp. Diabetes Care

57	M, Provider	Kenneth Henriksen, Advocate Physician Partners	The descriptive specification for this measure could benefit from clarification on the measures that comprise Comprehensive Care. The narrative statement for this measure (line 270) expresses that this composite measure includes Smoking Status and Cessation Advice or Treatment. However, the Appendix A: Measure Specifications statement for this measure does not include this element. Similarly, medical literature and comments by NQF staff in the past have expressed that segmenting the measurement and reporting of smoking cessation counseling and cessation advice is not optimal when measured by individual disease state; it is more effectively evaluated and used for quality improvement at a population health level. We have an interest in seeing the manner in which the composite measure uses threshold cutoffs and weights to generate a summary score. This detail did not appear to be provided in the report materials.	NQF staff has reviewed and cross walked the various documents - revisions have been made to assure consistency. The component weightings and the summary score calculation are included in the measure submission information posted on the project page at http://www.qualityforum.org/projects/Patient_Outcome_Measures_Phases1-2.aspx#t=2&s=&p=6%7C Measure Developer Response: Thank you for your comment. The ADA guidelines recommend that patients with diabetes do not smoke and that those who do smoke receive cessation counseling or treatment. It has also been introduced as a requirement of the Diabetes Provider Recognition (DRP) program and the provider-level data submitted supports the variability across providers and that there is still much room for improvement.	OT1-029: Comp. Diabetes Care
66	M, Health Professionals	G. Timothy Petito, American Optometric Association	The American Optometric Association is pleased with the inclusion of the eye exam in the diabetes composite measure. According to AOA's Clinical Practice Guideline for the Care of the Patient with Diabetes Mellitus, patients diagnosed with DM need regular eye examinations. Examination of the patient with DM should include all aspects of a comprehensive eye examination, with supplementary testing as indicated to detect and thoroughly evaluate ocular complications. The frequency of examination is determined on the basis of several factors, including the type of DM, duration of the disease, age of the patient, level of patient compliance, concurrent medical status, and both nonretinal and retinal ocular findings.	Thank you for your comment.	OT1-029: Comp. Diabetes Care
74	M, QMRI	Bernard M. Rosof, MD, MACP, Physician Consortium for Performance Improveme	Please see "Level of measurement" comments for OT2-22-09: Proportion of patients with a chronic condition that have a PAC.	Unlike measure OT2-22-09, the developer indicates that this measure is used for clinician-level measurement . This measure is used by NCQA for its Physician Recognition program.	OT1-029: Comp. Diabetes Care

75	M, QMRI	Bernard M. Rosof, MD, MACP, Physician Consortium for Performance Improveme	Clarification: We have noticed that measure OT1-029-09 appears in the report with two different names: Diabetes Composite (as on page 14 of the PDF report) and Comprehensive Diabetes Care (as on page 51 of the PDF report). We suggest that one name be used throughout the document.	We agree - the name has been standardized in the revised draft.	OT1-029: Comp. Diabetes Care
82	M, QMRI	Nancy H. Nielsen, MD, PhD, American Medical Association	Please see "Level of measurement" comments from OT2-022-09: Proportion of patients with a chronic condition that have a PAC.	Unlike measure OT2-22-09, the developer indicates that this measure is used for clinician-level measurement . This measure is used by NCQA for its Physician Recognition program.	OT1-029: Comp. Diabetes Care
83	M, QMRI	Nancy H. Nielsen, MD, PhD, American Medical Association	Clarification: We have noticed that measure OT1-029-09 appears in the report with two different names: Diabetes Composite (as on page 14 of the PDF report) and Comprehensive Diabetes Care (as on page 51 of the PDF report). We suggest that one name be used throughout the document.	We agree - the name has been standardized in the revised draft.	OT1-029: Comp. Diabetes Care
90	M, Health Plan	Rebecca Zimmerman, AHIP	Support.	Thank you for your comment.	OT1-029: Comp. Diabetes Care

99	M, Health Professionals	Janet Leiker, on behalf of the AAFP Commission on Quality and Practice, American Academy of Family Physicians	The AAFP supports the diabetes composite measure overall. There is a concern regarding the use of the same targets across such a large population (18-75 yrs old, type 1 & 2). These targets may be appropriate for some patients but not others. There are no exclusions to allow for consideration of individualized care and treatment goals.	Measure Developer Response: Thank you for your comment. The components of the submitted composite measure were included based on existing guideline recommendations for diabetes care and expert consensus. We recognize your concern about individualized care. The composite is flexible in that 100% performance is not required for the component measures and the targets included are the most reasonable based on existing evidence. We have included exclusions for the A1c <7% component only.	OT1-029: Comp. Diabetes Care
105	M, Consumer	Debra Ness, National Partnership for Women & Families	We support this measure.	Thank you for your comment.	OT1-029: Comp. Diabetes Care
112	M, Health Plan	Tom James, National Network Operations	Disagree with the inclusion of "smoking status and cessation advice or treatment" as part of the measure. That element is a process measure that does not hold up well in studies, per the Joint Commission article in the NEJM last month. The other elements are measureable and represent outcome measures. Without smoking status notation, this composite could be drawn from administrative or clinical sources. With the measure it requires chart audit.	Measure Developer Response: Thank you for your comment. The ADA guidelines recommend that patients with diabetes do not smoke and that those who do smoke receive cessation counseling or treatment. It has also been introduced as a requirement of the Diabetes Provider Recognition (DRP) program and the provider-level data submitted supports the variability across providers and that there is still much room for improvement.	OT1-029: Comp. Diabetes Care

127	M, Health Plan	Catherine MacLean, WellPoint, Inc.	WellPoint supports this composite measure and its component measures, except for component measure HbA1c < 7.0. An HbA1c < 7.0 is not indicated for all patients and may lead to poor outcomes in some patients. There is stronger evidence for reducing higher HbA1c levels than driving patients below 7. NCQA has a different denominator population for this measure to address the patients that might be harmed by HbA1c < 7.0. For these reasons, we do not support this component measure. We would also like to note that data collection is still difficult because CPT II codes are not routinely admitted and it is costly to collect lab values. Lastly, WellPoint would like to ask NCQA to be clearer about how it will report the total score. Available component scores should be available in addition to the total composite score for quality improvement purposes.	The Steering Committee will re-evaluate this measure with the Optimal Diabetes Care composite measure again in light of further discussion of the Hgb A1c < 7 measure. Measure Developer Response: Thank you for your comment. This measure has been collected as part of the Comprehensive Diabetes Care composite measure set for the HEDIS population for two years. the data collected indicates that there is significant variation among organizations and that there is room for improvement in the management of this select population. It has also been introduced as a requirement of the Diabetes Provider Recognition (DRP) program and the provider-level data submitted supports the variability across providers and that there is still much room for improvement. According to the evidence, lowering A1c to below or around 7% has been shown to reduce microvascular and neuropathic complications of type 1 and type 2 diabetes	OT1-029: Comp. Diabetes Care
140	P	Kay Jewell, Center for Consumers of Healthcare	Good measure - much needed but it is hard to support a composite when all the measures within are not considered able to stand alone.	NQF's Composite Measure Evaluation Framework describes the criteria for evaluating composite measures - see http://www.qualityforum.org/Publications/2009/08/Composite_Measure_Evaluation_Framework_and_National_Voluntary_Consensus_Standards_for_Mortality_and_Safety—Composite_Measures.aspx Information on NQF's composite measures evaluation framework will be added to the report. The composite criteria requires that the component measures be evaluated against the criteria but are not required to be sufficiently important as a stand alone measure.	OT1-029: Comp. Diabetes Care

159	M, Health Professionals	Ralph Sacco, American Heart Association, American Stroke Association; Ralph W. Brindis, President, American College of Cardiology; Frederick A. Masoudi, Chair, ACCF/AH	It is possible that we are misinterpreting the specifications for this measure due to the difficult tabular format, as noted above, but it appears that this measure doesn't discriminate between good and poor glycemic or blood pressure control. Moreover, even if it did, there is no evidence that glycemic targets are particularly helpful which, we would note, is given as the reason for not recommending endorsement of measure OT1-028-09—HbA1c Control for a Selected Population. Please also note that several of the numerator components listed in Appendix A (LDL-C screening, BP <130/80 mmHg, BP <140/90 mmHg) were not accurately duplicated in the list in the discussion section of the report, which created some confusion for our reviewers.	The measure submission forms have the final specifications. Apparently Appendix A did not include all the late changes. Corrections have been made in the revised report.	OT1-029: Comp. Diabetes Care
166	P	Hemal Shah, Boehringer Ingelheim Pharmaceuticals, Inc.	BI supports the endorsement of this composite. These eight measures provide a holistic assessment of the many aspects that are part of diabetes management. Because diabetes is a multi-faceted condition, the care provided to patients must address all aspects of the disease. In light of this fact, we recommend revision of the nephropathy assessment measure specifications. This measure currently does not include estimated glomerular filtration rate (eGFR) testing in the specifications only urine micro and macro-albumin testing. eGFR monitoring in the assessment of nephropathy is included in widely-accepted clinical guidelines. Incorporating this test into the measure specifications would ensure that providers utilize it consistently. As such, BI urges NQF to discuss the potential revision of this specification with the National Committee for Quality Assurance (NCQA), the measure developer.	Measure Developer Response: Thank you for your comment. This measure has been collected as part of the Comprehensive Diabetes Care composite measure set for the HEDIS population for years. We recognize your concern regarding eGFR and will take this into consideration as we work to re-evaluate the nephropathy measure.	OT1-029: Comp. Diabetes Care

