To: National Quality Forum

From: The Society of Thoracic Surgeons

RE: Comments on NQF proposed measures for Hospital Care: Outcomes and Efficiency

The Society of Thoracic Surgeons (STS) appreciates the opportunity to comment on the NQF proposed Hospital Care Outcomes and Efficiency Measures HOE-019-08 and HOE-022-08.

STS has long recognized the importance of risk-adjusted outcomes in cardiothoracic surgery. For two decades, information from the STS National Database has allowed us to use a large national population to develop validated, peer-reviewed statistical models that provide risk-adjusted outcomes for CABG. These CABG models are incorporated into the STS National Database and are used by approximately 90% of cardiac surgery centers in the United States. Models for valve replacement surgery were developed in 2000 and, after validation and independent peer-review, theses models were accepted for use in the STS National Database. These models will be publicly available on our website (sts.org) upon publication.

It should be emphasized that these models have been based on extensive clinical data from more than 3.8 million surgical records in the STS Adult Cardiac Surgery Database (STS Database). The models are developed using well-established, sophisticated statistical techniques employed by a team of biostatisticians from Duke Clinical Research Institute along with STS surgeons having long-standing expertise in outcomes analysis. The models are validated using standard statistical approaches and they are then subject to independent peer-review followed by publication in leading national journals. The most current models are described in a fully transparent manner, which will be published as a supplement to The Annals of Thoracic Surgery with its July issue this year.

These models are generated and endorsed by the major specialty society for cardiothoracic surgeons, but STS recognizes that there may be alternatives. We would likely endorse models that have the following characteristics:

1. The models are based on a large national experience.

2. The models are developed using well-accepted statistical techniques.

3. The models are developed with clinical input from those who practice the profession.

4. The models are validated using standard statistical techniques.

5. The models are tested for face validity in a “real-world” application of patient care.

6. There is strong evidence to confirm that use of the models will improve care.

7. The models are subject to independent review.

8. The models are published in major national journals.

Models considered for national use should certainly embody these characteristics. All of these are well-recognized features of STS models, but the proposed HOE CABG and AVR models have none of these attributes.

Accordingly, STS cannot support measures HOE-019-08 and HOE-022-08 and we strongly recommend that these measures be removed from consideration.

In addition to the reasons cited above, there are other compelling reasons to recommend against their NQF endorsement:

1. The HOE measures rely solely on administrative data. There is considerable evidence that administrative data alone are simply inadequate for risk adjustment in complex procedures such as CABG and valve replacement surgery (see [2] below). An additional and equally important limitation is the inability to accurately identify cases that are true isolated CABG. The steward's algorithm excludes only CABG cases combined with valve procedures. However, in a study of public reporting in Massachusetts (Circulation. 2007;115:1518-1527), the number of CABG + "other" procedures misclassified as isolated CABG was just a large (663 out of 1264 total misclassified cases) as the number of CABG + valve procedures. Furthermore, the mortality for the CABG + "other" cases was 7.39%, much higher than that of isolated CABG. Finally, such high mortality CABG + "other" procedures are performed in disproportionate numbers by large tertiary centers, so the prejudicial impact of misclassification is not equal across cardiac centers.

2. There is no provision for risk adjustment. An observed unadjusted mortality rate is proposed by the measure steward. This proposal flies in the face of a quarter-century of strong evidence confirming that there is a wide range of operative risk in the cardiac surgery population (Ann Thorac Surg 2004;78:1868 –77). Failure to account for such differences in case-severity among institutions seriously jeopardizes the validity of any subsequent performance profiling and renders this methodology unsuitable for public reporting. With this proposed methodology, an 85-year old patient with ischemic pulmonary edema requiring emergency CABG for an evolving myocardial infarction would be considered to have the same risk as a 45-year old patient having an elective CABG.

The steward has stated that risk-adjusted outcomes will be used where they exist, so it appears that the steward recognizes the inadequacy of unadjusted outcomes. It should be pointed out that a measure based on outcomes, sometimes adjusted – other times unadjusted, will create a

measure lacking in uniformity. The steward advocates one measure for some, but another for others. The point of performance measures is to provide one uniform standard.

The use of unadjusted outcomes in cardiac surgery defies well-known and long-standing clinical observation. Both cardiac surgeons and cardiologists will recognize the appalling lack of face validity of such a measure.

3. Use of volume data in cardiac surgery is notoriously inconclusive and unreliable. In cardiac surgery there is no consensus on the relation of volume to outcome; therefore, national standards should not be dependent on such an ill-defined and uncertain relationship.

