National Quality Forum

Comments on Draft Report: National Voluntary Consensus Standards for Patient Outcomes (Phases I & II): First Report

June 25, 2010

The Steering Committee reviewed the submitted comments and proposed responses during a conference call on June 21, 2010.

#	Member Council/ Public	Organization Contact	Topic	Comment	Response
78	M, QMRI	Barbara Corn, NAHQ	007: ICD Implantation	Will the ICD codes to identify the complications be specific to the procedure?	The complications are procedure specific. The ICD-9 codes used to identify complications and the associated interventions are listed below: 1. Pneumothorax or hemothorax with chest tube: [Pneumothorax or hemothorax: 512.1 or 511.8 (diagnosis code) Chest tube: 34.04, 34.05, 34.06, or 34.09 (procedure code)] 2. Hematoma with blood transfusion or evacuation: [Hematoma: 998.1 (diagnosis code) Blood transfusion: 518.7, 287.4, V59.01, V58.2 (diagnosis code), or 99.00, 99.03, 99.04 (procedure code) Evacuation: 34.04, 34.09 (procedure code)] 3. Cardiac tamponade or pericardiocentesis: [Cardiac tamponade: 420, 423.0, 423.3, 423.9 (diagnosis code), or 37.0, 37.12 (procedure code)] 4. Mechanical complications with system revision: [Mechanical complications with system revision: 996.0 (diagnosis code) System revision: 37.75, 37.79, 37.97, 37.99 or 00.52 (procedure code)] 5. Infection that is device related: [Infection: 996.61 (diagnosis code)] 6. Subsequent ICDs within 90 days of index procedure: [Inpatient ICD implantation: 00.50, 00.51, 00.52, 00.53, 00.54, or 37.94 (procedure codes) Outpatient ICD implantation: 33216, 33217, 33218, 33220, 33223, 33240, 33241, or 33249 (CPT codes)] 7. Death

217	M, Health Plan	Sheree Chin Ledwell, Aetna	007: ICD Implantation	This measure is based on Medicare members age 65+ and on National Cardiovascular Data Registry (NCDR-) dataset. We would need to seek access to this dataset. NQF indicates this measure could be applied to a broader population of patients undergoing ICD implantation if the required data elements were available with some additional work to optimize the risk adjustment methodology.	Measure developer response: As noted in the response to Dr. Henriksen, we look forward to exploring opportunities to expand the measure to include patients outside of the Medicare fee-for-service population. Information on the NCDR ICD Registry, including a full list of the collected data elements, is available here: http://www.ncdr.com/webncdr/ICD/default.aspx. The issue at this point is data availability.
235	M, Provider	Kenneth Henriksen, Advocate Physician Partners	007: ICD Implantation	This proposed measure, while valuable, appears to impact a small and distinct population of patients as the measure is currently presented. We would encourage broadening the measurement population as part of the endorsement process. As it is currently written, the measure calls into question whether measurement would comprise such a small "N" size that it could potentially impact the soundness of the measurement within certain health care organizations.	Measure developer response: We developed the measure in the Medicare ≥65 fee-for-service population as this is the only cohort of patients in whom we have the means of reliably identifying outcomes (complications and vital status) beyond the index hospitalization. When and if additional sources of outcome data become available, the measure could certainly be applied to the broader population of patients undergoing ICD implantation. This would require additional work to optimize the risk adjustment methodology, but is definitely feasible. Regardless, the number of patients captured in the measure as currently defined is adequate for quality assessment.

243	M, Purchaser	Barbara Rudolph, PhD, MSSW, The Leapfrog Group	007: ICD Implantation	The Leapfrog Group agrees that the ICD Implantation Complication Rate is important for both consumers and purchasers; however, we are concerned that this outcome measure utilizes a methodology that minimizes variation. In this case, hierarchical modeling pulls all but the most extreme outliers into average categories. This sends an inappropriate message to consumers and purchasers and fails to meet the most basic principle of measurement, "measures must reflect differences or they are not measures."	Measure developer response: We agree that the choice of modeling approach is a very important consideration in performance measurement. The proposed measure employs a hierarchical logistic regression model (HGLM) to create hospital risk-standardized 30 day readmission rates (RSRR) for hospitals performing ICD implantation. In brief, the approach simultaneously models two levels (patient and hospital) to account for the variance in patient outcomes within and between hospitals. At the patient level, each model adjusts the log-odds of a hospital readmission within 30-days of discharge for age, sex, selected clinical covariates, and a hospital-specific intercept. The second level models the hospital-specific intercepts as arising from a normal distribution. The hospital intercept represents the underlying risk of readmission at the hospital, after accounting for patient risk. The hospital-specific intercepts are given a distribution in order to account for the clustering (non-independence) of patients within the same hospital. If there were no differences among hospitals, then after adjusting for patient risk, the hospital intercepts should be identical across all hospitals. The RSRR is calculated as the ratio of the number of "predicted" to the number of "expected" readmissions, multiplied by the national unadjusted readmission rate. For each hospital, the "numerator" of the ratio is the number of readmissions within 30 days predicted on the basis of the hospital's performance with its observed case mix, and the "denominator" is the number of readmissions expected on the basis of the nation's performance with that hospital's case mix.
248	M, Purchaser	Gaye Fortner, HC21	007: ICD Implantation	These are both important measures that will provide outcome data on two high volume procedures (defibrillator implantation and PCI). I have some concern with the use of the hierarchical risk adjustment methodology used in both of these measures, since this type of methodology often puts many hospitals into the "average" category, and may not allow for differentiation in results among hospitals.	Measure developer response: Please see response to Dr. Rudolph/Leapfrog above. Of note, the methodology will allow us to accurately characterize true outliers.
292	M, Provider	Thomas Miner, Trinity Health	007: ICD Implantation	Due to the high complication rate for this procedure, this measure seems appropriate.	Thank you for your comments.

332	M, Health Professionals	Lea Anne Gardner RN, PhD (on behalf of the Performance Measurement Technical Advisory Committee), American College of Physicians	007: ICD Implantation	We had two concerns with this measure. 1. The table on page 27 of the main NQF report identifies the target denominator population for this measure as inpatient and outpatient ICD implants, yet the numerator counts complications in the measure only if they occur 30 to 90 days following an ICD implantation during a hospital admission (table on page 28 – numerator column). These two statements seem at odds. Can the developer please provide clarification? 2. There is a concern about the validity of this measure given that the risk model has a limited ability to predict the outcome of individual patients (c-statistic = 0.61).	Measure developer response: (1) The goal of the ICD complications measure is to assess hospital-level quality of all ICD implantations, regardless of care setting. Because some ICD implantations occur in the outpatient setting (e.g., in the hospital under observation status [not admitted]), the denominator statement includes both inpatient and outpatient ICD implantations. The numerator represents patients with one or more of the specified complications. The Technical Expert Panel (TEP) recommended that the outcome (complications) ought to represent only "significant" complications. Therefore, as a marker of severity, only complications associated with a readmission are counted as complications in the numerator of the measure. (2) The proposed ICD complications measure evaluates hospitals' contributions to variation in the outcome after adjusting for patient-level risk factors. The model fit as measured by a C-statistic reflects the extent to which patient-level factors included in the risk adjustment explain patient-level outcomes. A low C-statistic can result from the presence of significant unmeasured patient-level confounders, but it may also reflect the fact that variation in the outcome is being driven by variation in the quality of care delivered to patients. The C-statistic for this measure is similar to that for other measures that risk-adjust for patient risk factors likely to affect readmission rates, suggesting that the extent to which patient factors explain
346	M, Health Plan	Rebecca Zimmermann, AHIP	007: ICD Implantation	Support - This measure utilizes the ACC's National Cardiovascular Data Registry (NCDR). It would be helpful to assess if the measure's denominator could be expanded to include patients younger than 65.	Please see response to Kenneth Henriksen #235.
353	M, Health Plan	Catherine MacLean, WellPoint	007: ICD Implantation	WellPoint supports comments made by the Steering Committee that the measure should be expanded to a broader population. We would like to see the measure specified beyond the Medicare FFS population.	The Steering Committee has made this recommendation to the measure developer. Measure developer response: Please see response to Kenneth Henriksen.

362	M, Consumer	Debra Ness, National Partnership for Women & Families	007: ICD Implantation	This is a very important measure that will provide outcome data on a high volume procedure. We do have some concern with the use of the hierarchical risk adjustment methodology used in this measure, since this type of methodology often puts many hospitals into the "average" category, and may not allow for differentiation in results among hospitals. However, as we note in our general comments, there are no perfect measures, and having information on ICD complication rates will provide consumers with more information than is currently available.	Measure developer response: Please see response to Dr. Rudolph #243.
371	M, Health Professionals	Dale Lupu, American Academy of Hospice & Palliative Medicine	007: ICD Implantation	OT1-007-09: Hospital Risk-Standardized Complication Rate – ICD Implantation? Measuring the complication rate once ICD implantation has been performed is important. We would also like to see a measure that addresses whether appropriate patient-centered discussion about risks, benefits, and patient values was conducted prior to the decision to proceed with ICD implantation. Discussions regarding limitations of this technology; prognosis; and discussion around timing of deactivation should take place prior to implantation.	Another deliverable for the Patient Outcomes project is an identification of additional measures that should be developed to measure outcomes. We will include your recommendation in this report. Measure developer response: We agree that these issues are of critical importance when deciding whether to implant an ICD. Developing novel metrics of shared decision-making and procedural appropriateness is an important goal, but beyond the scope of this measure. This is a good topic for a future measure.
376	M, Health Professionals	Laura Blum, Heart Rythm Society	007: ICD Implantation	The Heart Rhythm Society appreciates the opportunity to participate in the measure development process. With Dr. Sana Al-Khatib's expertise on the Technical Advisory Panel, the NQF Steering Committee overwhelmingly supported the endorsement of this measure. This measure clearly meets the criteria for endorsement by NQF. The measure is in the public domain; there is an identified responsible entity and process to maintain and update the measure; and the intended use of the measure is both public reporting and quality improvement. In addition, this outcome measure focuses on a priority identified by the National Priorities Partners; namely, to improve the safety and reliability of America's healthcare system. The measure is well defined and precisely specified. It can be implemented consistently within and across organizations and will allow for comparability. There are clinically necessary measure exclusions and the investigators used an evidence-based risk adjustment strategy. The information produced by the measure is meaningful, understandable, and useful to the intended audiences for public reporting and informing quality improvement. Lastly, the required data are available and retrievable without undue burden and are available in electronic sources	Thank you for your comments.

392	M, Consumer	Carol Sakala, Childbirth Connection	007: ICD Implantation	This measure will provide outcome data on a high-volume procedure. We are concerned that the planned hierarchical risk adjustment may not meaningfully discriminate for consumers among hospitals in the locality, as many hospitals have middle-range performance with this method.	Measure developer response: Please see response to Dr. Rudolph #243.
401	M, Provider	Samantha Burch, Federation of American Hospitals	007: ICD Implantation	The FAH has concerns with this measure, including the low match rate (70%) and a c-statistic of 0.611 which indicates that the risk model has a limited ability to predict the outcome of individual patients. We also seek clarification on the specifications for this measure – there appears to be a discrepancy between the denominator which includes inpatient or outpatient ICD implants and the numerator which indicates that complications are counted in the measure only if they occur during a hospital admission. The appropriateness of an ICD implantation being performed in the inpatient vs. the outpatient setting has been raised by the RACs in their review of Medicare claims. Reclassification or non-payment of claims could impact this measure that relies in part on administrative claims data.	Measure developer response: The measure is designed to assess the outcomes of Medicare fee-for-service (FFS) patients undergoing ICD implantation. For model development, we linked the administrative claims data to the American College of Cardiology National Cardiovascular Data Registry's (NCDR) ICD Registry using indirect identifiers so that we could use clinical data for risk adjustment. We are unaware of other measures that linked administrative and similar registry data using indirect identifiers and achieved a higher match rate. Our match rate is similar to that of the other registry-based measures that use data from the NCDR CathPCI Registry. In addition, it is comparable to that achieved by investigators from Duke who independently linked data from the NCDR CathPCI Registry with administrative claims data (Douglas et al. JACC. 2009).The match rate was expected to be low because the ICD Registry captures information on implants regardless of payer status and accordingly contains a mix of patients with Medicare FFS, Medicare Advantage, and other health plans. Importantly, however, the measure will be implemented using direct identifiers, obviating the need for probabilistic match. The model will be recalibrated in the full cohort of Medicare FFS patients prior to implementation-Statistic/measure specifications-Please see response to Dr. Gardner. Reclassification of claims-The effect of reclassification and/or non-payment of claims may have an important impact on any

413	M, Purchaser	Christine Chen, Pacific Business Group on Health	007: ICD Implantation	Hospital risk-standardized complication rate following implantable cardioverter defibrillator and Hospital 30-day risk-standardized readmission rates following percutaneous coronary intervention (PCI): We believe that these measures provide important information on outcomes for two high volume procedures (defibrillator implantation and PCI). As discussed above, we do have concern with the use of the hierarchical risk adjustment methodology in both of these measures. This methodology frequently places many hospitals into the "average" category, and may not allow for differentiation in results among hospitals. While these measures may not be perfect, we believe that they will provide those who receive and pay for care with more useful information than is available currently.	Measure developer response: Please see response to Dr. Rudolph #243
426	M, Provider	Michael Phelan, Cleveland Clinic	007: ICD Implantation	Part 1 of 2: Significant problems with data definitions and data collection prohibit us from supporting this measure as currently written. For example definitions for transfusion related to hematoma are not precise. Often times blood transfusions during the same admission do not relate directly to the severity of the hematoma or to ICD implantation. For example, the patient may have a borderline hemoglobin prior to the procedure or may have intraoperative bleeding unrelated to ICD that contributes to the need for a transfusion. It would be better to measure 1) hematoma requiring evacuation or 2) bleeding from ICD requiring transfusion. Regarding infections: 50% of infections occur in the first year, 50% later. 25% occur in the first month. We are not certain how many ICD infections present in first 90 days. Is there literature to support the 90 day window? What happens if the patient presents for explanation to another hospital? We are not sure that this would be picked up through NCDR data base. Target populations should only include primary implantations (no prior device implanted, not just prior ICD implantation, but also pacemaker implantations) also Creatinine > 2mg% is associated with increased mortality in replacement devices. Prior implantations of pacemakers should be excluded for the same	Please see response below #427.

427	M, Provider	Michael Phelan, Cleveland Clinic	007: ICD Implantation	Part 2 of 2: Because this will under count the infection rate, moreover it is not clear if the NCDR from other institutions will augment reporting by the primary institution. Since the data is not collected with these definitions and there may not be sufficient manpower ensure the accuracy of data collecting and reporting. Even if completely accurate data were collected, the definitions are somewhat broad, particularly about infection and blood transfusions, as per the comments above. Focusing on specific complications that do not require specific auditing as a composite measure like death and re-implantation with 90 days, may be easier to implement than auditing some of the other complication rates that maybe more difficult to audit. Most of the listed complications are actually difficult to audit. This is a self- reported data base where the outcomes are not currently being audited; hence there are significant concerns about the accuracy of the data. A mechanism in place to audit and correct complications rates would be needed to support this measure. Focusing on specific complications that do not require auditing, such as, death, re-implantation with 90 days, and revisions maybe a better starting place.	Measure developer response: Our approach to identifying complications included extensive involvement and discussion with electrophysiologists and quality improvement experts. Their consensus opinion was that the codes captured clinically important adverse events with adequate sensitivity and specificity. However, we are conducting additional chart validation studies to evaluate the use of the codes specified for this measure. Similarly, the decision to use a 90-day window to identify ICD infections and mechanical complications was made in conjunction with our expert consultants after review of the data. We appreciate Dr. Phelan's comment about excluding prior pacemakers and will use data from the chart validation study to further explore the consequences of adding this exclusion as part of measure maintenance. The measure uses NCDR ICD Registry data for risk adjustment and Medicare fee-for-service administrative data to identify complications. A major strength of this approach is that it allows tracking of patient outcomes across different facilities. Accordingly, the measure will not rely on self-reporting of complications to the NCDR ICD Registry. We agree that accurate identification of complications is critical to the measure and will continue exploring options to ensure the accuracy of the codes as the measure moves towards implementation.

428	M, Health Professionals	Clyde Yancy, American Heart Association; Ralph Brindis, American College of Cardiology; Frederick Masoudi, ACCF/AHA Task Force on Performance Measures	007: ICD Implantation	The ACCF and the AHA strongly support endorsement of these measures. These measures were developed using a rigorous scientific methodology and should provide hospitals and consumers with valuable information that is not currently available and that is consistent with other publicly-reported CMS measures. The measures address a clinically relevant time frame and employ well-described methods for risk-standardization that combine claims data with reliable clinical data from national registries to appropriately represent patient outcomes. They address important outcomes of care and are congruent with our published standards for statistical models used for public reporting of health outcomes. The ACCF Board of Trustees has formally voted to endorse these measures for use in public reporting. We will provide input to CMS, when the opportunity arises, on the appropriate implementation of the measures in their public reporting programs, given the well-known limitations of administrative data in performance measurement and potential issues of attribution, especially for the PCI measure.	Thank you for your comments.
121	M, Health Professionals	Howard Levite, NYU	008: PCI Readmission	Should be limited to readmissions for treatment of the same lesions as the index event only.	The Steering Committee noted a philosophical difference among stakeholders - those that support a patient-centered, episode of care perspective in which a procedure is a part of the overall care for a chronic condition. Dissenting comments advocate a focus on the immediate and related aspects of the procedure only. The Steering Committee strongly supports the patient-centered approach. Measure developer response: Dr. Levite proposes narrowing the scope of the measure to focus only on readmissions during which the same segment of the same coronary artery is treated within 30 days of the index procedure. We agree that this is one way to characterize the care of PCI patients, and we believe that this might be a reasonable approach if the goal of the measure was simply to characterize procedural success. The goal of the measure, however, is to assess quality of the entire system of care and to provide a broad overview of the outcomes achieved by hospitals that perform PCI. As such, the measure reflects not only procedural success, but also subsequent care including the critical transition from the hospital to the outpatient setting. This approach has the potential to affect significant improvements in the care and outcomes of this vulnerable population.

189	P	Kay Jewell MD, Center for Consumers of Healthcare	008: PCI Readmission	Support - there is concern about focusing only on the procedure however, patients have comorbidities that must be managed and coordinated. Patients expect all their conditions will be managed - either personally by the one doing the PCI or by appropriate physicians. If not, they bear the brunt of high glucoses, fluid imbalance, BP too high or too low, medication doses not adjusted and other common problems after hospitalization.	Thank you for your comments.
218	M, Health Plan	Sheree Chin Ledwell, Aetna	008: PCI Readmission	This is based on claims data so can be calculated by health plans. However, Aetna suggests use of two measures, 15 day readmit and a 16-45 day readmit rate. This will enable capturing early and later readmissions separately as the predominant cause for readmission seems to differ in those two groups.	Measure developer response: We look forward to exploring opportunities to expand the measure to include patients outside of the Medicare fee-for-service population. We sought a timeframe that reflected the overarching, patient-centered goal of the measure of reflecting quality at discharge and in the early transition period.To select the most appropriate time period for quality measures, we relied on analysis of available data, clinical judgment, and the advice of expert consultants. As noted in the measure methodology report, we selected the 30 day timeframe it captures the period following discharge during which PCI patients appeared to be most vulnerable to readmission and can clearly be influenced by the quality of care delivered by hospitals. Expanding the measure to a 45 day timeframe is feasible, but there would be concerned that readmissions occurring between 31-45 days would be less attributable to the hospitals that performed the procedure. We did not consider breaking the measure into 2 distinct time periods, but our data suggests that the reasons for readmission are similar in the 0-15 and 16-30 day periods (Figure 2a and 2b below).

231	M, Health Professionals	Nancy Nielsen, MD, PhD, American Medical Association	008: PCI Readmission	The 30-day timeframe for this measure may not yield an accurate assessment when considering readmission rates related to Percutaneous Coronary Intervention (PCI). More specifically, the time-lapse between a patient's PCI procedure and a subsequent hospital readmission may exceed a clinically meaningful and actionable period. It is noted in the report that some Technical Advisory Panel (TAP) members similarly believed a shortened timeframe might be more appropriate. Specifically, it is noted "7 or 15 days might be more appropriate to capture readmissions related to the PCI procedure" (page 3, lines 170-179). We recommend that the measure be amended for a 7- or 15-day timeframe rather than a 30-day timeframe.	The time frame was discussed at length by the TAP and Steering Committee. The measure developers specifically chose the timeframe to align with other readmission measures and noted that the readmission curve levels off after 45 days. Measure developer response: To select the most appropriate time period for quality measures, we relied on analysis of available data, clinical judgment, and the advice of expert consultants. As evidenced by the public comments about the measure, there is a range of opinions about the most appropriate timeframe ranging from 7 to 45 days. During measure development, we considered a number of potential time periods for the outcome and ultimately selected a 30-day timeframe for several reasons. First, we reviewed a preliminary analysis of the hazard of readmission over a 90-day period (Figure 1). The risk of readmission was highest within the first 15 days but remained elevated up to 60 days following discharge. There was, however, the appearance of a plateau that occurred between 30 and 45 days after discharge. These results suggested that a 30-day timeframe would capture the time period at which patients are at highest risk for readmission. Furthermore, readmissions in this time period would more likely be attributable to the care delivered both within an index hospitalization and during the transition from that setting. A shorter timeframe such as 15 days might have a stronger association with the initial care of the patient, but would miss the substantial number of readmissions occurring between 15 and 30 days that are potentially related to the index hospitalization. Both the working group and TEP agreed that a 30-day readmission measure had potential to

232	M, Health Professionals	Nancy Nielsen, MD, PhD, American Medical Association	008: PCI Readmission	The over all fit and predictive power of the risk-adjustment model are low. The fit of the model measured by the percentage of variation explained by the risk factors (ie, adjusted R squared) is 6%. In terms of predictive accuracy of the model as noted in TAP/Workgroup evaluation in the NQF Measure Evaluation Form, Section 2h, Disparities in Care, "the C statistic of 0.66 is good but not very good/excellent." In fact, C statistics between 0.6 and 0.7 have limited clinical value. The predictive accuracy of a model used to construct the risk-adjusted measure can be expected to be even lower than the accuracy in the patient data used by the measure developer in specifying the model. (E. Magnus Ohman; Christopher B. Granger; Robert A. Harrington; et al. "Risk Stratification and Therapeutic Decision Making in Acute Coronary Syndromes." JAMA. 2000;284(7):876-878.) It is important to note that a coin toss, or random predictions, has a C statistic of 0.50. We recommend that endorsement of this measure be contingent upon more robust risk-adjustment model statistics.	Measure developer response: The proposed PCI measure evaluates hospitals' contributions to variation in the outcome after adjusting for patient-level risk factors. The model fit as measured by a C-statistic reflects the extent to which patient-level factors included in the risk adjustment explain patient-level outcomes. A low C-statistic can result from the presence of significant unmeasured patient-level confounders, but it may also reflect the fact that variation in the outcome is being driven by variation in the quality of care delivered to patients. The C-statistic for this measure is similar to that for other measures that risk-adjust for patient risk factors likely to affect readmission rates, suggesting that the extent to which patient factors explain variation in hospital readmission rates is limited. Moreover, the risk-adjustment is unlikely to be missing important patient-level predictors. A major strength of the proposed PCI readmission measure is that it leverages the robust clinical data collected in the NCDR CathPCI Registry for patient-level risk adjustment. The variables collected in the registry were determined by clinicians and experts in quality improvement and performance measurement. Using the registry data minimizes the likelihood of unmeasured clinical confounders. CMS also convened a Technical Expert Panel to advise on the selection of model risk adjustment variables. As the PCI readmission

244	M, Purchaser	Barbara Rudolph, PhD, MSSW, The Leapfrog Group	008: PCI Readmission	The Leapfrog Group agrees that measuring readmission rates following PCI is important to both consumers and purchasers; however, we are concerned that this outcome measure utilizes a methodology which minimizes variation. In this case, hierarchical modeling pulls all but the most extreme outliers into average categories. This sends an inappropriate message to consumers and purchasers and fails to meet the most basic principle of measurement, "measures must reflect differences or they are not measures."	Measure developer response: We agree that the choice of modeling approach is a very important consideration in performance measurement. The proposed measure employs a hierarchical logistic regression model (HGLM) to create hospital risk-standardized 30 day readmission rates (RSRR) for hospitals performing PCI. In brief, the approach simultaneously models two levels (patient and hospital) to account for the variance in patient outcomes within and between hospitals. At the patient level, each model adjusts the log-odds of a hospital readmission within 30-days of discharge for age, sex, selected clinical covariates, and a hospital-specific intercept. The second level models the hospital-specific intercepts as arising from a normal distribution. The hospital intercept represents the underlying risk of readmission at the hospital, after accounting for patient risk. The hospital-specific intercepts are given a distribution in order to account for the clustering (non-independence) of patients within the same hospital. If there were no differences among hospitals, then after adjusting for patient risk, the hospital intercepts should be identical across all hospitals.

