National Quality Forum

Measure Comment Report for SURGERY ENDORSEMENT MAINTENANCE 2010

Comments received as of 7/12/2011

ID#	Council/ Public	Commenter	Comment	Response	Topic
841	CON	Dr. Carol Sakala, MSPH, PhD; Childbirth Connection	We appreciate the work of the Society of Thoracic Surgeons relating to clincian group measures, and encourage extension of these to individual clinicians, whenever feasible (e.g., adequate numbers). Individual clinciian measurement is needed to foster patient informed choice of caregiver, to facilitate quality improvement of individual practitioners, and in recognition of the tremendous practice variation that can exist across groups. Robust adjustment is needed to account for crucial patient risk factors.	STS was given the opportunity to respond to this comment. Their response is included below: Level of reporting remains controversial, but STS has generally opposed individual surgeon reporting for a variety of reasons: 1. Especially with the decline in CABG volume, few surgeons perform enough procedures of one type to reliably discriminate performance at the surgeon level. Multiple year aggregation of results is one solution to this problem, but performance from several years ago may not reflect current performance. 2. Cardiac surgery is the ultimate team endeavor—surgeons, cardiac anesthesiologists, perfusionists, cardiac intensivists, specially trained nurses, etc. Patients should be interested in not just one component of that team, but rather how that entire team functions at an institution in order to achieve the optimal results. The best surgeon in the country will have poor results if the rest of the team is not functioning well. 3. The third major objection to surgeon-level reporting is risk aversion. It is critical that the most severely ill patients retain access to surgery, as they are often the very patients who benefit most (Jones, 1989; Lee et al., 2007). Evidence (Burack et al., 1999; Dranove et al., 2003; Omoigui et al., 1996; Schneider & Epstein, 1996) suggests that public reporting produces risk aversion—that is, surgeons are less willing to operate upon high-risk patients because of the impact that poor results might have on their report cards. This risk aversion may disproportionately impact minorities (Werner et al., 2005). Even the best risk adjustment does not completely allay these fears. When reporting is done at the hospital level, the results of particularly high-risk patients are diluted by the overall group experience, thus somewhat mitigating the potential for risk-aversion. When results are presented at the surgeon level, even one very high-risk patient may substantially impact overall performance results, and the potential for risk-aversion is increased. Steering Committee Response: The Committee is sensitive to a number of issues that should be considered as organizations determine at what level of analysis measures should be structured and reported including small sample sizes and potential for risk aversion. The Committee believes it appropriate to consider clinician level reporting where appropriate after consideration of the attendant issues. It is important that measures take into account patient risk factors while ensuring that variations in care are not obscured by risk adjustment. With respect to the STS measures, individual clinician information can be generated at the group or hospital level for use in quality improvement. Additionally, NQF will have a white paper on risk adjustment for CSAC review in Fall 2011. The current criteria are not specific as to appropriateness of risk model(s).	General

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813	PUR	Dr. David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	We agree that surgeons are not solely responsible for surgical outcomes; there are patient factors that are part of the equation. But that does not mean we shouldn't measure the performance and, once adjusted for critical patient risk factors, attribute it jointly -- in other words, subscribe to a concept of shared accountability -- to the surgeon, hospital, and the system they practice in.	Comment appreciated.	General

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812	PUR	Dr. David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	Publicly report information at the level of the individual surgeon: We are pleased to see that results from a number of the STS measures will be reported over the next one to three years (i.e., operative mortality for AVR, operative mortality for MV replacement, operative mortality for MV replacement + CABG surgery, etc.). But performance should be reported at the individual surgeon level when sample sizes are sufficient – STS has historically focused more on reporting at the group level. There are many good reasons for reporting at the individual surgeon level. Consumers need to select individual surgeons to be a part of their care team, even where team-based practice occurs. Other good reasons include: • The skill, technique, and orders submitted by the individual surgeon have a significant impact on outcomes. • Practice group-level data is not always representative of an individual surgeon's performance because the way surgeons within the same group care for their patients can vary significantly, and individual surgeons greatly impact the care that a patient receives.[1]. [1]Rodriguez et al, Attributing Sources of Variation in Patients' Experiences of Ambulatory Care, Medical Care, Vol. 47, No. 8, August 2009.	Measure Developer Response: Please see STS's response to comment ID#841. Steering Committee Response: Please see Committee response at ID#841 above.	General

