NATIONAL QUALITY FORUM

Memo

TO: Consensus Standards Approval Committee (CSAC)

FR: Reva Winkler, Andrew Lyzenga, Wunmi Isijola, and Amaru J. Sanchez

RE: Appeals on CABG Surgery Measures

DA: January 13, 2015

In accordance with the NQF Consensus Development Process (CDP), the measures recommended by the NQF Surgery Standing Committee were released for a 30-day appeals period. On December 11, 2014, the 30-day appeals period closed; NQF received eight (8) letters of appeal for two endorsed measures on behalf of the following organizations:

- **0119: Risk-Adjusted Operative Mortality for CABG**
  - University of Wisconsin School of Medicine and Public Health – Carbone Cancer Center
  - St. Mary's Hospital
  - Rutgers New Jersey Medical School
  - Palliative Care Network of Wisconsin
  - Ministry Health Care

- **2558: Hospital 30-Day All-Cause Risk-Standardized Mortality Rate Following CABG**
  - The Johns Hopkins Hospital
  - University of Wisconsin
  - Thomas Jefferson University

Accompanying this memo are the following documents:

1. **Appendix A** - Appeal Letters - 0119: Risk-Adjusted Operative Mortality for CABG
2. **Appendix B** - Appeal Letters - 2558: Hospital 30-Day All-Cause Risk-Standardized Mortality Rate Following CABG
3. **Appendix C –** Response from measure developers
4. **Appendix D** - Measure evaluation summary tables for CABG surgery measures

CSAC ACTION REQUIRED

The CSAC will review each letter of appeal, the responses submitted by the developers, and this memo in consideration of the appeal. The CSAC will determine whether to uphold the endorsement decision or uphold the appeal for each measure.

Summary of Issues Raised in the Appeal (excerpted from the memo):

The appellants requested reconsideration of the endorsement of measures #0119 and #2558, both of which measure risk-adjusted mortality rates within 30 days of coronary artery bypass graft (CABG)

surgery. Many of the comments stated that a 30-day mortality rate is merely a benchmark indicator of failure and does not necessarily reflect quality of care. Moreover, appellants argued that a 30-day mortality measure may have significant unintended consequences, including discouraging appropriate palliative care or appropriate withdrawal of post-operative life-supporting treatments despite patient or family preferences to limit life-supporting care. Appellants also suggested that surgeons may be more likely to decline to perform needed surgery on patients who are at high risk of complications or patients who have placed reasonable limits on their post-operative care. In addition, appellants stated that these measures are susceptible to 'gaming' (e.g., keeping patients alive until postoperative day 31 to avoid penalties, and then transitioning to palliative care). In general, appellants suggested that these measures are insufficiently sensitive to patient preferences and that they perpetuate non-patient-centered care.

Response on Behalf of the Surgery Standing Committee Co-Chairs:

The Surgery Standing Committee appreciates the concerns raised by the appellants, and agrees that consideration of potential unintended consequences is a critical part of the measure evaluation process. As the Society of Thoracic Surgeons (STS) and the Centers for Medicare & Medicaid Services/Yale-Center for Outcomes Research and Evaluation (CMS/Yale-CORE) describe in their responses, 30-day mortality measures should be—and are—part of a balanced approach to measurement that takes into account various indicators of healthcare quality and multiple outcomes that are important to patients. The Committee co-chairs believe it remains important to measure postoperative mortality as one facet of quality, and are satisfied that the developers have addressed the appellants' concerns in their responses.

0119: Risk- Adjusted Operative Mortality for CABG (The Society of Thoracic Surgeons);

Developer Response:

The developer is in agreement that mortality should not be the sole metric to assess quality in cardiothoracic surgery. In support of this, the developer noted that they had developed several other measures of post-surgical outcomes, including occurrence of any of the five major complications (stroke, renal failure, sternal infection, prolonged ventilation, reoperation for bleeding) accountable for the "major morbidities most commonly responsible for the lengthy and difficult postoperative courses described in the letters to NQF."