168	P	Hemal Shah, Boehringer Ingelheim Pharmaceuticals, Inc.	NQF notes that recent ACCORD findings suggest that the blood pressure (BP) threshold in this measure should be less aggressive. While BI acknowledges and supports the importance of considering newly published literature during the measure endorsement process, we urge NQF to also rely on the larger body of evidence on this topic. ACCORD has produced compelling results that prompt reflection in the diabetes community about how this study's finding can be incorporated into the larger body of evidence on management of diabetes. It is for this reason that we recommend that NQF postpone its decision for endorsement of this measure until relevant clinical guidelines are revised and released (e.g., those of the American Society of Hypertension, Institute for Clinical Systems Improvement, and the Eighth Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC 8)). Each of these entities will independently consider the ACCORD findings and will have valuable perspectives on the appropriate BP threshold for diabetes patients.	The Steering Committee will be re-evaluating both diabetes composite measures again after revisions to OT1-009-09 Optimal Diabetes Care are submitted (expected August 2010.)	OT1-029: Comp. Diabetes Care
169	P	Hemal Shah, Boehringer Ingelheim Pharmaceuticals, Inc.	Finally, BI agrees with NQF Committee member recommendations that the measure developer (Minnesota Community Measurement) consider adding metrics on eye examinations and renal function to this composite. We would additionally note that Body Mass Index (BMI) is another significant characteristic that has clear implications for diabetes management, as has been noted in national clinical guidelines; as such, this should also be considered for inclusion in this composite. These are all important aspects of diabetes management that should be applied to every patient. Like the proposed NCQA measure, we believe these metrics in tandem would provide a holistic assessment of diabetes management.	Measure Developer Response: Thank you for your comments. We agree that there are many processes that are important for the management of patients with diabetes for the prevention or reduction of complications. Measuring processes tells you that a service was performed, but does not demonstrate achievement of treatment goals. Focusing on Intermediate outcomes gets us closer to the goal of reducing the long term complications of this chronic disease. It is more valuable to know, for example, that 57% of patients had an LDL < 100 than 92% of the patients had an LDL lab test done in the last 12 months. At a recent measurement committee meeting, our members were discussing the value of publicly reporting a separate measure for retinal eye exams for diabetes patients. Currently, our state's HEDIS rates for this measure hover between 60 and 70%, but there are some potential flaws with this claim based measure in that patients who have their exams at Vision World or Wal-Mart are not necessarily captured by claims and included in this rate. One group's analysis of their diabetic patients demonstrated that 35% of patients were receiving their eye exams at one of these alternative locations.	OT1-029: Comp. Diabetes Care

9	M, Health Plan	Tariq Abu-Jaber, WellPoint, Inc.	Throughout the health care community, there is a rapidly growing interest and sense of urgency in establishing clinically meaningful metrics for defining the quality of care delivered by providers of all types. Our ability, as an industry and as a nation, to provide quality care at a sustainable cost demands that we develop universally accepted measures that allow us to distinguish relative care quality. Most of the measures currently used – as valuable as they are – focus on the process of care, the provision or omission of services. Outcomes measures are often cited as a "holy grail" in this field. Prometheus' Potentially Avoidable Complications metrics move towards this objective by removing the focus from the mechanical provision of an important service for a diagnosis (or avoidance of an inappropriate service) to the clinical result of the sum total of their care. Monitoring Potentially Avoidable Complications holds the promise of offering metrics that fully reflect outcomes. In addition, these are highly patient-centric metrics, since they look not only at the narrow range of activities related to a specific service performed or diagnosis treated, but to the patient's holistic experience resulting from their care, across all co-morbidities. For these reasons, I support the endorsement of Prometheus's PACs, including the Proportion of AMI	Thank you for your comment.	OT1-030: AMI-PAC
13	P	John Brush, Healthcare Incentives Improvement Institute, Inc.	The current high rate of potentially avoidable complications (PACs) represents an enormous opportunity to improve care and bring down health care costs. This measure incentivizes providers to broaden the scope of care and address outcomes that are of real concern to the patient. The risk-adjustment addresses the possible unintended consequences of incentivizing providers to shirk sick patients. Measuring and reporting PACs creates an opportunity, through payment reform, for providers to see a return on up-front investments to improve care.	Thank you for your comment.	OT1-030: AMI-PAC
56	M, Provider	Kenneth Henriksen, Advocate Physician Partners	The descriptive specification for this measure could benefit from clarification on the time period to be employed for measurement.	Measure Developer Response: The time windows are clearly defined for each of the measures in the measure specification. Chronic PACs are all PACs that occur during the one-year time window. Acute Medical PACs are all PACs that occur either during the index stay or during the 30-day post-acute time window of the acute medical event.	OT1-030: AMI-PAC
71	M, QMRI	Bernard M. Rosof, MD, MACP, Physician Consortium for Performance	Please see "Level of measurement", "Potentially avoidable complications – Definitions" and "Reliability" comments for OT2-22-09: Proportion of patients with a chronic condition that have a PAC.		OT1-030: AMI-PAC

79	M, QMRI	Nancy H. Nielsen, MD, PhD, American Medical Association	Please see "Level of measurement" and "Potentially avoidable complications - Definitions" comments from OT2-022-09: Proportion of patients with a chronic condition that have a PAC.		OT1-030: AMI-PAC
111	M, Health Plan	Tom James, National Network Operations	In the younger age group the causes of AMI include congenital anomalies as well as premature CAD so the population is different than a population aged 40 or older. Did the measure developer take different etiologies of AMI into account in developing this measure. Otherwise this is fine.	Measure Developer Response: We focused our developmental effort on commercially insured populations, between the ages of 18 and 65 years. Less than 2% of our AMI population was <40 years of age, with only 0.3% being between ages 18 and 29.	OT1-030: AMI-PAC
125	M, Health Plan	Catherine MacLean, WellPoint, Inc.	WellPoint supports this measure (as mentioned in a previous comment). We do have additional technical comments. Since the percentage of PACs in a region may be related to a number of issues (eg, patient access to care, the number of providers in an area, etc.), we believe that other measures would help to inform public understanding of the measure. Also, reporting PACS alone may be too broad to be useful – for QI purposes, providers may need access to rates for each type of PAC. Lastly, the denominator uses the phrase, "patients who were followed for one month after discharge." This implies that if patients aren't followed, they won't be included – this could lead to biased results if a provider has poor follow-up or if a provider only follows up with patients that are likely to have positive outcomes (e.g., healthier, less complicated patients). We would ask BTE to clarify how this will be addressed, or if it will also report percentage of patients lost to follow up.	Measure Developer Response: Currently the measure is developed based on claims data and so is limited to information that can be obtained from claims data. Access issues are very important and should be an integral part of any outcome measure. But that information is not available in claims data. The exclusion for lack of one year of follow-up only applies to plan members who have lost enrollment during the measurement window, not because they didn't receive follow-up care. As such, lack of follow-up care in a continuously enrolled patient would certainly not be an exclusion criteria.	OT1-030: AMI-PAC
143	P	Kay Jewell, Center for Consumers of Healthcare	Support	Thank you for your comment.	OT1-030: AMI-PAC

154	M, Health Professionals	Ralph Sacco, American Heart Association, American Stroke Association; Ralph W. Brindis, President, American College of Cardiology; Frederick A. Masoudi, Chair, ACCF/AHA Task Force on Performance Measures	We agree that the proportion of patients with a chronic condition with potentially avoidable conditions should not be aggregated at the individual clinician level. However, there is little justification why the other Bridges to Excellence measures permit aggregation at the practitioner level. It is not clear that practitioner-level linkage is feasible in most data systems, and also not clear that this approach will yield adequately robust denominators. We would strongly suggest aggregation at the institution or health plan levels. It is also not clear that administrative codes can identify potentially avoidable complications (PACs) in a valid manner. Although this is concerning for all of the measures, it seems particularly problematic for the PACs identified during the index hospitalization for acute conditions like stroke or MI. Indeed, many of the purported PACs are also manifestations of severe cases of the underlying condition. For instance, a patient who is admitted to the hospital with an acute MI (AMI) who is being transferred to the catheterization laboratory in a timely manner from the Emergency Department and suffers ventricular fibrillation (VF) in transit would result in a decrement in performance, despite the fact that the VF would reasonably be considered part of the clinical course of severe AMI. The ACCF and AHA urge NQF not to endorse these measures until there are adequate data validating the use of the proposed administrative codes against clinical data in identifying such events as PACs.	Measure Developer Response: The level of analysis for all the four measures is stated to be at the clinician group level, and not at an individual fractioned level. The measure is structured to encompass hospital care plus post-acute care, and an accountable entity in some locations could be a clinical group. In many regions, hospitals may not be able to take on accountability for post-acute care. Currently datasets that are most readily available are administrative datasets. Even though they may not be as authentic or as complete as clinical datasets, several papers (see enclosed Krumholz 2006 and Pine 2007) have been written showing the value of such datasets as compared to information obtained from expensive, cumbersome chart review. Until such time that EMRs are far more widely available, we may have to resort to less than ideal datasets rather than have no outcome measures at all. Yes, VF in the setting of AMI may be part of the clinical course, as is death. However, our point in measuring these complications is that they are not ALWAYS part of the natural clinical course. As such we measure VF in the same way that mortality is measured for AMI patients....because it matters to the patient for whom it could be prevented.	OT1-030: AMI-PAC

10	M, Health Plan	Tariq Abu-Jaber, WellPoint, Inc.	Throughout the health care community, there is a rapidly growing interest and sense of urgency in establishing clinically meaningful metrics for defining the quality of care delivered by providers of all types. Our ability, as an industry and as a nation, to provide quality care at a sustainable cost demands that we develop universally accepted measures that allow us to distinguish relative care quality. Most of the measures currently used – as valuable as they are – focus on the process of care, the provision or omission of services. Outcomes measures are often cited as a "holy grail" in this field. Prometheus' Potentially Avoidable Complications metrics move towards this objective by removing the focus from the mechanical provision of an important service for a diagnosis (or avoidance of an inappropriate service) to the clinical result of the sum total of their care. Monitoring Potentially Avoidable Complications holds the promise of offering metrics that fully reflect outcomes. In addition, these are highly patient-centric metrics, since they look not only at the narrow range of activities related to a specific service performed or diagnosis treated, but to the patient's holistic experience resulting from their care, across all co-morbidities. For these reasons, I support the endorsement of Prometheus's PACs - including the Proportion of Stroke Patients that have a PAC - as NQF Patient Outcomes Measures.	Thank you for your comment.	OT1-031: Stroke-PAC