ID#	Council/ Public	Commenter	Comment	Response	Topic
811	PUR	Dr. David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	The Society of Thoracic Surgeon (STS) developed a large number of the measures recommended for endorsement. We are very supportive of STS's commitment to publicly report results from many of these measures. At the same time, STS, NQF, and the steering committee should consider how to ensure that performance information from these measures is truly useful for consumers and others. We therefore recommend that they: • Encourage reporting performance information at the level of the individual surgeon. • Do not allow the use of risk adjustment methods that unduly mask variations in care (i.e., hierarchical logistic regression modeling – which is applied to STS measures). We articulate these points in greater detail below.	STS was given the opportunity to respond to this comment. Their response is included below: STS disagrees with the comment regarding "risk adjustment methods that unduly mask variations in care (i.e., hierarchical logistic regression modeling – which is applied to STS measures)." The overwhelming majority of statistical thought supports the use of hierarchical models, including the use of empirical Bayes shrinkage estimators. The latter has a long history dating back to the original work of Stein and James over 50 years ago (Stein, 1955), and the subsequent work of Efron and Morris (Efron & Morris, 1975). These approaches were first applied 30 years ago in the UK for use in profiling their educational system (Aitkin & Longford, 1986), and they were subsequently applied to healthcare profiling, specifically in cardiac surgery (Burgess, Jr. et al., 2000; Christiansen & Morris, 1997; Goldstein & Spiegelhalter, 1996; Goldstein et al., 2002; Normand et al., 1997; Thomas et al., 1994). These models provide the best estimates of true underlying performance from lower volume providers. The modeling technique we have adopted distinguishes true between-hospital variation from "sampling variation" (i.e., random variation or noise due to sample size). No one wants to reward or penalize a hospital on the basis of "sampling variation," and this is exactly why a hierarchical model is used. Thus, our approach accomplishes just the opposite of what the reviewer claims. By more appropriately separating between-hospital from within-hospital variation, we "unmask" true performance differences among providers. Steering Committee Response: Please see Committee response at ID#841 above.	General
838	CON	Dr. Carol Sakala, MSPH, PhD; Childbirth Connection	We would like to discourage the use of risk adjustment methods, such as hierarchical logistic regression modeling, that undulty mask variations in care. Such approaches minimize performance variation around the mean. The resulting characterization of the great majority of clinicans as average can mask important differences in quality that would be important to consumers. Such results can also inhibit individual, group, and institutional efforts to improve quality. More traditional logistic regression methods may be better suited to quality improvement aims.	Measure Developer Response: Please see STS's response to comment ID#811. Steering Committee Response: Please see Committee response at ID#841 above.	General

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814	PUR	Dr. David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	Do not use risk adjustment methods that unduly mask variations in care (i.e., hierarchical logistic regression modeling): We are very concerned about STS's use hierarchical logistic regression modeling, which may wash away nearly all of the variation observed in the raw data because of the way in which it shrinks performance data towards the mean. The result is that most individual providers may be labeled as "average." If NQF's goal is for publicly reported data to help consumers make better decisions about care, it may be undermined by the tendencies of this model. Regardless of which test is used to determine statistical significance, the shrinkage in the distribution resulting from this risk adjustment model may not allow for much differentiation of surgeon performance, resulting in little or no information for consumers (or for the surgeons themselves, for that matter). We strongly encourage NQF and STS to be proactive in addressing this concern. In our conversations with the statisticians, we have found that which risk adjustment method is used is a matter of philosophy as there is no consensus about which is the "best." As a result, we recommend that STS apply more traditional logistic regression approaches to their data.	Measure Developer Response: Please see STS's response to comment #811. Steering Committee Response: Please see Committee response at #841 above.	General

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836	CON	Ms. Debra L. Ness, MS; The National Partnership for Women & Families	The National Partnership has significant concerns with the use of hierarchical logistic regression modeling in the STS measures, which has the potential to virtually eliminate all variation observed in the data. As a result, most individual providers may be labeled as “average,” which will make them less-than-useful for both consumer decision-making and for performance improvement. The lack of meaningful variation/distribution resulting from this risk adjustment model may not allow for much differentiation of surgeon performance, resulting in little or no information for consumers (or for the surgeons themselves, for that matter). We strongly encourage NQF and STS to be proactive in addressing this concern. Dialogues with statisticians regarding this subject concluded that the hierarchical risk adjustment method is not always considered better than other more traditional logistic regression methods, thus we recommend that STS apply more traditional logistic regression approaches to their data.	Measure Developer Response: Please see STS's response to comment ID#811. Steering Committee Response: Please see Committee response at ID#841 above.	General