When the Steering Committee inquired about the volume relationship, the steward indicated that the relationship is established for these procedures. That may be true for some of the 6 measures proposed by this steward. However, it is highly problematic for CABG surgery, where numerous studies based on both administrative and clinical data have shown a very weak volume mortality association (Ann Surg 2004;239: 110–117; JAMA 2004;291:195-201; Ann Thorac Surg 2003;75:1048-58; Ann Thorac Surg 2005;80:2114-9; Ann Thorac Surg 1996 ;61:21-6; Ann Thorac Surg 1996;61:17-20; Ann Thorac Surg 2005;80:2114-9; J Thorac Cardiovasc Surg 2008;135:1202-9). Notably, the weakness of this relationship for CABG has even been demonstrated by the Leapfrog measure developers in a separate publication (Ann Surg 2006;243:411-7). Finally, in a presentation to the American Association for Thoracic Surgery on May 11, 2009, studies of 144,000 patients from the STS Database confirmed these findings and also showed that volume was unrelated to morbidity and to compliance with evidence-based best medication practices (abstract available upon request).

If the steward maintains this position, it seems reasonable to ask it to prove its point with contemporary scientific evidence from a broad national sample of cardiac surgery centers.

It should also be noted that a fundamental feature of the steward's methodology—"shrinkage" of low-volume providers' results to their volume-category mean rather than the overall population mean—rests primarily upon the belief that a significant volume outcome association exists. Absent proof of this, the methodology is problematic.

The steward offered reasons for endorsement of its measures. Most of these have been addressed above, but others merit specific comment:

1. The steward believes that its use of administrative data will make its models more widely available than STS models. It should be emphasized that the STS Database is used by approximately 90% of cardiac surgery centers in the United States and the number of participating centers continues to grow each year. The remaining 10% is made up largely of other regional cardiac surgery registries that have reliable risk models based on clinical data.

2. The steward states that these measures will allow reporting from hospitals with small case volumes. That has always been the case for participants in the STS Database. The STS models are based on a large national population, but the application of STS models can easily be carried out one patient at a time.

In summary, we believe that STS has established practical, accurate, and statistically valid models of cardiac surgery outcomes. There is strong evidence that the use of these STS models in concert with the STS Database reporting system has considerably improved the quality of care in cardiac surgery.

The new measures proposed by this steward offer an unproven approach using very controversial data elements. The fact that administrative data are inexpensive and widely available is not sufficient reason to advocate the use of a product based on speculative assumptions, particularly when a time-tested and proven product is available.

STS remains committed to improving patient care through both clinical analysis and reporting of quality data. STS is already sharing this type of data, with member written consent, with some national medical insurance companies and is now actively involved in exploring ways to present our national data in a format that will:

a. allow surgeons to pinpoint areas for improvement

b. provide the public with data that will facilitate informed choices of care

c. establish a fair and meaningful design for public reporting

STS appreciates the opportunity to comment on these proposed measures and we commend the steward for its interest in improving the quality of care in cardiac surgery.

To: National Quality Forum

From: The Society of Thoracic Surgeons

RE: Comments on NQF proposed measures for Hospital Care: Outcomes and Efficiency

The Society of Thoracic Surgeons (STS) appreciates the opportunity t comment on the NQF proposed Hospital Care Outcomes and Efficiency Measure HOE-023-08

The Society of Thoracic surgeons (STS) has long recognized the importance of risk-adjusted outcomes in cardiothoracic surgery. For two decades, information from the STS National Database has allowed us to use a large national population to develop validated, peer-reviewed statistical models that provide risk-adjusted outcomes for cardiac surgery. Starting in 2002, the STS began collecting data on general thoracic surgery patients. There are now over 130 participating sites across the US and more than 130,000 records in the General Thoracic database. STS models are developed using well-established, sophisticated statistical techniques employed by a team of biostatisticians from Duke Clinical Research Institute along with STS surgeons having long-standing expertise in outcomes analysis. The models are validated using standard statistical approaches and they are then subject to independent peer-review followed by publication in leading national journals

These models are generated and endorsed by the major specialty society for cardiothoracic surgeons, but STS recognizes that there may be alternatives. We would likely endorse models that have the following characteristics:

1. The models are based on a large national experience.

2. The models are developed using well-accepted statistical techniques.

3. The models are developed with clinical input from those who practice the profession.

4. The models are validated using standard statistical techniques.

5. The models are tested for face validity in a "real-world" application of patient care.

6. There is strong evidence to confirm that use of the models will improve care.

7. The models are subject to independent review.

8. The models are published in major national journals.

Models considered for national use should certainly embody these characteristics. All of these are well-recognized features of STS models, but the proposed HOE esophagectomy model does not.

Measurement of the quality of the surgical care of patients undergoing esophagectomy for cancer is an important goal for the NQF. However the low volume of esophagectomies

performed at the majority of hospitals in the US (the median number is only 4 [1]) means that risk-adjusted statistically valid comparisons of mortality alone are very problematic. Most reports studying the volume performance relationship indicate there is such a relationship in esophagectomy however the best study to date indicates there is no statistically valid cutoff point for what constitutes "high volume" [1]. Furthermore the covariate volume only explains about 1% of the variance in perioperative death [1]. We must remember that volume is a surrogate measure of quality and that it's primary advantage is ease of measurement. Risk-adjusted results remain the gold standard for valid comparison of morbidity and mortality after surgery. However the combination of very low case numbers and relatively low mortality with esophagectomy results in problematic statistically valid comparison of hospitals.