265	M, Health Professionals	Larry Dean, MD FSCAI, SCAI	008: PCI Readmission	Subject: SCAI comments re: 30-day PCI Readmission Measures (excluding staged procedures) [NQF Measure Number OT1-008-09]: The Society for Cardiovascular Angiography and Interventions (SCAI) appreciates the opportunity to provide comments to the National Quality Forum (NQF) regarding proposed 30-day readmission measures following Percutaneous Coronary Intervention (PCI), excluding staged procedures (The Quality Measure). SCAI is a professional organization representing over 4,000 invasive and interventional cardiologists. SCAI promotes excellence in cardiac catheterization, angiography, and interventional cardiology through physician education and representation, and quality initiatives to enhance patient care.	The TAP and Steering Committee heard these comments from SCAI during their meetings and considered them in their deliberations and recommendations. The Steering Committee noted a philosophical difference among stakeholders - those that support a patient-centered, episode of care perspective in which a procedure is a part of the overall care for a chronic condition. Dissenting comments advocate a focus on the immediate and related aspects of the procedure only. The Steering Committee strongly supports the patient-centered approach. Measure developer response: We appreciate and respect SCAI's concerns about the measure. However, we believe that the measure as currently specified will provide hospitals with important and actionable information that can be used to drive quality improvement efforts. During the process of measure development, we considered a wide range of potential outcomes. Ultimately, we selected all-cause readmission (except for staged procedures) as opposed to cardiac-specific readmission for several reasons. First, from the patient perspective, readmission for any reason is likely to be an undesirable outcome of care. Second, readmissions not associated with a cardiac diagnosis may in fact still be directly related to the care delivered during the index hospitalization. Examples include patients readmitted with acute renal failure due to a contrast nephropathy caused by the initial procedure, or patients readmitted with a pseudo aneurysm or other late-presenting vascular complication resulting from the initial procedure. In addition, the range of potentially avoidable readmissions also includes those not directly related to the PCI such as those resulting from poor communication or inadequate follow-up. The

266	M, Health Professionals	Larry Dean, MD FSCAI, SCAI	008: PCI Readmission	SCAI supports the concept of The Quality Measure but is very concerned that it will fail to achieve its objectives (and will in many ways make the problem worse) if it goes through as proposed. The Quality Measure uses data from the NCDR CathPCI Registry® for risk adjustment and uses Medicare Part A inpatient and outpatient administrative claims data to determine hospital-level "all-cause" readmissions. Unfortunately, all-cause readmissions include both cardiac and non-cardiac-related readmissions over a significant period of time. While The Quality Measure excludes PCI patients that may be readmitted for staged revascularization procedures, it lacks appropriate measure specifications that would identify direct PCI related readmissions that would allow programs to develop immediate system changes to improve patient care.	See response to comment #265..
267	M, Health Professionals	Larry Dean, MD FSCAI, SCAI	008: PCI Readmission	SCAI believes The Quality Measure has poor discrimination to attribute the readmission to either the indexed hospital stay or to attribute the readmission to care coordination. Considering that a high quality measure has a C-Statistic upwards past 0.8, a C-Statistic of 0.663 for The Quality Measure is disappointing. Sean O'Brien, Phd (Asst. Professor, Department of Biostatistics at DCRI) states in NQF-provided documents: (1) "C = 0.663 indicates a limited ability to predict the outcomes of individual patients " and (2) "a low C statistic should prompt the developers to search for important unmeasured risk factors that could be added to the NCDR data set " to support good discrimination.	Measure developer response: Please see response to Dr. Nielsen #232..

268	M, Health Professionals	Larry Dean, MD FSCAI, SCAI	008: PCI Readmission	SCAI does not support either non-cardiac diagnoses in the measure specification or any diagnosis unrelated to PCI procedure. Elimination of reimbursement codes that are not specific enough to provide hospitals and physicians an understanding of what alternative care could have been provided to reduce readmissions and if that readmission is preventable is warranted. In addition, several codes in the top 100 procedure codes associated with PCI readmissions appear unrelated to the initial admission for the PCI procedure and unlikely associated with a care transition: (1) laparoscopic cholecystectomy, (2) partial hip replacement, and (3) implantation or replacement of automatic cardioverter/defibrillator, among others unrelated to PCI procedure. Furthermore, it is well-known that certain PCI patient subgroups, such as patients with end-stage renal disease, are at greater risk of early readmission.	See response to comment #265.

269	M, Health Professionals	Larry Dean, MD FSCAI, SCAI	008: PCI Readmission	SCAI disagrees with the measure developer that "creating a comprehensive list of potential 'PCI-related' complications would be arbitrary. " Focusing on a subset of complications that are clinically meaningful to interventional cardiology and specific to our patients will help hospitals identify real problems associated with patient selection, the quality of the procedure, the discharge planning process, and care coordination. SCAI believes that a low C-statistic and the unwillingness to develop such a meaningful list demonstrates that the measure specifications were not completed and vetted in a manner equivalent to the ACC/AHA Performance Measurement Development process ("the gold standard for cardiology measures").	Measure developer response: We respectfully disagree with SCAI on these points. The process of measure development adhered closely to the standards set out in the ACC/AHA position papers on performance measurement (Spertus, Eagle, et al. 2005; Krumholz, Brindis, et al. 2006). These guidelines do not specify a threshold c-statistic as defining an acceptable measure, nor do they indicate that a narrowly defined outcome is preferable to a more broadly defined outcome. Spertus JA, Eagle KA, Krumholz HM, Mitchell KR, Normand SL; American College of Cardiology; American Heart Association Task Force on Performance Measures. American College of Cardiology and American Heart Association methodology for the selection and creation of performance measures for quantifying the quality of cardiovascular care. Circulation. 2005 Apr 5;111(13):1703-12. Krumholz, H. M., R. G. Brindis, et al. (2006). "Standards for statistical models used for public reporting of health outcomes: an American Heart Association Scientific Statement from the Quality of Care and Outcomes Research Interdisciplinary Writing Group: cosponsored by the Council on Epidemiology and Prevention and the Stroke Council. Endorsed by the American College of Cardiology Foundation." Circulation 113(3): 456-62.

270	M, Health Professionals	Larry Dean, MD FSCAI, SCAI	008: PCI Readmission	SCAI applauds the exclusion of staged procedures; however, other common scenarios of good care are being lumped into the all-cause measure. While complex multi-vessel procedures are not routine, physicians and their patients (i.e., patient preferences) sometimes elect to stage PCI procedures by bringing patients (such as those with renal insufficiency) back for additional procedures either during the same hospitalization or readmitting patients for revascularization following a period of recovery. As staged procedures are defined, SCAI believes it is appropriate to exclude any readmission with a planned revascularization (PCI/CABG) that is not associated with an acute code, including Heart Failure, Acute Myocardial Infarction, Unstable Angina, Arrhythmia, and Cardiac Arrest.	Measure developer response: As noted, the measure does not count admissions associated with a potentially staged procedure as a readmission. PCI and CABG procedures are considered as 'staged' if they are not associated with one of the acute diagnosis code listed above. Physicians would not be expected to pre-specify at the time of the initial implant whether or not they intended to perform a staged procedure. As such, the scenario outlined by SCAI would not count as a readmission as it would not be associated with an acute principal discharge diagnostic code.
271	M, Health Professionals	Larry Dean, MD FSCAI, SCAI	008: PCI Readmission	SCAI is concerned about possible scenarios that could lead to more aggressive/risk care for patients with multivessel disease. A physician may decide to perform PCI on the target lesion, allowing other less significant lesions to be managed medically because the patient is considered high risk. If that patient returns with angina within 30 days, which would count negatively to The Quality Measure since the physician did not schedule a staged intervention. This might lead operators to try more aggressive revascularization at the on-set than they otherwise would and perhaps lead to worse outcomes.	Measure developer response: As noted, the measure does not count admissions associated with a potentially staged procedure as a readmission. PCI and CABG procedures are considered as 'staged' if they are not associated with one of the acute diagnosis code listed above. Physicians would not be expected to pre-specify at the time of the initial implant whether or not they intended to perform a staged procedure. As such, the scenario outlined by SCAI would not count as a readmission as it would not be associated with an acute principal discharge diagnostic code.

272	M, Health Professionals	Larry Dean, MD FSCAI, SCAI	008: PCI Readmission	SCAI is concerned about possible scenarios that could lead to more aggressive/risk care for patients with multivessel disease who could not get a complete revascularization. For example, consider a typical patient with a severe proximal Left Anterior Descending (LAD) lesion that is a good target and also has a small diseased Obtuse Marginal (OM) that is a poor target. If this patient is not a candidate for surgery, the physician may hesitate to revascularize given the concern is that this patient would continue to have angina from the OM poor target and return to the hospital. If that patient returns with angina within 30 days, which would count negatively to The Quality Measure since the physician did not schedule a staged intervention. While this is less likely in some populations with good outpatient follow-up, some institutions where access to care is often through the Emergency Department could lead to more aggressive care. Given that there are no data elements to capture the underlying reason for readmission in CathPCI Registry; SCAI predicts an increase of staged procedures in future CathPCI Registry data.	Measure developer response: The goal of the present work is to improve patient outcomes by providing patients, physicians, and hospitals with information about risk adjusted readmission rates following PCI. All-cause PCI readmission is a patient-centered measure not focused solely on procedural issues or other processes of care, but rather on patients and the need for broad improvement in the transitions of care. Using registry data for the measure has several advantages for reaching this goal, including more robust risk adjustment and direct engagement of the clinicians and professional societies who have developed these registries. As noted above, the goal is not to bring readmission rates to zero, but to inform hospitals and the public how well hospitals and post acute care providers are doing on addressing this important outcome relative to other hospitals with similar types of patients.
273	M, Health Professionals	Larry Dean, MD FSCAI, SCAI	008: PCI Readmission	SCAI Principles for Public Reporting: SCAI supports publicly reporting of data and believe that validated results can be a valuable tool for both patients and improving healthcare systems. However, appropriate checks and balances should be in-place from the beginning to help make sure measure specifications do what they intend to do and are appropriately risk-adjusted. This way, patients will have access to the best possible information as they make shared decisions with their physicians about their care. Steps must be taken to ensure that both patients and doctors feel confident about the accuracy, quality and currency of data contained in public reports. In order to reflect the current level of care, clinical data in the registry must be kept up-to-date with appropriate data fields to define reasons for readmission. Given the rapid pace at which medicine and clinical guidelines evolve, old data (especially CMS or payer billing data) could potentially cause more harm than good. Rigorous audits of clinical data are essential to validate data for accuracy and completeness. This includes chart audits and on-site visits. CathPCI Registry audit results should be publicly reported. Risk-adjustment methodology and implementation must be sound, prospectively tested (not retrospectively as NQF allows), and clearly explained to users of	The TAP and Steering Committee heard these comments from SCAI during their meetings and considered them in their deliberations and recommendations.

274	M, Health Professionals	Larry Dean, MD FSCAI, SCAI	008: PCI Readmission	SCAI believes that public reporting should start with a very small number of key measures that are carefully selected because there is great confidence that accuracy and completeness are achievable with them. Use of a gradual, step-by-step approach to public reporting of outcomes makes sense because it will allow development of processes and timelines to ensure data integrity, verify data are accurate and up-to-date, correct inevitable errors, and appropriately disseminate reports to healthcare consumers. These processes and timelines should be developed collaboratively with representation from medical societies, practicing physicians, and patient advocacy groups, among others. Physicians must have the opportunity to evaluate and appeal reports about the care they deliver before reports are publicly disseminated.	Thank you for your comments.
275	M, Health Professionals	Larry Dean, MD FSCAI, SCAI	008: PCI Readmission	Preventing readmissions is a complex, system-wide problem that involves hospitals, physicians and other providers who manage patients' care, as well as patients and their families. Hospital leaders and clinicians who care for patients recognize that some readmissions can be prevented. But there are a number of factors beyond the hospital's control that affect whether a patient is readmitted, including the natural course of the disease, the limited availability of post-acute and ambulatory health care services, high levels of poverty among some hospitals' patients, and a lack of community-based social services. These factors substantially affect a hospital's performance on The Quality Measure.	Measure developer response: The goal of the present work is to improve patient outcomes by providing patients, physicians, and hospitals with information about risk adjusted readmission rates following PCI. All-cause PCI readmission is a patient-centered measure not focused solely on procedural issues or other processes of care, but rather on patients and the need for broad improvement in the transitions of care. Using registry data for the measure has several advantages for reaching this goal, including more robust risk adjustment and direct engagement of the clinicians and professional societies who have developed these registries. As noted above, the goal is not to bring readmission rates to zero, but to inform hospitals and the public how well hospitals and post acute care providers are doing on addressing this important outcome relative to other hospitals with similar types of patients.

276	M, Health Professionals	Larry Dean, MD FSCAI, SCAI	008: PCI Readmission	The intent of "preventable" readmission measures is for hospitals to improve readmission rates; there should be no expectation of zero readmissions. Hospitals and physicians have a responsibility to the public to mitigate preventable readmissions through appropriate patient selection, following appropriate use criteria, and implementing robust discharge protocols. Hospitals should evaluate their transitional care activities and discharge instructions to assure patients and their family understands the discharge instructions. Hiring translators and interpreters may be needed to serve minority families. A summary of care and medication orders upon discharge is vital. Scheduling patients for their first follow-up visit within 4 to 10 days of discharge is known to reduce readmissions. The Quality Measure should be paired with a "Physician Follow-up Visit and Patient Encounter Measure" in order to obtain the desired outcome of reducing readmissions. Among other socio-economic factors, patient absence for follow-up appointments due to transportation limitation is a driver for readmissions.	The Steering Committee discussed the many innovative ideas being evaluated for reducing readmissions. Measuring the outcome allows innovative approaches to be tested as hospitals reconsider their processes to reduce readmissions. Measure developer response: The goal of the present work is to improve patient outcomes by providing patients, physicians, and hospitals with information about risk adjusted readmission rates following PCI. All-cause PCI readmission is a patient-centered measure not focused solely on procedural issues or other processes of care, but rather on patients and the need for broad improvement in the transitions of care. Using registry data for the measure has several advantages for reaching this goal, including more robust risk adjustment and direct engagement of the clinicians and professional societies who have developed these registries. As noted above, the goal is not to bring readmission rates to zero, but to inform hospitals and the public how well hospitals and post acute care providers are doing on addressing this important outcome relative to other hospitals with similar types of patients.
277	M, Health Professionals	Larry Dean, MD FSCAI, SCAI	008: PCI Readmission	Conclusion SCAI believes that significant refinement will result in an appropriate metric to judge performance, change systems and improve patient care. SCAI recognize the inherent challenges of developing meaningful measures using administrative data sets; however, refinement is warranted given that The Quality Measure will be used to penalize hospitals with payment penalties. Moreover, we appreciate the necessity to work toward better satisfying the public demand for more information about the hospitals from which they receive care. Contact Joel C. Harder, MBA, Director Quality Initiatives and Clinical Documents at 202-552-0910 or jharder@scai.org if there are any questions or further requests. Sincerely, Larry Dean, M.D., FSCAI, President The Society for Cardiovascular Angiography and Interventions	Measure developer response: The goal of the present work is to improve patient outcomes by providing patients, physicians, and hospitals with information about risk adjusted readmission rates following PCI. All-cause PCI readmission is a patient-centered measure not focused solely on procedural issues or other processes of care, but rather on patients and the need for broad improvement in the transitions of care. Using registry data for the measure has several advantages for reaching this goal, including more robust risk adjustment and direct engagement of the clinicians and professional societies who have developed these registries. As noted above, the goal is not to bring readmission rates to zero, but to inform hospitals and the public how well hospitals and post acute care providers are doing on addressing this important outcome relative to other hospitals with similar types of patients.

293	M, Provider	Thomas Miner, Trinity Health	008: PCI Readmission	Acceptable – follows guidelines of readmission measure for AMI	Thank you for your comments.
325	M, QMRI	Bernard M. Rosof, MD, MACP, Physician Consortium for Performance Improvement ®	008: PCI Readmission	The 30-day timeframe for this measure may not yield an accurate assessment when considering readmission rates related to Percutaneous Coronary Intervention (PCI). More specifically, the time-lapse between a patient's PCI procedure and a subsequent hospital readmission may exceed a clinically meaningful and actionable period. It is noted in the report that some Technical Advisory Panel (TAP) members similarly believed a shortened timeframe might be more appropriate. Specifically, it is noted "7 or 15 days might be more appropriate to capture readmissions related to the PCI procedure" (page 3, lines 170-179). We recommend that the measure be amended for a 7- or 15-day timeframe rather than a 30-day timeframe.	The time frame was discussed at length by the TAP and Steering Committee. The measure developers specifically chose the timeframe to align with other readmission measures and noted that the readmission curve levels off after 45 days.
326	M, QMRI	Bernard M. Rosof, MD, MACP, Physician Consortium for Performance Improvement ®	008: PCI Readmission	The over all fit and predictive power of the risk-adjustment model are low. The fit of the model measured by the percentage of variation explained by the risk factors (ie, adjusted R squared) is 6%. In terms of predictive accuracy of the model as noted in TAP/Workgroup evaluation in the NQF Measure Evaluation Form, Section 2h, Disparities in Care, "the C statistic of 0.66 is good but not very good/excellent." In fact, C statistics between 0.6 and 0.7 have limited clinical value. The predictive accuracy of a model used to construct the risk-adjusted measure can be expected to be even lower than the accuracy in the patient data used by the measure developer in specifying the model. (E. Magnus Ohman; Christopher B. Granger; Robert A. Harrington; et al. "Risk Stratification and Therapeutic Decision Making in Acute Coronary Syndromes." JAMA. 2000;284(7):876-878.) It is important to note that a coin toss, or random predictions, has a C statistic of 0.50.We recommend that endorsement of this measure be contingent upon more robust risk-adjustment model statistics.	See measure developer response to Dr. Nielsen #231.

333	M, Health Professionals	Lea Anne Gardner RN, PhD (on behalf of the Performance Measurement Technical Advisory Committee), American College of Physicians	008: PCI Readmission	1. The ACP PMTAC is concerned about the inclusion of "all-causes" readmissions in this measure. Patients may be readmitted for reasons that are not PCI related. 2. We are also concerned about the validity of this measure given that the c-statistic identifies that the risk model has a limited ability to predict outcomes of individual patients.	The TAP and Steering Committee discussed all-cause readmissions at length for this measure. The majority felt that patients undergoing PCI procedure have underlying conditions - coronary artery disease and frequently other comorbidities - that are an essential part of patient care particularly when undergoing a procedure such as PCI. The Committee notes the harmonization with NQF endorsed all-cause readmission rates for AMI and heart failure. Measure developer response: (1) Please see response to Dr. Dean above. (2) Please see response to Dr. Nielsen above.
334	M, Provider	Jennifer Faerberg, Association of American Medical Colleges	008: PCI Readmission	While the previous readmission measures in AMI, HF and Pneumonia were developed and endorsed with a 30-day time window; the interval should not set the standard for all readmission measures. The AAMC believes this measure would be more appropriate at 15 days to identify the readmissions most closely linked to the procedure. The longer the time interval the greater the likelihood other factors unrelated to the procedure affect a possible readmission. Similarly, as we have commented on the previous readmission measures we are concerned with the use of "all-cause" and believe that only those readmissions unplanned and related to the actual procedure should be counted. The all cause structure allows readmissions to be counted that may be unrelated to the prior care received and beyond the control of the hospital. The AAMC continues to support the inclusion of socio-economic factors (SES) in the risk model as those factors greatly impact patient outcomes and most often are out of the control of the hospital. This measure does not address any SES factors in the risk model.	The Steering Committee noted a philosophical difference among stakeholders - those that support a patient-centered, episode of care perspective in which a procedure is a part of the overall care for a chronic condition. Dissenting comments advocate a focus on the immediate and related aspects of the procedure only. The Steering Committee strongly supports the patient-centered approach. The TAP and Steering Committee discussed all-cause readmissions at length for this measure. The majority felt that patients undergoing PCI procedure have underlying conditions - coronary artery disease and frequently other comorbidities - that are an essential part of patient care particularly when undergoing a procedure such as PCI. The Committee notes the harmonization with NQF endorsed all-cause readmission rates for AMI and heart failure. Measure developer response: All-cause readmission - Please see response to Dr. Dean above. SES -We understand the important role SES may have in performance measurement. As discussed during the NQF Steering Committee call, however, our preliminary analyses suggest that a stratified measure may not be warranted. We conducted stratified analyses of hospital risk standardized readmission rates (RSRR) by (a) hospital safety net status and (b) quartiles of median household income. Both sets of analyses suggested that the range of hospital similar irrespective of the SES of the patients treated. Specifically, the median RSRR for Safety Net hospitals was 11.1% with the median of the lowest decile 10.1% and highest

347	M, Health Plan	Rebecca Zimmermann, AHIP	008: PCI Readmission	Support – The measure developers should consider reporting the data in two cohorts - readmissions from 0 to 15 days and from 15 to 30 days. This would help to distinguish readmissions that are more closely related to the PCI from later readmissions which may be more directly attributable the patient's transition from hospital to the outpatient setting. AHIP also recommends assessing if the measure can be applied to patients younger than 65.	Measure developer response: Please see response to Sheree Chin Ledwell #218 above.
354	M, Health Plan	Catherine MacLean, WellPoint	008: PCI Readmission	WellPoint supports comments made by the Steering Committee that the measure should be expanded to a broader population. We would like to see the measure specified beyond the Medicare FFS population.	The Steering Committee made this recommendation to the developer. Measure developer response: We developed the measure in the Medicare ≥65 fee-for-service population as this is the only cohort of patients in whom we have the means of reliably identifying outcomes beyond the index hospitalization. When and if additional sources of outcome data become available, the measure could certainly be applied to the broader population of patients. This would require additional work to optimize the risk adjustment methodology, but is definitely feasible.
363	M, Consumer	Debra Ness, National Partnership for Women & Families	008: PCI Readmission	Similar to our comments on the ICD complications rate measure, we feel this is an important measure that will provide crucial outcome data on a high-volume condition/population. Again, however, we do want to express concern over the use of hierarchical risk adjustment methodology due to its effects on public reporting. We ask that NQF consider other methods to appropriately and accurately risk-adjust outcomes data in a way that does run the risk of bringing the data in toward the mean. That being said, we do support this measure.	Thank you for your comments. Measure developer response: Please see response to Dr. Rudolph #243 above.
393	M, Consumer	Carol Sakala, Childbirth Connection	008: PCI Readmission	This measure will provide outcome data on a high-volume procedure. We are concerned that the planned hierarchical risk adjustment may not meaningfully discriminate for consumers among hospitals in the locality, as many hospitals have middle-range performance with this method.	Thank you for your comments. Measure developer response: Please see response to Dr. Rudolph #243 above.

402	M, Provider	Samantha Burch, Federation of American Hospitals	008: PCI Readmission	The FAH shares the concern of some TAP members related to the measure being "all cause" and utilizing a 30-day timeframe. The measure developer indicated that the risk of readmission was greatest in the first 15 days and, therefore, we believe a 15-day timeframe would be more appropriate for measuring performance related to the PCI procedure. As with the other currently endorsed 30-day readmission measures for AMI, HF, and PN, the FAH is concerned that "all-cause" measures do not draw a strong enough link to the original procedure or condition for which the patient was admitted. The ability for the measure to have a strong association with the care received by patients during the original admission will be especially important as it relates to new readmissions payment policies that will be based on NQF-endorsed measures.	The Steering Committee noted a philosophical difference among stakeholders - those that support a patient-centered, episode of care perspective in which a procedure is a part of the overall care for a chronic condition. Dissenting comments advocate a focus on the immediate and related aspects of the procedure only. The Steering Committee strongly supports the patient-centered approach.The TAP and Steering Committee discussed all-cause readmissions at length for this measure. The majority felt that patients undergoing PCI procedure have underlying conditions - coronary artery disease and frequently other comorbidities - that are an essential part of patient care particularly when undergoing a procedure such as PCI. The Committee notes the harmonization with NQF endorsed all-cause readmission rates for AMI and heart failure. Measure developer response: Timeframe - Please see response to Dr. Ledwell #218 above. All-cause readmission - Please see response to Dr. Dean above #265-277.
418	M, Provider	Cleveland clinic, Cleveland clinic	008: PCI Readmission	There are concerns that this measure fails to take into account that 30-50% of re-admissions w/in 30 days of PCI are unrelated in any way to the PCI (or related care) —the measure is not robust enough. There are concerns that the measure as configured will not produce reliable and valid data about the quality of PCI care. Exclusions for non-cardiovascular reasons for admission (e.g., bronchitis, asthma, appendicitis, etc.) would be required. At this measure's NQF TAP meeting, the American College of Cardiology representative pushed for a more sophisticated measure eliminating the 40% or so of readmissions that had nothing to do with PCI.	The Steering Committee noted a philosophical difference among stakeholders - those that support a patient-centered, episode of care perspective in which a procedure is a part of the overall care for a chronic condition. Dissenting comments advocate a focus on the immediate and related aspects of the procedure only. The Steering Committee strongly supports the patient-centered approach.The TAP and Steering Committee discussed all-cause readmissions at length for this measure. The majority felt that patients undergoing PCI procedure have underlying conditions - coronary artery disease and frequently other comorbidities - that are an essential part of patient care particularly when undergoing a procedure such as PCI. The Committee notes the harmonization with NQF endorsed all-cause readmission rates for AMI and heart failure. Measure developer response: Please see response to Dr. Dean above #265-277.