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833	CON	Ms. Debra L. Ness, MS; The National Partnership for Women & Families	We want to particularly express our support for the Society of Thoracic Surgeon's measures, and applaud STS's commitment to publicly report results from many of these measures. At the same time, STS, NQF, and the steering committee should consider how to ensure that performance information from these measures is truly useful for consumers and others. We therefore recommend that all parties work together to encourage reporting performance information at the level of the individual surgeon. We also strongly urge that NQF, STS and the steering committee consider the importance of having risk adjustment methods included in measure specifications, such that variations in care are not unduly masked as they are when using hierarchical logistic regression as the risk adjustment model.	Measure Developer Response: Please see STS's response to comments ID#841 and ID#811. Steering Committee Response: Please see Committee response at ID#841 above.	General

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835	CON	Ms. Debra L. Ness, MS; The National Partnership for Women & Families	We are pleased to see that results from a number of the STS measures will be reported over the next one to three years (i.e., operative mortality for AVR, operative mortality for MV replacement, operative mortality for MV replacement + CABG surgery, etc.). While we commend the fact that several STS measures will be publicly reported over the next three years, we strongly believe that in order to make these data most meaningful to consumers, and to significantly improve performance and outcomes, performance should be reported at the individual surgeon level when sample sizes are sufficient. Stakeholders know that practice group-level data is not always representative of an individual surgeon's performance because the way surgeons within the same group care for their patients can vary significantly, and individual surgeons greatly impact the care that a patient receives. At the same time, we understand that surgeons are not solely responsible for surgical outcomes and there are other factors – both patient and institution-related that contribute (or take away from) outcomes. However, this acknowledgement of shared accountability includes the individual surgeon, as well as the hospital and the system in which the procedure was performed.	Measure Developer Response: Please see STS's response to comments ID#841. Steering Committee Response: Please see Committee response at ID#841 above.	General

ID#	Council/ Public	Commenter	Comment	Response	Topic
826	HPL	Ms. Carmella Bocchino, MBA, RN; America's Health Insurance Plans	AHIP appreciates the opportunity to provide comments on the NQF Surgery Endorsement Maintenance 2010, Phase I report. We support the continued endorsement of all measures. With respect to the STS measures, we appreciate NQF's efforts to monitor performance of these measures, as well as placing measures that have achieved high performance on “Reserve Status.” Such continual monitoring to ensure that there is room for improvement will be important as some of the health plans are seeing a similar trend with other measures (e.g., measure #0130 Risk-adjusted deep sternal wound infection rate (STS)). While we understand that data in the STS registry are validated by the Iowa Foundation for Medical Care, transparency of the validation methodology including key details would be helpful to the end user.	STS was given the opportunity to respond to this comment. Their response is included below: For audits conducted in 2010, all cases were pulled from surgeries performed in 2009. The Duke Clinical Research Institute (DCRI), STS’s data warehouse and analysis center, randomly selected 40 sites participating in the STS Adult Cardiac Surgery Database for this audit. For each site, 15 isolated CABG and 5 isolated valve cases were re-abstracted. Agreement rate results were calculated for 75 individual elements and an overall agreement rate for each site. In addition, agreement rates for each variable category (i.e., demographics, hospitalization, pre-operative risk factors, previous interventions, pre-operative cardiac status, pre-operative medications, pre-operative hemodynamics and catheterization, operative, coronary surgery, valve surgery,post-operative, complications, mortality, discharge) were calculated. Finally, an aggregate agreement rate for each variable, category, and overall for all categories was calculated for all sites. For the 2010 audit, the overall aggregate agreement rate was 95.85%. To evaluate the comprehensiveness of the database, a comparison was conducted between the number of cases submitted to DCRI and hospital logs of cases performed. Steering Committee Response: The Committee agrees that transparency is important for all users' proper use and understanding of the measure and results of its use.	General

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818	PRO	Dr. Ellen Schwalenstocker, PhD, MBA; The National Association of Children's Hospitals and Related Institutions	Thank you for the opportunity to comment on the Surgical Consensus Standards Endorsement Maintenance Phase I draft report. The National Association of Children's Hospitals and Related Institutions (NACHRI) recommends that NQF standardize the presentation of measures. All of the recommended measures appear to apply to adults only given the procedures and data sources. In some cases (measures 0114, 0115, 0129, 0131, 0119, 0116, 0118, 0130), the measure description clearly notes that the measure applies to patients 18 years of age or older. In other cases (0360, 0361), the measure description does not include the age group, but the denominator or numerator clearly specifies the age. In other cases (0120, 0121, 0122, 0123, 1501, 1502. 0218), the age group is not addressed in the measure description, the description of the denominator (the denominator reads 'all patients . . '), or exclusions, but the denominator categories include 18 years of age or older in the detailed measure specification. To avoid confusion and for efficiency in applying measures, we urge NQF to consistently include the age group in the measure description and denominator statements.	STS was given the opportunity to respond to this comment. Their response is included below: STS will make requested modifications to measure forms for #0120, 0121, 0122, 0123, 1501, 1502 by adding age specifications to measure descriptions and denominator statements. Steering Committee Response: The Committee supports the change that has been requested and agreed upon by STS. NQF is working to develop additional guidance to developers to encourage greater standardization to how measure descriptions, numerators, denominators, etc. are defined.	General
803	HPR	Dr. Joseph P. Drozda, Jr., MD; American College of Cardiology	Overall these measures are well thought out and appropriate and we agree with their endorsement. We do have some specific comments on individual measures.	No action required.	General