With regard to unintended consequences, the developer discussed how this measure is designed to provide a comprehensive view of mortality, disincentivizing the occurrence of some of the unintended consequences cited:

> "There is no incentive to discharge patients prematurely, as their out-of hospital deaths will still be recorded out to 30 days (by which time most early outpatient deaths will have occurred). There is also no incentive to keep the patient alive using extraordinary means until day 30, then to remove life-sustaining support. Because the patient is still hospitalized, their death is recorded, regardless of how long postoperatively it has occurred."

While recognizing anecdotes describing how providers may use supportive care measures in very ill patients until the 30-day threshold is reached, and only then discuss withdrawal of care, the developers deferred to local hospital ethics committees as best positioned to identify and mitigate these practices and unintended consequences.

2558: Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft CABG Surgery (Centers for Medicare & Medicaid Services)

Developer Response:

The developer noted the benefits achieved by measuring 30-day mortality following CABG surgery, such as providing hospitals with an incentive to reduce mortality through improved coordination of perioperative care and discharge planning. The developer discussed the state of California's success in reducing CABG mortality rates when using registry-based mortality measures. In addition, the developer noted the challenges associated with using patient-reported outcomes to replace or supplement mortality measurement:

> "[A]t at this time patient-reported outcomes are not routinely collected and thus cannot currently be used in a reliable manner for national measurement programs. Further, process measures unfortunately do not correlate closely with clinical outcomes and thus cannot fully supplant outcome measures. Until appropriate patient-reported outcome metrics are widely available, we believe there is greater good achieved by measuring CABG mortality than by not measuring this outcome at all."
>
> Finally, the developer discussed that "according to their clinical expert consultants and Technical Expert Panel, patients who are undergoing CABG surgery likely have a reasonable expectation of surviving more than 30-days beyond their surgery or physicians would not offer such an invasive procedure nor would patients likely consent to this procedure if their primary goal of care was comfort and not survival." Additionally, the developer noted several reevaluation processes, such as an internal annual review at CMS as well as the annual maintenance review by the NQF, which are available and designed to monitor for unintended consequences.

In response to potential unintended consequences, the developer discussed studies that support the methodological approach taken by the measures:

> "Thirty-day mortality (e.g., [measure] 2558) is superior to in-hospital mortality as a quality metric, as it uses a standardized time frame for endpoint ascertainment. This is preferred by statisticians and is used in virtually all government accountability programs. It also mitigates the bias resulting from differential access to post-acute care facilities."

Carbone Cancer Center
UNIVERSITY OF WISCONSIN
SCHOOL OF MEDICINE AND PUBLIC HEALTH

December 15, 2014

National Quality Forum
Appeals Process
Re: 30-day operative mortality

To Whom It May Concern:

In research and quality benchmarking choosing the right measurement tool is imperative. The 30-day mortality metric is a poor indicator of quality and, even worse, is one people can manipulate to make it appear as though quality is better. It occurs to me to first ask what we want to happen? What is true quality? For that we need a tangible outcome, like a patient who was discharged home for a routine recovery period and ultimately resuming an active life. In contrast, most people would not want a prolonged recovery period in an LTAC and then transitioning to live in a nursing home while bouncing back and forth from the hospital before dying months down the road. Both of those outcomes, from a 30-day mortality perspective, are equivalent but we can all recognize they are drastically different. Thus, measuring a 30-day mortality figure is merely an indicator of failure while not helping anyone improve their practice or identify quality surgeons and hospitals. 30-day mortality is not even a very good indicator of failure. After all, a patient whose operative course is complicated and who is certain not to have a good recovery could be transitioned to comfort care on POD 10 and allowed to die peacefully on POD 11 with their family at their side. I would submit this recognition would be a marker of good quality on the part of the surgical team.

In addition, a 30-day survival benchmark is absolutely a metric which smart clinicians can manipulate (e.g. keep a patient alive and transition to comfort care on day 31 or 33) and does nothing to reflect quality. I would strongly urge movement away from negative markers towards aspirational benchmarks. Could you find a measure which reflects the desired outcome? Like returning to work? Or able to play in the park with their grandchildren? But one that also rewards good decision making in the immediate post operative period in the event the patient is not likely to meet their outcome expectations? For example, a palliative care consultation and death after a decision to limit therapy rather than despite therapy, perhaps with even a limited number of ICU days suggesting the team realized reality relatively quickly to avoid causing additional suffering?