429	M, Health Professionals	Clyde Yancy, American Heart Association; Ralph Brindis, American College of Cardiology; Frederick Masoudi, ACCF/AHA Task Force on Performance Measures	008: PCI Readmission	The ACCF and the AHA strongly support endorsement of these measures. These measures were developed using a rigorous scientific methodology and should provide hospitals and consumers with valuable information that is not currently available and that is consistent with other publicly-reported CMS measures. The measures address a clinically relevant time frame and employ well-described methods for risk-standardization that combine claims data with reliable clinical data from national registries to appropriately represent patient outcomes. They address important outcomes of care and are congruent with our published standards for statistical models used for public reporting of health outcomes. The ACCF Board of Trustees has formally voted to endorse these measures for use in public reporting. We will provide input to CMS, when the opportunity arises, on the appropriate implementation of the measures in their public reporting programs, given the well-known limitations of administrative data in performance measurement and potential issues of attribution, especially for the PCI measure.	Thank you for your comments
133	M, Supplier/ Industry	Franz Fanuka, sanofi-aventis	016: AMI Discharge Care	We support the concept of additional measures to focus on improving the transition of care. A composite measure that includes all three factors – readmission, ED visit rate and E&M visit rate, will help focus attention and begin to track improvement over time. Transition of care is very important: patients need better connection to primary care physicians, support/contacts for questions about medications and what to do for changes in conditions between the time of their discharge and their first E&M appointment. This is a system-level problem that needs system-level attention to solve. This is especially true when a condition is new or has evolved or when medications have been changed or added. This is true for atrial fibrillation (AF) especially as a secondary condition. AF is one of the conditions listed in the developer's data on the top 50% of ED visits after a discharge. This supports our experience and the importance of the transition of care when AF is present as a secondary condition. The data on reasons for an ED visit after hospitalization for AMI lists atrial fibrillation in the top 50% of reasons for ED visits, lending additional data and support to the importance of atrial fibrillation as a high priority condition that contributes to clinical outcomes and increased cost of care. In addition to reporting the composite score, we would like to see the rates for the individual measures publicly reported.	Additional infomration regarding NQF's framework and evaluation of composite measures will be added to the report. One of the principles is transparency of the components. Measure developer response: We agree that the individual measures should be reported along with the composite measure.

164	P	Mellanie True Hills, StopAfib.org & American Foundation for Women's Health	016: AMI Discharge Care	While there is clearly a need for measures that help reduce readmission rates, we do not believe this composite measure will accomplish that. As patients, we know that follow-up appointments are important, but sometimes that is difficult to accomplish when the hospital doesn't help make the appointment, or they make it when we don't have transportation or have to work, or worse yet, we try to make the appointment and can't get one quickly or are told to just go to the ER. We need help getting follow-up visits or appropriate care, which may not necessarily be a doctor visit, such as in the case of medication management. This measure should only consider relevant follow up care—with a primary care physician, specialist, or appropriate PA or NP—rather than just any office visit. So even though this is important to patients, we must be sure that we are measuring the right things. A composite measure that blends negative and positive weighting factors just obfuscates the relevant detailed data, making it less actionable. And if the individual measures in this composite don't qualify for stand-alone endorsement, then how can they be valid within a composite? We need well-designed, validated individual measures if we are to accomplish significant change. The ED rate should only report ED visits relevant to the specific measure, not all ED visits. The E&M measure should only focus on relevant care, not capture all E&M visits. See OT1-017-09 for the rest of the comments.	The Steering Committee reviewed the data presented by the developer on how the components work together presented on page 54 of the measure information for OT1-016-09 at http://www.qualityforum.org/projects/Patient_Outcome_Measures_Phases1-2.aspx?section=CallforCandidateConsensusStandards2009-08-20#t=2&s=&p=5%7C The Committee did not recommend the E&M visit measure as a stand alone measure due to some of the issues you raise - however, works well enough in the composite where there are multiple ways to improve performance on the composite (reduce readmissions or ED visits or increase E&M visits). Measure developer response: The composite measure is intended to describe "care trajectories," which relate broadly to care coordination. It describes how well a hospital, and the other constituent components of the local delivery system, evaluate patients in a timely way after discharge so that problems can be identified and addressed. Potential problems are not limited to the AMI per se, but could include, for example, medication reconciliation related to other health conditions, or the emergence or exacerbation of comorbidities. Care coordination necessarily involves multiple providers, and sorting out circumstances related to multiple health conditions. Accordingly, this measure is not intended to single-out a thread of activity related to a single
180	P	Kay Jewell, Tara Center LLC	016: AMI Discharge Care	Quality measures are needed that focus on the transition of care and address rates of ED visits and E&M visits that occur before readmissions. The transition is especially important when there are has been a change in their condition, new symptoms to understand and management and medication changes. The discharge instructions are not always consistent with the verbal or prescription labels. Patients need clear instructions about who to talk with between the time they are discharged and their first appointment about medications and symptoms. Without it, patients need to seek care in the ED. Comorbid conditions and the medication used to manage them need to be addressed during the hospital stay and planned for at discharge. Diabetes is one of the conditions impacted by the stress of an AMI; it needs to be managed/stabilized in the hospital and transition instructions given. This is very important when the hyperglycemia and medication are new to the patient. DM is one of the top diagnoses associated with ED visits after AMI; the cumulative frequency was 32% in 2007, its frequency as the reason for the ED visit was 1.71%. This confirms its importance as a secondary condition and a high priority condition. It supports the need for better DM management during the acute hospitalization. As a composite measure, it would be	The Steering Committee reviewed the data presented by the developer on how the components work together presented on page 54 of the measure information for OT1-016-09 at http://www.qualityforum.org/projects/Patient_Outcome_Measures_Phases1-2.aspx?section=CallforCandidateConsensusStandards2009-08-20#t=2&s=&p=5%7C You describe some of the issues that need better attention to achieve successful transitions and avoid extra ED visits or readmissions. Measure developer response: We agree that the individual measures should be reported along with the composite measure.

213	M, Health Professionals	Rita Munley Gallagher, PhD, RN, American Nurses Association	016: AMI Discharge Care	The American Nurses Association (ANA) appreciates the concerns raised by the TAP in regards to the 30 day composite measures for AMI and Heart Failure. Specifically, ANA finds the inclusion of both positive and negative scores into a single composite to be of question. The effort is admirable but appears to be too inflexible to reach a firm conclusion on the outcomes in a way that allows for comparison.	The Steering Committee reviewed the data presented by the developer on how the components work together presented on page 54 of the measure information for OT1-016-09 at http://www.qualityforum.org/projects/Patient_Outcome_Measures_Phases1-2.aspx?section=CallforCandidateConsensusStandards2009-08-20#t=2&s=&p=5%7C Measure developer response: The positive and negative aspects of the composite weighting are not central to the understanding of the composite. The composite measure is intended to profile hospitals and deliver systems in terms of care trajectories. Some utilization events (such as a timely E&M visit) are often positive, whereas others (hospital readmission) are often negative. The proposed scoring of the individual measures within the composite is consistent with that intuition. In contrast, all three individual measures could have been scored as negative, for example, by replacing the current measure --positive occurrence of an E&M visit-- with its opposite: the absence of a timely E&M visit. In either case, the logic of the measure would be the same: the "care trajectories" profile can be improved by evaluating and managing patients soon after discharge, and avoiding the need for emergency care, and especially readmission to the hospital.
219	M, Health Plan	Sheree Chin Ledwell, Aetna	016: AMI Discharge Care	Aetna is supportive of NQF endorsing this valuable coordination-of-care measure. This outcome measure combines follow-up outpatient visit, ER visit, and readmission. There is a weighted scoring system with OP getting +1 point. Aetna recommends, however, that the scoring system be eliminated and to just show the outcomes for each of the 3 submeasures since the impact of the outpatient visit and an ER visit that might be preventing a hospitalization is unknown. In addition, as this measure is based on claims data, it can be calculated by health plans.	Measure developer response: We are proposing a composite measure, not just a triad of stand-alone measures. In other words, we believe that consumers of the information can benefit from understanding what the individual measures mean in concert, not just by themselves. The composite measure provides a convenient summary that reflects professional judgment about the relative contributions of the individual components to overall care trajectories. Either way, we agree that these utilization events are not simply links in a causal chain. Follow-up visits can help patients in many ways besides avoiding adverse utilization events. Similarly, the need for emergency care and readmission can be reduced by factors other than simply an E&M visit.

236	M, Provider	Kenneth Henriksen, Advocate Physician Partners	016: AMI Discharge Care	The descriptive specification for this measure could benefit from clarification on the risk adjustment methodology recommended. The Evaluation and Management Services (E&M) component of the composite weighting raises questions as to whether there would be consideration of the occurrence of more than one office visit within the 30 Days Post Discharge or whether one visit in isolation is the only criteria for assigning and scoring the composite weighting. It is felt that presence of more than one office visit within the 30 day time period would be an indication of tighter management of the patient in an outpatient setting which should warrant awarding of additional points in the weighted measurement of the composite scoring.	The revised draft report will attempt to clarify that the risk adjustment method for the ED visit and E&M visit is the same as for the endorsed readmission measure. Measure developer response on weighting: It seems to be a reasonable premise or hypothesis that "care trajectories" would be better or worse based on the number of utilization events, not just the single occurrence of utilization events. Of course, the measure applies to groups of patients; in this case, all patients discharged after an AMI. Some patients may benefit from multiple ambulatory visits. As it is, the proposed measure merely observes whether a patient was seen at least once to place them in the hands of the ambulatory care system. It is a transition measure not a full post-discharge care follow-up measure that may involve longer follow-up periods and more details
249	M, Purchaser	Gaye Fortner, HC21	016: AMI Discharge Care	These composite measures will be strong additions to the NQF measure portfolio, for they reflect not just outcomes but also care coordination. In addition to providing an overall picture of how care is provided at the time of discharge, they will contribute to a better understanding of the coordination that does or does not occur at the hospital setting for patients with AMI and/or heart failure. While the report did reflect some concerns regarding how understandable these measures may be when publicly reported, I believe that consumers can be provided with appropriate language in a public report to help them understand the distinct components that make up these composite measures, and that as a whole they are intuitively understandable.	Measure developer response: We agree. It is worth remembering that CMS works closely with Medicare beneficiaries in deciding how to display and explain publicly reported measures.

278	M, Health Professionals	Joanne Ray, AACVPR	016: AMI Discharge Care	The American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) agrees with the proposed 30-day past hospital AMI care transition composite outcome measures, including hospital readmission, emergency department visits, and E/M coded visits to an outpatient provider, for patients who have been recently discharged after an acute myocardial infarction (AMI). In our view, there is good evidence that these measures help to assess patient outcomes following AMI. However, AACVPR strongly recommends that these outcome measures also include an additional measure to assess the patient's participation in early outpatient cardiac rehabilitation following AMI. Assessment of such participation would include the documentation of cardiac rehabilitation CPT codes 93797 or 93798. Performance measures for cardiac rehabilitation referral have been recently endorsed by NQF for the post-hospital transition and coordination of care for all patients following AMI (NQF Care Coordination Measures, 2010). Furthermore, these performance measures have been endorsed by ACC, AHA, AACVPR, and 9 other partnering organizations. In addition, due to the evidence in support of its benefits, cardiac rehabilitation referral has been endorsed by several national organizations (American College of Cardiology (ACC), American Heart Association (AHA), AACVPR, and others).	Measure developer response: We understand that cardiac rehabilitation is an underutilized and often cost-effective therapy for patients after AMI. Coincidentally, much of the empirical work establishing the case for CR, including the articles you cite, was conducted by colleagues here at Brandeis University under contract to CMS. In fact, they compiled much of that work into a book that has just been published. The composite measure being proposed here is fairly generic in that it does not isolate specific therapies or services that are linked directly to the specific patient population. Rather, it summarizes care trajectories following discharge using utilization indicators that are broadly applicable to most, if not all, patients leaving the hospital. It is an empirical question, but it seems likely that hospitals and delivery systems that are able to connect patients to CR would perform well on the composite, at least in terms of E&M visits billed as part of, or in conjunction with CR since the CR itself also assesses patients for further follow-up. And getting this cardiac rehabilitation care early and then E&M follow up all should still occur within the 30 day period.
279	M, Health Professionals	Joanne Ray, AACVPR	016: AMI Discharge Care	There are several reasons why cardiac rehabilitation referral should be included as a 30-day outcome measure for patients following AMI: 1. Cardiac rehabilitation services have been shown to improve quality of life, morbidity, and mortality outcomes following AMI. Patients who participate in cardiac rehabilitation following AMI have a 5-year mortality rate that is 20-30% lower than those who don't participate in cardiac rehabilitation. Reference: Suaya JA, et al. J Am Coll Cardiol. 2009 Jun 30;54(1):25-33. 2. There is a significant gap in the provision of cardiac rehabilitation to eligible post-MI patients. Only 15% of eligible patients participate in cardiac rehabilitation following AMI. Reference: Suaya JA, et al. Circulation. 2007 Oct 9;116(15):1653-62. 3. Inclusion of cardiac rehabilitation referral with this composite measure will help to increase accountability for CR referral, reduce the gap in cardiac rehabilitation that currently exists, and help improve care and outcomes for patients following AMI.	Measure developer response: We understand that cardiac rehabilitation is an underutilized and often cost-effective therapy for patients after AMI. Coincidentally, much of the empirical work establishing the case for CR, including the articles you cite, was conducted by colleagues here at Brandeis University under contract to CMS. In fact, they compiled much of that work into a book that has just been published. The composite measure being proposed here is fairly generic in that it does not isolate specific therapies or services that are linked directly to the specific patient population. Rather, it summarizes care trajectories following discharge using utilization indicators that are broadly applicable to most, if not all, patients leaving the hospital. It is an empirical question, but it seems likely that hospitals and delivery systems that are able to connect patients to CR would perform well on the composite, at least in terms of E&M visits billed as part of, or in conjunction with CR since the CR itself also assesses patients for further follow-up. And getting this cardiac rehabilitation care early and then E&M follow up all should still occur within the 30 day period.

294	M, Provider	Thomas Miner, Trinity Health	016: AMI Discharge Care	Two of the measures in this composite score were not recommended as stand alone indicators. Should this measure be a time limited endorsed measure in order to determine if it is viable as a composite measure?	The Steering Committee reviewed the data presented by the developer on how the components work together presented on page 54 of the measure information for OT1-016-09 at http://www.qualityforum.org/projects/Patient_Outcome_Measures_Phases1-2.aspx?section=CallforCandidateConsensusStandards2009-08-20#t=2&s=&p=5%7C The Committee did not recommend the ED or E&M visit measures as a stand alone measures due to some of the issues described in the report, however, the Committee felt they work well enough in the composite where there are multiple ways to improve performance on the composite (reduce readmissions or ED visits or increase E&M visits). Measure developer response: Many of the experts stated that the meaning and value of the individual measures were conveyed best through their contribution to the composite measure, rather than as individual measures implemented in isolation. At the same time, they supported the notion that entities implementing the composite measure also should report the results of the individual measures.

328	M, Health Professionals	Lea Anne Gardner RN, PhD (on behalf of the Performance Measurement Technical Advisory Committee), American College of Physicians	016: AMI Discharge Care	The ACP Performance Measurement Technical Advisory Committee appreciates the need for outcomes measures, including the care transitions measures. These types of measures are very important to identify good quality care; however measures that are endorsed for accountability purposes must be validated and shown to be reliable. The following comments apply to the both of the AMI and HF measures. These two care transition composite measures are very interesting, but we do not understand why they are being proposed for endorsement. Based on the following issues we identified we recommend further evaluation and development before allowing them to be eligible for NQF endorsement. The measure developers admit to significant problems with the two individual "non-stand alone" measures and the need for further research. The weighting applied to these measures is arbitrary. These measures are not anchored on a gold standard. The 30-day post-hospital discharge measures are identified as having wide variations in reasons patients would seek care. Identifying an ED visit does not guarantee that the reason is related to an AMI or HF. The numerator and denominator definitions are imprecise. These measures do not state whether an ED visit counts in the measure if it occurs at a hospital other than the index hospital.	The Steering Committee discussed these comments at the June 21 conference call and noted that they had discussed these issues during their deliberations and remain comfortable with their decision to recommend the measure. Measure developer response: Regarding the individual measures, we agree with the experts convened by the NQF that the composite measure provides the best vehicle for conveying to audiences the relative importance of the individual utilization measures. We further agree that the individual measures should be reported in conjunction with the composite measure. The proposed relative weights within the composite measure are admittedly arbitrary, although throughout this process, no one has disagreed with them or proposed an empirical criterion that would seem to contradict them. It would be fine if someone wished to fund or undertake a special study that would hypothesize and estimate different empirical weights. In the meantime, we believe that the proposed ways accurately convey the individual contributions and relative importance of the individual measures. Regarding the absence of a gold standard, we have proposed these measures as inherently valuable and understandable; in other words, as the total patient-focused effects of better versus worse care coordination. As we have responded elsewhere, the composite measure summarizes
329	M, Health Professionals	Lea Anne Gardner RN, PhD (on behalf of the Performance Measurement Technical Advisory Committee), American College of Physicians	016: AMI Discharge Care	The comments presented here are a continuation of concerns with the AMI and HF Care Transition Composite measures. The 30-day E & M visit measures need further work before receiving endorsement as part of a composite measure. The developer indicates the bi-directionality of interpreting an E & M service. Both 30-day measures are identified as efficiency measures. Composite measures that include 30-day readmission for these two diagnoses should include evidence based care delivery quality measures – correlate efficiency with mortality, core measure performance, or patient satisfaction with care, for example. Simply basing quality measurement on "transactional" types of measurement (i.e. visits, readmissions, E&M versus procedural codes) without actually ascertaining whether quality care has been delivered according to guidelines (with proper adjustment for valid reasons for not following specific guideline recommendations) is a mistake.	The Steering Committee reviewed these ocmments at the June 21 conference call and noted that they had discussed these issues during their deliberations and remain comfortable recommending the measure.Measure developer response: The so-called bidirectionality of the individual measure was discussed in the context of risk adjustment, which in turn occurred in the larger context of process versus outcome measures. We have made the point that all of these utilization events are downstream "effects" of care and care coordination as it unfolds during and after the hospitalization. Specifically, patients may return for an E&M visit if they are sicker, on the one hand, or if they are scheduled to do so because of good care coordination. Accordingly, the risk adjustment model functions to "level the playing field" across hospitals to the extent that differences in morbidity lead directly to different expected rates of E&M visits. A hospital's reported performance is based on its actual versus expected (adjusted) visit rates. Furthermore, the measure signals hospitals to improve their performance by scheduling follow-up visits more consistently. The proposed composite measure profiles hospitals and delivery systems on care coordination, meaning the trajectories that patients take across settings and

335	M, Provider	Jennifer Faerberg, Association of American Medical Colleges	016: AMI Discharge Care	The AAMC supports the development of care transition programs and measurement; however, we have several concerns with how the AMI and HF composite measures are constructed. The overall concern is the ability of the hospital to control all aspects contained in this composite including patients' use of the Emergency Department (ED), patients' access to primary care physicians and our previously stated concerns with readmissions. The ED component measure is "all-cause" and therefore captures all visits to the ED post an AMI discharge. However, patients may return to the ED with an issue unrelated to the AMI most likely due to a chronic or co-morbid condition. In addition, particular patient populations utilize the ED for primary care services and may return to the ED for minor issues unrelated to the hospital admission. These types of ED visits would be included in the measure calculation and therefore count against a hospital. This could inappropriately affect those institutions that serve a high portion of high risk and underserved patient populations. We strongly recommend that only ED visits related to the AMI should be included.	The Steering Committee reviewed the data presented by the developer on how the components work together presented on page 54 of the measure information for OT1-016-09 at http://www.qualityforum.org/projects/Patient_Outcome_Measures_Phases1-2.aspx?section=CallforCandidateConsensusStandards2009-08-20#t=2&s=&p=5%7C The Committee did not recommend the ED or E&M visit measures as a stand alone measures due to some of the issues described in the report, however, the Committee felt they work well enough in the composite where there are multiple ways to improve performance on the composite (reduce readmissions or ED visits or increase E&M visits). Measure developer response: : We agree that a hospital operating in isolation would not be able to control everything that happens to patients after discharge. However, we believe that care coordination is appropriate and worth the attention of all providers, and furthermore that hospitals can or should influence (not strictly control) their patients' trajectories after discharge by scheduling and encouraging follow-up visits, providing appropriate education before discharge, and working collaboratively with providers in the community to ensure safe and effective transitions. Lastly, care coordination does not imply or encourage focused or exclusive attention on one health

336	M, Provider	Jennifer Faerberg, Association of American Medical Colleges	016: AMI Discharge Care	Similarly, if a patient were discharged with appropriate instructions for follow-up care and were unable to secure an appointment within the 30-day time window or; if an appointment was scheduled and the patient cancelled or did not show for their appointment that too would count against the hospital. Prior to the widespread adoption of Healthcare Innovation Zones (HIZs) or Accountable Care Organizations (ACOs), it is inappropriate to hold the hospital accountable for patients' access to primary care services. Lastly, we would like to seek clarification on the use of the E&M codes in this measure. It appears that any E&M code, not necessarily related to the AMI, within the 30-day discharge window would meet the criteria of the measure. Is this correct?	Measure developer response: We agree that hospitals cannot control patients in every case and in every way. Some patients will fail to show up for follow-up visits. If it is theoretically and practically true that some patients will always fail to show up, then it will always be the case that hospitals generally will fail to achieve perfect scores. All hospitals are profiled in relation to all other hospitals, and each hospital is profiled in relation to its own expected values, which are risk-adjusted. It is plausible that the risk adjustment model can be embellished in the future, for example, to distinguish impoverished patient populations. However, a possible first benefit of the measure is to uncover systematic deprivation, or failed care coordination, which might lead to hypotheses about how to improve the welfare of patients in those settings. 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.
348	M, Health Plan	Rebecca Zimmermann, AHIP	016: AMI Discharge Care	These measures assess 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. While the measure appears to assess hospital quality, the level of analysis included in the measure specifications is listed as "national." AHIP requests clarification regarding the level of analysis to which the measures apply. Measures reported at the national level will have limited actionability by providers and will not assist consumers in selecting high quality providers. AHIP would support these measures with a level of analysis at the provider level.	Measure developer response: To clarify, hospitals are combined and compared nationally for the sake of establishing expected values and peer comparisons. In fact, individual and composite measures will be reported for each hospital separately.

355	M, Health Plan	Catherine MacLean, WellPoint	016: AMI Discharge Care	WellPoint supports the idea of the two composite measures; however, we have some concerns as to whether the results 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.	The Steering Committee agreed that it will be important to include good educational information on interpreting the results of the composite for public reporting. Measure developer response: The measures report utilization events for all causes, systematically for groups of patients, and in terms of the actual versus expected rates. There are baseline hazard rates affecting all patients regardless of which hospital they entered for AMI or any other condition. These are subsumed in the expected rates for all hospitals, and there is no requirement or expectation that hospitals can achieve perfect scores. People differ philosophically, and with respect to their experience and judgment about the degree to which a utilization events is "caused by" or "related to" some prior utilization event. For example, one person might say that a hospital cannot be held responsible for a patient who falls and fractures a bone. However, another person might point to examples in which the patient fell for lack of medication reconciliation. CMS works closely with Medicare beneficiaries before deciding how to describe and display publicly reported measures, including the admission rates.
364	M, Consumer	Debra Ness, National Partnership for Women & Families	016: AMI Discharge Care	This composite measure will be a strong addition to the NQF measure portfolio, for it reflects both outcomes AND care coordination. We support this measure for its ability to provide an overall picture of how care is provided at the time of discharge, thereby contributing to a better understanding of the coordination that does or does not occur at the hospital setting for patients with AMI. While the report did reflect some concerns regarding how understandable these measures may be when publicly reported, we believe that consumers can be provided with appropriate language in a public report to help them understand the distinct components that make up these composite measures, and that as a whole they are intuitively understandable (i.e. you want to be seen outside of the hospital for follow-up evaluation and management and you want to avoid emergency department visits and readmission).	Measure developer response: We agree that the measure is intuitive for patients, leaving aside all of the technical steps needed to implement it. This central patient focus to this measure is essential to its design and interpretation. The hospital upon discharge is responsible for connecting the patient to all resources needed to connect to ambulatory follow up care and avoid the adverse events of ED and readmissions.