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834	CON	Ms. Debra L. Ness, MS; The National Partnership for Women & Families	We **oppose endorsement of measure 0113.** There are two issues here, both related to whether this measure meets the importance test, which we would argue it does not. First, performance is at 95% for most participating institutions. Second, there is not convincing evidence of a strong link between participating in a clinical registry and quality of care. Participation in a registry is not closely linked to high quality surgical outcomes. If there is evidence of this linkage, we ask that the measure developer provide it. While we have supported similar structural measures in the past, the time has now come for measure users to move beyond such remedial measures to measures of whether care truly made a difference for the patient, i.e., reporting the outcomes from these data bases.	STS was given the opportunity to respond to this comment. Their response is included below: It is axiomatic that you cannot improve what you cannot measure--there would be no way to determine if improvement had occurred. There are no randomized trials comparing performance improvement in areas with and without registries. However, there are substantial observational data, especially in general and cardiac surgery, that clinical registries contribute significantly to improvement by providing high quality, risk-adjusted data that are accepted as valid by providers (in contrast to administrative data) (Ferguson, Jr. et al., 2003; Grover et al., 1994; Grover, 1997; Grover et al., 2001; Hammermeister et al., 1994b; Hammermeister et al., 1994a; Khuri et al., 1998). Evidence suggests that the feedback of results based on high quality data, rather than public reporting, is the common denominator for such improvement. This is evidenced by the superior and nearly identical “best in class” performance improvement achieved within the publicly reported New York Cardiac Surgery Reporting System and the totally confidential Northern New England Cardiovascular Disease Study Group (Peterson et al., 1998), both of which are based on clinical registry data, as well as results from a registry-based feedback program in Ontario (Guru et al., 2006). Steering Committee Response: Registries continue to provide a way to collect, benchmark, and report back to participants about performance to facilitate appreciation of levels of performance and potential for improvement. NQF is facing a situation where reliable, valid and important measures may not retain endorsement due to lack of a performance gap. NQF has addressed this with "inactive endorsement with reserve status" to retain endorsement of highly credible, reliable and valid measures that have overall high levels of performance with little variability due to quality improvement actions so that performance could be monitored in the future to ensure that performance does not decline.	0113: Participation in a Systematic Database for Cardiac Surgery

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815	PUR	Dr. David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	Measure 0113, “Participation in a systematic database for cardiac surgery” - We **do not support endorsement of measure 0113**, which NQF provides “reserve status.” We question the necessity of maintaining this measure – not only is it topped out at 95%, as the steering committee recognizes, but we have not seen convincing evidence of a strong link between participating in a clinical registry and quality of care. The measure developer should produce evidence of this linkage. While we have supported similar structural measures in the past, the time has now come for measure users to move beyond such remedial measures to measures of whether care truly made a difference for the patient, i.e., reporting the outcomes from these data bases.	Measure Developer Response: Please see STS's response to comment ID#834. Steering Committee Response: Please see Committee response at ID#834.	0113: Participation in a Systematic Database for Cardiac Surgery
808	PUR	Ms. Gaye Fortner; HealthCare 21 Business Coalition	I **do not support endorsement of measure 0113**, which NQF provides “reserve status.” I question the necessity of maintaining this measure – not only is it topped out at 95%, as the steering committee recognizes, but I ame doubtful of the link between participating in a clinical registry and quality of care. The measure developer should produce evidence of this linkage. While I supported similar structural measures in the past, the time has now come for measure users to move beyond such remedial measures to measures of whether care truly made a difference for the patient.	Measure Developer Response: Please see STS's response to comment ID#834. Steering Committee Response: Please see Committee response at ID#834.	0113: Participation in a Systematic Database for Cardiac Surgery