The STS has developed a robust statistically valid risk-adjusted model for esophagectomy for esophageal cancer for a combined composite measure of major morbidity and mortality which allows better statistical discrimination since morbidity adds more events to model [2]. The model variables and regression coefficients are published and thus readily available. Interestingly the STS model did not demonstrate a significant volume performance relationship. Access to the STS General Thoracic Database is available across the US and is open to both thoracic and general surgeons.

The new measures proposed offer an unproven approach using controversial data elements. The fact that administrative data are inexpensive and easily available is not sufficient reason to advocate the use of a model based upon speculative assumptions, particularly when a time-tested and proven peer-reviewed product is available. Accordingly, STS cannot support measure HOE-023-08 and we recommend that this measure be removed from consideration. STS remains committed to improving patient care through both clinical analysis and reporting of quality data. STS appreciates the opportunity to comment on these proposed measures and is committed to improving the quality of care in thoracic surgery.

1. Meguid RA et al. The effect of volume on esophageal cancer resections: What constitutes acceptable resection volumes for centers of excellence? J Thorac Cardiovasc Surg 2009;137:23-29.

2. Wright C et al. Predictors of major morbidity and mortality after esophagectomy for esophageal cancer: A Society of Thoracic Surgeons general Thoracic Surgery Database risk adjustment model. J Thorac Cardiovasc Surg 2009;137:587-596.

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Chief Executive Officer
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October 14, 2008

Janet Corrigan, Ph.D., M.B.A.
President and CEO
The National Quality Forum
601 13th Street NW, Suite 500 North
Washington DC 20005

Dear Dr. Corrigan:

The American College of Cardiology (ACC) endorses the 30-day all-cause risk-standardized percutaneous coronary intervention (PCI) mortality rate for patients with ST segment elevation myocardial infarction (STEMI) or cardiogenic shock measure, and the 30-day all-cause risk-standardized PCI mortality rate for patients without STEMI and without cardiogenic shock measure that are being submitted by the Centers for Medicare and Medicaid (CMS) to The National Quality Forum (NQF) for measure evaluation. CMS indicates in the applications that these measures are intended for use in its public reporting program. The ACC has determined that these measures are developed using a rigorous scientific methodology and are consistent with ACC policy.

The ACC is a 34,000-member nonprofit medical society and bestows the credential Fellow of the American College of Cardiology upon physicians who meet its stringent qualifications. The College is a leader in the formulation of health policy, standards and guidelines, and is a staunch supporter of cardiovascular research. The ACC Board of Trustees (BOT) Executive Committee, which is comprised of national cardiologist leaders, is the official governing body with policy-making authority for the College. In deciding to endorse these measures, the BOT reviewed the science presented in the applications prepared for NQF and the work completed by the Yale New Haven Hospital-Center for Outcomes Research and Evaluation (YNHH-CORE) team, and received input from the members of the ACCF Task Force on Public Reporting of Hospital-Level Outcomes Measures, which is comprised of members of ACC and its partner societies and includes a biostatistician expert, and the ACC Interventional Council. The YNHH-CORE work was supported by an advisory group consisting of ACC's National Cardiovascular Data Registry (NCDR) physician members and staff.

The ACC established the NCDR in 1998 with its flagship CathPCI Registry as a confidential quality measurement program for cardiovascular specialists, hospitals, and cardiac catheterization labs committed to quality improvement and excellence in care. Participants use this information for improving patient care, supporting quality-improvement programs, and communicating with regulatory and contracting organizations. Additionally, the NCDR promotes research activities geared toward informing evidence-based medicine and supporting the expansion of outcomes research and quality improvement studies. The 30-day PCI mortality measures applications were developed using data from the CathPCI Registry, which is based on ACC/American Heart Association methodologies for development of data sets and performance measures (J Am Coll Cardiol 2007;49:831-7, and J Am Coll Cardiol 2005;45:1147–56).

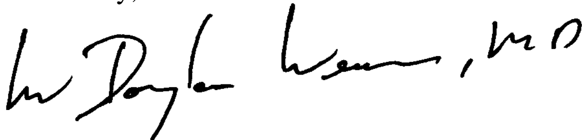
The mission of the American College of Cardiology Foundation is to advocate for quality cardiovascular care — through education, research promotion, development and application of standards and guidelines — and to influence health care policy.