47	M, Health Plan	Sheree Chin Ledwell, Aetna	Aetna recommends this measure for endorsement, only if NQF has plans for an annual review of published results or establish a time limited endorsement. More importantly, NQF needs to ensure that risk adjusters are present at the onset of the episode. Risk adjustment would be indicated, e.g. to adjust for members with multiple conditions that can lead to the instability that potentially adds to the propensity for PACs. Our primary concern is that much of this quality monitoring system may only have face validity. Not all 'complications' apply to all of the designated chronic conditions. Nevertheless, this is a major and important attempt to assess a system's ability to detect and reduce PACs. It is not intended that PACs can be eliminated, which suggests that the "potentially" needs very clear explanation especially to the public (otherwise readers might think that if something is "potentially" avoidable it should BE avoidable). The PAC concept is tied to the PROMETHEUS payment system and represents a strong initiative to rationalize P4P at a system rather than individual physician level. The PAC construct would be valuable for PCMHs that uses Health Information Exchange (HIE).	This measure does not meet the criteria for time-limited endorsement. After endorsement all measures undergo maintenance review every 3 year. Review of current data is part of maintenance updates. Measure developer response: As specified, the measures include severity adjustment. Please see attached document specific to PACs and risk-adjustment.	OT1-031: Stroke-PAC
55	M, Provider	Kenneth Henriksen, Advocate Physician Partners	The descriptive specification for this measure could benefit from clarification on the risk adjustment methodology recommended. In order to accurately compare performance results from one entity to another, comparable risk adjustment practices need to be employed consistently.	Measure Developer Response: We have a consistent risk-adjustment methodology that is used to adjust for the severity of the population studied (see enclosed report).	OT1-031: Stroke-PAC
72	M, QMRI	Bernard M. Rosof, MD, MACP, Physician Consortium for Performance Improveme	Please see "Level of measurement", "Potentially avoidable complications – Definitions" and "Reliability" comments for OT2-22-09: Proportion of patients with a chronic condition that have a PAC.		OT1-031: Stroke-PAC

80	M, QMRI	Nancy H. Nielsen, MD, PhD, American Medical Association	Please see "Level of measurement" and "Potentially avoidable complications - Definitions" comments from OT2-022-09: Proportion of patients with a chronic condition that have a PAC.		OT1-031: Stroke-PAC
126	M, Health Plan	Catherine MacLean, WellPoint, Inc.	WellPoint supports this measure (as mentioned in a previous comment). We do have additional technical comments. Since the percentage of PACs in a region may be related to a number of issues (eg, patient access to care, the number of providers in an area, etc.), we believe that other measures would help to inform public understanding of the measure. Also, reporting PACS alone may be too broad to be useful – for QI purposes, providers may need access to rates for each type of PAC. Lastly, the denominator uses the phrase, "patients who were followed for one month after discharge." This implies that if patients aren't followed, they won't be included – this could lead to biased results if a provider has poor follow-up or if a provider only follows up with patients that are likely to have positive outcomes (e.g., healthier, less complicated patients). We would ask BTE to clarify how this will be addressed, or if it will also report percentage of patients lost to follow up.	Measure Developer Response: Currently the measure is developed based on claims data and so is limited to information that can be obtained from claims data. Access issues are very important and should be an integral part of any outcome measure. But that information is not available in claims data. The exclusion for lack of one year of follow-up only applies to plan members who have lost enrollment during the measurement window, not because they didn't receive follow-up care. As such, lack of follow-up care in a continuously enrolled patient would certainly not be an exclusion criteria.	OT1-031: Stroke-PAC
144	P	Kay Jewell, Center for Consumers of Healthcare	Support	Thank you for your comment.	OT1-031: Stroke-PAC

146	M, Health Professionals	Ralph Sacco, American Heart Association, American Stroke Association	The ASA would like to take this opportunity to oppose the endorsement of this measure by NQF for a number of reasons, each of which is delineated in more detail in this letter, but can be summarized as follows: There is insufficient evidence to support the risk-adjustment model used in this measure. While we agree that risk adjustment is necessary when evaluating stroke outcomes, the ASA does not feel there is sufficient evidence to support the risk-adjustment model proposed for the OT1-031-09 measure. First, in the case of measures that require risk-adjustment, it is important that appropriate studies be conducted to assess the value of the measure and to validate the risk-adjustment model. To our knowledge, the performance of the OT1-031-09 measure, and its risk-adjustment model, has not been evaluated and the results published in a peer-reviewed publication. As a result, there is no way to substantiate that this model provides adequate discrimination of a potentially avoidable complication (PAC) at the patient or hospital level, or has adequate calibration at the hospital level. Second, according to the measure description, the model is calibrated to predict stroke costs: "Conditions and services that lead to higher costs and increased resource consumption are weighted more heavily in our model." Based on our review of this measure, the developer applied a cost model to adjust for complications for this PAC measure. The ASA does not believe it is appropriate to correlate that a model which predicts costs will work similarly well to predict stroke complications.	Measure Developer Response: The risk-adjustment model that we have used has been published in a peer-reviewed publication as part of a study on knee-replacement episodes (see enclosed Rastogi 2009). The severity adjustment method used in that work is the same as the severity adjustment in these measures. We disagree with the AHA/ASA's statement on predictability of stroke complications. PACs don't predict stroke complications, they measure them. The severity-adjustment model is not designed to predict occurrences, but rather to adjust the observation of PAC occurrences between measured organizations based on the relative severity of each organization's population. Severity adjustment is designed to explain variation related to factors such as age, gender, co-morbid conditions that are not a consequence of the care received and are therefore appropriate adjusters. Cost is used as a surrogate for intensity of services e.g. use of DME in frail patients. The balance of the variation in PACs from one institution to another would therefore come from factors other than patient factors, e.g. institutional factors such as patient safety processes, etc.	OT1-031: Stroke-PAC

147	M, Health Professionals	Ralph Sacco, American Heart Association, American Stroke Association	Third, without stroke severity the ability to risk-adjust will be limited regardless of type of administrative data used. It is well known that presenting stroke deficit severity is the single dominating prognostic factor, yet this factor is not included in the measure's model even though this is the strongest predictor of adverse outcomes. Most administrative data sets do not reliably collect stroke severity information such as the NIH Stroke Scale which is a strong predictor of outcomes. No disease severity adjustment algorithm for stroke that fails to incorporate presenting deficit severity is acceptable for use in a quality measure, irrespective of how many other factors it incorporates. Finally, it would be preferable to have a measure focused on a more limited set of complications, or a single complication, for which there is better evidence that the complications are partly avoidable and cause excess mortality less attributable to baseline severity such as pneumonia, deep vein thrombosis (DVT), and urinary tract infection.	Measure Developer Response: As specified, conditions and complications present on admission would be excluded. We disagree with the position taken by the AHA/ASA that a more limited set of PACs would be a more valid measure. The purpose of this measure is to create "system" accountability around the patient. The comments of the ASA/AHA seem to be centered on a very tight definition of accountability which is partially, we believe, the reason why there are few, if any, patient-centered systems of care. This measure is designed to create broad accountability for the many complications that occur to patients who suffer from strokes.	OT1-031: Stroke-PAC

148	M, Health Professionals	Ralph Sacco, American Heart Association, American Stroke Association	The ASA believes that quality measures should only measure that which a hospital healthcare team has the ability to influence or control. Too many of the PACs included in the OT1-031-09 measure will occur as a function of the patient's disease severity and co-morbidities, and not the care that the patient receives at the hospital. To illustrate this point, we have included in this comment letter some examples of the concerns that we have with the proposed list of "preventable events" included in this measure. In the proposed measure specifications, the measure developer includes in the description for PACs during the index stay (Hospitalization), the following language: 1) 1 or > PACs related to the index condition (S) during initial hosp: hypertensive encephalopathy, malignant HTN, coma, anoxic brain damage, or resp failure, etc. resulting directly from S or its management. 2) PACs due to comorbidities: developed if comorbid conditions are not controlled or exacerbated during the hosp (i.e., not present on admission). Eg: diabetic emergency with hypo- or hyperglycemia, pneumonia, lung complications, AMI, gastritis, ulcer, GI hemorrhage, etc. 3) PACs suggesting patient safety failures: Examples: septicemia, meningitis, other infections, phlebitis, DT, pulmonary embolism, or any of the CMS-defined hosp acquired conditions (HACs). Many of the above conditions reflect the patient's initial presentation, which in turn may reflect their pre-morbid status, their own delays in seeking care, as well as the primary care that they received before hospitalization.	Measure Developer Response: As mentioned in the prior response, the AHA/ASA seem to oppose the use of any measures that would bind a team together, arguing that there are no such teams. We argue that the lack of measures that create system wide accountability is partially the reason why there are no teams. As such PACs include events that occur outside the hospital, post-discharge, while the patient is in the community. These potentially avoidable complications are, in fact, potentially avoidable, and a true team approach to care that would cut across institutional boundaries would enable their avoidance.	OT1-031: Stroke-PAC

149	M, Health Professionals	Ralph Sacco, American Heart Association, American Stroke Association	With respect to “PACs due to comorbidities,” the ASA would note that there is no evidence that a process exists that can be performed by the health care team to prevent acute myocardial infarction (AMI). While the chance of exacerbation of AMI after stroke can be reduced with good medical care, which includes the administration of medications such as ASA, Statin, ACE-I, even with these drugs, an AMI event may still occur and cannot be said to be "avoidable." Another area of concern is the inclusion of dysphagia as a preventable event. Dysphagia occurs as a result of stroke, not based on the treatment that is provided by the institution. While it is well known that patients with dysphagia are at high risk for pneumonia, even if an institution withholds oral input, very large ischemic strokes may still develop pneumonia. While there is evidence that performing a dysphagia screen reduces the risk of pneumonia, dysphagia screening does not eliminate the risk of pneumonia developing. There is no adequate risk prediction model, as of yet, that can predict development of pneumonia. Furthermore, there are only a few potentially avoidable complications for ischemic stroke. Deep vein thrombosis (DVT), and perhaps congestive heart failure, or urinary tract infection are complications for ischemic stroke which can be reasonably avoided. Other patient outcomes that are not necessarily avoidable include “coma” due to malignant MCA infarction or large intracerebral hemorrhage, “anoxic brain injury” in ischemic stroke and events that are known to be not reliably codable in stroke patients (e.g.; “respiratory failure” since many patients are intubated for airway protection, not respiratory failure).	Measure developer response: We agree dysphagia could be a consequence of the stroke and is NOT a PAC and it is not in our list of PACs. We do not argue, nor have we argued, that PACs are absolutely avoidable. However, we feel strongly that even if one event can be avoided, then it is worthy to be measured. We are pleased that in their comments, AHA/ASA have outlined best practices that could be more universally adopted to avoid these potential complications. That is exactly what we want this measure to stir up, to let the provider community develop processes of care to cut down the occurrences of these PACs. If implementing best practices can avoid a single AMI, a single pneumonia, we feel the measure has served its purpose. Not measuring a potentially avoidable complication because it's hard to avoid is tantamount to saying that it's ok if it happens. We don't think it's ok and neither do the patients to whom it happens.	OT1-031: Stroke-PAC