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831	CON	Dr. Carol Sakala, MSPH, PhD; Childbirth Connection	We **do not support endorsement of measure 0113** for several reasons: it is topped out at 95%, the relationship between quality of care and participation in a registry has not been provided, and we feel the need to prioritize measures with a clear and stronger connection to making a difference for patients.	Measure Developer Response: Please see STS's response to comment ID#834. Steering Committee Response: Please see Committee response at ID#834.	0113: Participation in a Systematic Database for Cardiac Surgery
828	PRO	Ms. Samantha Burch; The Federation of American Hospitals	The Federation of American Hospitals appreciates the opportunity to comment. We **do not support the continued endorsement** of this measure. We do not believe that participation in a registry (or database) is in itself a measure of quality performance. Further, we believe that the recommended designation of "reserve status" is misleading. Reserve status is intended to indicate that a measure with a high level of performance is still credible, reliable and valid despite there being little opportunity for improvement. We do not believe that this a true "quality measure" and therefore there is, in actuality, no room for improvement because quality performance is not being assessed.	Measure Developer Response: Please see STS's response to comment ID#834. Steering Committee Response: Please see Committee response at ID#834.	0113: Participation in a Systematic Database for Cardiac Surgery

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832	CON	Ms. Debra L. Ness, MS; The National Partnership for Women & Families	The National Partnership for Women & Families appreciates the opportunity to comment on NQF's Surgery Endorsement Maintenance 2010, Phase I: A Consensus Report. We support the report's focus on outcomes of cardiac surgery and the way it addresses the need to shift away from the use of measures for which performance is already extremely high. The Nationl Partnership supports the steering committee's endorsement recommendations **with the exception of measure 0113**, "Participation in a systematic database for cardiac surgery." We also **encourage the steering committee to endorse measure 0124,**"Surgical volume –(a) isolated coronary artery bypass graft (CABG) surgery, (b) valve surgery, (c) 306 CABG + valve surgery." It is currently in the category of measures "not recommend for endorsement," based on the assumptionthat volume is not a standalone quality measure. However, higher volume is associated with better quality for some procedures. Consumers understand the volume-quality relationship when it comes to surgical procedures, and we believe that this measure would resonate very strongly with the consumer community.	STS was given the opportunity to respond to this comment. Their response is included below: Please see STS's response to comment #834 There is a strong volume outcome association for some measures such as esophagectomy and pancreatectomy, but not for CABG. As we have multiple direct outcomes measures, the use of a surrogate or proxy (volume) for quality is not warranted. Thus, the Surgery Steering Committee decided not to recommend the volume measure for endorsement during this endorsement review. Steering Committee Response: With respect to Measure #0113, see response at ID#834. With respect to Measure #0124, the Committee has been consistent in its position that volume alone is insufficient to convey information about quality except in instances where there is clear evidence of a volume/outcome relationship. Even in those cases, volume measures must be considered with caution. Based on the literature and its considerable discussion, the Committee determined there was insufficient data to support continued endorsement of Measure #0124.	0113: Participation in a Systematic Database for Cardiac Surgery and Measure not Recommended-0124

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810	PUR	Dr. David S. P. Hopkins, MS, PhD; Pacific Business Group on Health	The Consumer-Purchaser Disclosure Project appreciates the opportunity to comment on NQF's Surgery Endorsement Maintenance 2010, Phase I: A Consensus Report. The document importantly focuses on outcomes of cardiac surgery and addresses the need to shift away from the use of "topped out" measures. We support endorsing all of the recommended measures **with the exception of measure 0113**, "Participation in a systematic database for cardiac surgery." We also **encourage the steering committee to endorse measure 0124**, "Surgical volume –(a) isolated coronary artery bypass graft (CABG) surgery, (b) valve surgery, (c) 306 CABG + valve surgery." Currently, the steering committee does not recommend this measure for endorsement, based on the assumption that volume is not a standalone quality measure. However, higher volume is associated with better quality for some procedures.	Measure Developer Response: Please see STS's response to comment ID#832. Steering Committee Response: Please see response at ID#832 above.	0113: Participation in a Systematic Database for Cardiac Surgery and Measure not Recommended-0124
809	PUR	Ms. Gaye Fortner; HealthCare 21 Business Coalition	I support endorsing all of the recommended measures **with the exception of measure 0113**, "Participation in a systematic database for cardiac surgery." I also encourage the steering committee to **endorse measure 0124,**"Surgical volume –(a) isolated coronary artery bypass graft (CABG) surgery, (b) valve surgery, (c) 306 CABG + valve surgery."	Measure Developer Response: Please see STS's response to comment ID#832. Steering Committee Response: Please see response at ID#832 above.	0113: Participation in a Systematic Database for Cardiac Surgery and Measure not Recommended-0124