372	M, Health Professionals	Dale Lupu, American Academy of Hospice & Palliative Medicine	016: AMI Discharge Care	Recommend adding a fourth event type: admission to hospice using CMS data.	Measure developer response: Thank you for this suggestion. In their deliberations, experts serving NQF noted that hospitals that achieved high rates of referrals to hospices also probably would fare well on a composite measure, with low rates of adverse utilization events. Further research on hospice issues after implementation may be useful and helpful to understanding the long term impact of the measure.
378	M, Health Plan	Tom James, Humana, Inc.	016: AMI Discharge Care	Line 187—30 day post-hospital AMI discharge care transition composite measure, This is a good composite, but I would hope that the weighting would place greater weight on hospital readmission than on ER visits, and than E and M codes.	The weighting is -4 for readmission, -2 for ED visit and +1 for E&M visit. Measure developer response: In the proposed weighting scheme, readmissions do indeed have four times the weight of E&M visits, and ED visits have twice the weight just as suggested.
394	M, Consumer	Carol Sakala, Childbirth Connection	016: AMI Discharge Care	We believe that this composite measure will be a strong addition to the NQF outcome portfolio, as it captures both outcome and care coordination. In public reporting, it will be important to provide consumers with the support to understand the meaning of this measure.	Measure developer response: CMS routinely supports patients with descriptions and explanations of the public on all reported measures, and since this one is patient-focused, it will be important to make those connections and communications.
403	M, Provider	Samantha Burch, Federation of American Hospitals	016: AMI Discharge Care	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 AMI discharge ED visit rate" and the "30-day post-hospital AMI 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.	All of the component measures have been evaluated according to NQF's Consensus Development Process. The technical review of the measures is provided on the project web site at http://www.qualityforum.org/projects/Patient_Outcome_Measures_Phases1-2.aspx?section=CallforCandidateConsensusStandards2009-08-20#t=2&s=&p=5%7C using the links for OT1-002-09, OT1-003-09, OT1-004-09, and OT1-006-09. Measure developer response: This would not be the first instance in which a composite measure was endorsed by NQF, even though not all of the individual measures were endorsed. The consensus to recommend endorsement of the composite measure without necessarily endorsing the individual measures in this case was not due to confusion or lack of information about the individual measures, but rather because the experts thought that the best and most useful way to use the information in the individual measures was to display them as part of the composite. At the same time, the consensus was that entities implementing the composite measure ought to display the individual measures, to aid interpretation and for full disclosure. Many of the experts were inclined to recommend endorsement of the individual measures, too, but apparently that was not the consensus position.

414	M, Purchaser	Christine Chen, Pacific Business Group on Health	016: AMI Discharge Care	30-day post-hospital AMI discharge care transition composite measure and 30-day post hospital heart failure discharge transition composite measure: These two composite measures are of significant value to employers and their employees as they reflect outcomes and care transitions: the measures capture the end result of the care provided for patients with AMI and heart failure within the inpatient setting and provide information on how effectively hospitals follow-up with these patients after they are discharged. The report notes that the method of weighting different components within these composite measures may be challenging for some to understand when publicly reported. However, we believe that those who receive and pay for care will be able to effectively understand and use information from the composites if they are accompanied by language that: • Describes the distinct components that make up these composite measures • Helps users understand the relevance of the composite measure as a whole (i.e. you want a hospital to follow-up with you after you leave the hospital for evaluation and management and you want to avoid emergency department visits and readmission).	Thank you for your comments.
419	M, Provider	Cleveland clinic, CC	016: AMI Discharge Care	This composite measure appears to drive efficiency in integrated care networks where it creates an impetus for better and earlier outpatient care, but we are concerned that emergency visits are portrayed negatively. This would become more evident when applied to more fragmented or less integrated healthcare delivery areas. Each revisitation is weighted as -4 for readmission, -2 for ED revisit, and +1 for E&M (office) visit. Variability may be driven by geographical, primary care and other access issues. The option for ED revisitation for EKG and biomarkers to exclude in-stent thrombosis after AMI is a valuable service and better care for the patient than an E&M (office) visit. We are unaware of studies regarding the impact of ED visits vs. office visits for chest pain s/p PCI and their respective outcomes. Is there data to show what percentage of post-AMI ED visits are related to the index visit and what percentages are not? This might help adjust the impact of EM visit not related to the index care. The idea that emergency medicine care for post-AMI patients is given a negative rating is concerning in that it may impact the quality of care by limiting patient access to appropriate emergency care in the future. Would a post- PCI/AMI patient be better served by going to an office with chest pain or heading to an ED immediately? What about access to care in off hours? Since only 33% of weekdays are covered by most offices, what about night and evening and weekend post PCI/AMI	Measure developer response: It may be true that some delivery systems have an advantage over others in terms of their ability to coordinate patient care, and hence improve care trajectories following discharge. So be it. Measuring and reporting systematic differences across hospitals, delivery systems, market areas, and regions can be the first step toward awareness, and eventually improvement by emulation or innovation. E&M visits are counted positively in the composite measure when they occur within the 30-day period post discharge, and before any ED visit or hospital admission. Rather than specifying a certain amount of time (e.g., seven days) for a follow-up visit, the measure signals to hospitals that patients should be seen before it is likely or expected that circumstances may arise or worsen that would lead to emergency services or readmission to the hospital. By all means, once a certain situation or acuity has been reached, it may be best for the patient to receive emergency care even without stopping, at that point, for evaluation in an office setting. If a hospital is finding that its ED visit rate is relatively high, then it seems likely it should shorten the time to scheduled ambulatory follow-up visits so that patients do not so routinely reach that higher level of acuity.

424	M, Health Professionals	Angela Franklin, American College of Emergency Physicians	016: AMI Discharge Care	ACEP is concerned that the composite measures OT1-016-09 and OT1-017-09 could limit patient access to care. Patients with chest pain post MI should be coming directly to the emergency department(ED). Data on time delay for patients with acute MI coming to the ED shows that the United States (compared to other countries or its own historical control) has not addressed the access to care issue. The mean patient delay before patients with MI arrive at ED's has remained 3 hours for more than two decades indicating patient hesitancy to seek medical care when they should. ACEP believes would be better to measure the completeness of the follow-up plans put in place for individual patients with MI or HF rather than safety net use.	Measure developer response: Please see full prior response. To repeat a portion of that here, once a certain situation or acuity has been reached, it may be best for the patient to receive emergency care even without stopping, at that point, for evaluation in an office setting. If a hospital is finding that its ED visit rate is relatively high, then it seems likely it should shorten the time to scheduled ambulatory follow-up visits so that patients do not so routinely reach that higher level of acuity. And the use of expected valuations for this means that the general background expectations for post-AMI chest pain are built into the model.
430	M, Health Professionals	Clyde Yancy, American Heart Association; Ralph Brindis, American College of Cardiology; Frederick Masoudi, ACCF/AHA Task Force on Performance Measures	016: AMI Discharge Care	The ACCF and AHA strongly urge the NQF not to endorse these measures. These composite measures use entirely arbitrary point assignments for weighting the component measures; they also completely neglect case mix adjustment/risk standardization. Implementing these measures may discourage physicians and hospitals from caring for certain "difficult" or "sick" patients and significantly risk creating or exacerbating disparities in care Such distortions have the potential to diminish rather than improve quality and equity of care. Regarding the component measures, we concur with the Cardiovascular TAP's concerns that use of the ED varies by local conditions such as availability of primary care and the relationship between clinicians and the ED, particularly after hours. Many ED visits would not have any relationship to the antecedent hospitalization so the data for "all cause" ED visits would potentially not be specific to AMI or heart failure. It is uncertain that the use of E & M services alone guarantees quality of service. In addition, not all provider efforts at follow up, e.g., post-discharge phone calls, would be captured by an E & M service. Given current systems of care, these measures are unlikely to accurately identify differences in performance that are due to failure to provide adequate care coordination. Finally, it is quite possible that despite the best efforts of a provider and health system to provide early follow-up, a patient may not adhere with their instructions. Thus, the measures may inappropriately penalize providers who care for disadvantaged populations or for patients	The Steering Committee discussed these comments during the June 21 conference call. The measure developer confirmed that the measure was developed and tested using a 100% Medicare FFS data set for the discharge diagnosis for AMI (and for the heart failure measure). All component measures are risk adjusted using the same methodology of the NQF-endorsed readmission measures. The three compnents of the composite measure allow a hospital to imporve performance in one of three ways -- reduce readmissions or ED visits or increase E&M visits. USing the outcome measure allows each facilties to create their own quality imporvement approach suitable to thei local situation.

439	P	Christopher Corsico, Boehringer Ingelheim Pharmaceuticals, Inc.	016: AMI Discharge Care	In this report, NQF has put forth measures on several cardiovascular conditions, including acute myocardial infarction (AMI) and heart failure (HF). The proposed measures are important outcomes measures that have the potential to improve the quality of care. In addition, BI encourages NQF to consider endorsing current Centers for Medicare and Medicaid (CMS) composite measures, used by the American Heart Association (AHA) in its Get with the Guidelines program. http://www.americanheart.org/presenter.jhtml?identifier=1165	It is unclear from the reference exactly the composite measures you are referring to. However, NQF will consider for endorsement any measures submitted in response to a "Call for Measures".
134	M, Supplier/ Industry	Franz Fanuka, sanofi-aventis	017: HF Discharge Care	See the comments on AMI for general support of this measure. Additional comments for HF: Patients with CHF often have comorbid conditions, e.g., atrial fibrillation that impact the hospitalization and outcomes (e.g., mortality). They require in-hospital management and can be the reason for ED visits and readmission. The data provided on reasons for an ED visit after hospitalization for HF lists atrial fibrillation (AF) in the top 50% of reasons for ED visits. The frequency of AF as a reason for the ED visit is higher in 2007 than it was in 2003. This supports the importance of Atrial Fibrillation the research and clinical experience with AF as a factor as a secondary diagnosis in CHF. In addition to reporting the composite score, we would like to see the rates for the individual measures publicly reported.	See response to comment #133. The measure developer agrees that the individual measures should be reported along with the composite measure.
165	P	Mellanie True Hills, StopAfib.org & American Foundation for Women's Health	017: HF Discharge Care	See our comments on AMI (OT1-016-09) regarding use of a composite measure. While we notice that the developer provided data on the reasons patients go to the ED, we are concerned because atrial fibrillation (AF) was given a low priority. We don't believe the full range of impact of atrial fibrillation was addressed or understood. We provided comments earlier about the need to reexamine the evidence and raise the priority ranking for atrial fibrillation. The data for this measure includes atrial fibrillation as a reason patients go to the ED after an admission for AMI or HF. This supports our experience and the importance of the transition of care when atrial fibrillation is present as a secondary condition. We would like to see the rates for the individual measures publicly reported, like the table presented by the developer. Many of the primary diagnoses presented in the table — palpitations, shortness of breath, fatigue, dizziness, syncope, respiratory issues — could in fact be atrial fibrillation, especially since atrial fibrillation is very frequently the CAUSE of congestive heart failure. Thus, if heart failure is important enough to warrant the development of quality measures, then certainly atrial fibrillation, which can lead to heart failure, should be important enough to justify having quality measures, too.	See response to comment # 164. Measure developer response: We agree that the individual measures should be reported along with the composite measure. Presumably, providers who see patients soon after discharge should be able to identify and monitor secondary conditions, avoiding higher acuity and adverse utilization events in the process.

172	P	Kay Jewell MD, Tara Center LLC	017: HF Discharge Care	We support the concept of outcome measures to improve the discharge process & reduce readmissions. Timely transition of care to outpatient physicians is an important issue for conditions that require continued prophylaxis & hospital acquired conditions that require treatment & follow-up, such as deep vein thrombosis and/or pulmonary emboli (VTE). Patients need support/contacts for questions about medications & what to do for changes in conditions between the time of their discharge & their first E&M appointment. This is a system-level problem that needs system-level solutions. If this measure is endorsed, we would like to see the rates for the individual measures publicly reported, like the table provided by the developer. It would be valuable for the hospital & or the consumer to understand the issue better. Just reporting the score does not provide a very clear picture of how the hospital manages discharge transitions.	Measure developer response: We agree that the individual measures should be reported along with the composite measure. We also agree that hospitals and consumers should learn how to improve patient outcomes, for example, by special studies, pilot programs, emulation or innovation.
181	P	Kay Jewell, Tara Center LLC	017: HF Discharge Care	See the comments for AMI (OT1-016-09). The developer's data on ED visits shows that the frequency of DM as a reason for the ED visit after CHF was 1.35% in 2004 (cumulative frequency – 36%) and more frequent in 2007-2.08% (cumulative frequency-24.5%). This supports the need for better management during the hospital stay and support for management of the diabetes in the transition period after the hospital stay.	See response to comment # 180. It is hoped that measuring and publicly reporting data on care transitions will stimulate development of better care processes to address these issues. Measure developer response: We agree that providers need to identify and manage comorbidities and other circumstances confronting the patients, in addition to the specific cause of hospitalization.

183	P	Kay Jewell MD, Center for Consumers of Healthcare	017: HF Discharge Care	We support the concept of outcome measures to improve the discharge process & reduce readmissions but cannot support this measure or the measure for AMI. We recognize the effort required by hospitals to implement & improve care based on performance measures. Therefore, the link between the process measures (ED visits and E&M visits) & the desired outcome (lower readmissions) should be supported by the literature/guidelines &/or data analysis. With the lack of evidence in the current literature correlating rates of ED visits and E&M visits with better readmission rates, we are concerned that the individual measures & the composite have not been tested to determine if they will lower readmissions. "face value" is not a sufficient reason for a measure that would be applied to all hospitals. The measures will have a significant impact on the hospital - on use of resources and focus to reduce readmissions. It needs to be process/interventions that will be feasible, with reasonable costs, and have a track record for success. The track record for "face value" approaches is not very successful. Despite more than 33 demonstrations to improve the situation, CMS has not yet identified the key factors that reduce readmissions. The data on HF Discharge – Hernandez, JAMA 2010, is beginning t identify the critical issues but still leaves many questions unanswered	Measure developer response: The proposed composite measure includes readmissions but also includes E&M and ED visits because they help to complete the utilization story associated with care trajectories. Ambulatory follow-up visits are not useful merely because they reduce hospital readmission rates. Similarly, the occurrence of high acuity and literally emergency situations within the 30 days after discharge is dangerous, inconvenient, costly, distressing, and likely associated with more adverse circumstances afterwards, for many patients, even if they don't necessarily go back to the hospital right away. The consensus among the experts informing NQF was not that the additional measures were "not adequately designed and tested to be able to stand alone," but instead, that the most valuable information and interpretation of those measures were in the context of the composite measure. Furthermore, the consensus was that the additional measures ought to be reported along with the composite measure.
184	P	Kay Jewell MD, Center for Consumers of Healthcare	017: HF Discharge Care	Medicare - Coordination of care demonstrations (Diabetes, HF, CAD)– 13 of the 15 programs showed no significant differences in hospitalizations. (Peikes Jama 2009). Disease Management –CMS had 7 demonstrations in 35 programs. Of the final 20 programs, 3 had quality improvement at or near budget neutrality. (Bott, Health Affairs, 2009). We do not see how a composite with 2 of the 3 base measures not adequately designed and tested to be able to stand alone can be useful or tell an accurate story of what is happening and what needs to happen to reduce readmissions. Just because we can develop a measure using data and it separates hospitals into different groupings does not mean that it will have any success reducing readmissions. That has not been tested and proven.	Measure developer response: The proposed composite measure includes readmissions but also includes E&M and ED visits because they help to complete the utilization story associated with care trajectories. Ambulatory follow-up visits are not useful merely because they reduce hospital readmission rates. Similarly, the occurrence of high acuity and literally emergency situations within the 30 days after discharge is dangerous, inconvenient, costly, distressing, and likely associated with more adverse circumstances afterwards, for many patients, even if they don't necessarily go back to the hospital right away. The consensus among the experts informing NQF was not that the additional measures were "not adequately designed and tested to be able to stand alone," but instead, that the most valuable information and interpretation of those measures were in the context of the composite measure. Furthermore, the consensus was that the additional measures ought to be reported along with the composite measure.

214	M, Health Professionals	Rita Munley Gallagher, PhD, RN, American Nurses Association	017: HF Discharge Care	The American Nurses Association (ANA) appreciates the concerns raised by the TAP in regards to the 30 day composite measures for AMI and Heart Failure. Specifically, ANA finds the inclusion of both positive and negative scores into a single composite to be of question. The effort is admirable but appears to be too inflexible to reach a firm conclusion on the outcomes in a way that allows for comparison.	The Steering Committee reviewed the data presented by the developer on how the components work together presented on page 54 of the measure information for OT1-016-09 at http://www.qualityforum.org/projects/Patient_Outcome_Measures_Phases1-2.aspx?section=CallforCandidateConsensusStandards2009-08-20#t=2&s=&p=5%7C Measure developer response: The positive and negative aspects of the composite weighting are not central to the understanding of the composite. The composite measure is intended to profile hospitals and deliver systems in terms of care trajectories. Some utilization events (such as a timely E&M visit) are often positive, whereas others (hospital readmission) are often negative. The proposed scoring of the individual measures within the composite is consistent with that intuition. In contrast, all three individual measures could have been scored as negative, for example, by replacing the current measure --positive occurrence of an E&M visit-- with its opposite: the absence of a timely E&M visit. In either case, the logic of the measure would be the same: the "care trajectories" profile can be improved by evaluating and managing patients soon after discharge, and avoiding the need for emergency care, and especially readmission to the hospital.
220	M, Health Plan	Sheree Chin Ledwell, Aetna	017: HF Discharge Care	Aetna is supportive of NQF endorsing this valuable coordination-of-care measure. This outcome measure combines follow-up outpatient visit, ER visit, and readmission. There is a weighted scoring system with OP getting +1 point. Aetna recommends, however, that the scoring system be eliminated and to just show the outcomes for each of the 3 submeasures since the impact of the outpatient visit and an ER visit that might be preventing a hospitalization is unknown. In addition, as this measure is based on claims data, it can be calculated by health plans.	See response to comment #219. Measure developer response: We are proposing a composite measure, not just a triad of stand-alone measures. In other words, we believe that consumers of the information can benefit from understanding what the individual measures mean in concert, not just by themselves. The composite measure provides a convenient summary that reflects professional judgment about the relative contributions of the individual components to overall care trajectories. Either way, we agree that these utilization events are not simply links in a causal chain. Follow-up visits can help patients in many ways besides avoiding adverse utilization events. Similarly, the need for emergency care and readmission can be reduced by factors other than simply an E&M visit.

237	M, Provider	Kenneth Henriksen, Advocate Physician Partners	017: HF Discharge Care	The descriptive specification for this measure could benefit from clarification on the risk adjustment methodology recommended. The Evaluation and Management Services (E&M) component of the composite weighting raises questions as to whether there would be consideration of the occurrence of more than one office visit within the 30 Days Post Discharge or whether one visit in isolation is the only criteria for assigning and scoring the composite weighting. It is felt that presence of more than one office visit within the 30 day time period would be an indication of tighter management of the patient in an outpatient setting which should warrant awarding of additional points in the weighted measurement of the composite scoring.	The revised draft report will attempt to clarify that the risk adjustment method for the ED visit and E&M visit is the same as for the endorsed readmission measure. Measure developer response on weighting: It seems to be a reasonable premise or hypothesis that "care trajectories" would be better or worse based on the number of utilization events, not just the single occurrence of utilization events. Of course, the measure applies to groups of patients; in this case, all patients discharged after an AMI. Some patients may benefit from multiple ambulatory visits. As it is, the proposed measure merely observes whether a patient was seen at least once to place them in the hands of the ambulatory care system. It is a transition measure not a full post-discharge care follow-up measure that may involve longer follow-up periods and more details.
295	M, Provider	Thomas Miner, Trinity Health	017: HF Discharge Care	Two of the measures in this composite score were not recommended as stand alone indicators. Should this measure be a time limited endorsed measure in order to determine if it is viable as a composite measure?	The Steering Committee reviewed the data presented by the developer on how the components work together presented on page 54 of the measure information for OT1-016-09 at http://www.qualityforum.org/projects/Patient_Outcome_Measures_Phases1-2.aspx?section=CallforCandidateConsensusStandards2009-08-20#t=2&s=&p=5%7C The Committee did not recommend the ED or E&M visit measures as a stand alone measures due to some of the issues described in the report, however, the Committee felt they work well enough in the composite where there are multiple ways to improve performance on the composite (reduce readmissions or ED visits or increase E&M visits). Measure developer response: The consensus among the experts informing NQF was that the most valuable information and interpretation of those measures were in the context of the composite measure. Furthermore, the consensus was that the additional measures ought to be reported along with the composite measure.

337	M, Provider	Jennifer Faerberg, Association of American Medical Colleges	017: HF Discharge Care	The AAMC supports the development of care transition programs and measurement; however, we have several concerns with how the AMI and HF composite measures are constructed. The overall concern is the ability of the hospital to control all aspects contained in this composite including patients' use of the Emergency Department (ED), patients' access to primary care physicians and our previously stated concerns with readmissions. The ED component measure is "all-cause" and therefore captures all visits to the ED post a HF discharge. However, patients may return to the ED with an issue unrelated to HF most likely due to a chronic or co-morbid condition. In addition, particular patient populations utilize the ED for primary care services and may return to the ED for minor issues unrelated to the hospital admission. These types of ED visits would be included in the measure calculation and therefore count against a hospital. This could inappropriately affect those institutions that serve a high portion of high risk and underserved patient populations. We strongly recommend that only ED visits related to HF should be included.	See response to comment # 335. The Steering Committee reviewed the data presented by the developer on how the components work together presented on page 54 of the measure information for OT1-016-09 at http://www.qualityforum.org/projects/Patient_Outcome_Measures_Phases1-2.aspx?section=CallforCandidateConsensusStandards2009-08-20#t=2&s=&p=5%7C The Committee did not recommend the ED or E&M visit measures as a stand alone measures due to some of the issues described in the report, however, the Committee felt they work well enough in the composite where there are multiple ways to improve performance on the composite (reduce readmissions or ED visits or increase E&M visits). Measure developer response: We agree that a hospital operating in isolation would not be able to control everything that happens to patients after discharge. However, we believe that care coordination is appropriate and worth the attention of all providers, and furthermore that hospitals can or should influence (not strictly control) their patients' trajectories after discharge by scheduling and encouraging follow-up visits, providing appropriate education before discharge, and working collaboratively with providers in the community to ensure safe and effective transitions. Lastly, care coordination does not imply

338	M, Provider	Jennifer Faerberg, Association of American Medical Colleges	017: HF Discharge Care	Similarly, if a patient were discharged with appropriate instructions for follow-up care and were unable to secure an appointment within the 30-day time window or; if an appointment was scheduled and the patient cancelled or did not show for their appointment that too would count against the hospital. Prior to the widespread adoption of Healthcare Innovation Zones (HIZs) or Accountable Care Organizations (ACOs), it is inappropriate to hold the hospital accountable for patients' access to primary care services. Lastly, we would like to seek clarification on the use of the E&M codes in this measure. It appears that any E&M code, not necessarily related to HF, within the 30-day discharge window would meet the criteria of the measure. Is this correct?	Measure developer response: We agree that hospitals cannot control patients in every case and in every way. Some patients will fail to show up for follow-up visits. If it is theoretically and practically true that some patients will always fail to show up, then it will always be the case that hospitals generally will fail to achieve perfect scores. All hospitals are profiled in relation to all other hospitals, and each hospital is profiled in relation to its own expected values, which are risk-adjusted. It is plausible that the risk adjustment model can be embellished in the future, for example, to distinguish impoverished patient populations. However, a possible first benefit of the measure is to uncover systematic deprivation, or failed care coordination, which might lead to hypotheses about how to improve the welfare of patients in those settings. 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.
356	M, Health Plan	Catherine MacLean, WellPoint	017: HF Discharge Care	WellPoint supports the idea of the two composite measures; however, we have some concerns as to whether the results 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.	The Steering Committee agreed that it will be important to include good educational information on interpreting the results of the composite for public reporting. Measure developer response: The measures report utilization events for all causes, systematically for groups of patients, and in terms of the actual versus expected rates. There are baseline hazard rates affecting all patients regardless of which hospital they entered for AMI or any other condition. These are subsumed in the expected rates for all hospitals, and there is no requirement or expectation that hospitals can achieve perfect scores. People differ philosophically, and with respect to their experience and judgment about the degree to which a utilization events is "caused by" or "related to" some prior utilization event. For example, one person might say that a hospital cannot be held responsible for a patient who falls and fractures a bone. However, another person might point to examples in which the patient fell for lack of medication reconciliation. CMS works closely with Medicare beneficiaries before deciding how to describe and display publicly reported measures, including the admission rates.