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Carbone Cancer Center
UNIVERSITY OF WISCONSIN
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Thank you for your consideration. Please do not hesitate to contact me with any questions, 608-263-3962.

Regards,

Toby C. Campbell, M.D, MSCI
Associate Professor of Medicine
Thoracic Oncology
Chief of Palliative Care Medicine
Fellowship Director, Hospice and Palliative Care Medicine

Appeal Submitter
St. Mary's Hospital
Eric Marty
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Summary of Appeal:
Please reconsider addition of a 30-day risk-adjusted operative mortality for as a quality metric for CABG. It will incentivize surgeons to delay appropriate care for cases in which perioperative complications result in a disease burden, treatment burden, or quality of life that is unacceptable to affected patients. Not only does this metric not accurately capture quality care, it is not patient and family-centered. While it may satisfy our apparent need to have a simple, easy, capturable metric, it will undoubtedly result in delay in access to, or even lack of access to, the best care possible for the subset of patients who the odds tell us will, despite all attempts at rigorous patient selection, experience life-limiting complications. Unfortunately quality of care cannot be captured with such an unsophisticated metric.

Article I. Beyond 30-Day Mortality Aligning Surgical Quality With Outcomes That Patients Value

Margaret L. Schwarze, MD, MPP[1,2]; Karen J. Brasel, MD, MPH[3]; Anne C. Mosenthal, MD[4]

Appeal Submitter
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Summary of Appeal:
As a surgeon, I urge the NQF to reconsider 30-day mortality for CABG as a quality metric due to the potential unintended consequences of it use. While operative mortality is important, the overemphasis of 30-day outcomes may alter surgeons' treatment decisions in ways that are not in the best interest of patients. Despite being "risk-adjusted," this metric cannot account for the preop wishes of patients who desire surgery, but who place reasonable limitations on their postop care. This creates a disincentive for surgeons to offer surgery, despite its potential benefits. In addition, when patients wish to limit ongoing heroic care required to sustain life for 30 postop days, this metric puts surgeons in a double bind between honoring patients' preferences and optimizing their reportable "quality" outcomes. In the interest of true quality, the NQF should champion the efforts of surgeons to act as patient advocates, as opposed to placing ethical barriers to patient-centered behavior.

VIEWPOINT

Beyond 30-Day Mortality
Aligning Surgical Quality With Outcomes That Patients Value

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Because of their strong sense of responsibility for the lives of patients, surgeons frequently struggle to withdraw postoperative life-supporting treatments when patients or their families request it.[1] Although surgeons experience this as therapeutic optimism or the emotional pull of error and responsibility, these forces are accentuated by the increasing emphasis on 30-day mortality reporting. The recent expansion of outcomes profiling imposes an unconscious bias in these critical decisions: surgeons who report concern about physician profiling are more likely to decline to operate on a patient who prefers to limit life support, or are more likely to refuse to withdraw life support postoperatively, than surgeons who perceive less pressure from outcomes reporting.[2,3]

Public reporting of 30-day mortality may motivate surgeons and hospitals to improve outcomes and theoretically empowers patients to make informed choices.[4] However, use of this single metric unintentionally fails to accommodate patients who might benefit from palliative surgery, or patients who would prefer death to prolonged postoperative treatment in the intensive care unit or long-term chronic care after a major complication. Surgeons should be able to offer informed patients a risky but potentially beneficial surgical option and then allow patients to refuse aggressive treatments if they have become overly burdensome or when patients' goals for surgery are no longer possible.

Reconciling the effects of an approach designed to ensure high-quality surgical care with the needs of vulnerable patients is challenging, particularly for high-risk operations in which hard outcomes, such as mortality, are easily observed and other important outcomes are more difficult to assess. Strategies to mitigate the impact of 30-day mortality reporting through consideration of alternative quality metrics are required to protect the needs of surgical patients and the practices of surgeons who could make a valuable contribution to their patients' quality of life.