150	M, Health Professionals	Ralph Sacco, American Heart Association, American Stroke Association	Additionally, we are concerned with the 30 day post-discharge component of the measure. For example, the PACs "During 30-Days Post-DC" states in Section 3 that: PACs suggesting pt safety failures: Readm & ER visits 30-days post-dc if due to: sepsis, infections, DVT, pulmonary embolism, or for any of the CMS-defined hosp acquired conditions (HACs). The ASA disagrees with the measure developer's intent to attribute to any one facility a DVT that occurs at anytime within 30 days. The primary (or first) institution has total control over prevention while caring for the patient. Once a patient leaves the health care facility (unless the patient leaves to their home) the new facility is also now responsible to continue to prevention measures. The first institution has no control over what is done at the second, and visa versa. Finally, we do not believe that there is adequate data source to capture this data reliably post hospital discharge and administrative codes are entirely unsuitable. Over the long term, hospitals should function as part of systems that include the community and primary care. However, at present, we do not believe it is appropriate to judge hospitals on the criteria included in this measure.	Measure Developer Response: We do not specify in our measure who the PAC should be attributed to. It could be attributed to the health system, provider group or any other accountable entity that AHA /ASA or any other body wants to hold responsible. We agree the whole purpose of the measure is to create system accountability.	OT1-031: Stroke-PAC
151	M, Health Professionals	Ralph Sacco, American Heart Association, American Stroke Association	III. This measure inappropriately limits the population age to 18-65 years of age Our last comment addresses the age parameters for this measure. After reviewing the measure specifications, the ASA does not understand why this measure is confined to patients between the ages of 18-65. A large number of strokes occur in patients 65 and older. Based on pooled data from the Framingham Heart Study, Atherosclerosis Risk in Communities and Cardiovascular Health Study studies of the National Heart, Lung, and Blood Institute, the percent who die one year following a first stroke are as follows5: – At ages 40–69: 14 percent of white men, 20 percent of white women, 19 percent of black men and 19 percent of black women; and - At age 70 and older: 24 percent of white men, 27 percent of white women, 25 percent of black men and 22 percent of black women. Given the number of strokes that occur over the age of 65, we are uncertain as to why the measure developer decided to exclude this patient population.	Measure Developer Response: We agree that stroke is an important condition in the elderly. However, our database was limited to an under 65 commercially-insured population. Since then we have studied PACs in 20 other health plan databases all having commercially insured populations. We have not had access to linked Medicare data to create a unit of accountability around a stroke index condition along with post-acute care information. As such, our measure only applies to a commercially insured population.	OT1-031: Stroke-PAC

152	M, Health Professionals	Ralph Sacco, American Heart Association, American Stroke Association	In conclusion, the ASA does not support the adoption of the measure OT1-031-09: Proportion of patients hospitalized with stroke that have a potentially avoidable complication (during the index stay or in the 30-day post-discharge period). Currently, there is not sufficient data to support the risk-adjustment model which is the basis for this measure. This measure includes "preventable events" which are unavoidable by an institution, even if it has a coordinated healthcare quality team. Finally, a significant number of strokes occur after the age of 65, yet this measure limits the age range to 18-65 years of age. If the NQF believes there is a need to have such a measure endorsed at this time, the ASA would be willing to put together a panel of stroke content experts to work with the methodologists who developed OT1-031-09 in order to create a version of this measure that would be useful for assessing stroke care.	Measure Developer Response: Currently there is a dearth of outcomes measures. ASA's offer to put together a panel of stroke experts is laudable. When ASA does come up with such a measure, we would be happy to retire or update this measure.	OT1-031: Stroke-PAC
155	M, Health Professionals	Ralph Sacco, American Heart Association, American Stroke Association; Ralph W. Brindis, President, American College of Cardiology; Frederick A. Masoudi, Chair, ACCF/AHA Task Force on Performance Measures	We agree that the proportion of patients with a chronic condition with potentially avoidable conditions should not be aggregated at the individual clinician level. However, there is little justification why the other Bridges to Excellence measures permit aggregation at the practitioner level. It is not clear that practitioner-level linkage is feasible in most data systems, and also not clear that this approach will yield adequately robust denominators. We would strongly suggest aggregation at the institution or health plan levels. It is also not clear that administrative codes can identify potentially avoidable complications (PACs) in a valid manner. Although this is concerning for all of the measures, it seems particularly problematic for the PACs identified during the index hospitalization for acute conditions like stroke or MI. Indeed, many of the purported PACs are also manifestations of severe cases of the underlying condition. For instance, a patient who is admitted to the hospital with an acute MI (AMI) who is being transferred to the catheterization laboratory in a timely manner from the Emergency Department and suffers ventricular fibrillation (VF) in transit would result in a decrement in performance, despite the fact that the VF would reasonably be considered part of the clinical course of severe AMI. The ACCF and AHA urge NQF not to endorse these measures until there are adequate data validating the use of the proposed administrative codes against clinical data in identifying such events as PACs.	Measure Developer Response: The level of analysis for all the four measures is stated to be at the clinician group level, and not at an individual fractioned level. The measure is structured to encompass hospital care plus post-acute care, and an accountable entity in some locations could be a clinical group. In many regions, hospitals may not be able to take on accountability for post-acute care. Currently datasets that are most readily available are administrative datasets. Even though they may not be as authentic or as complete as clinical datasets, several papers (see enclosed Krumholz 2006 and Pine 2007) have been written showing the value of such datasets as compared to information obtained from expensive, cumbersome chart review. Until such time that EMRs are far more widely available, we may have to resort to less than ideal datasets rather than have no outcome measures at all. Yes, VF in the setting of AMI may be part of the clinical course, as is death. However, our point in measuring these complications is that they are not ALWAYS part of the natural clinical course. As such we measure VF in the same way that mortality is measured for AMI patients....because it matters to the patient for whom it could be prevented.	OT1-031: Stroke-PAC

156	M, Health Professionals	Ralph Sacco, American Heart Association, American Stroke Association; Ralph W. Brindis, President, American College of	Our colleagues at the American Stroke Association recently sent you a letter outlining their significant concerns regarding this measure. The ACCF and AHA support the position taken in their letter and urge the NQF to carefully consider their detailed comments.	Thank you for your comment.	OT1-031: Stroke-PAC
165	P	Hemal Shah, Boehringer Ingelheim Pharmaceuticals, Inc.	BI supports the endorsement of this measure. An assessment of complications among stroke patients post-hospital discharge may help to improve patient management during this time. Deep vein thrombosis (DVT) and pulmonary embolism (PE) should clearly be considered PACs under this measure since they are important complications after stroke and a significant reason for morbidity and mortality in acute stroke patients. Early diagnosis and timely use of anticoagulant for prophylaxis against DVT and PE post-stroke has been shown to be effective.	Thank you for your comment.	OT1-031: Stroke-PAC
170	M, Health Professionals	Rachel Groman, American Association of Neurological Surgeons	The data provided gives the frequency and costs associated with each of these types of PACs during the index hospitalization and for readmissions and emergency room visits during the 30 day post discharge period. The information is based on a two-year nationally commercially insured population (CIP) database. The database had 4.7 million covered lives and $95 billion in "allowed amounts" for claims costs. The database was an administrative claims data base with medical as well as pharmacy claims. The data source was based upon electronic administrative data/claims, paper medical record and flowsheet data. We praise the NQF and measure developers for moving toward reporting of outcome measures. As pointed out: "Outcome measures also focus attention on much needed system level improvements because achieving the best patient outcomes often requires carefully designed care processes, teamwork, and coordinated action on the part of many providers." However, in describing the scope of patient outcomes, the report lists service utilization as a proxy for patient outcome (e.g., change in condition) or potential indicator of efficiency. Also the principal source of data is based upon administrative data and claims.	Thank you for your comment.	OT1-031: Stroke-PAC

171	M, Health Professionals	Rachel Groman, American Association of Neurological Surgeons	It should be noted that inaccurate financial claims data may lead those using this Consensus Standard to misinterpret the results. Claims data is set up for billing, and not for quality measurement or assessment of outcome results. We are concerned that the uses of data derived from this Standard will not necessarily provide more accurate information to those attempting to reduce the incidence of PACs because the claims data utilized is inherently flawed. Also, the PACs that occur in the 30 day discharge period are not totally at the control of the health care providers. In some instances, the occurrence of PACs during the 30 day period after discharge may be due to patient behavior and the measures fail to adjust for that behavior. The PACs described in OT1-031-09 do not fully capture patient outcomes and offer only a cursory view of the overall care provided by health care organizations. "[By] relying on highly focused quality metrics one at a time, [we] are viewing care through a tiny keyhole." Measuring Physicians' Quality and Performance." Journal of American Medical Association, December 2009	Measure Developer Response: The value of administrative data as compared to expensive, cumbersome chart extraction has been reported in literature (see enclosed papers by Krumholz 2007, Pine 2008). For lack of better and readily available data, billing data is what we have to resort to until EMR data becomes a norm. For long we have waited for physician leaders to step forward and introduce systemness in healthcare. Even after several IOM reports, and the appalling nature of lack of care coordination, our healthcare delivery continues to be fragmented with tremendous amount of waste, in the form of PACs, among other things. We are surprised that the specialty societies are not pleased by these measures. Is it not our collective goal to improve care? And the first step towards improvement is to measure the current state. If we wait for the perfect database, the perfect outcome measure, we may have waited too long. We challenge the AHA/ASA/ AANS and other specialty societies to develop a measure that will force NQF to retire our current measure. Until then...	OT1-031: Stroke-PAC