365	M, Consumer	Debra Ness, National Partnership for Women & Families	017: HF Discharge Care	Similar to our Post-Hospital AMI Discharge Care Transition Composite measure comments, the fact that this measure reflects both outcomes AND care coordination will make it a strong addition to the measure portfolio. Again, this measure will provide an overall picture of how care is delivered at the time of discharge, thereby contributing to a better understanding of the coordination that does or does not occur at the hospital setting for patients with heart failure. And again, we believe that consumers can be provided with appropriate language in a public report to help them understand the distinct components that make up these composite measures, and that as a whole they are outside of the hospital for follow-up evaluation and management and you want to avoid emergency department visits and readmission).	Measure developer response: We agree that the measure is intuitive for patients, leaving aside all of the technical steps needed to implement it. This central patient focus to this measure is essential to its design and interpretation. The hospital upon discharge is responsible for connecting the patient to all resources needed to connect to ambulatory follow-up care and avoid the adverse events of ED and readmissions.
373	M, Health Professionals	Dale Lupu, American Academy of Hospice & Palliative Medicine	017: HF Discharge Care	Recommend adding a fourth event type: admission to hospice using CMS data.	Measure developer response: Thank you for this suggestion. In their deliberations, experts serving NQF noted that hospitals that achieved high rates of referrals to hospices also probably would fare well on a composite measure, with low rates of adverse utilization events. Further research on hospice issues after implementation may be useful and helpful to understanding the long term impact of the measure.
395	M, Consumer	Carol Sakala, Childbirth Connection	017: HF Discharge Care	We believe that this composite measure will be a strong addition to the NQF outcome portfolio, as it captures both outcome and care coordination. In public reporting, it will be important to provide consumers with the support to understand the meaning of this measure.	Measure developer response: CMS routinely supports patients with descriptions and explanations of the public on all reported measures, and since this one is patient-focused, it will be important to make those connections and communications.

404	M, Provider	Samantha Burch, Federation of American Hospitals	017: HF Discharge Care	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 HF discharge ED visit rate" and the "30-day post-hospital HF 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.	All of the component measures have been fully evaluated according to NQF's Consensus Development Process. The technical review of the measures is provided on the project web site at http://www.qualityforum.org/projects/Patient_Outcome_Measures_Phases1-2.aspx?section=CallforCandidateConsensusStandards2009-08-20#t=2&s=&p=5%7C using the links for OT1-002-09, OT1-003-09, OT1-004-09, and OT1-006-09. Measure developer response: This would not be the first instance in which a composite measure was endorsed by NQF, even though not all of the individual measures were endorsed. The consensus to recommend endorsement of the composite measure without necessarily endorsing the individual measures in this case was not due to confusion or lack of information about the individual measures, but rather because the experts thought that the best and most useful way to use the information in the individual measures was to display them as part of the composite. At the same time, the consensus was that entities implementing the composite measure ought to display the individual measures, to aid interpretation and for full disclosure. Many of the experts were inclined to recommend endorsement of the individual measures, too, but apparently that was not the consensus position.

420	M, Provider	Cleveland clinic, CC	017: HF Discharge Care	Ultimately, we think these measures drive efficiency in integrated care networks where they create an impetus for better and earlier outpatient care, but we are not sure how well they will do when applied to more fragmented or less integrated healthcare delivery areas. Emergency Medicine is the safety net for many patients, especially when patients are unable to get in contact with a primary care provider (nights, weekends, and holidays), a cardiologist or when none is available. Another concern is if care is shifted to cardiologists' or primary care providers' offices, will an acutely decompensate heart failure patient get the same level of care as in an emergency departing setting and will the quality of care be affected? We believe that focusing on 30-day readmissions alone (as is currently done by CMS) without taking into account other factors is problematic. The proposed measure goes a step in positive direction by acknowledging ED visits and evaluation and management services in a global way. We support a composite measure of HF post-discharge/transition quality of care. The problems with the current proposal are: (1) it leaves out 30-day all-cause mortality, (2) it uses a speculative weighting scheme that is un-validated, (3) data on patients utilizing services in other institutions post discharge are not available to the index hospital.	Measure developer response: It may be true that some delivery systems have an advantage over others in terms of their ability to coordinate patient care, and hence improve care trajectories following discharge. So be it. Measuring and reporting systematic differences across hospitals, delivery systems, market areas, and regions can be the first step toward awareness, and eventually improvement by emulation or innovation. E&M visits are counted positively in the composite measure when they occur within the 30-day period post discharge, and before any ED visit or hospital admission. Rather than specifying a certain amount of time (e.g., seven days) for a follow-up visit, the measure signals to hospitals that patients should be seen before it is likely or expected that circumstances may arise or worsen that would lead to emergency services or readmission to the hospital. By all means, once a certain situation or acuity has been reached, it may be best for the patient to receive emergency care even without stopping, at that point, for evaluation in an office setting. If a hospital is finding that its ED visit rate is relatively high, then it seems likely it should shorten the time to scheduled ambulatory follow-up visits so that patients do not so routinely reach that higher level of acuity. We agree that there are other potential outcome measures for patients discharged from the hospital,
425	M, Health Professionals	Angela Franklin, American College of Emergency Physicians	017: HF Discharge Care	ACEP is concerned that the composite measures OT1-016-09 and OT1-017-09 could limit patient access to care. Patients with chest pain post MI should be coming directly to the emergency department(ED). Data on time delay for patients with acute MI coming to the ED shows that the United States (compared to other countries or its own historical control) has not addressed the access to care issue. The mean patient delay before patients with MI arrive at ED's has remained 3 hours for more than two decades indicating patient hesitancy to seek medical care when they should. ACEP believes would be better to measure the completeness of the follow-up plans put in place for individual patients with MI or HF rather than safety net use.	See response to comment # 424. Measure developer response: Once a certain situation or acuity has been reached, it may be best for the patient to receive emergency care even without stopping, at that point, for evaluation in an office setting. If a hospital is finding that its ED visit rate is relatively high, then it seems likely it should shorten the time to scheduled ambulatory follow-up visits so that patients do not so routinely reach that higher level of acuity. And the use of expected valuations for this means that the general background expectations are built into the model.

431	M, Health Professionals	Clyde Yancy, American Heart Association; Ralph Brindis, American College of Cardiology; Frederick Masoudi, ACCF/AHA Task Force on Performance Measures	017: HF Discharge Care	The ACCF and AHA strongly urge the NQF not to endorse these measures. These composite measures use entirely arbitrary point assignments for weighting the component measures; they also completely neglect case mix adjustment/risk standardization. Implementing these measures may discourage physicians and hospitals from caring for certain "difficult" or "sick" patients and significantly risk creating or exacerbating disparities in care Such distortions have the potential to diminish rather than improve quality and equity of care. Regarding the component measures, we concur with the Cardiovascular TAP's concerns that use of the ED varies by local conditions such as availability of primary care and the relationship between clinicians and the ED, particularly after hours. Many ED visits would not have any relationship to the antecedent hospitalization so the data for "all cause" ED visits would potentially not be specific to AMI or heart failure. It is uncertain that the use of E & M services alone guarantees quality of service. In addition, not all provider efforts at follow up, e.g., post-discharge phone calls, would be captured by an E & M service. Given current systems of care, these measures are unlikely to accurately identify differences in performance that are due to failure to provide adequate care coordination. Finally, it is quite possible that despite the best efforts of a provider and health system to provide early follow-up, a patient may not adhere with their instructions. Thus, the measures may inappropriately penalize providers who care for disadvantaged populations or for patients	See response to comment # 430.
440	P	Christopher Corsico, Boehringer Ingelheim Pharmaceuticals, Inc.	017: HF Discharge Care	The scope of Phase I of this project had called for measure submissions across several other cardiovascular disease areas, including atrial fibrillation (AF). Very often, AMI, HF, and AF are co-morbid conditions with AF a common complication of AMI or HF. As a result, AF is prevalent in 20 to 30 percent of patients with HF. Given this level of overlap, the CMS composite measures on coronary artery disease (CAD), HF, and stroke provide an appropriate assessment for patients with these co-morbidities. These composite measures encompass the following: 1) CAD: discharge acetylsalicylic acid (ASA), early ASA, discharge beta-blocker (BB), discharge angiotensin-converting enzyme inhibitor/amgiotension II receptor blocker (ACE/ARB) (left ventricular systolic dysfunction (LVSD) patients only), discharge smoking counseling, discharge lipid-lowering therapy; 2) Heart Failure: discharge instructions, left ventricular failure (LVF) assessment, discharge ACE/ARB (LVSD patients only), discharge smoking counseling, discharge BB; 3) Stroke: Fibrinolytic within three hours of symptom onset, antithrombotics within 48 hours, discharge antithrombotics, discharge anticoagulants, deep venous thrombosis (DVT) prophylaxis by second day, discharge lipid-lowering therapy, discharge smoking advice or medication. We propose that these three composite measures be considered for NQF endorsement as part of the	Thank you for your comments.

77	M, QMRI	Barbara Corn, NAHQ	019: HRQOL in COPD Pts	Is the CRQ consistently completed on each patient and is this incorporated into the EHR to be able to extract this information?	Measure developer response: The CRQ is consistantly completed on each patient and incorperated into the EHR where the capability exists.
115	P	Joyce Bruno-Reitzner, American College of Chest Physicians	019: HRQOL in COPD Pts	Approve with comments: On behalf of the American College of Chest Physicians (ACCP) the ACCP Quality Improvement Committee (QIC) appreciates the opportunity to comment on this measure. The QIC questions whether or not there exists a gap that would necessitate this measure. The QIC understands that this measure will be time-limited endorsed and would like to see the data from this measure to determine if a gap truly exists. The QIC also recommends removing the statement or similar tool or specifically define which other tools are appropriate to ensure that all physicians are using the same measurement tool to decrease any possible variability between tools.	Measure developer response: Thank you for your comments. The CRQ will be indentified at the primary QOL measurement tool with rationale. Data from the analysis will be available for review.
119	P	Timothy Myers, American Association for Respiratory Care	019: HRQOL in COPD Pts	The American Association for Respiratory Care is a professional organization representing 50,000 respiratory therapists nationwide who treat patients with chronic pulmonary diseases including COPD. COPD is a common, under diagnosed and undertreated disorder associated with significant morbidity and disability. There is strong evidence for the benefit for pulmonary rehabilitation in persons with COPD where it translates into improved function, quality of life, symptom control including dyspnea, and reduction in health care utilization based on well-designed randomized, controlled trials. Endorsement by the National Quality Forum of the outcome measure on health-related quality of life in COPD patients before and after pulmonary rehabilitation (i.e., Chronic Respiratory Questionnaire) will support further evidence of the impact of pulmonary rehabilitation in COPD. The AARC recommends NQF endorsement.	Thank you for your comments.

149	P	Gary Ewart, American Thoracic Society	019: HRQOL in COPD Pts	On behalf of the American Thoracic Society (ATS), the Quality Improvement Committee (QIC) appreciates that NQF has identified pulmonary rehabilitation as a quality improvement target and opens an opportunity for public comment on this measure. As with functional capacity assessment, we question the utility of before/after health-related quality of life (HRQoL) assessment and whether a quality gap exists that would necessitate this measure. We understand that this measure will be time-limited endorsed and call for data to explore from this measure if a gap exists. Ideally, programs should be asked to report on the same HRQOL measure to avoid unnecessary variability between providers, however at this point data to not support the use of any single measure above the rest.	Measure developer response: The CRQ will be indentified at the primary QOL measurement tool with rationale. Data from the analysis will be available for review.
175	P	Kay Jewell, Tara Center LLC	019: HRQOL in COPD Pts	We support this measure with the time-limited endorsement. Pulmonary Rehabilitation (PR) is one of 2 interventions that have been demonstrated to be effective in reducing hospital length of stay, exercise capacity, dyspnea and fatigue. (Qaseem) The second intervention is optimal medication management, which is part of the PR program. A measure that focuses attention on PR is valuable because it draws attention to an area with significant gap in physician knowledge of CPGs for COPD and appropriate management. Few physicians believe there is much that will have a positive impact on COPD outcome. In Yawn's survey, only 32% of the physicians had access to PR and only 3% ordered it. We need measures to address this gap. The component s of PR are optimal medication management, patient education, behavioral interventions, exercise capacity, health status, and nutrition. (GOLD) However it is not clear which component(s) is(are) responsible for clinical improvement and better outcomes and which is the best element to test. The additional testing to satisfy the time-limited endorsement will provide valuable information and guidance on how to better assess the outcome of PR to focus attention on improving function and quality of life for these patients. The presence of measures will stimulate awareness and education and hopefully increase use of PR. For References - see OTI-20-09	The Steering Committee discussed these issues.
185	P	Kay Jewell MD, Center for Consumers of Healthcare	019: HRQOL in COPD Pts	Support - important area and issue. Good to require time-limited endorsement.	Thank you for your comments.

215	M, Health Professionals	Rita Munley Gallagher, PhD, RN, American Nurses Association	019: HRQOL in COPD Pts	The American Nurses Association (ANA) notes that the measurement of quality of life in COPD patients may be premature given the lack of standardized metrics at this point in time.	Measure developer response: Clinicians and investigators acknowledge the importance of health-related quality of life In clinical studies of patients with chronic respiratory disease (CRD).The chronic respiratory questionnaire (CRQ), one of the most widely used measures of HRQL in patients with CRD, has served as a model in many methodological HRQL studies]. Guell R, Casan P, Sangenis M, Morante F, Belda J,Guyatt GH. Eur Respir J 1998; 11:55–60., van den Boom G, Rutten-van Molken MP, Molema J,Tirimanna PR, van Weel C, van Schayck CP. Am J Crit Care Med 2001; 164: 2057–2066., Bendstrup KE, Ingemann Jensen J, Holm S, Bengtsson B. Eur Respir J 1997; 10:2801–2806.,Green RH, Singh SJ, Williams J, Morgan MD. Thorax 2001; 56: 143–145., Neder JA, Sword D, Ward SA, Mackay E, Cochrane LM,Clark CJ. Thorax 2002; 57: 333–337. Guyatt GH, Berman LB, Townsend M, Pugsley SO,Chambers LW. Thorax 1987; 42: 773–778., van den Boom G, Rutten-van Molken MP, Tirimanna PR,van Schayck CP, Folgering H, van Weel C. Eur Respir J 1998; 11: 67–72., 8 Brightling CE, Monteiro W, Ward R, et al. S. Lancet 2000; 356: 1480–1485.
223	M, Health Plan	Sheree Chin Ledwell, Aetna	019: HRQOL in COPD Pts	This measure is a good start, but the measure was developed and validated to evaluate whether the individual patients were making progress, not for program evaluation. The measure should be tested for its new purpose. In addition as this measure is based on member response to therapy it is not available in administrative data. Therefore, health plans will not likely use this measure.	The measure is recommended for time-limited endorsement due to lack of testing for program evaluation. Testing results will be evaluated prior to granting full endorsement.
226	M, Health Professionals	Nancy Nielsen, MD, PhD, American Medical Association	019: HRQOL in COPD Pts	While these measures address the important topics of quality of life, length of stay, and mortality rates, we cannot support these measures 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 this patient population across the healthcare setting. These types of measures are best represented as facility-based measures. We recommend removing "Clinician" as a Level of Measurement/Analysis for proposed measures OT1-019-09, 0T1-023-09, and 0T1-024-09.	Measure developer response: Thank you for your comments. These measures will improve the understanding of the impact of pulmonary rehabilitation on quality of life in persons with COPD. This is particularly important given the recent advent of Medicare coverage for pulmonary rehabilitation in persons with COPD.

240	M, Provider	Kenneth Henriksen, Advocate Physician Partners	019: HRQOL in COPD Pts	It appears that this measure currently has a number of specification issues still to be defined and testing to occur prior to completing the NQF criteria for measure selection and endorsement. Recognizing the administrative burden to health care organizations of adopting a measure that has not been fully tested, our organization would be reluctant to implement a measure that has so many unanswered questions at this stage in the endorsement effort.	Measure developer response: Current Medicare coverage of pulmonary rehabilitation in moderate to very severe COPD requires outcome assessment of clincial measures of effectiveness. Pre and post measurment and analysis of CRQ will not add significant resource expenditure to pulmonary rehabilitation programs beyond what is currently required by CMS. Measure developer response: Current Medicare coverage of pulmonary rehabilitation in moderate to very severe COPD requires outcome assessment of clincial measures of effectiveness. Time limited endorsement will allow further testing.
252	M, Purchaser	Gaye Fortner, HC21	019: HRQOL in COPD Pts	I am supportive of these two measures for their potential to provide critical information on functional status and quality of life following a high volume treatment (pulmonary rehab). In general, I am pleased to see the addition of functional status measures, beyond the ones currently in the portfolio which mainly relate to orthopedic care.	Thank you for your comments.
253	M, Health Professionals	Janet Leiker, on behalf of the AAFP Commission on Quality and Practice, American Academy of Family Physicians	019: HRQOL in COPD Pts	This measure represents an attempt to assess the quality of life for patients and whether their pulmonary rehabilitation was of any benefit, which is at the heart of what measurement is about. A complementary process measure could be the number of (appropriate) patients receiving pulmonary rehabilitation.	Thank you for your comments.
260	M, Health Professionals	Roshunda Drummond-Dye, American Physical Therapy Association	019: HRQOL in COPD Pts	Health-related quality of life in COPD patients before and after pulmonary rehabilitation: The assessment of HRQOL is achieved with the use of questionnaires that are either self-administered or conducted by an interviewer. Generic HRQOL instruments are broadly applicable to different health problems. It has the advantage of functioning as a common assessment tool to compare HRQOL across several diseases. Disease-specific HRQOL instruments are designed to have better sensitivity in detecting clinically important changes that are related to a particular disease. A good HRQOL instrument must be valid, responsive, and reliable. Detailed reviews on several HRQOL instruments used in COPD and methodologic issues have recently been published.	Thank you for your comments.

296	M, Provider	Thomas Miner, Trinity Health	019: HRQOL in COPD Pts	This measure looks at populations who have completed pulmonary rehabilitation presumably in an out patient setting. It requires a pre and post quality of life assessment that may be burdensome to the providers. However, it is important to include measures that attempt to quantify the benefits of treatments.	Thank you for your comments.
320	M, QMRI	Bernard M. Rosof, MD, MACP, Physician Consortium for Performance Improvement ®	019: HRQOL in COPD Pts	While these measures address the important topics of quality of life, length of stay, and mortality rates, we cannot support these measures 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 this patient population across the healthcare setting. These types of measures are best represented as facility-based measures. We recommend removing "Clinician" as a Level of Measurement/Analysis for proposed measures OT1-019-09, 0T1-023-09, and 0T1-024-09.	Measure developer response: These measures will improve the understanding of the impact of pulmonary rehabilitation on quality of life in persons with COPD. This is particularly important given the recent advent of Medicare coverage for pulmonary rehabilitation in persons with COPD.
330	M, Health Professionals	Lea Anne Gardner RN, PhD (on behalf of the Performance Measurement Technical Advisory Committee), American College of Physicians	019: HRQOL in COPD Pts	This measure, like the questionnaire that is recommended for use in this measure to evaluate health related quality of life (HRQOL) has not been tested as a performance measure. We are concerned with the numerator statement which identifies that a 1.0 point change in the HRQOL needs to occur. According to the document, the literature states that a 0.5 point difference is the "minimum clinical difference". The document states that there is no data on discrimination but expert opinion is that this does discriminate. There needs to be further research done to determine which target number is appropriate for this measure.	Measure developer response: The sponsors recommend changing the the point change to 0.5 for consistancy with the MCID. This is a lime limited measure that will support further understanding regarding the appropriate target number and discrimination.
349	M, Health Plan	Rebecca Zimmermann, AHIP	019: HRQOL in COPD Pts	These measures were developed to assess individual patient progress with pulmonary rehabilitation. It does not appear that the measures were developed to assess program level performance. AHIP recommends that during the time-limited endorsement period more testing should be conducted on the use of these measures for program level assessment. Additionally, the measures do not capture patients that began rehabilitation but did not complete the program. The measure developer should consider pairing the measures with a process measure to assess those patients who did not complete therapy.	Under time-limited endorsement, the developer is required to present data on testing of the measure within 12 months.

357	M, Health Plan	Catherine MacLean, WellPoint	019: HRQOL in COPD Pts	WellPoint supports the two pulmonary rehab measures. However, two additional measures will provide a more complete picture of the care received by patients with COPD: 1) a process measure to capture the percentage of eligible patients with COPD who are referred to pulmonary rehab when appropriate; 2) a process measure to assess the percentage of patients referred to pulmonary rehab that complete rehab.	The TAP and Steering Committee agree and have made those recommendations.
366	M, Consumer	Debra Ness, National Partnership for Women & Families	019: HRQOL in COPD Pts	We are very supportive of this measure for its potential to provide critical information on functional status and quality of life following a high volume treatment (pulmonary rehab). In general, we are pleased to see the addition of functional status measures, beyond the ones currently in the portfolio which mainly relate to orthopedic care.	Thank you for your comments.
374	M, Health Professionals	Dale Lupu, American Academy of Hospice & Palliative Medicine	019: HRQOL in COPD Pts	We are pleased to see an outcome measure that measures quality of life as a primary outcome.	Thank you for your comments.
380	M, Health Plan	Tom James, Humana, Inc.	019: HRQOL in COPD Pts	Line 259—Health-related quality of life in COPD patients before and after pulmonary rehab. Would suggest that this is really a value statement so needs the resource units expended, whether it is real or standardized dollars	Measure developer response: Current Medicare coverage of pulmonary rehabilitation in moderate to very severe COPD requires outcome assessment of clincial measures of effectiveness. Pre and post measurment and analysis of CRQ will not add significant resource expenditure to pulmonary rehabilitation programs beyond what is currently required by CMS.
398	M, Consumer	Carol Sakala, Childbirth Connection	019: HRQOL in COPD Pts	We are very supportive of this measure to provide crucial quality of life data about the high-volume hospital area of pulmonary rehabilitation.	Thank you for your comments.

416	M, Purchaser	Christine Chen, Pacific Business Group on Health	019: HRQOL in COPD Pts	Health-related quality of life in COPD patients before and after pulmonary rehab and Functional capacity in COPD patients before and after pulmonary rehab: We strongly support these two measures as they provide critical information on functional status and quality of life following a high volume treatment (pulmonary rehab). While we are disappointed not to see more such measures coming out of this Steering Committee for heart and pulmonary conditions, we are encouraged by NQF's incorporation of these measure of functional status as it helps to expand NQF's current portfolio of functional status measures which largely focus on orthopedic care. We also appreciate that both of these measures report the actual change that patients experienced as a result of rehabilitation, and that the health-related quality of life measure reflects the patient perspective.	Thank you for your comments.
421	M, Provider	Cleveland clinic, Cleveland clinic	019: HRQOL in COPD Pts	We support this measure with reservations related to stratification for disease severity, co-morbidities and type of COPD. Quality of Life (QoL) is important for COPD patients and instruments like this can measure this change. However the impact can be small and temporary. Minimal clinically important change is debatable. There is likely a 'sweet' spot where advanced patients are too ill to improve, well patients are at a ceiling and cannot improve, leaving a small number of "impactable" patients. Another concern is how the data would be collected and audited.	Measure developer response: GOLD guidelines identify COPD stages II-IV as impacted by exercise deconditioning, social isolation, altered mood states, muscle wasting and weight loss. According to GOLD 2008 (page 56), in all COPD patients, exercise training results in improved exercise tolerance, dyspnea and fatigue (Evidence A), with greatest improvement seen in stages II-IV. GOLD identifies pulmonary rehabilitation as the standard of care for patients with stages II-IV and that all stages benefit from exercise training programs, improving both exercise tolerance and symptoms of dyspnea and fatigue (Berry MJ et al, 1999).

436	P	Christopher Corsico, Boehringer Ingelheim Pharmaceuticals, Inc.	019: HRQOL in COPD Pts	BI supports the inclusion of performance measures for chronic obstructive pulmonary disease (COPD) in this project. COPD, which encompasses chronic bronchitis and emphysema, currently affects over 12 million people. It is also estimated that another 12 million Americans may have COPD and not know it. Further, COPD is the fourth leading cause of death in the UD. The burden of the condition is clear and rising. COPD is a chronic condition that impacts many aspects of patients' lives. Evidence-based guidelines endorse the use of chronic maintenance treatments to manage this condition. However, current quality measure for COPD do not adequately address chronic treatment. There is a need not only for more COPD measures that assess new areas of care such as chronic treatment, but also for the endorsement of key measures that already exist. http://www.nhlbi.nih.gov/health/public/lung/copd/index-htm http://www.nhlbi.nih.gov/health/public/lung/copd/lmbb-campaign/index.htm	Thank you for your comments.
116	P	Joyce Bruno-Reitzner, American College of Chest Physicians	020: Functional Capacity	Approve with comments: On behalf of the American College of Chest Physicians (ACCP) the ACCP Quality Improvement Committee (QIC) appreciates the opportunity to comment on this measure. The QIC questions whether or not there exists a gap that would necessitate this measure. The QIC understands that this measure will be time-limited endorsed and would like to see the data from this measure to determine if a gap truly exists.	Measure developer response: Thank you for your comments. The CRQ will be indentified at the primary QOL measurement tool with rationale. Data from the analysis will be available for review.