In addition to the scientific support presented with these measures, the ACC reviewed the measures and the intended use against its policy statement on principles for public reporting (J Am Coll Cardiol 2008;51:1993-2001). We find that the development and intended use of these measures are consistent with these principles, specifically because:

- the measures development work demonstrates enough variation in care that reporting the outcomes to hospitals can promote quality improvement;
- public reporting of these measures is based on scientific validity of the measures as demonstrated in the applications;
- these measures were developed in partnership with physicians;
- the measures rely on standardized data elements to asses and report performance and to make the submission process uniform across the public reporting program, and combine the reliable, well-established, and robust clinical data from the NCDR's CathPCI Registry with claims data to develop a risk stratification that more appropriately represents patient outcomes;
- the measures appropriately report on outcomes of care at the hospital level, which takes into account process of care issues that can impact patient outcomes beyond the control of individual physicians; and
- CMS has awarded a new contract to YNHH-CORE that supports a formal process for evaluating these measures to ensure that the methods continue to be aligned with emerging evidence, refinement of the standardized data source, and the impact on the quality of health care being reported including an assessment of unintended consequences.

We look forward to these measures being endorsed by NQF as a result of its review process. If you need additional information regarding ACC's support for these measures, please contact Lara Slattery, Director of Quality Services for the NCDR. Her phone number is 202-375-6460 and her e-mail address is lslatter@acc.org.

Sincerely,



W. Douglas Weaver, M.D., F.A.C.C.
President, American College of Cardiology

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May 21, 2009

The National Quality Forum
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Re: NQF Member Pre-voting Review for *National Voluntary Consensus Standards for Hospital Care: Outcomes and Efficiency, Phase II*

The American Society of Health-System Pharmacists (ASHP) is pleased to submit comments on the draft measures for *Hospital Care: Outcomes and Efficiency, Phase II.* ASHP represents pharmacists who practice in hospitals and health systems. The Society's more than 35,000 members include pharmacists and pharmacy technicians who practice in a variety of health-system settings, including inpatient, outpatient, home care, and long-term-care settings.

HOE-012-08 Potentially Preventable Readmissions (PPRs)

Pharmacists are critical but underutilized personnel in health systems that are well-positioned to improve patient outcomes while reducing costs and overuse of healthcare services. There is a rapidly expanding body of literature[1-6] that demonstrates that when pharmacists provide care to patients, especially those with heart failure, there is a significant reduction in mortality, readmissions, emergency department visits, and costs. Patients demonstrate improved understanding of and adherence to the discharge plan when pharmacists provide discharge counseling. This evidence suggests that inclusion of pharmacists in teams caring for heart failure patients should be strongly considered by health policy makers.[5]

Continuity of care is a responsibility of the entire health care system spanning hospitals, clinics, and health plans; thus, the ideal level of measurement is the integrated delivery system. However, ASHP suggests that the definition of a true integrated delivery system should be explored and described. For example, a patient may have numerous options X, Y, and Z to choose a primary care provider; however, provider X may be in health-system 1, 2, or 3. Due to this continuity of care issue, there is an inherent weakness of using the individual clinician level to measure and report readmission because readmission depends on care provided by the interdisciplinary team. The Society recommends that measurement on the individual clinician level should be removed.

Thank you for the opportunity to provide feedback on the proposed *National Voluntary Consensus Standards for Hospital Care: Outcomes and Efficiency, Phase II*. If you have any questions concerning the Society's comments, please contact me by phone at (301) 664-8815 or via e-mail at mandrawis@ashp.org.

Regards,

Mary Andrawis, Pharm.D., M.P.H.
Medication-Use Quality Improvement Associate
American Society of Health-System Pharmacists

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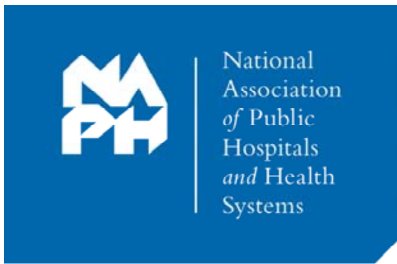

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May 21, 2009

Thank you for the opportunity to comment on the National Voluntary Consensus Standards for Hospital Care: Outcomes and Efficiency, Phase II. In that document, the NQF states:

> "Factors such as race, gender, and socioeconomic status require careful scrutiny as they also are linked to inequalities in healthcare services and practices and inclusion as risk factors would mask those disparities. Including these factors in risk models implies that lower performance is acceptable for a certain case mix or providers do not need to try to identify and reduce disparities."

This statement places NAPH hospitals at particular risk compared to non-safety net hospitals. Public hospitals serve a disproportionate number of patients with lower socioeconomic status (SES). These patients suffer from lower incomes, lower education levels and fewer resources. The outcome measures outlined in the NQF statement are highly dependent on socioeconomic factors. Mortality after surgical procedures is higher in lower SES patients. Birkmeyer and colleagues demonstrated that lower SES patients had an odds ratio for mortality of 1.14 for coronary artery bypass grafting and 1.13 for aortic valve replacement after adjustment for patient characteristics.(1) The mortality and admission rates for patients with lower SES are increased in patients with acute myocardial infarction. Beard, et al. demonstrated that patients with the lowest SES were 1.4 times more likely to die compared to those at the highest SES.(2) Shaw and colleagues focused on women with lower SES. They found that lower income, lower education and lack of private insurance were associated with increased risk of cardiovascular death and myocardial infarction in women.(3) Additionally, the current variables in the model for heart failure readmission explains <40% of the variation.(4) The authors admit that performance measures and system effects may affect readmission rates.