ID#	Council/ Public	Commenter	Comment	Response	Topic
804	HPR	Dr. Joseph P. Drozda, Jr., MD; American College of Cardiology	It is not clear how modifiable risk-adjusted post-operative renal failure is without affecting other outcomes measures. Because there are no universally agreed upon measures for preventing this adverse event, the measure may be confusing for public reporting purposes, unless reported as being below, above, or within with the 95% CI of predicted risk of this outcome.	STS was given the opportunity to respond to this comment. Their response is included below: STS risk-adjusted results are always presented as point estimates with associated confidence intervals. Our public reporting initiative bundles together the five major cardiac surgical complications as a risk-adjusted, any-or-none measure and presents both numerical results with confidence intervals and a star rating (above average, below average, or average). Steering Committee Response: The Committee recommends endorsement of measures for quality improvement and public reporting. Bundling complications can add power to the ability for greater discrimination thus there is value in portraying things such as complications in this way. The reporting approach is not delineated though NQF-endorsed™ guidance for reporting is included in the report titled National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information. While various methods may be used to convey information, the star rating is not part of the endorsed standard.	0114: Risk-Adjusted Post-operative Renal Failure
805	HPR	Dr. Joseph P. Drozda, Jr., MD; American College of Cardiology	The risk adjusted surgical re-exploration measure has many causes bundled into one measure. It would be more informative to separate the re-exploration for bleeding from re-exploration for other causes.	STS was given the opportunity to respond to this comment. Their response is included below: For the purposes of public reporting, STS bundles together the major cardiac surgical causes for re-exploration and excludes other causes Steering Committee Response: The Committee determined this measure addresses surgical re-exploration as a complication of the surgical procedure and acknowledges that bleeding is one of the major causes.	0115: Risk-Adjusted Surgical Re-exploration
819	PRO	Dr. Ellen Schwalenstocker, PhD, MBA; The National Association of Children's Hospitals and Related Institutions	Please include the age specification in the measure description and denominator statements.	STS was given the opportunity to respond to this comment. Their response is included below: STS will make this modification. Steering Committee Response: The Committee supports the change that has been requested and agreed upon by STS.	0120: Risk-Adjusted Operative Mortality for Aortic Valve Replacement (AVR)

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820	PRO	Dr. Ellen Schwalenstocker, PhD, MBA; The National Association of Children's Hospitals and Related Institutions	Please include the age specification in the measure description and denominator statements.	STS was given the opportunity to respond to this comment. Their response is included below: STS will make this modification. Steering Committee Response: The Committee supports the change that has been requested and agreed upon by STS.	0121: Risk-Adjusted Operative Mortality for Mitral Valve (MV) Replacement
821	PRO	Dr. Ellen Schwalenstocker, PhD, MBA; The National Association of Children's Hospitals and Related Institutions	Please include the age specification in the measure description and denominator statements.	STS was given the opportunity to respond to this comment. Their response is included below: STS will make this modification. Steering Committee Response: The Committee supports the change that has been requested and agreed upon by STS.	0122: Risk-Adjusted Operative Mortality MV Replacement + CABG Surgery
822	PRO	Dr. Ellen Schwalenstocker, PhD, MBA; The National Association of Children's Hospitals and Related Institutions	Please include the age specification in the measure description and denominator statements.	STS was given the opportunity to respond to this comment. Their response is included below: STS will make this modification. Steering Committee Response: The Committee supports the change that has been requested and agreed upon by STS.	0123: Risk-Adjusted Operative Mortality for Aortic Valve Replacement (AVR) + CABG Surgery