172	M, Health Professionals	Rachel Groman, American Association of Neurological Surgeons	The AANS has concerns regarding the PACs that are listed. The occurrence of events such as malignant hypertension, respiratory failure, coma and anoxic brain damage, for example, which occur outside the confines of the index hospital admission, may not be related to quality issues in the care episode for the patient. The AANS would also question the statistical validity of such data. Are there enough patients with the various PACs described to support statistically valid measurement? The AANS acknowledges that more accurate information is needed on the incidence of these PACs and on the quality issues and costs related to them. We encourage the NQF to work with all relevant parties to develop a Consensus Standard that will enable us to reach a point where we can describe those steps that will enable us to improve outcomes in an accurate, reliable, reasonable, and useful manner. Ratings based upon metrics used in this standard may be unproductive because they are judgmental, motivate through blame and fear, and engender adversarial relationships rather than effectively engage practitioners in change. Public reporting of relative ranks based on claims data is, in the view of the AANS, not a valid strategy. We believe that this could mislead patients, health care providers, and payers and not lead to the improvement in outcomes we are all looking for.	Measure Developer Response: The measure is designed to be a comprehensive accounting of bad patient outcomes. We agree that in our data analysis, we found that each of the PACs listed by the AANS had a small volume in the post-acute care period, but collectively, along with other PACs, they were present in 10% of stroke patients (requiring a readmission) and it amounted to 12% of costs related to stroke care. Our hope is that such actionable data would serve as an impetus for specialty societies such as AANS to introduce systems that will encourage better coordinated care post discharge with a goal of reducing these potentially avoidable complications that cause harm to patients. The emphasis is not on ranking of providers or of public reporting but on looking at trends over time with the goal of reducing PACs. Hanan, in his various articles on public dissemination of CABG outcomes data demonstrated that the only individuals who thoroughly read and acted on those reports were the cardiologists and not the patients. Fearing patient reactions from public dissemination of known complications of care does not seem to be the most productive way to addressing the root cause of these complications. Measuring them and holding everyone jointly accountable to reducing them is more in the patients' interests.	OT1-031: Stroke-PAC
6	P	John Allen, Minnesota Gastroenterology	Supported by NSQIP which makes this measure valid and strong. Important endpoints.	Thank you for your comment.	OT2-002: Colorectal Surgery

41	M, Provider	Tricia Kassab, City of Hope	After reviewing the metric , 'Risk-Adjusted Colorectal Surgery Outcome Measures' , there are several issues that will make this metric difficult to collect and analyze. 1. The use of CPT codes - our current system of coding is based off of the ICD-9 codes. There are limited CPT codes found within our charge data however since these are specific to physician billing, they are not as complete as the ICD-9 for hospital billing. An analysis of the charge data in the data warehouse show that of the CPT codes listed in the specifications, there were no patients with the CPT code attached to them. Using a rough conversion to ICD9, there were about 60 patients for 2009 that were eligible (colectomy, proctectomy, proctopexy) 2. The data is meant to be a replica of the NSQIP model including the items found in the database as well as their risk adjustment methodology. Without having the database available, this data pull to meet the metric would need to be risk adjusted through another mean. Our future risk adjustment system, UHC, will not have the same risk adjustment methodology. We would be unable to risk adjust the metric in-house in our current state.	Measure Developer Response: The measure is based on CPT codes, which is also true of the ACS NSQIP in general. Existing hospital participants in the NSQIP have established a number of different practices to obtain the CPT codes for procedures or attach appropriate codes: currently roughly 300 hospitals in the program nationwide are accomplishing this. Within the surgical profession, there is strong preference for the level of procedure detail captured by the professional CPT codes in comparison to the substantially lower specificity of ICD9 procedure codes. Thus, basing this measure on CPT codes is viewed as a strength. Point #2- The measure is based on a very small, parsimonious data set that would be submitted for each eligible case. The model uses six risk adjustment variables, of which two are the CPT code and the ICD9 code, and tracks 16 outcomes as an aggregate. If the measure were implemented by an organization such as CMS, this small set of data for each case would be submitted to that organization centrally and the modeling would be run centrally. Individual hospitals would not be expected to perform the risk modeling themselves. The measure is not to be based on any other risk adjustment schema, such as that of UHC, which is based on administrative codes rather than gold-standard clinical data.	OT2-002: Colorectal Surgery

42	M, Provider	Tricia Kassab, City of Hope	3. Additional data elements that are needed for this metric (for proper risk adjustment) include ASA score, preoperative functional class, smoking history, alcohol use history, steroid use, wound class, etc. A few of these metrics are available in the Surgical Information System however the majority would need to be abstracted manually through chart review. 4. The numerator of the metric are the outcomes which include cardiac arrest, AMI, DVT, Sepsis, Surgical Site Infections, Unplanned intubation and return to OR, etc. We would be able to abstract some of these measures electronically through the ICD9 coded complications, however there is not one source that would have all complications. The SSI's would have to come from Bernie's data, and the Unplanned Return to OR currently comes through self-reported peer review cases. As for the other metrics listed in the report, one other that may affect us currently would be the other NSQIP based metric regarding outcomes of elderly surgery. The specifications do not exclude a cancer diagnosis and this would apply to patients over 65 years of age. This would have the same issues for COH as the above NSQIP based metric. All other metrics exclude cancer patients from the population	Measure Developer Response: Correction, the model uses six risk adjustment variables: CPT code, ICD9 code, ASA Class at surgery, Functional Status prior to surgery, emergency case designation, and surgical wound class. The estimated burden of abstracting this information is discussed in detail in the measure specification and materials. The burden is believed to be similar to or less than the burden associated with other common measures. Please see our additional commentary on burden of data collection in responses below. Point #4- The outcomes for this measure are specifically and rigorously defined, based on years of experience in the ACS NSQIP. There is a modest data collection burden associated with these outcomes, as described and discussed in responses to comments both above and below. The outcomes are derived from the medical record, as a gold standard. The outcomes do not map precisely to ICD9 codes, and as ICD9 coding practices are tremendously variable, it is not suggested or recommended that the outcomes be obtained from these codes. Regarding the final comments of the entry- Responses to comments specific to the elderly surgery measure are provided under that measure. These final comments appear to be an internal remark. Thank you.	OT2-002: Colorectal Surgery
52	M, Health Plan	Sheree Chin Ledwell, Aetna	The calculation of this measure would require medical record abstraction. For health plans this would be an intensive use of resources. For those using this measure, Aetna suggests that reporting should be stratified to take account of disparities.	Measure Developer Response: We do recognize that there is a burden of data abstraction, which we specifically estimate and comment upon in our submitted measure materials. Given the relatively low requirement for number of cases reported (~65) and the very limited data set specified by the measure, we believe the burden would actually be less than the burden currently associated with other quality measures which might be retired. There are just six risk adjustment variables. The outcomes monitored are 16 defined outcomes. As stated in our submitted materials, we believe the measure can easily be carried out with approximately 0.05-0.125 FTE. The measure is not currently stratified by race or ethnicity. The measure is risk-adjusted, without inclusion of race or ethnicity, as per NQF guidelines. However, as stated in our submitted materials, post hoc stratification by race or ethnicity could be performed for the purpose of identifying disparities if race/ethnicity variables are collected.	OT2-002: Colorectal Surgery

58	M, Provider	Kenneth Henriksen, Advocate Physician Partners	We share the concerns expressed in the narrative statement regarding hospitals applying this measure in the absence of participation in the National Surgical Quality Improvement Program. Hospitals will have a difficult time mimicking the database capabilities which are a component of NSQIP participation. The measure will be burdensome for health care entities to collect and report consistently.	Measure Developer Response: We have reemphasized estimates of the burden of data collection and clarified issues surrounding burden in responses above. The burden has been minimized, and although the measure was developed out of the NSQIP, participation in the NSQIP is not required and the burden for this measure is not equivalent to participating in the NSQIP. As per our responses to City of Hope above, institutions would not be expected to perform analyses or risk adjustment locally.	OT2-002: Colorectal Surgery
92	M, Health Plan	Rebecca Zimmerman, AHIP	Comments on ACS Measures: These measures are included in the National Surgical Quality Improvement Program (NSQIP) registry. Hospitals that do not participate in the NSQIP registry will have a much higher administrative burden to collect and report these measures. As with the STS registry measures it is unclear if the registry is open to users to assess what adjustments are being made.	Measure Developer Response: We have commented on the burden of data collection in our submitted materials and in response to other comments above. The list of CPT codes was submitted to the NQF along with all other measure materials, and was evaluated by the technical advisory panel.	OT2-002: Colorectal Surgery
97	M, Provider	Samantha Burch, Federation of American Hospitals	The FAH is concerned that because this measure is based on a year's worth of data and not one encounter, it could prove challenging to implement. Further, while the measure represents 85% of colorectal surgery cases, it will only capture 40-50% of hospitals. This is a concern for public reporting and the ability to make meaningful national comparisons, especially if only one hospital in a region has enough cases (65) to report the measure. In addition, only 270 hospitals currently participate in NSQIP. We believe, as pointed out by a steering committee member, that it will be resource intensive and burdensome for non-NSQIP hospitals to conform to the methodology and collect all of the required data from many sources.	Measure Developer Response: We do not believe any approach to risk-adjusted clinical outcomes could be based on an individual encounter. A large number of performance measures already approved or in practice are based on performance over periods comparable to a year. We do state that the measure should be applicable to the ~42% of hospitals meeting the volume requirement, and that this likely captures ~85% of the cases performed in the country. We believe it is a true fact that NO measure encompassing risk-adjusted, true clinical outcomes will ever be applicable to 100% of hospitals in the country, due to differing case volumes across hospitals. The measure would likely be best applied to hospitals meeting a threshold volume, whereas hospitals below that threshold might be held responsible for different measures. We provide explicit information in our submitted materials on distinguishing performance reliably, and this principle is used in the derivation of the case volume requirement. Once again, participation in the NSQIP is not required for this measure. We have commented on issues of burden above. To reemphasize, we estimate that the measure could be carried out with 0.05 to 0.125 FTE annually, which we believe is justified for a measure based on gold-standard clinical outcomes. Please see our additional commentary on burden in responses above.	OT2-002: Colorectal Surgery