Performance on evidence-based guidelines can decrease readmission rate slightly, but this effect is minimal. MetroHealth Medical Center in Cleveland, Ohio dramatically improved their performance on composite process measures from 2004 through 2008, but their 30-day readmission rate did not improve over this same time period. Despite dramatic improvement in the quality of care delivered, the readmission rate remains stable.

From a practical standpoint, patients with lower SES are at higher risk of mortality and readmission because they are:

- Less able to afford their medications
- Less able to afford close follow up even if it is arranged
- Less likely to have resources such as a telephone or a car for follow up and support
- More likely to have lower education levels
- Less likely to have resources to purchase healthier food alternatives

Public hospitals have higher rates of lower SES patients and more frequently serve uninsured patients. The percentage of uninsured patients at NAPH hospitals is 22% compared to 6% in other US hospitals. (5)

The NQF statement indicates that risk adjustment for socioeconomic factors makes lower performance acceptable. While this may be true for performance measures, outcome measures are more dependent on factors other than good medical care. Public hospitals can certainly compete with private hospitals on evidence-based treatments. The difficulty arises when reported <u>outcomes rely on factors unrelated to the quality of care delivered</u>.

Public reporting of these outcome measures has the potential for significant unintended consequences. Accounting for variables out of the control of the institution levels the playing field for participation. While these measures are intended for hospitals to improve their outcomes, public reporting will make them useful for advertising and promotion of one hospital over another. Measures that depend on SES status will promote "cherry picking" of only those patients who are able to afford medications, etc. Migration of high SES patients away from hospitals with poor outcomes (patients with lower SES will have less opportunity to "shop with their feet") will place safety net hospitals in jeopardy of losing revenue resulting in lower improvements and quality of care.

HOE-008-08 Hospital specific risk adjusted measure of mortality or one or more major complications within 30 days of a lower extremity bypass

It may be difficult to capture data on one of the Risk Factors, specifically Functional Status. For some facilities, this would require manual review of the record and manually enter that information.

HOE-010-08 30-day all-cause risk-standardized mortality rate following percutaneous coronary intervention (PCI) for patients without or with ST segment elevation cardiogenic shock

It is very important that the hospital would not be required to join any additional registries.

HOE-019-08 Survival Predictor for CABG Surgery

NAPH opposes this measure. This measure is unadjusted for patient and hospital variables. Thus, hospitals that treat sicker patients, such as safety net hospitals, would be penalized.

HOE-020-08 Survival Predictor for PCI

NAPH opposes this measure. This measure is unadjusted for patient and hospital variables.

In summary, NAPH strongly urges NQF to incorporate SES in a risk adjustment for outcome and efficiency measures because there are differences among patients of different socioeconomic status that impact performance and are beyond the control of providers. To fail to properly risk adjust for SES would unfairly penalize providers whose mission is to serve these patients. Such providers are at the forefront of addressing disparities because they want to do what is best for the patient populations they serve. Proper risk adjustment is not an excuse for poor performance; it is a way to eliminate variables that are beyond the control of providers.

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Chief of Clinical Cardiology, MetroHealth Medical Center

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NQF Form - National Voluntary Consensus Standards for Hospital Care: Outcomes and Efficiency
Additional Comments from AGS

1. The proposed outcomes measures remain highly focused on surgical and cardiovascular process measures. Although the NQF is committed to the creation of measures of outcomes related to hospitalization the challenges of defining and capturing meaningful measures of physical, cognitive and social functioning are daunting and largely unmet. As a result the currently proposed measures fail to capture outcomes that are distinctly relevant to the older adult population, who have the highest rates of hospitalization of all adult age groups. For the oldest patients, particularly those age 75 years and older, the most relevant outcomes of hospital care are related to their quality of life: the ability to perform activities of daily living (functional status), to regain independent self-care and normal mental and emotional health, and to return to independent living or the lowest level of assisted care. In part the limitation of the NQF measures is related to the absence of a universal methodology for measuring and capturing measures of functional status. There remains no requirement that hospitals obtain or report measures of physical functioning or cognition. Functional status measures are both strong predictors and outcomes of hospitalization. Models that adjust for case-mix or even socio-demographic variables will fail to fully account for quality of patient care if functional status (ADL, mobility, walking, cognition, affect, etc) measures are not included in the risk adjustments. I would encourage the NQF to work with other organizations to engage in a dialogue to define and measure functional status as an outcome of hospitalization.