Alternative Outcomes to 30-Day Mortality

A system that prioritizes one metric, 30-day mortality, above all others is unlikely to produce outcomes that are desirable for all stakeholders. The purpose of reporting 30-day mortality is to assess surgical safety, but patients desire surgical safety only to the degree that it predicts efficacy (longer-term survival and quality of life). Although most patients wish to survive for 30 days after their operation, the notion that surgery has intrinsic value to patients if they could live just 30 days is outdated, as if additional survival time is an unexpected luxury. Reporting mortality statistics at other time points, including 60 days and 6 months, would help align patients' and surgeons' goals at concordantly valuable touch points and would de-emphasize the singular importance of 30-day survival. By broadening the time horizon, this strategy could reduce the external pressure to achieve a specific target with limited impact on safety assessment as postoperative complications are tightly linked to longer-term postoperative survival.[5]

Other safety metrics that matter to patients should be elevated to the current status of mortality: intensive care unit days, prolonged mechanical ventilation (longer than 96 hours), and discharge destination. There is a clear distinction between the patient who has an extended hepatectomy, spends 24 hours in the intensive care unit and 5 days in the hospital, and is discharged to home with physical therapy and the patient who has the same operation, spends 14 days in the intensive care unit on a ventilator and 33 days in the hospital, and is discharged to a long-term acute care hospital with a tracheostomy. Although the differences between these 2 outcomes are striking, this distinction is not well captured by the equivalent 30-day survival assigned to both episodes.

Report Patient-Centered Outcomes

The collection of data on patient-centered outcomes in quality improvement programs and surgical registries for all operations would help both patients and surgeons. In addition to procedure-specific morbidity, reported outcomes should match the goals of surgery. For example, a 3-month measurement of fatigue and bone pain after parathyroidectomy or the ability to eat solid food after gastrectomy should be reported along with surgical site infection and postoperative readmission. Although these additional metrics focus on efficacy, rather than safety, surgical quality should be judged by both. Patients will undertake significant risk in pursuit of a specific goal; measuring and reporting these outcomes will improve their ability to evaluate the trade-offs inherent in surgical treatment and will provide clarity about what is a realistic postoperative goal.

Emphasize Process Measures for Palliative Operations

For patients who have operations with palliative intent, quality of care should not be judged by mortality but by robust reporting of outcomes that reflect high-quality palliative care. This would include clear delineation and postoperative measurement of the symptoms the operation is intended to address. For example, re-

porting for an enteric bypass for obstructing cancer should measure relief of nausea and vomiting. Other metrics of high-quality palliative care include documentation of a preoperative goals-of-care conversation, pain scores, family meetings, and even time between a do-not-resuscitate order and death. Although the collection of survival rates after palliative operations might help inform future patients about the value of an operation, the 30-day mortality rates for these operations should not be interpreted or publicly reported as a quality metric.

Attend to the Needs of Poor-Risk Patients

Targeting surgical mortality likely decreases the number of operations on poor-risk candidates, as it has for percutaneous coronary interventions.[6] However, when 30-day mortality reporting influences the decision making for poor-risk patients, this can result in mistrust, inconsistency, and discriminatory practices. To promote quality and reduce ineffective or marginally beneficial care, it is necessary to delineate both upper and lower boundaries around the patients who are appropriate operative candidates. Expansion of guidelines, such as those for lung volume reduction surgery, that define indications for the performance of surgery, including a clear description of patients who are not surgical candidates because of unlikely long-term survival and prohibitive morbidity, would lead to consistent practices about who should be refused surgery based on defined prognostic features and would reduce concern that the decision was influenced by performance metrics.

Patients frequently proceed with surgery because they perceive no other option, even though surgery is unlikely to meet their needs. Preoperative conversations typically stress risks and benefits, rather than a detailed discussion of patient preferences and goals. Often, the postoperative care required is not consistent with patients' desires, even if all goes well. Although penalties for high 30-day mortality would reduce the number of operations on high-risk patients, such penalties do not consider whether the treatment received was aligned with the patient's values.[7] Although difficult to operationalize, incentives that reward patient engagement rather than a specific outcome would credit surgeons for identifying both the patients who are unlikely to value risky surgery and the patients who would value surgical intervention and be accepting of the necessary postoperative life support.