107	M, Consumer	Debra Ness, National Partnership for Women & Families	Overall, we support this measure. It targets a high-volume, high cost procedure, for which patients will want to know how the hospitals in their area perform. We note that the fact that this measure requires that a hospital conduct at least 65 of these procedures annually to be able to report it will provide consumers with valuable information on the volume at their local hospitals, and will hopefully drive patients to those hospitals that have the most experience with this surgery. While there is not an established volume-outcome relationship for every procedure, knowing whether or not a hospital has done at least 65 of these procedures is valuable information that a consumer can take to their provider to seek more knowledge on the quality of care and outcomes at their local hospitals. In terms of the measure data itself, it will be imperative for public report sponsors to provide appropriate context and interpretation information for consumers when implementing this measure, given that the results are to be reported as a ratio of odds/expected outcome, which is not intuitively understandable.	Measure Developer Response: Thank you for these positive comments. We certainly agree that there will be value in educating consumers about the context and interpretation of reported ratios, but our longstanding experience in the ACS NSQIP demonstrates that the information is processed routinely and is increasingly a standard format for performance reporting.	OT2-002: Colorectal Surgery
122	M, Health Plan	Catherine MacLean, WellPoint, Inc.	WellPoint believes that many hospitals will not have the capacity to report this measure, since it relies on medical record review, and will require matching of administrative data (used to capture 30-day events) with medical record data. Hospitals that have been involved with NSQIP may be better able to capture and report this data, but hospitals that have not been involved with NSQIP may have significantly less reliable or valid results, as they adjust to the NSQIP reporting methodology.	Measure Developer Response: Please see our other responses to comments above regarding the burden associated with the measure. There is no matching to administrative data as outcomes are not captured by that mechanism. The outcomes for the measure are not defined in terms of ICD9 codes. We believe the simplicity of the measure specification and required data fields will enable any hospital to comply, and estimate that perhaps 40% of hospitals, performing more than 85% of cases in the country, will have adequate volumes to do so (as per submitted materials). It is true that hospitals already participating in NSQIP will find the measure specifications familiar, but we do not believe that this represents any performance advantage. In any actual implementation of the measure, it is likely that the implementing organization would propose an associated auditing mechanism.	OT2-002: Colorectal Surgery

51	M, Health Plan	Sheree Chin Ledwell, Aetna	Aetna believes this is a promising measure of system performance and should be implemented. However, the specific weights used to generate the composite score are (as the authors recognize) somewhat arbitrary and the report must clearly state this so that the reader can intelligently interpret the results. We strongly encourage NQF to include encounters other than physician visits as qualifying as evidence of a care transition (e.g. home nurse visits). Evidence should be further developed that an outpatient encounter soon after discharge actually results in reduced readmissions. Reporting should be stratified to take account of disparities.	Measure Developer Response: We agree that anyone interpreting the composite measure should be made aware of the weights applied to the individual components. The measure of care transition recognizes any professional service for evaluation and management; including services billed in conjunction with home health or skilled nursing. The value of ambulatory follow-up is intended to reflect desirable transitions and care coordination post discharge; one of many potential benefits could include avoiding readmissions.	OT2-005: PNA Discharge
91	M, Health Plan	Rebecca Zimmerman, AHIP	This measure assesses three important components of post-hospital discharge care – follow up outpatient visits, ER visits, and hospital readmissions. AHIP recommends that the results of the three components be reported individually along with the composite result. AHIP requests clarification regarding the level of analysis to which the measures apply. The measure appears to assess hospital quality but the level of analysis included in the measure specifications is listed as "national." Measures reported at the national level will have limited actionability by providers and will not assist consumers in selecting high quality providers within their local market. AHIP would support these measures with a level of analysis at the provider level.	Measure Developer Response: We agree that users should report results for the individual components in addition to the composite measure. The Medicare database used to develop the measure specifications was national; however, application of the measure is intended at the provider (hospital) level.	OT2-005: PNA Discharge
95	M, Provider	Samantha Burch, Federation of American Hospitals	While the FAH believes that there may be circumstances under which a measure that could not stand on its own would be included in a composite, we believe that there should be a justification included in the report for not taking a component measure through the full endorsement process. This would apply to the "30-day post-hospital PN discharge ED visit rate" and the "30-day post-hospital PN discharge evaluation and management service" measures. It would be helpful to see a more robust technical review of these non-endorsed component measures in order to be able to more thoroughly analyze the overall composite measure. In addition, because the measure was tested using Medicare claims, we have concerns about a hospital's ability to use this measure to make real time improvements in outpatient follow-up care for patients.	All components have been evaluated by NQF's CDP. The Committee did not recommend the ED and E&M components as stand alone measure but felt they worked well together in the composite. NQF's composite evaluation criteria doe not require that component measures be endorsed as stand alone measures. Measure Developer Response: The endorsement process certainly has included thorough attention to the composite measure and to the individual components. Our submission included all of the empirical results for the individual and composite measures. The measures are intended to profile hospitals and to track changes in performance over time; however, the measures allow providers to judge their recent performance but not to follow individual patients "in real time."	OT2-005: PNA Discharge

106	M, Consumer	Debra Ness, National Partnership for Women & Families	We support this measure, as we did the previous HF and AMI discharge care transition composites that were in Phase I of this project. We believe that the results will be understandable by consumers, and that the content of the measure will be meaningful and will also drive improvements in care coordination and transitions.	Thank you for your comment.	OT2-005: PNA Discharge
121	M, Health Plan	Catherine MacLean, WellPoint, Inc.	WellPoint supported this measure, as it supported the other two care transition composite measures from these measure developers. However, we do have several concerns about whether the measure will be actionable and understandable for the public and hospitals. By including all-cause ED visits and readmissions, the composite does not communicate to hospitals how they might improve their rates. Also, WellPoint would like to note that the methodology used to develop the composite score is complicated, and may not be understood by consumers. The measure and its methodology must be understandable in order for it to be useful. Lastly, WellPoint would like to encourage the measure developer to conduct deep dives into the data sets once the measure is implemented, to assess whether there are correlations between the measure results and actual quality.	Measure Developer Response: CMS typically is very careful about how measures are displayed and explained to beneficiaries. The utilization events are counted regardless of "cause," including diagnoses associated with ED visits The approach of this measure is fundamentally patient-centered, not disease-centered, although we do have the index discharge consistency as the anchor point. The measures were motivated to address care coordination and efficiency.	OT2-005: PNA Discharge

11	M, Health Plan	Tariq Abu-Jaber, WellPoint, Inc.	Throughout the health care community, there is a rapidly growing interest and sense of urgency in establishing clinically meaningful metrics for defining the quality of care delivered by providers of all types. Our ability, as an industry and as a nation, to provide quality care at a sustainable cost demands that we develop universally accepted measures that allow us to distinguish relative care quality. Most of the measures currently used – as valuable as they are – focus on the process of care, the provision or omission of services. Outcomes measures are often cited as a "holy grail" in this field. Prometheus' Potentially Avoidable Complications metrics move towards this objective by removing the focus from the mechanical provision of an important service for a diagnosis (or avoidance of an inappropriate service) to the clinical result of the sum total of their care. Monitoring Potentially Avoidable Complications holds the promise of offering metrics that fully reflect outcomes. In addition, these are highly patient-centric metrics, since they look not only at the narrow range of activities related to a specific service performed or diagnosis treated, but to the patient's holistic experience resulting from their care, across all co-morbidities. For these reasons, I support the endorsement of Prometheus's PACs - including the Proportion of Pneumonia Patients that have a PAC - as NQF Patient Outcomes Measures.	Thank you for your comment.	OT2-013: PNA-PAC

48	M, Health Plan	Sheree Chin Ledwell, Aetna	Aetna recommends this measure for endorsement, only if NQF has plans for an annual review of published results or establish a time limited endorsement. More importantly, NQF needs to ensure that risk adjusters are present at the onset of the episode. Risk adjustment would be indicated, e.g. to adjust for members with multiple conditions that can lead to the instability that potentially adds to the propensity for PACs.nOur primary concern is that much of this quality monitoring system may only have face validity. Not all 'complications' apply to all of the designated chronic conditions. Nevertheless, this is a major and important attempt to assess a system's ability to detect and reduce PACs. It is not intended that PACs can be eliminated, which suggests that the "potentially" needs very clear explanation especially to the public (otherwise readers might think that if something is "potentially" avoidable it should BE avoidable). The PAC concept is tied to the PROMETHEUS payment system and represents a strong initiative to rationalize P4P at a system rather than individual physician level. The PAC construct would be valuable for PCMHs that uses Health Information Exchange (HIE).	Measure developer response: As specified, the measures include severity adjustment. Please see attached document specific to PACs and risk-adjustment.	OT2-013: PNA-PAC
73	M, QMRI	Bernard M. Rosof, MD, MACP, Physician Consortium for Performance Improvement®	Please see "Level of measurement", "Potentially avoidable complications – Definitions" and "Reliability" comments for OT2-22-09: Proportion of patients with a chronic condition that have a PAC.		OT2-013: PNA-PAC
81	M, QMRI	Nancy H. Nielsen, MD, PhD, American Medical Association	Please see "Level of measurement" and "Potentially avoidable complications - Definitions" comments from OT2-022-09: Proportion of patients with a chronic condition that have a PAC.		OT2-013: PNA-PAC

94	M, Provider	Samantha Burch, Federation of American Hospitals	While the FAH believes it is important to look at avoidable complications, we have concerns related to the feasibility of this measure. Specifically, we are concerned about the ability to implement this measure and replicate it on a nationwide basis.	Measure Developer Response: We have thoroughly tested these measures in close to 20 different datasets and have had no issue whatsoever is creating the measures or reporting them. As such, there is no issue that we have discovered that would prevent the measure to be replicated on a national basis.	OT2-013: PNA-PAC
8	M, Health Plan	Tariq Abu-Jaber, WellPoint, Inc.	Throughout the health care community, there is a rapidly growing interest and sense of urgency in establishing clinically meaningful metrics for defining the quality of care delivered by providers of all types. Our ability, as an industry and as a nation, to provide quality care at a sustainable cost demands that we develop universally accepted measures that allow us to distinguish relative care quality. Most of the measures currently used – as valuable as they are – focus on the process of care, the provision or omission of services. Outcomes measures are often cited as a "holy grail" in this field. Prometheus' Potentially Avoidable Complications metrics move towards this objective by removing the focus from the mechanical provision of an important service for a diagnosis (or avoidance of an inappropriate service) to the clinical result of the sum total of their care. Monitoring Potentially Avoidable Complications holds the promise of offering metrics that fully reflect outcomes. In addition, these are highly patient-centric metrics, since they look not only at the narrow range of activities related to a specific service performed or diagnosis treated, but to the patient's holistic experience resulting from their care, across all co-morbidities. For these reasons, I support the endorsement of Prometheus's PACs - including the Proportion of Patients with a Chronic Condition that have a PAC - as NQF Patient Outcomes Measures.	Thank you for your comment.	OT2-022: Chronic Condition