120	P	Timothy Myers, American Association for Respiratory Care	020: Functional Capacity	The American Association for Respiratory Care is a professional organization representing 50,000 respiratory therapists nationwide who treat patients with chronic pulmonary diseases including COPD. COPD is a common, underdiagnosed and undertreated disorder associated with significant morbidity and disability. There is strong evidence for the benefit for pulmonary rehabilitation in persons with COPD where it translates into improved function, quality of life, symptom control including dyspnea, and reduction in health care utilization based on well-designed randomized, controlled trials. Endorsement by the National Quality Forum of the outcome measure on functional capacity in COPD patients before and after pulmonary rehabilitation (i.e., 6-minute walk) will support further evidence of the impact of pulmonary rehabilitation in COPD. The AARC recommends NQF endorsement.	Thank you for your comments.
148	P	Gary Ewart, American Thoracic Society	020: Functional Capacity	On behalf of the American Thoracic Society (ATS), the Quality Improvement Committee (QIC) appreciates that NQF has identified pulmonary rehabilitation as a quality improvement target and opens an opportunity for public comment on this measure. The ATS is unclear of data that supports a quality gap that would necessitate this measure. Although NQF endorsement would be time-limited, a specific call for data from this measure to determine if a gap truly exists would be warranted. We further note, recent data (and expert opinion), has not supported the figure of 54 meters for the 6MWT. This measure should be changed to indicate 25 meters as a clinically important difference. [Reference Holland AE, CJ Hill T Rasekaba et al. 2010 Updating the minimal important difference for six-minute walk distance in patients with chronic obstructive pulmonary disease. Arch Phys Med Rehabil 91:221-225.]	The developers have changed the specifications to 25m. Deevloper response: Time limited endorsement will allow analysis to respond to many of these issues including the appropirate MCID for 6MWT.

176	P	Kay Jewell, Tara Center LLC	020: Functional Capacity	We support this measure with the time-limited endorsement. See OTI-19-09 for details. References Global Initiative for Chronic Obstructive Lung Disease. Workshop report: global strategy for diagnosis, management, and prevention of COPD; updated 2008: NHLBI, NIH, WHO; 2008. Qaseem A, Snow V, Shekelle P, et al. Diagnosis and management of stable chronic obstructive pulmonary disease: a clinical practice guideline from the American College of Physicians. Ann Intern Med. 2007 Nov 6 2007; 147(9):633-638. Barbara P Yawn, Peter C Wollan. Knowledge and attitudes of family physicians coming to COPD continuing medical education. Int J Chron Obstruct Pulmon Dis. 2008 June; 3(2): 311–318.	Thank you for your comments.
186	P	Kay Jewell MD, Center for Consumers of Healthcare	020: Functional Capacity	See #19.	
224	M, Health Plan	Sheree Chin Ledwell, Aetna	020: Functional Capacity	"Functional capacity," is defined by a 6-minute walk time. The measure was developed and validated to evaluate whether the individual patients were making progress, not for program evaluation. So it is unknown how useful the measure is in evaluating and comparing program and/or provider. In addition as this measure is based on member response to therapy it is not available in administrative data. Therefore, health plans will not likely use this measure.	The Steering Committee considered data collection in its deliberations and recommendations.
233	M, Health Professionals	Nancy Nielsen, MD, PhD, American Medical Association	020: Functional Capacity	The TAP discusses in the report, lines 286-291, a newly released publication indicating an appropriate functional capacity increase of 25 meters (m) from a 54m threshold is reasonable. While this change, from 54m to 25m, is reflected in the measure description (lines 282-285), the specification tables at the end of the report are in need of this change also, specifically, in the descriptions for the measure, numerator, and denominator. Please provide clarification on this discrepancy.	The developer has changed the specifications to 25 m. Measure developer repsonse: Time limited endorsment will allow analysis to respond to many of these issues including the appropirate MCID for 6MWT.

241	M, Provider	Kenneth Henriksen, Advocate Physician Partners	020: Functional Capacity	It appears that this measure currently has a number of specification issues still to be defined and data testing to occur prior to completing the NQF criteria for measure selection and endorsement. Recognizing the administrative burden to health care organizations of adopting a measure that has not been fully tested, our organization would be reluctant to implement a measure that has so many unanswered questions at this stage in the endorsement effort.	Under time-limited endorsement, the developer is required to present data on testing of the measure within 12 months.
254	M, Health Professionals	Janet Leiker, on behalf of the AAFP Commission on Quality and Practice, American Academy of Family Physicians	020: Functional Capacity	This measure represents an attempt to assess the quality of life for patients and whether their pulmonary rehabilitation was of any benefit, which is at the heart of what measurement is about. A complementary process measure could be the number of (appropriate) patients receiving pulmonary rehabilitation.	Thank you for your comments.
261	M, Health Professionals	Roshunda Drummond-Dye, American Physical Therapy Association	020: Functional Capacity	Functional Capacity in COPD patients before and after pulmonary rehabilitation: There are several modalities available for the objective evaluation of functional exercise capacity. Some provide a very complete assessment of all systems involved in exercise performance (high tech), whereas others provide basic information but are low tech and are simpler to perform. The modality used should be chosen based on the clinical question to be addressed and on available resources. The most popular clinical exercise tests in order of increasing complexity are stair climbing, a 6-minute walk test (6MWT), a shuttle-walk test, detection of exercise-induced asthma, a cardiac stress test (e.g., Bruce protocol), and a cardiopulmonary exercise test . In clinical practice, the 6MWT is commonly used to assess changes in functional exercise capacity in COPD patients following pulmonary rehabilitation with the primary outcome reported being the distance walked during the test (i.e. 6MWD). The 6MWD has demonstrated validity, reliability after one familiarization test and the capacity to detect changes following pulmonary rehabilitation. In addition to assessing the outcomes of pulmonary rehabilitation, 6MWD may be used to quantify the magnitude of a patient's disability, prescribe a walking programmed, and identify patients likely to benefit from a rollator and to identify the presence of exercise-induced hypoxaemia	Thank you for your comments.

262	M, Health Professionals	Roshunda Drummond-Dye, American Physical Therapy Association	020: Functional Capacity	The 6MWT is a practical simple test that requires a 100-ft hallway but no exercise equipment or advanced training for technicians. Walking is an activity performed daily by all but the most severely impaired patients. This test measures the distance that a patient can quickly walk on a flat, hard surface in a period of 6 minutes (the 6MWD). It evaluates the global and integrated responses of all the systems involved during exercise, including the pulmonary and cardiovascular systems, systemic circulation, peripheral circulation, blood, neuromuscular units, and muscle metabolism .	Thank you for your comments.
327	M, QMRI	Bernard M. Rosof, MD, MACP, Physician Consortium for Performance Improvement ®	020: Functional Capacity	The TAP discusses in the report, lines 286-291, a newly released publication indicating an appropriate functional capacity increase of 25 meters (m) from a 54m threshold is reasonable. While this change, from 54m to 25m, is reflected in the measure description (lines 282-285), the specification tables at the end of the report are in need of this change also, specifically, in the descriptions for the measure, numerator, and denominator. Please provide clarification on this discrepancy.	The devceloper has changed the specifcations in the table. Measure developer response: Time limited endorsment will allow analysis to respond to many of these issues including the appropirate MCID for 6MWT.
331	M, Health Professionals	Lea Anne Gardner RN, PhD (on behalf of the Performance Measurement Technical Advisory Committee), American College of Physicians	020: Functional Capacity	There were questions raised about the benchmark for the functional capacity distance of 54 meters (176 feet). Different distances are identified in the literature. The 6 mile walk test (6MWT) has not been tested for reliability or validity as a quality measure. The document also identifies that the benchmark is not related to function or QOL. We recommend further evaluation of this measure.	The developer has changed the specifications to 25 m.Measure developer response: The MCID change from 54m to 25m is reflected in the measure description. Time limited endorsment will allow analysis to respond to many of these issues including the appropirate MCID for 6MWT.
341	P	Basil Eldadah, National Institute on Aging	020: Functional Capacity	Including a measure of gait speed is an important outcome as gait speed independently predicts a variety of adverse outcomes. The measure in this outcome uses maximal gait speed, which may reflect motivational factors in addition to changes in cardiopulmonary function. The Committee may also wish to consider developing outcomes based on self-selected gait speed, which may be less prone to confounding by motivational factors.	Another deliverable for the Patient Outcomes project is an identification of additional measures that should be developed to measure outcomes. We will include your recommendation in this report.

358	M, Health Plan	Catherine MacLean, WellPoint	020: Functional Capacity	WellPoint supports the two pulmonary rehab measures. However, two additional measures will provide a more complete picture of the care received by patients with COPD: 1) a process measure to capture the percentage of eligible patients with COPD who are referred to pulmonary rehab when appropriate; 2) a process measure to assess the percentage of patients referred to pulmonary rehab that complete rehab.	This has been recommended by the TAP and Steering Committee.
367	M, Consumer	Debra Ness, National Partnership for Women & Families	020: Functional Capacity	Our comments on this measure are similar to those for measure OT1-019-09, HRQOL in COPD Patients - Pulmonary Rehab, in that we are very supportive of this measure and feel it adds significant value to the NQF measurement portfolio.	Thank you for your comments.
399	M, Consumer	Carol Sakala, Childbirth Connection	020: Functional Capacity	We are very supportive of this measure to provide crucial functional capacity data about the high-volume hospital area of pulmonary rehabilitation.	Thank you for your comments.
405	M, Provider	Samantha Burch, Federation of American Hospitals	020: Functional Capacity	While the FAH believes it is important to expand the NQF's portfolio related to quality of life measures, we are concerned that this measure specifies the use of one specific tool (the CRQ) when alternative tools are equally validated and widely used (as noted in the draft report). The NQF board discussed this issue in the context of preferred practices at the May board meeting and there seemed to be generally concern about limiting providers to the use of one tool where multiple tools that are equally valid exist. In addition, the report indicates that this measure, as specified, has not been tested for reliability and validity as a performance measure. Given that PR is a new Medicare benefit, and in light of issues raised by TAP members around this measure only capturing patients who complete PR, we believe that testing for reliability and validity is critical prior to this measure receiving any level of endorsement, full or time-limited.	Under time-limited endorsement, the developer is required to present data on testing of the measure within 12 months.

422	M, Provider	Cleveland clinic, Cleveland clinic	020: Functional Capacity	Although the six-minute walk distance is correlated with QoL it is affected by issues other than COPD and the actual impact on QoL can be small and temporary. Minimal clinically important change is debatable. There is likely a 'sweet' spot where advanced patients are too ill to improve, well patients are at a ceiling and cannot improve, leaving a small number of "impactable" patients. Another concern is that no significant therapeutic studies of COPD use functional capacity as an endpoint. Because variability with co morbidities and ceiling/floor effects make interpretation difficult and dependent upon the study population we are not supporting the usability of this metric. A significant burden for data of collection and auditing would occur for some institutions. We do not support this metric owing to variability in response, issues of co-morbidities and differential response of disease severity.	Measure developer response: GOLD guidelines identify COPD stages II-IV as impacted by exercise deconditioning, social isolation, altered mood states, muscle wasting and weight loss. According to GOLD 2008 (page 56), in all COPD patients, exercise training results in improved exercise tolerance, dyspnea and fatigue (Evidence A), with greatest improvement seen in stages II-IV. GOLD identifies pulmonary rehabilitation as the standard of care for patients with stages II-IV and that all stages benefit from exercise training programs, improving both exercise tolerance and symptoms of dyspnea and fatigue (Berry MJ et al, 1999).
437	P	Christopher Corsico, Boehringer Ingelheim Pharmaceuticals, Inc.	020: Functional Capacity	BI supports the decision for NQF to endorse two measures on COPD quality of life and functional capacity in patients before and after pulmonary rehabilitation. The symptoms of COPD significantly impact everyday activities and well being. Outcome measures assessing quality of life and functional capacity provide insight into whether a patient is receiving appropriate therapy to control their symptoms.	Thank you for your comments.
438	P	Christopher Corsico, Boehringer Ingelheim Pharmaceuticals, Inc.	020: Functional Capacity	Finally, though it is not within the scope of this particular project, BI would like to emphasize the importance of developing COPD measures around hospital readmissions for exacerbations. In its priority-setting role, we believe that NQF can play a pivotal role in specifying the most important topics to be addressed by new performance measures through the organization's interaction with measure developers. The aforementioned topics are currently not addressed in existing measures, and we believe they represent crucial aspects of appropriate care for COPD patients.	Another deliverable of the Patient Outcomes project is recommendations on filling important gaps in outcome measures. Your recommendations will be included in that report.
79	M, QMRI	Barbara Corn, NAHQ	023: ICU LOS	Appears that this will require significant data abstraction time even with electronic records.	Burden of data abstraction was discussed as part of the evaluation of the TAP and Steering Committee.

117	P	Joyce Bruno-Reitzner, American College of Chest Physicians	023: ICU LOS	Disapprove with comments: On behalf of the American College of Chest Physicians (ACCP) the ACCP Quality Improvement Committee (QIC) appreciates the opportunity to comment on this measure. The QIC feels that this measure does not measure quality. The QIC also noted that while this measure can be risk-adjusted for patient factors, it cannot be risk-adjusted for other factors, such as, availability of step-down units, long-term ventilator facilities, nurse staffing and bed availability.	Measure developer response: We agree that these hospital systems' issues might influence length-of-stay but feel like those are reasons to measure and report LOS; to get hospitals to deal with their system factors.
135	M, Supplier/ Industry	Franz Fanuka, sanofi-aventis	023: ICU LOS	We support this measure. Optimal management of patients in the ICU is important to the patients and to achieving better outcomes. The experience with supraventricular cardiac arrhythmias (SVAs), illustrates the importance of atrial fibrillation as a high priority medical condition, especially in Medicare age patients. (Goodman) SVAs, most often intermittent or sustained AF, may result in prolonged ICU and hospitals stays. They are also associated with higher mortality in the hospital and in the long term. Goodman S, Shirov T, Weissman C. Supraventricular arrhythmias in intensive care unit patients: short and long-term consequences. Anesth Analg. Apr 2007; 104(4):880-886.	Thank you for your comments.
150	P	Gary Ewart, American Thoracic Society	023: ICU LOS	On behalf of the American Thoracic Society (ATS), the Quality Improvement Committee (QIC) appreciates that NQF has identified ICU practice for quality improvement and its invitation for public comment on this measure. We do not approve of this measure based on insufficient risk adjustment to validly measure quality. Sources of variation on this measure could be attributed to unmeasured patient factors and more significantly system-level factors that are uncontrolled, such as hospital use of intermediate/step-down units, long-term ventilator facilities as well as nurse staffing ratios and bed availability. Additionally, as an efficiency measure (LOS is closely tied to resource utilization), it is not patient-centered of itself and per our ATS policy statement should thus be tied to actual quality assessment. There is potential for adverse consequences, especially surrounding end-of-life issues. Kahn JM, Scales DC, Au DH, Carson SS, Curtis JR, Dudley RA, Iwashyna TJ, Krishnan JA, Maurer JR, Mularski R, Popovich J Jr, Rubenfeld GD, Heffner JE; American Thoracic Society Pay-for-Performance Working Group. An official American Thoracic Society policy statement: pay-for-performance in pulmonary, critical care, and sleep medicine. Am J Respir Crit Care Med. 2010;181: 752-61	Measure developer response: We agree that these hospital systems' issues might influence length-of-stay but feel like those are reasons to measure and report LOS; to get hospitals to deal with their system factors.

166	P	Mellanie True Hills, StopAfib.org & American Foundation for Women's Health	023: ICU LOS	We support this measure. Atrial fibrillation occurs often in patients in the ICU, and can extend their length of stay. This is additional evidence of the need to increase the priority for atrial fibrillation as a primary and secondary condition for Medicare.	Thank you for your comments.
173	P	Kay Jewell MD, Tara Center LLC	023: ICU LOS	We support this measure. Optimal management of patients in the ICU is important to the patients and to achieving better outcomes, to the hospital and the healthcare system. These two measures will be the outcome counterpart to other endorsed measures that impact care in the ICU: appropriate VTE prophylaxis in the ICU, as identified in the VTE-2 (NQF-#0217) measure and STK-1 (NQF #0438) and Ventilator Bundle (NQF # 302) and Safe Practices 23A and 28. These will help achieve lower mortality and LOS.	Thank you for your comments.
178	P	Kay Jewell, Tara Center LLC	023: ICU LOS	We fully support this measure. Attention to improving care through performance measurement and improvement through PDSA cycles will benefit the patients with COPD exacerbations and other pulmonary conditions who require care in the ICU	Thank you for your comments.
187	P	Kay Jewell MD, Center for Consumers of Healthcare	023: ICU LOS	Support.	Thank you for your comments.
221	M, Health Plan	Sheree Chin Ledwell, Aetna	023: ICU LOS	Health plans use the revenue codes to define ICU care and therefore these members can be identified and define the ICU LOS. The measure is reported with the predicted LOS measured using an adjustment model based on the (Mortality Probability Model) MPM III. Organizations using this measure would have to understand better what this adjustment method is. In addition, this measure needs to complement the Intensive care: in hospital mortality measure (safety indicator to check on whether shorter LOS is associated with increased mortality)	The MPM models were originally developed by a consortium of academic institutions and are one of the 3 most widely used sets of models (along with APACHE and SAPS models) in critical care research. Despite its academic origins, MPM III's use for risk-adjusting LOS was validated in a sample of hospitals in California that included all types of hospitals, not just academic centers (see previously cited reference: Vasilevskis, EE, Kuzniewicz, MW, Cason, B, Lane, R, Dean, ML, Clay, T, Rennie, DJ, Vittinghoff, E, Dudley, RA. Mortality Probability Model III and Simplified Acute Physiology Score: Assessing their Value in Predicting Length of Stay and Comparison to APACHE IV. CHEST, 2009; 136(1):89-101).

227	M, Health Professionals	Nancy Nielsen, MD, PhD, American Medical Association	023: ICU LOS	While these measures address the important topics of quality of life, length of stay, and mortality rates, we cannot support these measures 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 this patient population across the healthcare setting. These types of measures are best represented as facility-based measures. We recommend removing "Clinician" as a Level of Measurement/Analysis for proposed measures OT1-019-09, 0T1-023-09, and 0T1-024-09.	The developer has removed "clinician" from the submission. Measure developer response: We agree and have never used the tools that way. The measure developer understands that many individuals and systems factors within hospitals have important roles in determining these outcomes.
229	M, Health Professionals	Nancy Nielsen, MD, PhD, American Medical Association	023: ICU LOS	For the paired intensive care unit measures (OT1-23-09 and OT1-024-09), we are concerned with the reporting out of observed rates in addition to risk-adjusted rates. While such data are valuable for internal quality improvement, there is the potential that non-risk adjusted rates may be improperly interpreted, inferring quality of care delivered by clinicians, hospitals and other healthcare providers. In this instance, only measures that are risk-adjusted should be reported for accountability purposes. We recommend that these measures report out risk-adjusted rates only.	Measure developer response: We are fine with either approach and tends to base their reporting on the audience. The hospital members get both and the public only sees the risk-adjusted rates.
238	M, Provider	Kenneth Henriksen, Advocate Physician Partners	023: ICU LOS	The narrative statement for this measure expresses that is 'paired together' with the ICU Mortality Rate measure, however, it is not clear to future administrators of these measures how to interpret this observation. For example, are the two elements/measures to be measured as a composite, or are they to be bundled together within scoring. If adopted by an organization, are the two not to be used exclusively or both need to be implemented by the health care organization? It would be helpful to have some further clarification on this point.	"Pairing" indicates that both measures are to be used at the same time. The Committee felt that the LOS measure must be balanced by concurrent mortality data. This is not a composite or bundled scoring recommendation.
245	M, Purchaser	Barbara Rudolph, PhD, MSSW, The Leapfrog Group	023: ICU LOS	The Leapfrog Group supports the ICU Length of Stay measure. Given the research by Wennberg et al., related to Medicare population ICU resource use variation, we believe this measure is critical to stemming the inappropriate use of ICU resources and healthcare dollars. The measure also provides a strong example of appropriate uses for clinically enriched administrative data.	Thank you for your comments.

250	M, Purchaser	Gaye Fortner, HC21	023: ICU LOS	The ICU measures, when used together as specified, will provide extremely important information on the quality of care provided at the ICU level, which is a high volume care setting within the hospital. This measure is significant for its use of clinically-enriched administrative data, which allows for greater understanding of the reasons behind the LOS and mortality rate.	Thank you for your comments.
321	M, QMRI	Bernard M. Rosof, MD, MACP, Physician Consortium for Performance Improvement ®	023: ICU LOS	While these measures address the important topics of quality of life, length of stay, and mortality rates, we cannot support these measures 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 this patient population across the healthcare setting. These types of measures are best represented as facility-based measures. We recommend removing "Clinician" as a Level of Measurement/Analysis for proposed measures OT1-019-09, 0T1-023-09, and 0T1-024-09.	The developer has removed "clinician" from the submission form. Measure developer response: We agree and have never used the tools that way. The measure developer understands that many individuals and systems factors within hospitals have important roles in determining these outcomes.
323	M, QMRI	Bernard M. Rosof, MD, MACP, Physician Consortium for Performance Improvement ®	023: ICU LOS	For the paired intensive care unit measures (OT1-23-09 and OT1-024-09), we are concerned with the reporting out of observed rates in addition to risk-adjusted rates. While such data are valuable for internal quality improvement, there is the potential that non-risk adjusted rates may be improperly interpreted, inferring quality of care delivered by clinicians, hospitals and other healthcare providers. In this instance, only measures that are risk-adjusted should be reported for accountability purposes. We recommend that these measures report out risk-adjusted rates only.	Measure developer response: We are fine with either approach and tends to base their reporting on the audience. The hospital members get both and the public only sees the risk-adjusted rates.

339	M, Provider	Jennifer Faerberg, Association of American Medical Colleges	023: ICU LOS	While the ICU length of stay measure is risk adjusted, this measure does not take into account (or provide exclusion for, or exclusion of) end-of-life cases, particularly for ICU patients who are placed on comfort care after an ICU admission. Without the differentiation of these cases, the usefulness of the measure is minimized. We would like to seek clarification on how multiple admissions to the ICU during a single hospital stay would be counted. From the measure specifications, it states that only index admissions would be included, therefore no readmissions to the ICU during the same hospital stay would be counted. Is this correct? We agree with the steering committee that this measure should never be reported as a stand alone measure and should only be reported in conjunction with the mortality measure giving a more appropriate picture of care. As stated previously with the readmission measures we strongly believe that SES factors and, particularly for ICU patients, cultural factors should be incorporated into the risk model as they greatly impact patient outcomes. While these factors have not been included in the model, we strongly recommend that the results of the LOS/Mortality measures be stratified by hospital type providing a more appropriate comparison of performance and identification of disparities.	Measure developer response: This factor was discussed and the following reasons were why an end-of-life variable was not included: 1) if the patient arrives and is known to be at end-of-life, they should not go into the ICU at all, 2) if the patient arrives and is not know to be at EOL, but that decision is made later, this is not likely to penalize hospitals, because most such patients will spend very little time in the ICU after the decision (so being recognized as being at EOL will not add much to ICU LOS), and 3) we had an incomplete proxy for this (DNR at time of admission) and it had little impact on our ratings of hospitals (this is described in the Vasilevskis paper Mortality Probability Model III and Simplified Acute Physiology Score: Assessing their Value in Predicting Length of Stay and Comparison to APACHE IV. CHEST, 2009; 136(1):89-101).
343	M, Supplier/ Industry	Dirksen Lehman, Edwards Lifesciences	023: ICU LOS	Edwards Lifesciences welcomes the endorsement of patient outcomes measures OT1-023-09 (ICU length of stay) and OT1-024-09 (ICU in-hospital mortality). Both measures are well recognized and accepted endpoints commonly used and sought after in published clinical studies to demonstrate the clinical efficacy and cost effectiveness of various treatment modalities. As you know, these clinical studies are an invaluable resource for numerous stakeholders, including clinicians, hospitals, payers, and other organizations, in making critical decisions about patient care. Endorsement of these measures would facilitate broader and more frequent tracking of these measures via electronic medical records, ultimately supporting the true application of evidence-based medicine. The idea of pairing both of these measures together in order to provide a more comprehensive picture makes sense, although ICU in-hospital mortality may not always be an accurate reflection of "unintended consequences of inappropriate reductions in LOS." In certain situations, inappropriate reductions in LOS may lead to other unfavorable consequences, such as avoidable readmissions, overuse of step-down facilities, or post 30-day mortality. With that said, we support endorsement of these measures whether paired or developed as standalone measures.	Thank you for your comments.

344	M, Supplier/ Industry	Dirksen Lehman, Edwards Lifesciences	023: ICU LOS	Finally, although racial, ethnic, and socioeconomic disparities will not be able to be addressed initially, we believe that this imperfection should not stand in the way of the endorsement with high hopes and confidence that future iterations of the MPM risk model will include this important element of analysis.	NQF's evaluation criteria indicates that disparities characteristics should not be included in risk models but the data elements should be collected and stratification by characteristic as appropriate.
350	M, Health Plan	Rebecca Zimmermann, AHIP	023: ICU LOS	AHIP supports the collection of data to assess intensive care mortality and length of stay. However, we are concerned with the administrative burden associated with the collection of these measures. In the supporting materials, the measure developer notes that medical record review is recommended to be collected by a nurse and estimates that it takes approximately 11 minutes per record. Given this significant burden of data collection, implementation by hospitals may be challenging. AHIP also recommends that the ICU length of stay measure be paired with a hospital readmissions measure in order to assess if patients are being discharged from the ICU too soon.	Measure developer response: We have noted that the data elements are collected by EHRs and when more hospitals use EHRs the burden will be reduced.
359	M, Health Plan	Catherine MacLean, WellPoint	023: ICU LOS	WellPoint supports this measure.	Thank you for your comments.
368	M, Consumer	Debra Ness, National Partnership for Women & Families	023: ICU LOS	This ICU measure, when used together as specified with the ICU in-hospital mortality rate, will provide extremely important information on the quality of care provided at the ICU level, which is a high volume care setting within the hospital. This measure is significant for its use of clinically-enriched administrative data, which allows for greater understanding of the reasons behind the LOS and mortality rate.	Thank you for your comments.