The benefits of detailed reporting of surgical outcomes, specifically highly visible mortality statistics, will be limited unless we focus on results that are valuable to patients. It is time for surgical quality metrics to evolve because there is much at stake for both patients and surgeons. The way forward requires (1) an alignment of the goals of surgery with the outcomes that are measured and (2) a more sophisticated and nuanced approach in order to value the full range of outcomes that surgeons have to offer patients beyond 30-day survival.

ARTICLE INFORMATION

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Appeal Submitter
Palliative Care Network of Wisconsin
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Summary of Appeal:
We are deeply concerned about the 30-day post CABG all-cause mortality as a quality metric. This should be reconsidered.
As palliative medicine clinicians, we see the detrimental effects of the delay of palliative care for our most vulnerable and sick patients.We routinely see how patient care can be dictated not by a patient's wishes but rather by a doctor trying to satisfy quality and number expectations. Using quality measures is important but not if the specific measuring tool leads to increased suffering.
Higher risk surgery may be indicated in certain situations. If a patient or family consents to such a risky surgery, should they be penalized by having to continue with aggresive care for up to 30 days even after poor outcomes? A patient's option to switch to a comfort approach or less aggressive care should not be influenced by a clinician's fear to maintain arbitrary quality measures.

Appeal Submitter

Ministry Health Care
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Summary of Appeal:

Please reconsider addition of 30-day post CABG all-cause mortality as a quality metric. Surgeons often struggle to withdraw life supporting treatments on postoperative patients despite patient or family preferences. While this conflict genuinely stems from deep notions of responsibility our data demonstrate that surgeons who report concern about profiling are more likely to refuse to withdraw life support before POD 30. This game-able metric harms patients and families, the surgeon patient relationship and fails to capture important safety information. Consider the patient who spends 24 hours in ICU and is discharged to home post-operative day 5 versus the patient who has the same operation, spends 20 days in ICU, is transferred to an LTAC and then palliative care on POD 32. These vastly different outcomes are not captured by the equivalent 30-day survival assigned to both episodes: it fails to capture what is truly valuable to patients who don’t want to live to just 30 days.

Failure-to-Pursue Rescue

Explaining Excess Mortality in Elderly Emergency General Surgical Patients with Preexisting "Do-Not-Resuscitate" Orders

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Objective: To describe the outcomes of elderly patients with do-not-resuscitate (DNR) status who undergo emergency general surgery and to improve understanding of the relationship between preoperative DNR status and postoperative mortality.

Background: Preoperative DNR status has previously been shown to predict increased postoperative mortality, although the reasons for this association are not well understood.

Methods: Patients 65 years or older undergoing emergency operation for 1 of 10 common general surgical diagnoses were extracted from the 2005–2010 National Surgical Quality Improvement database. Propensity score techniques were used to match patients with and without preoperative DNR orders on indication for procedure, patient demographics, comorbid disease burden, acute physical status at the time of operation, and procedure complexity. The postoperative outcomes of this matched cohort were then compared.

Results: A total of 25,558 patients were included for analysis (DNR, n =1061; non-DNR, n =24,497). DNR patients seemed to be more acutely and chronically ill than non-DNR patients in the overall study sample but did not seem to be treated less aggressively before or during their operations. Propensity-matching techniques resulted in the creation of a cohort of DNR and non-DNR patients who were well matched for all preoperative and intraoperative variables. DNR patients from the matched cohort had a significantly higher postoperative mortality rate than non-DNR patients (36.9% vs 22.3%, $P < 0.0001$) despite having a similar rate of major postoperative complications (42.1% vs 40.2%, $P = 0.38$). DNR patients in the propensity-matched cohort were much less likely to undergo reoperation (8.3% vs 12.0%, $P = 0.006$) than non-DNR patients and were significantly more likely to die in the setting of a major postoperative complication (56.7% vs 41.4%, $P = 0.001$).