12	P	John Brush, Healthcare Incentives Improvement Institute, Inc.	The current high rate of potentially avoidable complications (PACs) represents an enormous opportunity to improve care and bring down health care costs. This measure provides a way to track possible defects, which will cause a provider to take on a more comprehensive view on care. The risk-adjustment addresses the possible unintended consequences of incentivizing providers to shirk sick patients. The measure will allow providers to be graded and therefore rewarded for improving long-term outcomes. It incentivizes providers to increase the scope of their responsibility and to make up-front investments that will serve to improve long-term outcomes, while providing an opportunity, through payment reform, for providers to see a return on that investment.	Thank you for your comment.	OT2-022: Chronic Condition
46	M, Health Plan	Sheree Chin Ledwell, Aetna	Aetna recommends this measure for endorsement, only if NQF has plans for an annual review of published results or establish a time limited endorsement. More importantly, NQF needs to ensure that risk adjusters are present at the onset of the episode. Risk adjustment would be indicated, e.g. to adjust for members with multiple conditions that can lead to the instability that potentially adds to the propensity for PACs. Our primary concern is that much of this quality monitoring system may only have face validity. Not all 'complications' apply to all of the designated chronic conditions. Nevertheless, this is a major and important attempt to assess a system's ability to detect and reduce PACs. It is not intended that PACs can be eliminated, which suggests that the "potentially" needs very clear explanation especially to the public (otherwise readers might think that if something is "potentially" avoidable it should BE avoidable). The PAC concept is tied to the PROMETHEUS payment system and represents a strong initiative to rationalize P4P at a system rather than individual physician level. The PAC construct would be valuable for PCMHs that uses Health Information Exchange (HIE).	Measure developer response: As specified, the measures include severity adjustment. Please see attached document specific to PACs and risk-adjustment.	OT2-022: Chronic Condition

54	M, Provider	Kenneth Henriksen, Advocate Physician Partners	This proposed measure, appears to have been tested in health plan or employer group entities. This measure does not appear to have been tested in a health care delivery environment; please clarify if that is the case. As written, this measure may only be able to be collected efficiently via electronic medical record or in health care entities that perform claim processing functionalities. These two scenarios support automated reporting of the data elements needed to compile this measure. We agree that this measure should only be used at the group, plan or system level of analysis - not at the individual clinician level.	Measure Developer Response: These measures are being tested in several health care systems including Partners Health Care in MA, Spectrum Health in Grand Rapids MI and Crozer-Keystone Health System in PA. Any entity that has access to claims information can process these measures.	OT2-022: Chronic Condition
68	M, QMRI	Bernard M. Rosof, MD, MACP, Physician Consortium for Performance Improvement®	Level of measurement: While these measures address important areas of care, we cannot support them as accountability measures at the clinician level to be used for public reporting. There are other factors beyond the care directly provided by clinicians (including the efforts of other health care professionals) that could affect the care of those patients who would be impacted by these measures. We believe that performance measures are only appropriate at the clinician level when it has been consistently shown that the outcome is directly dependent on the clinician, and not when such results are dependent on other healthcare professionals or other factors exogenous to the care a clinician provides. Accordingly, these types of measures are best represented at "higher" levels of measurement/analysis. We recommend removing "Clinician" as a Level of Measurement/Analysis for proposed measures OT2-029-09, 0T2-022-09, OT1-030-09, OT1-031-09, and OT2-013-09.	The PAC measures were evaluated as submitted for use at plan, group, system level and not at the individual clinician-level of measurement. Measure Developer Response: For accountability purposes, we have specified that these measures could be used for public accountability only at levels higher than the individual clinician (see comment ID 54 for concurrence).	OT2-022: Chronic Condition

69	M, QMRI	Bernard M. Rosof, MD, MACP, Physician Consortium for Performance Improvement®	Potentially avoidable complications – Definitions: The PCPI is concerned about the use of the term, Potentially Avoidable Complications (PAC). While we believe that conditions such as those indicated as PACs should be avoided, there is considerable ambiguity with regards to the determination of what constitutes a PAC in the context of these measures. The term itself is unclear, particularly as some PACs noted in these measures are of greater clinical significance than others. Without additional description as to how these PACs were specified, these measures may engender confusion and may be interpreted incorrectly. We recommend that the endorsement of these measures (0T2-022-09, OT1-030-09, OT1-031-09, and OT2-013-09) be postponed until such time that more information is provided regarding the determination of the PACs as well as additional information regarding how PACs should be appropriately assessed.	Measure Developer Response: We have clearly defined the nature and type of each Potentially Avoidable Complication that is included in the overall metric. The term Potentially was selected very specifically to connote that these complications are potentially avoidable, not absolutely avoidable.	OT2-022: Chronic Condition
70	M, QMRI	Bernard M. Rosof, MD, MACP, Physician Consortium for Performance Improvement®	Reliability: There is continued concern related to the methodological approaches and corresponding results related to measure reliability and validity of particular measures. Several of the measures recommended for full endorsement fail to provide sufficient evidence of the measure's reliability. For these four measures, the measure developers indicate in the measure submission forms that "No formal reliability testing was done." In section 2b (reliability testing) reliability is described as being based on the measures having been constructed from two samples of claims data, and the resulting performance rates described as being consistent across those sample estimates. This vague notion of consistency is not an appropriate test for reliability of a performance measure. Until additional reliability information is provided by the measure developers, we cannot support these measures (0T2-022-09, OT1-030-09, OT1-031-09, and OT2-013-09).	The SC discussed the testing of the PAC measures with the developer in detail. The additional data from 20 new sites was considered. The COmmittee felt that reliabilty centeres around data and abstraction reliablilty and calculation relaibility. Given the type of measure and data, the COmmittee did not feel that additional testing would provide new information on reliabilty. Measure Developer Response: Since the time of initial submission, we have been able to test the measures in over 20 different datasets, some stemming from large employers, some stemming from provider-owned health plans, some stemming from public sector Medicaid plans. The results have been consistent and the measures' reliability is, in our opinion, very high. By definition, PACs include a host of other measures that have been and are being used for public accountability and, in the newly passed legislation, for payment, such as Hospital Acquired Conditions and Patient Safety failures in hospitals. All these measures have very high degrees of reliability.	OT2-022: Chronic Condition

77	M, QMRI	Nancy H. Nielsen, MD, PhD, American Medical Association	Level of measurement: While these measures address important areas of care, we cannot support them as accountability measures at the clinician level to be used for public reporting. There are many factors and other healthcare professionals who provide care to patients who would be affected by these measures. These types of measures are best represented at "higher" levels of measurement/analysis. We recommend removing "Clinician" as a Level of Measurement/Analysis for proposed measures OT2-029-09, 0T2-022-09, OT1-030-09, OT1-031-09, and OT2-013-09.	Measure Developer Response: Same as response for Rosof - comment ID#68.	OT2-022: Chronic Condition
78	M, QMRI	Nancy H. Nielsen, MD, PhD, American Medical Association	Potentially avoidable complications - Definitions: The PCPI is concerned about the use of the term, Potentially Avoidable Complications (PAC). While we believe that conditions such as those indicated as PACs should be avoided, there is considerable ambiguity with regards to the determination of what constitutes a PAC in the context of these measures. The term itself is unclear, particularly as some PACs noted in these measures are of greater clinical significance than others. Without additional description as to how these PACs were specified, these measures may engender confusion and may be interpreted incorrectly. We recommend that the endorsement of these measures (0T2-022-09, OT1-030-09, OT1-031-09, and OT2-013-09) be postponed until such time that more information is provided regarding the determination of the PACs as well as additional information regarding how PACs should be appropriately assessed.	Measure Developer Response: This is a simple copy of the comment from Bernard Rosof and our answer is the same - see comment ID #69.	OT2-022: Chronic Condition
84	M, Provider	Thomas Miner, Trinity Health	This comment applies to all measures that incorporate the term Potentially Avoidable Complications (PAC). These measures sound great and I would like to know more about the definition of PACs. I reviewed several documents and noticed a reference to an Excel Workbook entitled "NQF_Chronic_Care_All_Codes_2.9.10" which gives the detailed codes for PACs. How can I get access to this Excel workbook?	Staff will post the excel workbook on the OT2-022-09 PDF file. The file is located under the Member and Public Comment-2nd Report tab on the project webpage.	OT2-022: Chronic Condition

86	M, Health Plan	Rebecca Zimmerman, AHIP	Comments on BTE Measures: We support assessing potentially avoidable complications for chronic conditions or following an inpatient stay for AMI, stroke, and pneumonia, however we have several questions on the above measures where additional clarity would be helpful. The conditions and potentially avoidable complications (PACs) included in the measures may be affected by a patient's timely access to care. It is unclear from the measure's specifications if the risk adjustment methodology used will account for patients with lower socioeconomic status or patients without access to post-discharge care or delayed access due to patient choice. Without taking these factors into account, comparing performance among providers may not provide fair, reliable information on performance differences. The measures' specifications also indicate that the level of analysis is the clinician group, health plan, or population level. As the measures assess avoidable complications based on an inpatient event and 30-days post-discharge, hospitals should also be included as a unit of analysis. Additionally, the PACs are aggregated together and then reported, including those related to the index visit, patient safety failures, and comorbidities. Reporting the PACs as a aggregate measure may not result in actionable information for providers. The measure developer should be encouraged to provide drill-down data to providers to use for quality improvement.	Measure Developer Response: Thank you for your support of these measures. The severity adjustment model currently does not account for socio-economic differences and resulting issues about access to care. These additional data points would be valuable in expanding on the severity-adjustment model and we would certainly encourage their incorporation if they could be gathered readily. PAC reports actually provide a drill-down of location and type of PAC as was evident in the example provided to NQF at the time of submission and help to make this data actionable. However, the purpose of this measure is to create joint accountability between providers around a patient and re-segmenting PACs would be counter to the measure's objective. Hospitals are most certainly a unit of appropriate accountability for PACs.	OT2-022: Chronic Condition
87	M, Health Plan	Rebecca Zimmerman, AHIP	Comments on BTE Measures, continued: The measures also exclude patients that are lost due to follow up in the 30-day post-discharge period. Patients lost due to follow up represent missed opportunities for care coordination and should be included when reporting the measures. Finally, measure OT2-022-09 reports PAC rates for a variety of chronic conditions. We suggest that each condition be reported separately in addition to the composite in order to produce more actionable data and to provide clear information to consumers for decision-making.	Measure Developer Response: Since we are dealing with claims data from health plans, if a patient is lost to follow-up because they are no longer enrolled in the health plan, we do not know if they have other coverage and their care is captured in some other database. As such, only those patients who have lost enrollment are excluded. PACs can be calculated separately for each chronic condition. The measure is the same, but the underlying result would be specific to a class of patients, say diabetics. As such, a user of the measure could clearly determine rates of PACs for patients with a specific chronic condition, not for all patients with chronic conditions taken as a whole.	OT2-022: Chronic Condition