2. Lines 321-325 address inequalities. The risk adjustment for socioeconomic factors is challenging and current methods likely underestimate the impact of social dysfunction, health illiteracy, and poverty on anticipated outcomes of hospitalization for the 9 conditions. Hospitals, health systems and practitioners should not be held accountable for poor outcomes that are outside of their control or influence. For the safety net hospitals, that serve this population, further assumptions of risks and thus of quality need to be defined and taken into consideration when judging health care quality and outcomes.

AHIP Hospital Outcomes & Efficiency Measures

Background
The report includes 11 measures for evaluating outcomes of hospital care. While the project aimed to include efficiency measures, none were submitted to the NQF for review. The 11 measures in the set address hospital mortality, healthcare-acquired complications, and readmissions.

The NQF has previously endorsed hospital mortality measures for CABG, aortic valve replacement, abdominal aortic artery repair, esophageal resection, pancreatic resection mortality, as well as an all-cause readmission rate following heart failure hospitalization. In this new set, several measures also assess hospital survival rates for these procedures. These measures were submitted by different measure developers. NQF specifically asked stakeholders to comment on endorsing similar measures.

General Comments
The National Quality Forum has taken an important step in reviewing hospital performance measures that assess mortality and readmission rates. These measures are important indicators to assess quality of care, appropriate discharge planning, efficiency, and fill an important gap in the NQF hospital measures' set.

Measures AHIP Supports
In previously submitted comments (October 2008), AHIP suggested that NQF endorse mortality and readmission measures for populations other than Medicare beneficiaries and for other conditions, such as COPD, asthma, renal failure, abdominal pain, diabetes, and seizure disorders. AHIP appreciates the inclusion of measure HOE-015-08, Postoperative Respiratory Failure, which includes all adults 18 and over. Similarly, measure HOE-004-08, Risk-Adjusted 30-Day Readmission Rate for Heart Failure, includes adults younger than 65. This measure will complement the previously endorsed CHF mortality measure for adults 65 and older. AHIP supports endorsement of both measures.

Measures AHIP Recommends Time-limited Endorsement

- HOE-008-08 Hospital specific risk-adjusted measure of mortality or one or more major complications within 30 days of a lower extremity bypass (LEB).
- HOE-009-08 30-day all-cause risk-standardized percutaneous coronary intervention (PCI) mortality rate for patients without ST segment elevation myocardial infarction (STEMI) and without cardiogenic shock.
- HOE-010-08 30-day all-cause risk-standardized Percutaneous Coronary Intervention (PCI) mortality rate for patients with ST segment elevation myocardial infarction (STEMI) or cardiogenic shock.

AHIP has questions regarding the three mortality measures developed by CMS via the NSQIP registry. While the report notes that participation in the registry is voluntary, it is unclear how burdensome the measures would be for hospitals that do not currently participate in the registry. For that reason, AHIP supports conferring the measures time-

limited review. A review within the two-year time frame will allow for close monitoring of administrative burden for hospitals that do not participate in the NSQIP registry.

Abstain from Commenting

- HOE-019-08 Survival Predictor for CABG Surgery© (Leapfrog Group)
- HOE-020-08 Survival Predictor for Percutaneous Coronary Interventions (PCI)© (Leapfrog Group)
- HOE-021-08 Survival Predictor for Abdominal Aortic Aneurysm (AAA)© (Leapfrog Group)
- HOE-022-08 Survival Predictor for Aortic Valve Replacement (AVR)© (Leapfrog Group)
- HOE-023-08 Survival Predictor for Esophagectomy Surgery© (Leapfrog Group)
- HOE-024-08 Survival Predictor for Pancreatic Resection Surgery© (Leapfrog Group)

The Society for Cardiovascular Angiography and Interventions

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Norm Linsky
Executive Director

October 28, 2008

Janet Corrigan, Ph.D., M.B.A.
President and CEO
The National Quality Forum
601 13th Street NW, Suite 500 North
Washington DC 20005

Dear Dr. Corrigan:

The Society for Cardiovascular Angiography and Interventions (SCAI) is a professional association 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. We support the proposed:

- 30-day all-cause risk-standardized percutaneous coronary intervention (PCI) mortality rate for patients with ST segment elevation myocardial infarction (STEMI) or cardiogenic shock measure, and the
- 30-day all-cause risk-standardized PCI mortality rate for patients without STEMI and without cardiogenic shock measure.

The measures are being submitted by the Centers for Medicare and Medicaid Services (CMS) to the National Quality Forum (NQF) for measure evaluation and additional comments are below.

The SCAI firmly believes that the proposed measures are superior to measures created using administrative data only, but remains concerned about the accuracy of these measures and the ability to truly validate all of the information used to construct the model. Public reporting has several potential benefits, but also has important negative and unintended consequences which are well described. Because of this, it is imperative that any measure be accurate and well validated before implemented for public reporting.