Conclusions: Emergency general surgery in elderly patients with preoperative DNR orders is associated with significant rates of postoperative morbidity and mortality. One reason for the excess mortality in these patients, relative to otherwise similar patients who do not have preoperative DNR orders, may be their greater reluctance to pursue aggressive management of major complications in the postoperative period.

Keywords: acute care surgery, do not resuscitate, failure to rescue, geriatrics, general surgery, geriatrics, failure to rescue do not resuscitate palliative surgery general surgery

(*Ann Surg* 2012;256: 453–461)

General surgeons increasingly care for elderly patients who develop acute surgical disease in the setting of a preexisting do-not-resuscitate (DNR) order or other advanced directive.[1,2] In the emergency setting, there is little time for these patients to weigh their previously asserted preference against aggressive medical intervention against an assuredly grim prognosis should such intervention be declined. The surgical literature currently lacks a comprehensive description of what these patients might expect should they opt to pursue emergency general surgery. Instead, patients must rely on the anecdotal experience of their surgeon when deciding whether the potential outcomes associated with emergency operation are consistent with their overall goals of care. A clearer understanding of the likely postoperative outcomes in this growing population of patients would not only enable surgeons to provide patients with more informed counsel but might also influence patient preference regarding the desirability of aggressive surgical intervention.[3–5]

The presence of a preoperative DNR order has previously been shown to have an independent association with postoperative mortality among adults undergoing surgical procedures.[6,7] Although the underlying reason for this association is not clear, several potential explanations exist. DNR status may simply serve as a marker of overall health, with patients who have preoperative DNR orders being more prone to postoperative morbidity and mortality because of more extensive and severe comorbid disease relative to patients without such orders.[7,8] Alternatively, there is some concern based on published evidence that patients with DNR orders may receive less aggressive care due to a false perception among health care providers that a patient's DNR status reflects his or her attitude toward medical care in general.[1,9,10] Finally, it is also possible that the patients themselves may opt against aggressive management in the postoperative period despite having given their consent to the index operation, either because they have had more time to consider their goals of care or because an unexpected or unwanted event has occurred in the postoperative period.[3]

The objectives of our study were (1) to provide a description of anticipated postoperative outcomes following emergency general surgical procedures in patients with and without DNR orders and (2) to improve understanding of the relationship between preoperative DNR status and postoperative mortality. We hope that these data can be used to better inform the decisions of elderly DNR patients who must decide whether or not to accept emergency operative intervention for acute surgical disease.

METHODS

Patients from the 2005 to 2010 American College of Surgeons National Surgical Quality Improvement Program Participant User Files were included for analysis if they were 65 years or older and underwent an emergency operation for 1 of 10 common general surgical conditions (as determined by the postoperative *International Classification of Diseases, Ninth Revision, Clinical Modification*, code). These diagnoses included acute appendicitis, intestinal obstruction, gallbladder disease, intestinal ischemia, ventral hernia, intestinal perforation, diverticular disease, groin hernia, gastroduodenal ulcer, and colorectal malignancy. Patients with missing data for any of the data variables (except for preoperative serum albumin level) that were used in the analysis were excluded from the study. Patients without recorded albumin levels in our analysis were

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assumed to not have serum albumin levels checked, as opposed to levels checked but not recorded. We therefore considered preoperative serum albumin as a 3-level categorical variable (*normal*, *low*, or *not checked*).

The primary predictor variable for our analysis was patient preoperative DNR status (DNR vs non-DNR). The American College of Surgeons National Surgical Quality Improvement Program defines DNR as the presence of an order signed or cosigned by an attending physician in the 30 days before surgery (regardless of whether the DNR order was subsequently rescinded immediately before the index operation).[11] Patients with whom a DNR order had been discussed but not formally ordered and signed by an attending physician were not considered to belong to the DNR group. Numerous other predictor variables were also included in our analysis to adequately account for patient demographics, chronic comorbid conditions (including the presence of physical debilitation), acute preoperative patient condition, and complexity of the index emergency operation (Tables 1–4). Continuous predictor variables such as patient age, body mass index, operative time, and total work relative value units associated with the index operation were transformed into multilevel categorical variables whenever possible to facilitate statistical analyses and presentation of results. Total work relative value units were included in our analysis as an indicator of the complexity of the index operation received by each patient in our sample.[12] Preoperative blood transfusion and preoperative mechanical ventilation, which were included as variables reflective of acute preoperative patient condition, were also considered to represent potential markers of aggressiveness of preoperative care. Similarly, operative time and total work relative value units, which were included as variables reflective of intraoperative conduct, were considered to represent potential markers of aggressiveness of intraoperative care.