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806	HPR	Dr. Joseph P. Drozda, Jr., MD; American College of Cardiology	It is not clear how modifiable risk-adjusted stroke/cerebrovascular accident is without affecting other outcomes measures. Because there are no universally agreed upon measures for preventing this adverse event, the measure may be confusing for public reporting purposes, unless reported as being below, above, or within with the 95% CI of predicted risk of this outcome.	STS was given the opportunity to respond to this comment. Their response is included below: STS risk-adjusted results are generally presented as point estimates with associated confidence intervals. Our public reporting initiative bundles together the five major cardiac surgical complications as a risk-adjusted, any-or-none measure and presents both numerical results with confidence intervals and a star rating (above average, below average, or average). Steering Committee Response: The Committee recommends endorsement of measures for quality improvement and public reporting. Bundling complications can add power to the ability for greater discrimination thus there is value in portraying things such as complications in this way. The reporting approach is not delineated though NQF-endorsed™ guidance for reporting is included in the report titled *National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information* . While various methods may be used to convey information, the star rating is not part of the endorsed standard.	0131: Risk-Adjusted Stroke/Cerebrovascular Accident
823	PRO	Dr. Ellen Schwalenstocker, PhD, MBA; The National Association of Children's Hospitals and Related Institutions	Please include the age specification in the measure description and denominator statements.	CMS was given the opportunity to respond to this comment. Their response is included below: We appreciate your comments. The Centers for Medicare & Medicaid Services (CMS) measures are designed to target a specific age group. While the targeted age group may not be mentioned in the denominator statement, it is clearly delineated in the measure specifications. The current measures on VTE prophylaxis focus on adults (18 years and older) because of a lack of consensus on use of VTE prophylaxis in children having surgery. Steering Committee Response: The Committee agrees that prominent placement of age range in the measure description and denominator is desirable and, while recognizing that the age range is included in the specifications, has encouraged the developer to place it in the description and denominator. As noted above, NQF is working to develop additional guidance to developers to encourage greater standardization to how measure descriptions, numerators, denominators, etc. are defined.	0218: Surgery Patients Who Received Appropriate Venous Thromboembolism (VTE) Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery End Time

ID#	Council/ Public	Commenter	Comment	Response	Topic
807	SPI	Mr. Christopher M. Dezii, RN, MBA, CPHQ; Bristol-Myers Squibb Company	Thank you for the opportunity to comment: The term "Factor Xa Inhibitor (Fondaparinux)" is used throughout the document. One suggestion we have is to delete the Fondaparinux reference and adjust to state "Factor Xa Inhibitor with a VTE prophylaxis indication". This would allow for the measure to be somewhat flexible in adapting to innovation in the short and intermediate term. This may be a possible given that the data sources include "paper" which means they wouldn't be limited by drug coding requirements. We also suggest clarification of the definition of " appropriate venous thromboembolism prophylaxis" in the report . Is it defined as receiving VTE prophylaxis that is in accordance with the recommendations from theclinical guidelines? Are guideline- recommended VTE prophylaxis regimen (pharmacological or mechanical) at the appropriate dose (if a pharmacological regimen was recommended) and for the appropriate duration considered in the definition of "appropriate venous thromboembolism prophylaxis"?	CMS was given the opportunity to respond to this comment. Their response is included below: We appreciate your feedback. In the near future, we plan to integrate language into the specifications that will allow abstractors to select a pharmacologic agent that may be newly approved for a clinical indication with a "not otherwise specified" value to cover scenarios such as you describe. However, we have to be cautious about broadly allowing categories of agents (such as factor Xa inhibitors) to be selected because many of these agents are FDA approved for only specific types of operations. The appropriate venous thromboembolism prophylaxis selections included in the measure are based on current guidelines and ongoing input from a technical expert panel that includes many guideline authors and experts in the field. We currently do not evaluate dosing of agents because of patient-specific factors that may alter dosing requirements for some agents, and because we are mindful of the abstraction burden that facilities experience with performance measurement. Additional performance measures to address appropriate duration of VTE prophylaxis are under consideration for development. Steering Committee Response: The Committee supports the CMS rationale and plans for refinement and development of additional future measures.	0218: Surgery Patients Who Received Appropriate Venous Thromboembolism (VTE) Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery End Time

ID#	Council/ Public	Commenter	Comment	Response	Topic
830	HPR	Ms. Jean Brereton; The American Academy of Otolaryngology-Head and Neck surgery	The American Academy of Otolaryngology- Head and Neck surgery has some concerns in regards to the measure specifications and the specialties listed as appropriate to report on the measure. The Academy believes otolaryngology-head and neck surgery procedures should be listed as a category as appropriate to report on in the measure specifications. Many of the patients that otolaryngologist's operate on have indications for VTE prophylaxis. In addition, we do not understand why these measures are categorized under cardiac surgery CABG, since the description of the measures is very inclusive of most specialty/subspecialty surgeries	CMS was given the opportunity to respond to this comment. Their response is included below: The Technical Expert Panel supporting these measures reviewed current guideline recommendations and evaluated a comprehensive list of major surgeries and selected the procedures to be evaluated with this measure. The selection of operations included in the measure denominator was based on guidelines recommendations and focuses only on those operations for which VTE prophylaxis is always recommended. The performance measure does not include any risk stratification data that might be used to determine if a patient undergoing head and neck surgery needs prophylaxis. The goal of the limited denominator is to include only those operations for which there is no controversy about the need for VTE prophylaxis. The measure developers did not categorize the measure under "cardiac surgery/CABG." Steering Committee Response: The Committee supports the rationale submitted by CMS. NQF staff will place the measure under a more inclusive heading in the report.	0218: Surgery Patients Who Received Appropriate Venous Thromboembolism (VTE) Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery End Time
824	PRO	Dr. Ellen Schwalenstocker, PhD, MBA; The National Association of Children's Hospitals and Related Institutions	Please include the age specification in the measure description and denominator statements.	STS was given the opportunity to respond to this comment. Their response is included below: STS will make this modification. Steering Committee Response: The Committee supports the change that has been requested and agreed upon by STS.	1501: Risk-Adjusted Operative Mortality for Mitral Valve (MV) Repair