SCAI initiated the effort to collect data on outcomes in catheterization laboratories in the late 1970s. Now, as a partner with ACC in the National Cardiovascular Data Registry's Cath/PCI Data Registry (see: https://www.ncdr.com/webncdr/DefaultCathPCI.aspx), SCAI continues to support accurate data collection for performance improvement. However, combining these data with other databases and publicly reporting those findings before there is an absolute assurance that this is a sound methodology is premature.

While we believe that using NCDR data for risk adjustment will improve the accuracy of all-cause PCI 30-day mortality measures, that does not mean that the data will be reliable enough for the public to make informed choices based on the data presented. Suggested improvements include:

- An actual and verified matching of government data to NCDR data is essential. The probabilistic matching methodology used by Yale is likely the best which could be done with the data available, but failed to match a significant percentage of patients. As noted in the Yale report, "direct patient identifiers to link to external databases such as the Social Security Death Index or National Death Index will be necessary to ensure the accurate determination of patients' vital status."[1]
- To be of the greatest use to the public, most hospitals performing PCI should be included in this performance measurement. While the SCAI supports membership in the NCDR for all PCI-capable hospitals, there are a substantial number of hospitals that do not participate in the NCDR. Public reporting could lead to incentives to join or withdraw from NCDR based on the rewards or sanctions tied to these performance measures. Steps must be taken to accommodate other data collection efforts and/or to encourage more facilities to participate in NCDR's Cath PCI registry before these data become the basis for public performance reporting.
- The 30 day mortality data should exclude deaths not related to procedural complications. If the non-procedure related deaths aren't excluded from this measure, the statistical estimates of reliability should account for the decreased reliability of this measure.
    - Medicare beneficiaries have an average mortality rate of 0.42% per month.[2] Given that in-hospital mortality rates for PCI in large series from experienced operators ranged from 0.5 to 1.7 pecent[3] it is reasonable to assume that non-procedure related events will be a significant confounding factor in 30-day data particularly in the high risk patients and those that are otherwise not candidates for other therapies.
    - CMS and other payers should apply the same standard 95% confidence intervals to any publicly reported data that physicians use when evaluating scientific data. Assertions that that "the models provide reliable estimates of risk-standardized mortality rates for hospitals with more than 36 patients (STEMI or shock cohort)

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[1] YNHH-CORE (2008). Medicare Quality Measurement Support Project: Mortality Implementation and Measure Development and Monitoring: Measure Specific Literature Review-Cardiac Registry Task. New Haven, CT, Yale New Haven Hospital-Center for Outcomes Research & Evaluation: 1-21. (page 54)

[2] Hogan C, Lunney J, Gabel J, et al. Medicare Beneficiaries' Costs Of Care In The Last Year Of Life. *Health Affairs*. July/August 2001; 20(4): 188-195.

[3] Carrozza J, Cutlip D, Levin T. (2008). Periprocedural complications of percutaneous coronary intervention. . UpToDate. B. Rose. Waltham, MA.

> or 19 patients (no STEMI and no shock cohort)"[4] lack face validity unless CMS and NQF are willing to accept very unreliable data.

Even perfect measures could lead to unintended and unfortunate responses when they are publicly reported. A recent systemic review of the data on the effect of publishing performance data concluded that "The effect of public reporting on effectiveness, safety, and patient-centeredness remains uncertain." and "Several studies, which received a range of global ratings, found unintended consequences, such as a reluctance to care for high-risk patients after the NYS CSRS data were released."[5] ACC's policy statement on principles for public reporting (J Am Coll Cardiol 2008;51:1993-2001) also concluded that public reporting was:

> ". . . also associated with some unintended consequences including provider "gaming" and exacerbation of existing disparities in care.[6] The Pennsylvania CABG public reporting program has had a similar experience.[7] The Massachusetts cardiac surgery reporting program utilized the STS database but also compared performance measures based on these clinical data sources with those from administrative billing sources.[8] It was concluded that, "Cardiac surgery report cards using administrative data are problematic compared with those derived from audited and validated clinical data, primarily because of case misclassification and non-standardized end points."

Additionally, a recently reported study showed that "pay-for-performance programs that fail to account for differences in patient populations and treatment opportunities may unfairly classify some hospitals as poor performers" presumably encouraging inappropriate decisions on the part of patients on where to receive care.[9]

Any accepted public release of performance measures must proactively identify potential unintended consequences and those who release and/or use such data must, as a measure of professional responsibility make every reasonable effort to ensure that the release of the

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[4] Email from YNHH-CORE Medicare Quality Measurement Support Project. "Draft Changes to Measure Methodology" October 23, 2008.

[5] Fung CH, Lim YW, Mattke S, et. al Systematic Review: The Evidence That Publishing Patient Care Performance Data Improves Quality of Care. *Ann Intern Med.* 2008;148:111-123.