102	M, Consumer	Debra Ness, National Partnership for Women & Families	We support the entire group of "Potentially Avoidable Conditions" measures, so this comment relates to measures 022, 030, 031, and 013. From a consumer perspective, these are extremely important and meaningful, and the complications that are included in the specifications are comprehensive. In terms of public reporting and payment policy, these measures should be intuitively understandable and useful, respectively. We also strongly believe that measures such as these will be drive the system toward improvements in care coordination.	Thank you for your comment.	OT2-022: Chronic Condition
110	M, Health Plan	Tom James, National Network Operations	This is a complex measure; the list of PACs is not included in the table; the method of calculation is not transparent. Until these are resolved, this measure does not appear ready to be employed.	The measure submission materials contain the specifications. Measure developer response: All these measures have been thoroughly specified in detail and these details are readily accessible on our web site: www.hci3.org	OT2-022: Chronic Condition
118	M, Provider	Nancy Foster, American Hospital Association	The description of this and the other measures created by the Bridges to Excellence program do not clearly identify how potentially preventable complications are separated from those that could not be prevented. The implication of some of the descriptive language is that they are not (lines 189 - 192). If this is true, and these measures really incorporate all complications except those that were present on admission, we suggest that the Steering Committee recommend that the names of the measures be changed to not create false expectations in the mind of those who might be using the data generated by these measures. Simply referring to them as "complications in care" would be clear and precise, and no less compelling as a subject for improvement efforts because no provider, purchaser or policy maker wants patients suffering complications, and certainly no patient wants a complication.	Measure Developer Response: The definition of a PAC is that it is potentially avoidable (or preventable). It is a broader term than the standard definitions of complications used by clinicians; particularly it includes ER visits, preventable hospitalizations in ambulatory sensitive conditions (ASCs) as defined by AHRQ, patient safety indicators (PSIs), as well as preventable readmissions in acute conditions.	OT2-022: Chronic Condition

124	M, Health Plan	Catherine MacLean, WellPoint, Inc.	WellPoint supports this measure (as mentioned in a previous comment). We do have additional technical comments. Since the percentage of PACs in a region may be related to a number of issues (eg, patient access to care, the number of providers in an area, etc.), we believe that other measures would help to inform public understanding of the measure. Also, reporting PACS alone may be too broad to be useful – for QI purposes, providers will need access to rates for each condition and possibly for each type of PAC. Lastly, the denominator uses the phrase, "patients who were followed for one year." This implies that if patients aren't followed, they won't be included – this could lead to biased results if a provider has poor follow-up or if a provider only follows up with patients that are likely to have positive outcomes (e.g., healthier, less complicated patients). We would ask BTE to clarify how this will be addressed, or if it will also report percentage of patients lost to follow up.	Measure Developer Response: Currently the measure is developed based on claims data and so is limited to information that can be obtained from claims data. Access issues are very important and should be an integral part of any outcome measure. But that information is not available in claims data. The exclusion for lack of one year of follow-up only applies to plan members who have lost enrollment during the measurement window, not because they didn't receive follow-up care. As such, lack of follow-up care in a continuously enrolled patient would certainly not be an exclusion criteria.	OT2-022: Chronic Condition
142	P	Kay Jewell, Center for Consumers of Healthcare	Support	Thank you for your comment.	OT2-022: Chronic Condition

153	M, Health Professionals	Ralph Sacco, American Heart Association, American Stroke Association; Ralph W. Brindis, President, American College of Cardiology; Frederick A. Masoudi, Chair, ACCF/AHA Task Force on Performance Measures	We agree that the proportion of patients with a chronic condition with potentially avoidable conditions should not be aggregated at the individual clinician level. However, there is little justification why the other Bridges to Excellence measures permit aggregation at the practitioner level. It is not clear that practitioner-level linkage is feasible in most data systems, and also not clear that this approach will yield adequately robust denominators. We would strongly suggest aggregation at the institution or health plan levels. It is also not clear that administrative codes can identify potentially avoidable complications (PACs) in a valid manner. Although this is concerning for all of the measures, it seems particularly problematic for the PACs identified during the index hospitalization for acute conditions like stroke or MI. Indeed, many of the purported PACs are also manifestations of severe cases of the underlying condition. For instance, a patient who is admitted to the hospital with an acute MI (AMI) who is being transferred to the catheterization laboratory in a timely manner from the Emergency Department and suffers ventricular fibrillation (VF) in transit would result in a decrement in performance, despite the fact that the VF would reasonably be considered part of the clinical course of severe AMI. The ACCF and AHA urge NQF not to endorse these measures until there are adequate data validating the use of the proposed administrative codes against clinical data in identifying such events as PACs.	Measure Developer Response: The level of analysis for all the four measures is stated to be at the clinician group level, and not at an individual fractioned level. The measure is structured to encompass hospital care plus post-acute care, and an accountable entity in some locations could be a clinical group. In many regions, hospitals may not be able to take on accountability for post-acute care. Currently datasets that are most readily available are administrative datasets. Even though they may not be as authentic or as complete as clinical datasets, several papers (see enclosed Krumholz 2006 and Pine 2007) have been written showing the value of such datasets as compared to information obtained from expensive, cumbersome chart review. Until such time that EMRs are far more widely available, we may have to resort to less than ideal datasets rather than have no outcome measures at all. Yes, VF in the setting of AMI may be part of the clinical course, as is death. However, our point in measuring these complications is that they are not ALWAYS part of the natural clinical course. As such we measure VF in the same way that mortality is measured for AMI patients....because it matters to the patient for whom it could be prevented.	OT2-022: Chronic Condition

161	P	Hemal Shah, Boehringer Ingelheim Pharmaceuticals, Inc.	BI supports the endorsement of this measure. All six of the conditions specified in the measure are high-impact chronic illnesses. For each of these conditions, there is considerable variation in quality of care. We believe that several of the conditions are particularly important. Chronic obstructive pulmonary disease (COPD), which encompasses chronic bronchitis and emphysema, currently affects over 12 million people and is the fourth leading cause of death in the U.S. COPD is the fifth most common reason for hospitalization of Americans over 65. Numerous factors contribute to complications of this condition, including co-morbidities, patient access to care, socioeconomic status, and sub-optimal medical management. Published literature has specifically shown that a significant number of COPD patients are non-adherent to their prescribed therapies. Further, physicians often do not widely follow clinical guidelines. These statistics clearly underscore a need for evidence-based approached (e.g., performance measures) that can help improve adherence to protocols that may prevent COPD complications.	Thank you for your comment.	OT2-022: Chronic Condition
162	P	Hemal Shah, Boehringer Ingelheim Pharmaceuticals, Inc.	An estimated 73 million people in the U.S. have high blood pressure. Hypertension is an important risk factor for other cardiovascular disease, including coronary heart disease, stroke, and congestive heart failure. Hypertension is associated with a shorter overall life expectancy. While many patients are aware of their condition, many studies estimate that less than half have their high blood pressure under control. Inadequate control of hypertension is associated with many clinical implications. "Problems with screening and behavioral counseling; controversial definition and classifications of hypertension; unclear treatment goals; and complex or costly pharmacotherapy (or both difficulties) can lead to patient and physician nonadherence to existing guidelines. Inclusion of hypertension in the proposed measure highlights the importance of improving hypertension management to avoid preventable complications.	Thank you for your comment.	OT2-022: Chronic Condition

163	P	Hemal Shah, Boehringer Ingelheim Pharmaceuticals, Inc.	Approximately 27 million Americans have diabetes, making it a diagnosis for over eight percent of the population. Diabetic complications are burdensome and costly. Adults with diabetes have heart disease death rates about two to four times higher than adults without diabetes. Diabetes is the leading cause of kidney failure and new cases of blindness among adults aged 20 to 74 years. Over 60 percent of nontraumatic lower-limb amputations occur in people with diabetes. Finally, diabetes patients are at least twice as likely as non-diabetics to have a stroke. Diabetes management encompasses lifestyle and medical interventions aimed at controlling the condition, preventing complications, and maintaining glycemic control, which is one critical component. Strong evidence from clinical trials shows that poor glycemic control increases the risk of microvascular complications that can result in hospitalization. Poor glycemic control can also have an impact on other types of health care utilization and on co-morbidities including chronic kidney disease (CKD). Like COPD and hypertension, measures to assess preventable diabetic complications are needed.	Thank you for your comment.	OT2-022: Chronic Condition
164	P	Hemal Shah, Boehringer Ingelheim Pharmaceuticals, Inc.	An assessment of COPD, hypertension, and diabetes complications can facilitate better care for COPD, hypertension and diabetes patients across settings because it captures complications that may be prevented through appropriate treatment. As explained by Prometheus Payment, Inc., a PAC would occur "instead of a normal progression of the condition." If provider groups adhere to the recommendations put forth in evidence-based clinical guidelines for care of the condition (e.g., certain interventions or therapies), then they improve the likelihood of avoiding some complications. Appropriate management includes not only ongoing adherence to prescribed regimens, but also begins with early diagnosis and timely treatment. BI supports this measure because it may incentivize such behaviors.	Thank you for your comment.	OT2-022: Chronic Condition