ID#	Council/ Public	Commenter	Comment	Response	Topic
825	PRO	Dr. Ellen Schwalenstocker, PhD, MBA; The National Association of Children's Hospitals and Related Institutions	Please include the age specification in the measure description and denominator statements.	STS was given the opportunity to respond to this comment. Their response is included below: STS will make this modification. Steering Committee Response: The Committee supports the change that has been requested and agreed upon by STS.	1502: Risk-Adjusted Operative Mortality for MV Repair + CABG Surgery

ID#	Council/ Public	Commenter	Comment	Response	Topic
816	PUR	Ms. Rabia Khan, MPH on behalf of Michael Rapp; CMS	Comments regarding measure 0300 Cardiac Surgery Patients with Controlled 6am Glucose (currently pending Steering Committee recommendation): CMS agrees with the NQF's stance of endorsing measures closest to the patient outcome and agree with the NQF Steering Committee on the continuation of endorsement for measures that have a strong evidence base. However, we disagree with the Steering Committee recommendations to revise the specifications for SCIP Infection-4 Cardiac Surgery Patients With Controlled 6 A.M. Postoperative Blood Glucose. While we generally agree that 6AM is an arbitrary time, we do not agree on the recommendation to extend the time-frame for glucose control to 18-24 hours post op. Rather, we would recommend a time-frame 8-12 hours post op. Controlling glucose after surgery has been shown to reduce the risk of surgical site infection significantly, especially in cardiac surgery. Please reconsider the post op time-frame for SCIP Infection-4.	CMS was given the opportunity to respond to this comment. Their response is included below: The recommendation to evaluate glucose control at 18-24 hours after surgery end time was submitted to the NQF steering committee by a technical expert panel which included representation from the Society of Thoracic Surgeons. The measure developers agreed to modify the specifications based on NQF Steering Committee feedback. While it is probably true that picking any time frame after the end of the operation to achieve normoglycemia is probably arbitrary, the technical expert panel felt that the the 18-24 hour time frame should be less controversial than too early after surgery (i.e, it gives the hospital more than enough time to control the blood sugar and should be achievable in the majority of cardiac operations). Also remember that if the hospital tried to "game" the measure by not recording any blood sugars between 18-24 hours, the revised specifications require them to look at the 12-18 hour time range after the end of the operation. Steering Committee Response: The timeframe was modified based on a recommendation of the Committee to move from the arbitrary 6 am timeframe to an evidence based timeframe. This was accomplished by a CMS technical panel in consultation with STS where the evidence considered indicated that blood sugars should be controlled by 18 to 24 hours after surgery. Based on the evidence cited, the Steering Committee agreed with the revised timeframe in the measure submission.	0300: Cardiac surgery patients with controlled 6am glucose
842	CON	Dr. Carol Sakala, MSPH, PhD; Childbirth Connection	We encourage the Steering Committee to reconsider inclusion of measure 0124, volume of CABG, valve or CABG plus valve surgeries. While we agree that volume is not inherently a quality measure, higher volume is associated with better outcomes for some procedures.	Measure Developer Response: Please see STS's response to comment #832. Steering Committee Response: Please see response at #832.	Measures Not Recommended-0124

ID#	Council/ Public	Commenter	Comment	Response	Topic
837	CON	Ms. Debra L. Ness, MS; The National Partnership for Women & Families	The National Partnership strongly urges the steering committee to reconsider measure 0124,“Surgical volume –(a) isolated coronary artery bypass graft (CABG) surgery, (b) valve surgery, (c) 306 CABG + valve surgery.” Currently, the steering committee does not recommend this measure for endorsement, based on the assumptionthat volume is not a standalone quality measure. However, higher volume is associated with better quality for some procedures, and consumers find measures of volume to be very meaningful and actionable.	Measure Developer Response: Please see STS's response to comment #832. Steering Committee Response: Please see response at #832.	Measures Not Recommended 0124