[6] Werner RM, Asch DA, Polsky D. Racial profiling: the unintended consequences of CABG report cards. *Circulation* 2005;111:1257-1263

[7] Bentley JM, Nash DB. How Pennsylvania hospitals have responded to publicly released reports on coronary artery bypass graft surgery. *Jt Comm J Qual Improv* 1998;24:40-49.

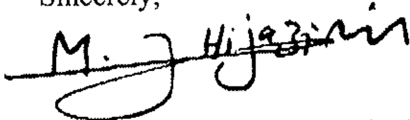
[8] Shahian DM, Silverstein T, Lovett AF, Wolf RE, Normand ST. Comparison of clinical and administrative data sources for hospital coronary artery bypass graft surgery report cards. *Circulation* 2007;1151518–7.

[9] Mehta RH, Liang L, Karve AM, et al. Association of Patient Case-Mix Adjustment, Hospital Process Performance Rankings, and Eligibility for Financial Incentives. *JAMA*, October 22/29, 2008—Vol 300, No. 16

performance measures actually improves performance. Those who presume to measure performance should measure and publicly report on the impact of their presumptions.

Conclusion
SCAI greatly appreciates all the effort to develop and improve publicly reportable performance measures. The methods develop by Yale represent a major step forward compared with efforts based on administrative claims data, but more needs to be done to provide the public with truly valid performance measures that can improve the quality of health care in America. Moving too quickly with data that would not be accepted by the professional community or independent analysts would only hamper efforts to improve the quality of care or perhaps challenge the credibility of the organizations advocating for these changes. SCAI would like to work with ACC, CMS, NQF and Yale as efforts to improve the quality of interventional cardiovascular care moves forward. We all support the same goal. Please respond to me and Wayne Powell at wpowell@scai.org or (202)741-9869.

Sincerely,



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Statement of Dr. Charles Chambers, FSCAI
SCAI NQF Representative
Hospital Care Outcomes & Efficiency Steering Committee
March 3-4, 2009

Members of the Steering Committee:

I am Dr. Charles Chambers, a practicing interventional cardiologist at Hershey Medical Center in Hershey, Pennsylvania. I understand that you have been provided the Society's letter submitted to the National Quality Forum (NQF) on October 28, 2008 that states our initial recommendations regarding the measures before you. We have actively participated in the recent Technical Advisory Panel, and thank you for the opportunity to speak to you today.

The Society supports 'time-limited endorsement' for both 30-day PCI Outcome Measures. Additional evidence collected through a rigorous validation plan is vital to refine the methodology and address all the concerns. Provided are the reasons why validation is needed:

- **Probabilistic Matching, defined as the use of indirect modifiers to link data from different databases, is an unproven method that needs to be studied for unintended consequences.** Only 65% of the sample was successfully matched to CMS claims data using indirect identifiers such as patient age, gender, date of admission, date of discharge, etc. What happens to the other 35% of Medicare beneficiaries excluded from the analysis? Is this retrospective analysis valid in the future based on an ever-changing regulatory environment? Rigorous validation is warranted to collect evidence that may support a legislative change to allow for usage of direct identifiers such as Social Security Number, Patient Name, among other efforts[1] to link databases for public reporting. In their report, the measure developer agrees that "direct patient identifiers to link to

[1] http://www.rand.org/commentary/2008/10/30/TH.html

external databases such as the Social Security Death Index or National Death Index will be necessary to ensure the accurate determination of patients' vital status."

- **Cardiogenic shock is subjective and the most significant area of discrepancy in the adjudication process in Massachusetts, which has state-level audit of their data**. Collected evidence will drive more efforts to enhance consistency and reduce variation of care between hospitals. The CathPCI Registry will implement the next version of it registry in July, 2009 followed by an on-going program to educate participants on the changes. We are committed to addressing this issue in that rollout. While CathPCI Registry audit program conducts some validation of the data, a rigorous validation plan targeted to these measures and the associated concerns provides an extra level of assurance.

- **Excluding Outpatient PCI patients need to be studied for unintended consequences**. CMS staffers, as recently as the February 2009 APC Panel meeting, reported significant increase in the number of Outpatient PCIs. Since these measures are based on billing data, we believe that many of our patients (depending on the center) may fall out of the analysis. The focus on high risk patients is valid but there are some hospitals that admit lower risk patients based on local protocol and local coverage decisions. Hospitals at the forefront of the shift to outpatient PCIs will have a much sicker mix of inpatient PCI patients and worse publicly reported outcomes relative to others.

The Society supports incremental, data-driven approaches to establishing high quality measures suitable for public reporting. While the Society endorses these measures, the Society does not support full endorsement at this time. We hope that the Steering Committee agrees with our rationale on why validation of these measures is needed. We look at this situation as an opportunity for NQF to fulfill its mission and believe that a 'model NQF application' will be supported by a 'model validation plan.'

Thank you for the opportunity to speak. I welcome any questions from the steering committee.