The primary outcome variable for our analysis was overall 30-day postoperative mortality. Secondary outcome variables included 30-day major postoperative complication rate, failure-to-rescue rate (defined as postoperative mortality in the setting of 1 or more major complications), reoperation within 30 days of the index procedure, and length of postoperative hospitalization (assuming postoperative survival).[13,14] For the purpose of our analysis, patients were considered to have a major complication if they developed 1 or more of the following specific complications within 30 days of their index operation: organ/space surgical site infection, wound dehiscence, pneumonia, pulmonary embolism, mechanical ventilatory requirement greater than 48 hours, unplanned reintubation, cardiac arrest requiring cardiopulmonary resuscitation, myocardial infarction, progressive renal insufficiency, acute renal failure requiring dialysis, stroke, coma length greater than 24 hours, failure of graft/prosthesis requiring intervention, bleeding requiring more than 3 units of packed red blood cells within 72 hours after index operation, systemic sepsis, and/or septic shock. Other complications that are tracked by the American College of Surgeons National Surgical Quality Improvement Program but that were not considered to be major complications in our analysis included superficial surgical site infection, deep incisional surgical site infection, urinary tract infection, deep venous thrombosis, and peripheral nerve injury.

Using the entire American College of Surgeons National Surgical Quality Improvement Program sample of elderly emergency general surgical patients, univariate comparison of preoperative/intraoperative variables for the DNR versus non-DNR groups was performed using Pearson χ^2 tests for categorical variables and Wilcoxon rank sum tests for continuous variables. Propensity score-matching techniques were then used in an attempt to draw from the overall American College of Surgeons National Surgical Quality Improvement Program study sample a well-matched cohort of non-DNR and DNR patients for comparison of postoperative outcomes. In brief, a multivariate logistic regression model was used to identify predictors of a patient's chances of having a preoperative DNR order. Potential predictor variables in this regression model included all patient- and procedure-related characteristics (Tables 1–4) that had a significant association with preoperative DNR status at the $P < 0.1$ level. A propensity score for having a preoperative DNR order was then calculated for each patient in the overall study sample using logit coefficients for the predictors that were derived from the regression model. These propensity scores were then applied to create an evenly matched cohort of DNR and non-DNR patients, using a caliper-matching algorithm (with caliper distance of 0.005), with controls being used only once in the matching. The desired result of this process was for each DNR patient included in the cohort to have a non-DNR counterpart who was well matched with respect to preoperative and intraoperative characteristics. Comparisons of the perioperative characteristics and postoperative outcomes of the DNR versus non-DNR members of this matched cohort of patients were then performed using McNemar χ^2 tests for binary categorical variables, conditional logistic regression for multilevel categorical variables, and the Wilcoxon signed rank sum test for the length of postoperative hospitalization. Comparison of the complication-specific postoperative mortality rates of the DNR versus non-DNR members of the matched cohort was also performed using Pearson χ^2 tests. All statistical analyses were performed using Stata Version 11.0 (College Station, TX).

RESULTS

A total of 25,558 patients who met our inclusion criteria and had complete information for all variables were included for analysis. Of these, 1061 patients (4.2%) had preoperative DNR orders in place before their index operation (DNR group) whereas 24,497 (95.9%) did not have such orders (non-DNR group). Tables 1 to 4 show the preoperative and operative characteristics for the overall American College of Surgeons National Surgical Quality Improvement Program study sample, stratified by preoperative DNR status. In general, DNR patients were older, more likely to be female, and more likely to be underweight or normal in weight than non-DNR patients. DNR patients were also more likely than non-DNR patients to be admitted to the hospital preoperatively rather than taken to the operating room from the emergency department (66.5% vs 45.2%).