381	M, Health Professionals	Valerie Oster, American College of Surgeons	023: ICU LOS	We have a number of concerns about developing a quality measure looking at ICU Length of Stay. We agree that measuring and evaluating overuse is important and that overuse can have a significant impact on the quality of patient care in certain circumstances. However, with this measure we are concerned about how users of this measure will distinguish between overuse of the ICU and quality patient care. In turn, will this measure give users the false impression that clinicians with a low patient LOS in the ICU should be considered high quality? In addition, we are concerned about the how this measure takes the wide variety of hospital system issues (eg: bed availability) into account when calculating the LOS. If a step down unit is needed but a bed is not available and the patient is in need of a higher level of care than the medical unit, will the hospitals be penalized for their LOS in an available ICU bed? Lastly, we are concerned about the unintended consequences and potential risks of this measure. What safeguards are in place to assure patients that a clinician will not intentionally avoid appropriately transferring them to the ICU in order to keep their LOS down or that a hospital will not avoid potentially high risk patients altogether for fear their ICU LOS will rise?	Measure developer response: We agree that these hospital systems' issues might influence length-of-stay but feel like those are reasons to measure and report LOS; to get hospitals to deal with their system factors. The measure developer agrees that poor ICU care could shorten stay, but it is unlikely to do so without also worsening outcomes. For that reason, the developer suggest only using ICU LOS in a pair with the mortality measure (OT1-024-09).
382	M, Provider	Cleveland Clinic, Cleveland Clinic	023: ICU LOS	We do not support this measure. There is such variability among ICUs in types of patients (pulmonary vs. cardiac vs. post- surgical, etc.), severity of illness and physician preference for admission to ICUs that meaningful comparison among institutions regarding LOS would be difficult. While it is possible to partially adjust for severity of illness for the care of patients with certain illnesses (e.g., heart failure), there is too much variability in outcomes among different conditions to adequately risk adjust all ICU patients. Moreover, the acuity scores and predictive scores are not validated for institutions that have large numbers of transfers. The correlation between LOS and quality is sparse. There are other factors outside of the control of an ICU (e.g., bed availability) that may also affect LOS.	Measure developer response: This measure is used in California by more than 250 hospital of all types and sizes. The LOS measure must be used with the mortality measure.
396	M, Consumer	Carol Sakala, Childbirth Connection	023: ICU LOS	When paired with the companion ICU measure, this measure will provide important information about the outcome of care in this high-volume, high-cost segment of hospital care. The use of clinically enriched administrative data will help with meaningful interpretation of results.	Thank you for your comments.

415	M, Purchaser	Christine Chen, Pacific Business Group on Health	023: ICU LOS	ICU Length of Stay and ICU In-hospital Mortality Rate: These ICU measures can provide critical information about quality of care in ICUs which is a high volume care setting within hospitals and also the location of most in-hospital deaths when they occur. These measures are already in use in California through the California Hospital Assessment and Reporting Taskforce (CHART) and have proven immensely valuable there. Additionally, we agree with the Steering Committee's recommendation that measures of ICU LOS and mortality rate be considered together to "balance potential unintended consequences of inappropriate reductions in LOS."	Thank you for your comments.
423	M, Health Professionals	Angela Franklin, American College of Emergency Physicians	023: ICU LOS	ACEP is concerned that meaningful comparisons with this measure are not possible due to the high rate of variability between ICU's in the types of patients (pulmonary vs. cardiac vs. post-surgical etc.), and severity of illness. While it is possible to partially adjust for severity of illness for the care of specific illnesses (e.g. heart failure), there is too much variability in outcomes between different types of conditions to adequately risk adjust for all ICU patients.	Measure developer response: This measure is currently used in California by more than 250 hospitals of various types and sizes. Experience in California indicates that improvements in mortality and LOS are possible.
443	M, Provider	Gail Grant, Cedars-Sinai Medical Center	023: ICU LOS	Although risk-adjusted, this measure does not take into account - or provide provision for, or exclusion of - end-of-life cases, particularly for ICU patients who are placed on comfort care after ICU admission. Without differentiation of these cases, the usefulness of this measure is questionable. (***Late submission)	Measure developer response: Our group discussed this and 3 points were made that led us not to include an end-of-life (EOL) variable: 1) if the patient arrives and is known to be at end-of-life, they should not go into the ICU at all, 2) if the patient arrives and is not know to be at EOL, but that decision is made later, this is not likely to penalize hospitals, because most such patients will spend very little time in the ICU after the decision (so being recognized as being at EOL will not add much to ICU LOS), and 3) we tested the best available proxy for being at EOL (Do Not Resuscitate-DNR-at time of admission) and it no statistically significant impact on our ratings of hospitals (it wasn't even close).{Vasilevskis, EE, Kuzniewicz, MW, Cason, B, Lane, R, Dean, ML, Clay, T, Rennie, DJ, Vittinghoff, E, Dudley, RA. Mortality Probability Model III and Simplified Acute Physiology Score: Assessing their Value in Predicting Length of Stay and Comparison to APACHE IV. CHEST, 2009; 136(1):89-101} While DNR at admission may not be a perfect proxy for EOL, it is the best available. As long as hospitals do not keep patients who are known to be at EOL in the ICU, they should have nothing to worry about in terms of these patients changing their risk-adjusted ICU LOS. Since most are already do this, waiting for a more perfect proxy for EOL than being DNR probably won't

444	M, Provider	Gail Grant, Cedars-Sinai Medical Center	023: ICU LOS	Based on our experience in reviewing our ICU mortality, we have concerns about the usefulness of the MPM risk adjustment methodology incorporated in both of these measures (see below). (***Late submission)	Measure developer response: In fact, it has always been the case that it did not matter much which of the 3 competing risk adjustment systems (MPM, SAPS, APACHE) one used to rate hospitals. This was first shown by the Society for Critical Care Medicine, which found fairly high correlations (.74-.79) between the 3 systems if you used them exactly as they first appeared in a journal, without trying to fit them to the population on which you were reporting.{Glance, LG, Osler, TM, Dick, A. Rating the quality of intensive care units: Is it a function of the intensive care unit scoring system? Crit Care Med, 2002; 30(9):1976-1982} Numerous studies since then have shown that you need to update the weights on each variable in each model to fit it to the population of interest. (For example, Medicare, in its ongoing public reporting of heart failure mortality rates, doesn't use one model forever. Every year, they recalculate how much weight to give age and the other variables in predicting the probability of death). Our group did a study comparing the 3 models after recalculating these weights for our study population-a more real world test of whether the choice of model mattered. Again, the choice of model made little difference. We found very high correlations between the rankings hospitals received (0.82-0.92).{Dudley, RA, Kuzniewicz, M, Dean, M, Lane, RK, Rennie,
118	P	Joyce Bruno-Reitzner, American College of Chest Physicians	024: ICU Mortality	Disapprove with comments: On behalf of the American College of Chest Physicians (ACCP) the ACCP Quality Improvement Committee (QIC) appreciates the opportunity to comment on this measure. The QIC applauds the principle and understands the need for measuring mortality in terms of quality care. However, the QIC notes that there are too many variables that cannot be accounted in this measure. The QIC noted that there is not any narrowly defined expected outcomes in this area. The QIC fears that this measure may be gamed for more favorable results.	The Steering Committee considered these issues, but noted that use and public reporting of this measure by more than 250 hospitals in California demonstrates the utility and feasibility of the measure.
136	M, Supplier/ Industry	Franz Fanuka, sanofi-aventis	024: ICU Mortality	Support. See comments on OT1-023-09.	Thank you for your comments.

151	P	Gary Ewart, American Thoracic Society	024: ICU Mortality	On behalf of the American Thoracic Society (ATS), the Quality Improvement Committee (QIC) appreciates that NQF has identified ICU practice for quality improvement and its invitation for public comment on this measure. We do not approve of this measure based on the absence of defined expected outcomes for this measure that opens itself to gaming and too many unaccounted covariates. There is significant potential for adverse consequences. This measure can be easily gamed through early discharge to post-acute care facilities such as SNFs and long-term acute care hospitals. Hospitals can artificially improve their mortality rate by transferring high-risk patients to other facilities/hospitals, and therefore shifting the mortality burden. This effect has been demonstrated in several studies.1, 2 Besides gaming, this issue could also lead to health disparities if elderly patients or ethnic minorities were deferentially transferred. 1. Kahn JM, Kramer AA, Rubenfeld GD. Transferring critically ill patients out of hospital improves the standardized mortality ratio: a simulation study. Chest. 2007;131:68-75. 2. Vasilevskis EE, Kuzniewicz MW, Dean ML, et al. Relationship between discharge practices and intensive care unit in-hospital mortality performance: evidence of a discharge bias. Med Care. 2009;47:803-812.	The Steering Committee considered these issues, but noted that use and public reporting of this measure by more than 250 hospitals in California demonstrates the utility and feasibility of the measure.
167	P	Mellanie True Hills, StopAfib.org & American Foundation for Women's Health	024: ICU Mortality	We support this measure as well since atrial fibrillation occurs often in patients in the ICU, and can increase mortality if it leads to a stroke or other heart issues. There is a need to increase the priority of atrial fibrillation as a primary and secondary condition for Medicare, especially since atrial fibrillation doubles the risk of mortality.	Thank you for your comments.
174	P	Kay Jewell MD, Tara Center LLC	024: ICU Mortality	Support. See comments on OT1-023-09.	Thank you for your comments.
179	P	Kay Jewell, Tara Center LLC	024: ICU Mortality	We fully support this measure. See comments on OT1-023-09.	Thank you for your comments.

182	P	Kay Jewell, Tara Center LLC	024: ICU Mortality	We fully support this measure. See comments on OT1-023-09. References: Newton C and Young S. Financial implications of glycemic control: Results of an inpatient diabetes management program. Endocr Pract: 2006: 12 (Suppl 3); 43-48. Van den Berghe G, Wilmer A, Hermans G, Meersseman W, Wouters P et al. Intensive insulin therapy in the medical ICU. N Engl J Med 2006; 354(5): 449-461.	Thank you for your comments.
188	P	Kay Jewell MD, Center for Consumers of Healthcare	024: ICU Mortality	Support	Thank you for your comments.
222	M, Health Plan	Sheree Chin Ledwell, Aetna	024: ICU Mortality	Aetna has historically been concerned that there is underreporting of discharge disposition codes on hospital claims that indicate the member has expired. If we assume that the discharge disposition is correct, the measure can be utilized. In addition, this measure needs to complement the ICU LOS measure (safety indicator to check on whether shorter LOS is associated with increased mortality)	The Steering Committee agrees that the ICU mortality and LOS measures are best used together.
228	M, Health Professionals	Nancy Nielsen, MD, PhD, American Medical Association	024: ICU Mortality	While these measures address the important topics of quality of life, length of stay, and mortality rates, we cannot support these measures 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 this patient population across the healthcare setting. These types of measures are best represented as facility-based measures. We recommend removing "Clinician" as a Level of Measurement/Analysis for proposed measures OT1-019-09, 0T1-023-09, and 0T1-024-09.	The developer has removed "clinician" from the submission. Measure developer response: We agree and have never used the tools that way. The measure developer understands that many individuals and systems factors within hospitals have important roles in determining these outcomes.
230	M, Health Professionals	Nancy Nielsen, MD, PhD, American Medical Association	024: ICU Mortality	For the paired intensive care unit measures (OT1-23-09 and OT1-024-09), we are concerned with the reporting out of observed rates in addition to risk-adjusted rates. While such data are valuable for internal quality improvement, there is the potential that non-risk adjusted rates may be improperly interpreted, inferring quality of care delivered by clinicians, hospitals and other healthcare providers. In this instance, only measures that are risk-adjusted should be reported for accountability purposes. We recommend that these measures report out risk-adjusted rates only.	Measure developer response: We are fine with either approach and tends to base their reporting on the audience. The hospital members get both and the public only sees the risk-adjusted rates.

239	M, Provider	Kenneth Henriksen, Advocate Physician Partners	024: ICU Mortality	The narrative statement for this measure expresses that is 'paired together' with the ICU Length of Stay measure, however, it is not clear to future administrators of these measures how to interpret this observation. For example, are the two elements/measures to be measured as a composite, or are they to be bundled together within scoring. If adopted by an organization, are the two not to be used exclusively or both need to be implemented by the health care organization? It would be helpful to have some further clarification on this point.	"Pairing" indicates that both measures are to be used at the same time. The Committee felt that the LOS measure must be balanced by concurrent mortality data. This is not a composite or bundled scoring recommendation.
246	M, Purchaser	Barbara Rudolph, PhD, MSSW, The Leapfrog Group	024: ICU Mortality	The Leapfrog Group supports the ICU In-Hospital Mortality Rate measure. It provides us (consumers and purchasers) with an opportunity to assess variation in ICU mortality rates across hospitals. While consumers have not historically made hospital selection using ICU data, those seeking high risk procedures could benefit from this information. Hospitals would also be able to assess how well they are performing, and if needed, implement new processes of care for the ICU, or new structures of care.	Thank you for your comments.
251	M, Purchaser	Gaye Fortner, HC21	024: ICU Mortality	The ICU measures, when used together as specified, will provide extremely important information on the quality of care provided at the ICU level, which is a high volume care setting within the hospital. This measure is significant for its use of clinically-enriched administrative data, which allows for greater understanding of the reasons behind the LOS and mortality rate.	Thank you for your comments.
322	M, QMRI	Bernard M. Rosof, MD, MACP, Physician Consortium for Performance Improvement ®	024: ICU Mortality	While these measures address the important topics of quality of life, length of stay, and mortality rates, we cannot support these measures 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 this patient population across the healthcare setting. These types of measures are best represented as facility-based measures. We recommend removing "Clinician" as a Level of Measurement/Analysis for proposed measures OT1-019-09, 0T1-023-09, and 0T1-024-09.	The developer has removed "clinician" from the submission form. developer response: We agree and have never used the tools that way. The measure developer understands that many individuals and systems factors within hospitals have important roles in determining these outcomes.

324	M, QMRI	Bernard M. Rosof, MD, MACP, Physician Consortium for Performance Improvement ®	024: ICU Mortality	For the paired intensive care unit measures (OT1-23-09 and OT1-024-09), we are concerned with the reporting out of observed rates in addition to risk-adjusted rates. While such data are valuable for internal quality improvement, there is the potential that non-risk adjusted rates may be improperly interpreted, inferring quality of care delivered by clinicians, hospitals and other healthcare providers. In this instance, only measures that are risk-adjusted should be reported for accountability purposes. We recommend that these measures report out risk-adjusted rates only.	Measure developer response: We are fine with either approach and tends to base their reporting on the audience. The hospital members get both and the public only sees the risk-adjusted rates.
340	M, Provider	Jennifer Faerberg, Association of American Medical Colleges	024: ICU Mortality	The ICU "in hospital mortality rate" is based on patient status at time of discharge from the hospital. Hence, mortalities that occur during, as well as after, an ICU admission are included in the calculation. Since other factors in hospital care could play a role in the eventual outcome of any given patient, one could argue that this is not a true reflection of the quality of care in the ICU. As stated previously with the readmission measures we strongly believe that SES factors and, particularly for ICU patients, cultural factors should be incorporated into the risk model as they greatly impact patient outcomes. While these factors have not been included in the model we strongly recommend that the results of the LOS/Mortality measures be stratified by hospital type providing a more appropriate comparison of performance and identification of disparities.	Measure developer response: We agree that the measure includes deaths that could occur after the ICU stay and may not reflect ICU care. However, this is the general approach taken in this field (by APACHE and by the Society of Critical Care Medicine in their Project Impact). The concept is that the measures is not just measuring ICU care, but "How well does this hospital do with critically ill patients?". Since critically ill patients and their families care whether they survive and go home, not just whether they make it out the ICU doors, it is appropriate to consider the entire hospital stay. Furthermore, failing to do so invites gaming the system, by allowing hospitals to transfer patients out of the ICU to a quiet room for their last minutes, which would render the ICU mortality measure useless. The measure developer believes the SES factors in the model would probably improve predictive power some, but cannot get such variables. Holding out until they are available is allowing perfect to be the enemy of the good. Further, this argument applies to almost all outcome measures and the issue of a lack of a source for SES data also applies to those measures, so we'd have to stop all outcome measurement until SES data were consistently and accurately available. We do not believe it is worth the wait.
360	M, Health Plan	Catherine MacLean, WellPoint	024: ICU Mortality	WellPoint supports this measure.	Thank you for your comments.
369	M, Consumer	Debra Ness, National Partnership for Women & Families	024: ICU Mortality	The National Partnership for Women & Families is very supportive of this measure, as noted in our comments on OT1-023-09: ICU Length-of-stay.	Thank you for your comments.

375	M, Health Professionals	Dale Lupu, American Academy of Hospice & Palliative Medicine	024: ICU Mortality	Recommend future consideration of developing a patient-centered risk adjustment based on documentation of family meeting or goals of care discussion, in addition to risk adjustment based on race, ethnicity and SES.	The Steering Committee has made a global recommendation that further work should be done on risk models to include patient factors such as shared decision making and other patient perspectives. The recommendation will be included in a future report of the Patient Outcomes project.
379	M, Health Plan	Tom James, Humana, Inc.	024: ICU Mortality	Line 239—ICU In-hospital mortality rate. While ICU is defined in terms of 1 or 2 nurses per patient, the ICU definition do not appear to include appropriateness for admission or nature of the patient population. This may have been tested in California, but it may not do well in other regions because of heterogeneity of the ICU populations between hospitals	Measure developer response: We agree and would like to avoid inappropriate ICU admissions, however, there is no data yet to address this issue.
383	M, Provider	Cleveland Clinic, Cleveland Clinic	024: ICU Mortality	Although not calibrated for larger institutions and regional transfer centers, mortality rate is a more widely accepted outcome measure than LOS. However, there are still concerns that this mortality measure is not sufficiently indexed to acuity and would therefore not accommodate facilities that accept a large amount of patient transfers.	Thank you for your comments.
397	M, Consumer	Carol Sakala, Childbirth Connection	024: ICU Mortality	When paired with the companion ICU measure, this measure will provide important information about the outcome of care in this high-volume, high-cost segment of hospital care. The use of clinically enriched administrative data will help with meaningful interpretation of results.	Thank you for your comments.

432	P	Gary Ewart, American Thoracic Society	024: ICU Mortality	On behalf of the American Thoracic Society (ATS), the Quality Improvement Committee (QIC) appreciates that NQF has identified ICU practice for quality improvement and its invitation for public comment on this measure. We do not approve of this measure based on validity deficits due to inadequacy of the risk adjustment. The MPM risk adjustment model does not contain ICU admission source (ED, ward, other hospital, etc.). Prior work has shown that receiving patients in transfer can adversely affect risk-adjusted mortality.3 Thus this measure could harm academic hospitals that transfer in a lot of patients. Suggestion for improvement: 30-day mortality is vastly preferred over in-hospital mortality. Medicare's AMI mortality measure is 30-day, not in-hospital, for just this reason. Although it is very difficult for hospitals to get 30-day mortality data now, with expansion of the IT infrastructure and/or linkage to other data sets, it's possible. The measure collects SSN so no reason not to link to NDI later. It is preferable to endorse a valid measure now and develop the IT later than it is to endorse an invalid measure; Exclude patients transferred to other acute care hospitals from the denominator. Thus hospitals will not get credit for a "save" when all they did was transfer a patient to another hospital; Exclude patients admitted in transfer from another hospital from the numerator and denominator. This will avoid punishing large referral centers. Alternatively, use admission source in the risk-adjustment model.	The Steering Committee considered these issues, but noted that use and public reporting of this measure by more than 250 hospitals in California demonstrates the utility and feasibility of the measure.
445	M, Provider	Gail Grant, Cedars-Sinai Medical Center	024: ICU Mortality	The measure specifications include mortalities that occur during, as well as after, an ICU admission. We do not think that such a calculation is not a true reflection of the quality of ICU care, since other factors in hospital care could also play in role in the eventual outcome of any given patient's hospitalization. (***Late submission)	Measure developer response: This is the general approach taken in this field (by APACHE and by the Society of Critical Care Medicine in their Project Impact). The concept is that we are measuring not just ICU care, but "How well does this hospital do with critically ill patients?". Since critically ill patients and their families care whether they survive and go home, not just whether they make it out the ICU doors, it is appropriate to consider the entire hospital stay. Furthermore, failing to do so invites gaming the system, by allowing hospitals to transfer patients out of the ICU to a quiet room for their last minutes, which would render the ICU mortality measure useless. On the positive side, including post-ICU events encourages the ICU team to interact with floor teams to make sure that transitions are well managed and that excellent care continues throughout the hospital stay.

446	M, Provider	Gail Grant, Cedars-Sinai Medical Center	024: ICU Mortality	We have concerns about the methodology (MPM) proposed for risk adjustment of both of these measures. Although apparently designed to minimize the data collection burden, it has been our experience that this risk adjustment methodology needs to be enhanced to facilitate comparisons between hospitals. Although more burdensome for data collection, the APACHE risk adjustment methodology is more well-established and includes sufficient clinical data to provide a more robust risk adjustment. Because of its inherent high data collection burden, however, such a risk adjustment system is more amenable for use in systems allowing electronic capture and submission of such data. As such, until such systems are widely used, we do not recommend endorsement of either ICU measure. (***Late submission)	Measure developer response: Please see our description above that a hospital's quality ranking does not change much whether one uses MPM or APACHE. It DOES MATTER, however, which model one picks, because the data collection required for APACHE takes more than 3 times as long as the data collection for MPM (37 minutes vs. 11 minutes, p<0.001), which we also describe in the enclosed paper.{Kuzniewicz, MW, Vasilevskis, EE, Lane, R, Dean, ML, Trivedi, NG, Rennie, DJ, Clay, T, Kotler, PK, Dudley, RA. Variation in ICU Risk-adjusted Mortality: Impact of Methods of Assessment and Potential Confounders. CHEST, 2008; 133(6):1319-27} Since you get the same rating regardless of model, we recommend the model that uses the fewest data collection resources, so that those resources can instead be used either on quality improvement or on measuring quality in some other domain.
212	M, Health Professionals	Rita Munley Gallagher, PhD, RN, American Nurses Association	General Comments	The American Nurses Association (ANA) concurs that the outcomes of an episode of health care are inherently important because they reflect the reason consumers seek care as well as the result healthcare providers, themselves, are trying to achieve. Outcome measures are integral to high quality health care. ANA applauds NQF's efforts to identify and endorse additional measures of patient outcomes to fill gaps in its current portfolio. NQF's efforts in that regard are laudable.	Thank you for your comments.
216	M, Health Plan	Sheree Chin Ledwell, Aetna	General Comments	Risk adjustment: the Probability Model MPM III is referenced as a risk adjustment method in several measures. We would need to understand this logic as well as the specific risk adjustment that has been applied to the measures that do not specify this MPM III method.	The MPM III risk model has been published -see HigginsTL, Teres D, et al, Assessing contemporary intensive care unit outcome: An updated Mortality Probability Admission Model (MPM0-III). Crit Care Med 2007; 35:827-835. The risk model for any proposed measure is described in the specifications of the measure submission form. Please refer to the additional posted information.

225	M, Health Professionals	Nancy Nielsen, MD, PhD, American Medical Association	General Comments	The American Medical Association (AMA) appreciates the opportunity to comment on the National Quality Forum's (NQF) National Voluntary Consensus Standards for Patient Outcomes, First Report for Phases 1 and 2: A Consensus Report. We are pleased that NQF has taken up the difficult task of continuing to review and recommend the endorsement of outcomes measures. 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 the efforts of this report, we have concerns regarding the following: level of measurement for certain recommended standards; the potential for the misinterpretation of observed rates (as compared to risk-adjusted rates); the timeframe suggested for the PCI readmissions measure; and the methodology employed for risk adjustment for the PCI readmissions measure. We also request clarification regarding one measure. We provide the measure specific comments in the respective measure comment fields.	See responses to the individual measure comments.
234	M, Provider	Kenneth Henriksen, Advocate Physician Partners	General Comments	The focus of this NQF Project and the patient outcome measures put forth to date focus largely on the in-patient service setting. As organizations work to control health care costs, a larger proportion of health care delivery will be shifting to an outpatient setting. This first report for Phases 1 and 2 of the Patient Outcomes Project recognizes that a greater focus be placed on filling gaps in existing patient outcome measures; it is suggested that future consideration be given to outcome measures applicable to an ambulatory setting. In the categorization of the proposed patient outcomes measures, reference is made to application of the Donabedian model for defining outcomes. It is recommended that consideration be given to categorizing each proposed measure based upon placement within the Donabedian framework of Proximate, Intermediate or Ultimate Outcome. This direction would assist organizations looking to administer these measurements to prioritize their implementation.	This is the first of four reports for the Patient Outcomes project. The second report included ambulatory measures for diabetes and avoidable conditions for chronic conditions. The reports for Mental Health and Child Health will recommend measures for ambulatory settings.

242	M, Purchaser	Barbara Rudolph, PhD, MSSW, The Leapfrog Group	General Comments	The Leapfrog Group supports the efforts of the National Quality Forum as it seeks to increase the number of outcome measures in its portfolio. Outcome measures are very salient to the information needs of both consumers and purchasers, as they make decisions about healthcare providers. While we regret that early efforts were focused on hundreds of process measures, we are pleased that current efforts are focused on outcomes of care and efficiency. We are concerned however, about outcome measures that utilize methodologies resulting in very little variation--methodologies that pull all but the most extreme outliers into average categories.	The Steering Committee identified issues with risk models and noted that this is not a project-specific issue. The Committee has recommended that NQF consider additional guidance in for evaluation of risk models.
247	M, Purchaser	Gaye Fortner, HC21	General Comments	I support NQF as it endeavors to increase the number of meaningful, patient-centered outcomes measures. I agree with the language in the introduction to the draft report that describes the importance of outcome measures in helping consumers and purchasers reflect on the overall quality of care patients receive. I understand and acknowledge the fact that outcome measures are more complex to develop, and in some cases, to report, than are process measures. At the same time, I believe that the importance of having good outcome measures for consumers and purchasers to use in their decision-making is both critical and long overdue, and this outweighs the call for perfection. I feel that the eight measures being recommended for endorsement by the patient outcomes steering committee will provide meaningful information for consumers and purchasers, as well as for quality improvement. In terms of future outcome measure development, I support the additional recommendations included in the draft report around expanding measures to cover as many populations as possible; specifying measures to allow for stratification by race, ethnicity, language and gender; and providing a rationale for the use of hierarchical modeling.	Thank you for your comments.

255	M, Health Professionals	Roshunda Drummond-Dye, American Physical Therapy Association	General Comments	On behalf of the American Physical Therapy Association, we would like to applaud the National Quality Forum (NQF) for the development of measures: OT1-019-09 Health-related quality of life in COPD patients before and after pulmonary rehabilitation and OT1-020-09 Functional Capacity in COPD patients before and after pulmonary rehabilitation. We believe that these measures are a critical step in the development of further evidence related to the impact of pulmonary rehabilitation on functional capacity and quality of life using two well validated tools. APTA is a professional organization representing the interests of over 74,000 physical therapists, physical therapist assistants, and students of physical therapy. APTA is structured into specialty categories and the Association has a section dedicated to cardiopulmonary disorders. The Section has a 30-year history of promotion and advancement of cardiovascular and pulmonary physical therapy practice, education and research. Our membership spans the United States as well as four other countries and reflects diverse practice settings, perspectives and experiences. The Cardiovascular and Pulmonary Section APTA, Inc serves its members and the physical therapy profession by promoting the development, application and advancement of cardiovascular and pulmonary physical therapy practice, education and research.	Thank you for your comments.
256	M, Health Professionals	Roshunda Drummond-Dye, American Physical Therapy Association	General Comments	The Section is also a leading advocate and resource for consumers as well as physical therapists, physical therapist assistants, and PT/PTA students who provide health, wellness, and prevention and/or rehabilitation services in a variety of practice settings to individuals of all ages at risk for, or diagnosed with, cardiovascular or pulmonary impairments. Therefore, in addition to supporting the endorsement of these measures, APTA would also be happy to lend its expertise to any expert or technical panels while these or other measures related to cardiopulmonary are reviewed.	Thank you for your comments.

257	M, Health Professionals	Roshunda Drummond-Dye, American Physical Therapy Association	General Comments	Physical therapists are an integral part of a pulmonary rehabilitation program as they perform extensive examinations, develop appropriate plans of care, provide individualized exercise techniques, and promote increased functionality for patients that aid them in successfully maximizing optimal function when participating in a pulmonary rehabilitation program. Physical therapists are highly trained, professionally educated at the college or university level and licensed after satisfactorily completing a national exam. As of January 2002, the Commission on Accreditation in Physical Therapy Education accreditation was limited to only those professional education programs that award the post-baccalaureate degree. There are a variety of skill sets that a graduate must possess specific to cardiovascular and pulmonary care. In general, most programs have courses dedicated to cardiovascular and pulmonary rehabilitation and therapeutic techniques. Vital sign monitoring, screening for medical disease, exercise prescription and exercise testing, pathology, and pharmacology are components of physical therapist education. All of this preparatory coursework, as well as clinical affiliations, ensure safe and effective patient care. In addition, licensure, as well as compliance with scope of practice, is required in all states in which a physical therapist practices.	Thank you for your comments.
258	M, Health Professionals	Roshunda Drummond-Dye, American Physical Therapy Association	General Comments	Physical therapists are uniquely qualified, by virtue of the content of professional curricula to address impairments, limitations, and disabilities related to changes in musculoskeletal and neuromuscular system function that are either the source or the consequence of respiratory dysfunction. The Guide to Physical Therapist Practice contains multiple interventions performed by physical therapists for patients with pulmonary disorders. Physical therapists have the requisite education and skills to apply and interpret these measures in order to develop and re-evaluate plans of care. Pulmonary rehabilitation is accepted as a multidisciplinary program of care often including physicians, nurses, respiratory therapists, physical therapists, occupational therapists, psychologists and social workers. Referring to the guidelines set forth by the American Association for Cardiovascular & Pulmonary Rehabilitation for program directors, physical therapists have the credentials to be directors of pulmonary rehabilitation programs, and many physical therapists currently act in that capacity. Physical therapists are uniquely qualified among the multidisciplinary pulmonary rehabilitation team to intervene with respect to function and activities of daily living. Physical therapists focus on individual function and the needs of the patient with the	Thank you for your comments.

259	M, Health Professionals	Roshunda Drummond-Dye, American Physical Therapy Association	General Comments	Physical therapists are increasingly using various outcome tools to gather data on patient with pulmonary dysfunctions throughout the spectrum of treatment. Selecting the optimal tool to use with a patient population can be challenging as there are many outcome tools available. It is important to consider if the tool will be used to classify a patient into a treatment category, to provide a prognosis, to compare the patient to others with a similar diagnosis, or to demonstrate response to treatment. Both the six-minute walk test and health-related quality of life indicators have been studied extensively and are well-validated and reliable outcome tools . It is also important to note, from the physical therapy perspective that these measures focus on the functional capacity of the patient.	Thank you for your comments.
263	M, Health Professionals	Roshunda Drummond-Dye, American Physical Therapy Association	General Comments	Therefore, APTA strongly supports the endorsement of these measures by the NQF. As stated earlier, we believe that the adoption and endorsement of such measures will further evidence related to the impact of pulmonary rehabilitation on functional capacity and quality of life using two well validated tools. If you have questions regarding our comments, please contact Roshunda Drummond-Dye at (703) 706-8547 or roshundadrummond-dye@apta.org.	Thank you for your comments.
264	M, Health Professionals	Roshunda Drummond-Dye, American Physical Therapy Association	General Comments	American Physical Therapy Association: Guide to Physical Therapist Practice, Ed. 2, Alexandria, VA. 2001. American College of Chest Physicians/ American Association of Cardiovascular and Pulmonary Rehabilitation: Pulmonary Rehabilitation Joint ACCP/AACVPR Evidence-Based Clinical Practice Guidelines. Outcome Measures in Cardio Pulmonary Physical Therapy Use of Patients Specific Functional Scale (2007) Cardiopulmonary Section of the American Physical Therapy Association Improving Health Related Quality of Life in Chronic Obstructive Instruments to Measure Health Related Quality of Life Physiotherapy Vol. 93, Issue 3 September 2007, 175-182 American Journal of Respiratory and Critical Care Medicine Vol 166. pp. 111-117, (2002) – Medscape WebMD, Cum Opin Pulm Med 2004, 10(2)	Thank you for your comments.

291	M, Provider	Thomas Miner, Trinity Health	General Comments	At Trinity Health we are firmly committed to improving patient safety and quality across all of our care settings. We recognize the importance of quality measures to drive improvement. We also understand the burden that reporting can create for our associates and favor measures that can be derived from clinical data that is readily available.	Thank you for your comments.
319	M, QMRI	Bernard M. Rosof, MD, MACP, Physician Consortium for Performance Improvement ®	General Comments	The Physician Consortium for Performance Improvement® (PCPI) appreciates the opportunity to comment on the National Quality Forum's (NQF) National Voluntary Consensus Standards for Patient Outcomes, First Report for Phases 1 and 2: A Consensus Report. We are pleased that NQF has taken up the difficult task of continuing to review and recommend the endorsement of outcomes measures. 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 the efforts of this report, we have concerns regarding the following: level of measurement for certain recommended standards; the potential for the misinterpretation of observed rates (as compared to risk-adjusted rates); the timeframe suggested for the PCI readmissions measure; and the methodology employed for risk adjustment for the PCI readmissions measure. We also request clarification regarding one measure. We provide the measure specific comments in the respective measure comment fields.	See responses to the individual measure comments.
345	M, Health Plan	Rebecca Zimmermann, AHIP	General Comments	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. This project is an important step forward in endorsing measures that will provide meaningful information to consumers and other stakeholders. AHIP is concerned that half of the proposed measures are specified only for Medicare beneficiaries. While Medicare covers the majority of the over 65 insured population, there are over 200 million non-elderly insured and about 50 million uninsured people in the U.S. for which these measures are not applicable. We encourage NQF to review outcomes measures that are applicable to all populations.	The Steering Committee discussed this issue with measure developers who responded that their developmental data sets were limited to the insured over 65 population. The Committee recommended that developers peruse further development to apply the measures to the broadest population possible.

351	M, Health Professionals	Andrea Klein, National Association of Pediatric Nurse Practitioners (NAPNAP)	General Comments	NAPNAP has reviewed the documents and finds that the document looks appropriate. NAPNAP would like to applaud NQF on addressing 'disparities' in all that we do. These measures in Phase 1 & 2 are adult focused outcome measures (excluding patients < 18 years of age) - which is appropriate. We look forward to commenting on Phase 3 which is going to specifically address Child Health and Mental Health.	Thank you for your comments.
352	M, QMRI	Indira Jevaji, NIH/ORWH	General Comments	The Office of Research on Women?s Health (ORWH) serves as the focal point for women's health research at the National Institutes of Health, NIH. ORWH advances its mission in partnership with the NIH Institutes and Centers and supports innovative research on women?s health and the role of sex and gender in health and disease. The ORWH is pleased to have the opportunity to comment on the proposed quality of care related patient outcome measures. The ORWH recommends that the NQF routinely collect report and conduct analyses for possible differences or similarities in quality of care patient outcomes by sex /gender and race/ethnicity to provide research based evidence for any findings.	NQF's measure evaluation criteria includes assessment of a measure's capability for detecting disparities. The Steering Committee was very focused on the need to evaluate disparities with the measures. NQF does not collect data or perform analyses or report measures.
361	M, Consumer	Debra Ness, National Partnership for Women & Families	General Comments	The National Partnership for Women & Families strongly supports the National Quality Forum as it endeavors to increase the number of meaningful, patient-centered outcomes measures. We have long advocated on the importance of outcome measures for providing critical information on the overall quality of care patients receive – including processes, coordination, and results – across the care continuum. We understand and acknowledge the fact that outcome measures are more complex to develop, and in some cases, to report, than are process measures. At the same time, outcome measures are critical to allowing consumers to make informed decisions, and this should outweigh the call for perfection. Additionally, we feel that the eight measures being recommended for endorsement by the patient outcomes steering committee will provide not only meaningful information for public reporting purposes, but also will be useful for quality improvement. In terms of future outcome measure development, we strongly support the additional recommendations included in the draft report around expanding measures to cover as many populations as possible; specifying measures to allow for stratification by race, ethnicity, language and gender; and providing a rationale for the use of hierarchical modeling.	Thank you for your comments.

377	M, Health Plan	Tom James, Humana, Inc.	General Comments	As a new member of the National Quality Forum, Humana is pleased to have the opportunity to comment on this Draft. We would like to offer several general comments on the project: Line 59-60 refers to "measure what makes a difference." We would like to encourage the NQF to interpret that in the context of both clinical outcomes but also patient expectations for care. Cultural and ethnic mores may value specific clinical outcomes differently. Line 67: Emphasize composites—the issue comes with the relative weight of each measure when multiple measures are joined as a composite. Further, there is a need to test the relevance of the composite with patients as well as with medical scientists. Line 70—Move toward outcome measurement—we agree with the need for more outcome measures; but the choice of outcome must be relevant to multiple stakeholders. Line 76—focus on disparities in all that we do—This is stated here but is not taken up to any extent in the specific measures. Line 106—Patient experience of care. This definition does not usually encompass patient "adherence" as a marker of the patient's experience. There are too many assumptions that would need to be made to correlate the patient's positive experience in the health care arena with their compliance. Other factors such as physician's ability to persuade	The section on NQF's Strategic Directions applies to all NQF work and not just this project. The usability criterion of NQF's standard measure evaluation criteria addresses the usability of the information provided from the measures for various audiences for public reporting as well as accountability. The Steering Committee evaluated each measure's ability to measure disparities and offered suggestion to measure developers to enhance that aspect of the measure specifications. The Committee also made an overarching recommendation regarding disparities as important characteristics of measures.
390	M, Consumer	Carol Sakala, Childbirth Connection	General Comments	Childbirth Connection expresses its appreciation to NQF, the measure developers and the Patient Outcomes Project Phase 1 and 2 Committee and Technical Advisory Panel for the progress toward additional national consensus outcome standards. We are strongly supportive of endorsing and implementing quality measures that clarify the impact of the health system on consequential matters for consumers/patients and those who pay for their care. These can work in concert with other health system innovations (e.g., care coordination, aligning financial incentives with value through bundled payment systems for episodes of care, transparent reporting to the various stakeholders, informed decision making tools, and high-performing health information technology systems) to drive the needed advances in quality and value. We concur with the language in the report introduction clarifying the value and significance of outcome measures to consumers/patients and other stakeholders.	Thank you for your comments.

391	M, Consumer	Carol Sakala, Childbirth Connection	General Comments	Childbirth Connection strongly supports the draft report's recommendations for development of outcome measures that will cover broad, diverse populations without unnecessary restrictions; be able to measure disparities by stratifying by race/ethnicity, language and gender; and provide meaningful information for public reporting. We also encourage the future development of meaningful composite measures and measures that address priority areas of the National Priorities Partnership. We recommend that the report recommendations section include clarification of the meaning of "hierarchical modeling" for readers.	Additional description will be included to the recommendation on hierarchical modeling.
400	M, Provider	Samantha Burch, Federation of American Hospitals	General Comments	The Federation of American Hospitals appreciates the opportunity to comment on the National Voluntary Consensus Standards for Patient Outcomes, First 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. We appreciate that this report includes an explanation of how the recommended measures align with the NPP Priorities.	Thank you for your comments.

409	M, Purchaser	Christine Chen, Pacific Business Group on Health	General Comments	Employers have long advocated for meaningful outcome measures to better ensure that their employees receive high quality and high value care. Unfortunately, all too often the measurement enterprise has focused on process measures - which are of limited to use to those who receive and pay for care - rather than outcome measures. While we recognize that outcome measures may be more challenging to develop, relative to process measures, they are of vital importance to employers and their employees. And the desire for "perfect" outcome measures must be balanced by the immediate need for these measures (we encourage NQF to refer to an article on consumers' ability to accept less than "perfect" performance information at http://www.hschange.com/CONTENT/921/921.pdf). We are therefore very supportive of NQF's efforts to identify outcome measures for national use. NQF's efforts reflects an understanding of the growing importance of outcome measures in not only performance measurement and public reporting, but in generating the data needed to advance comparative effectiveness research, testing of better ways to pay for care, and meaningful use of health information technology.	Thank you for your comments.
410	M, Purchaser	Christine Chen, Pacific Business Group on Health	General Comments	We believe that the eight measures being recommended for endorsement represent a good start in increasing the number of meaningful outcome measures in NQF's portfolio. It is our hope that this portfolio will be further expanded by the Affordable Care Act's significant investment in developing provider performance measures, which includes a focus on measures of outcomes.	Thank you for your comments.

411	M, Purchaser	Christine Chen, Pacific Business Group on Health	General Comments	We also support the Steering Committee's recommendations on how measure developers can build more robust measures: making eligible populations for each measure as broad as possible and specifying measures to allow for stratification by race, ethnicity, language and gender. As for the recommendation for measure developers to provide a rationale for use of the hierarchical modeling approach to risk adjustment, we would urge the Steering Committee to strengthen this statement. The materials presented to the Patient Outcomes Steering Committee for these measures clearly shows that the approach is biased in terms of its weighting of specificity over sensitivity. While this approach ensures that the few providers that can be identified as "outliers" almost surely are, it deprives purchasers and their members/employees of valuable information on probable outliers at the community level. Since other methods for risk-adjustment that allow for more balance between specificity and sensitivity are known and accepted by the health services research community, we would hope to see additional NQF measure evaluation requirements adopted to ensure that measures can produce adequate discrimination in provider performance.	The Steering Committee identified issues with risk models and noted that this is not a project-specific issue. The Committee has recommended that NQF consider additional guidance in for evaluation of risk models.
412	M, Purchaser	Christine Chen, Pacific Business Group on Health	General Comments	Finally, we do not agree with the Steering Committee's recommendation by a narrow majority to vote down the two ED visit rate measures (OT1-002-09 and OT1-006-09). The rationale given is not convincing. First, the likelihood that situations unrelated to the underlying condition of AMI or heart failure would cause patients to need emergency care within 30 days is small and unlikely to influence measure results, especially when compared across hospitals. Second, to the extent that local circumstances affect ED use, this would presumably be reflected in all the hospitals being measured in a given community. For QI purposes, the hospitals would know that. For consumer choice purposes, all that matters is relative performance of hospitals in a given community. Therefore, we would urge the Steering Committee to recommend these measures for endorsement.	The Steering Committee reviewed the comments and their prior voting on the ED visit measures at the June 21 conference call. The Committee decided not to revisit their recommendation for these measures.

433	P	Christopher Corsico, Boehringer Ingelheim Pharmaceuticals, Inc.	General Comments	In the draft report, NQF describes its strategic direction which outlines a vision for the future of quality measures. Each of these elements raises important issues, and out comments on two of these points below. Emphasize composite measures: BI believes that composite measures many be better able to holistically assess quality for multiple elements of a patient's care and are appropriate for certain conditions. There are clearly disease areas for which composite measures are not yet possible or necessarily suitable. Composites are most valuable for conditions in which there is agreement among stakeholders on a discrete set of processes and outcomes that should be assessed for that patient population.	Thank you for your comments in support of NQF's strategic directions.
434	P	Christopher Corsico, Boehringer Ingelheim Pharmaceuticals, Inc.	General Comments	In the draft report, NQF describes its strategic direction which outlines a vision for the future of quality measures. Each of these elements raises important issues, and out comments on two of these points below. Move toward outcome measurement: BI agrees that a move toward more measures of outcomes rather than care processes can ensure more accurate, meaningful quality assessments. In this and future projects, NQF should continue to foster the use of emerging data sources, such as registries and electronic health records (EHRs), in measure reporting. These sources will best enable the collection of relevant clinical (rather than, or in addition to, administrative) information, particularly for outcomes measures.	Thank you for your comments.

435	P	Christopher Corsico, Boehringer Ingelheim Pharmaceuticals, Inc.	General Comments	BI is supportive of patient outcomes measures because they contribute significantly to broader efforts to improve quality of care. Performance measures have evolved over the years, expanding beyond process and structure metrics to include assessments of the clinically meaningful patient outcomes. For this project, NQF has selected an appropriate range of types of patient outcomes to address, as they touch upon the physiologic, the mental, and the social aspects of care. Additionally, the project focuses on "high-impact" conditions. BI believes it is important to develop appropriate evidence-based measures for such important disease areas. However, we emphasize that the definition of "high-impact" should be carefully constructed. Quality measure development should focus on outcomes improvement and be balanced appropriately with the desire to enhance efficiency and value. the current definition should due expanded to take into account unmet patient need. Moving forward, BI also encourages NQF to consider focusing on conditions for which performance measures have not been developed. BI looks forward to the release of this project's second report, which will address the remainder of measures assessed under this project. We look forward to participating in the upcoming process of additional review and endorsement.	Thank you for your comments.
441	P	Christopher Corsico, Boehringer Ingelheim Pharmaceuticals, Inc.	General Comments	The "additional recommendations" in the conclusion of this report highlight some important considerations on measure use: 1) Apply to broadest populations: Widespread use of measures maximizes their impact. As such, measures should be applied to the broadest possible appropriate populations. A clear focus on the individuals for whom the measure is most relevant will ensure the greatest effect. Additionally, restrictive measures around payer or coverage type are not necessarily appropriate; restrictions around measures should always be grounded in scientific data; 2) Provide rationale for use of hierarchical modeling: Though hierarchical modeling helps to remove bias in the estimates, it is a complex approach. BI supports the recommendation that a clear rationale be provided for its use since these sophisticated statistical techniques may be challenging for stakeholders to understand and use.	Thank you for your comments.

442	P	Christopher Corsico, Boehringer Ingelheim Pharmaceuticals, Inc.	General Comments	In addition to the guidance put forth in this report, BI would like to note some further considerations on the use of NQF-endorsed measures. The NQF process for endorsing performance measures must be transparent because the measures are being used in CMS quality-focused programs in the hospital and physician settings. Users and implementers of performance measures should also continue to actively provide feedback to both NQF and measure developers regarding their feasibility and impact. It is only through such constant evaluation that the measures can be maintained and revised to have the greatest impact on improving quality of care and patient outcomes.	One of the cardinal principles of NQF's Consensus Development Process is transparency. You can follow the steps of the CDP on the project page as measures are evaluated and progress toward endorsement. http://www.qualityforum.org/projects/Patient_Outcome_Measures_Phases1-2.aspx#t=2&s=&p=
168	P	Mellanie True Hills, StopAfib.org & American Foundation for Women's Health	Measures Not Recommended	OT1-002-09: 30-Day post-hospital AMI discharge ED visit rate (patient was readmitted within 30 days & prior to readmission). We definitely want to see measures to reduce readmissions and believe ED visits and office visits are part of the solution. However, we need actionable measures and feel that these measures need more work to better define and validate that they actually help reduce readmissions and improve the care for patients after a hospital stay.	Thank you for your comments.
169	P	Mellanie True Hills, StopAfib.org & American Foundation for Women's Health	Measures Not Recommended	OT1-006-09: 30-Day post-hospital heart failure (HF) discharge ED visit rate. We definitely want to see measures to reduce readmissions and believe ED visits and office visits are part of the solution. However, we need actionable measures and feel that these measures need more work to better define and validate that they actually help reduce readmissions and improve the care for patients after a hospital stay.	Thank you for your comments.
170	P	Mellanie True Hills, StopAfib.org & American Foundation for Women's Health	Measures Not Recommended	OT1-003-09: 30-Day post-hospital AMI discharge evaluation and management service (and prior to any hospital readmission or ED visit during this period). We definitely want to see measures to reduce readmissions and believe ED visits and office visits are part of the solution. However, we need actionable measures and feel that these measures need more work to better define and validate that they actually help reduce readmissions and improve the care for patients after a hospital stay.	Thank you for your comments.

171	P	Mellanie True Hills, StopAfib.org & American Foundation for Women's Health	Measures Not Recommended	OT1-004-09: 30-Day post-hospital HF discharge evaluation and management service (and prior to any hospital readmission or ED visit during this period). We definitely want to see measures to reduce readmissions and believe ED visits and office visits are part of the solution. However, we need actionable measures and feel that these measures need more work to better define and validate that they actually help reduce readmissions and improve the care for patients after a hospital stay.	Thank you for your comments.
342	P	Basil Eldadah, National Institute on Aging	Measures Not Recommended	OT1-002-09 & OT1-006-09: the shortcomings of these outcomes are acknowledged; however, they may still merit consideration, as all-cause ED visits may be important even if they are for issues that are deemed "unrelated" to the recent hospitalization. Such visits may represent aspects of underlying disease burden in individuals with multiple chronic conditions, even though the issue precipitating ED presentation is not directly related to the previous hospital admission.	The Steering Committee reviewed the comments and their prior voting on the ED visit measures at the June 21 conference call. The Committee decided not to revisit their recommendation for these measures.
370	M, Health Professionals	Dale Lupu, American Academy of Hospice & Palliative Medicine	Measures Not Recommended	Proposed measure:OT1-003-09: 30-day Post-hospital AMI Discharge E&M Service and OT1-004-09: 30-day Post-hospital HF Discharge E&M Service We agree with committee that only measuring E&M services is too narrow. Need to also measure appropriate use of additional outpatient services that may not include E&M physician billing, such as visiting nurses, disease management, and hospice.	Thank you for your comments.