Table 2 shows variables reflective of functional status and chronic comorbid illness for all patients in our study. DNR patients were significantly more likely than non-DNR patients to show evidence of functional impairment (as seen by a higher incidence of nonindependent baseline functional status and decreased physical mobility due to neurological conditions). DNR patients were also more likely to be chronically ill, having a significantly higher incidence than non-DNR patients in 7 of the 9 comorbid conditions that were included in our analysis. Similarly, DNR patients also seemed to be more acutely ill upon presentation to the hospital than non-DNR patients as suggested by a comparison of markers of acute patient physiological status (Table 3). For example, DNR patients were twice as likely as non-DNR patients (52.6% vs 26.7%) to be assigned an American Society of Anesthesiologists' Physical Status Classification of 4 or more (American Society of Anesthesiologists' class 4 corresponds to having a severe systemic disease that presents a constant threat to life). DNR patients were also less likely to have a normal preoperative serum albumin level than non-DNR patients and more likely to present with sepsis or septic shock. DNR patients were also more likely to receive significant preoperative transfusion (define by the American College of Surgeons National Surgical

TABLE 1. Demographic Characteristics of All Elderly NSQIP Patients Undergoing Emergency General Surgery, Stratified by Preoperative DNR Status

	DNR (N = 1,061)	Non-DNR (N = 24,497)	*P*
Patient age, yr			<0.0001
65–69	70 (6.6%)	6,096 (24.9%)	
70–74	86 (8.1%)	5,002 (20.4%)	
75–79	153 (14.4%)	4,914 (20.1%)	
80–84	250 (23.6%)	4,381 (17.9%)	
85–89	272 (25.6%)	2,823 (11.5%)	
≥90	230 (21.7%)	1,281 (5.2%)	
Female	701 (66.1%)	13,596 (55.5%)	<0.0001
Body mass index			<0.0001
Underweight (<20 kg/m^2)	222 (20.9%)	3,676 (15.0%)	
Normal (20–24 kg/m^2)	360 (33.9%)	7,289 (29.8%)	
Overweight (25–29 kg/m^2)	291 (27.4%)	7,342 (30.0%)	
Obese (≥ 30 kg/m^2)	188 (17.7%)	6,190 (25.3%)	
Preoperative admission status			<0.0001
Not admitted	356 (33.6%)	13,428 (54.8%)	
Admitted to surgical service	340 (32.1%)	5,913 (24.1%)	
Admitted to nonsurgical service	365 (34.4%)	5,156 (21.1%)	
Intraoperative surgical trainee participation	604 (56.9%)	14,847 (60.6%)	0.02

NSQIP indicates National Surgical Quality Improvement Program; kg, kilogram; m, meter.

TABLE 2. Cognitive/Functional Status and Chronic Comorbid Conditions for All Elderly NSQIP Patients Undergoing Emergency General Surgery, Stratified by Preoperative DNR Status

	DNR (N = 1,061)	Non-DNR (N = 24,497)	*P*
Nonindependent functional status	335 (31.6%)	2,017 (8.2%)	<0.0001
Decreased physical mobility	62 (5.8%)	513 (2.1%)	<0.0001
Diabetes mellitus	212 (20.0%)	4,557 (18.6%)	0.26
Chronic obstructive pulmonary disease	207 (19.5%)	3,008 (12.3%)	<0.0001
Congestive heart failure	95 (9.0%)	829 (3.4%)	<0.0001
Coronary artery disease	234 (22.1%)	4,920 (20.1%)	0.12
Renal dysfunction	91 (8.6%)	1,285 (5.3%)	<0.0001
Chronic steroid use	94 (8.9%)	1,535 (6.3%)	0.001
Bleeding disorder	247 (23.3%)	4,063 (16.6%)	<0.0001
Known malignancy	88 (8.3%)	1,125 (4.6%)	<0.0001
Cerebrovascular disease	266 (25.1%)	2,959 (12.1%)	<0.0001

NSQIP indicates National Surgical Quality Improvement Program.

Quality Improvement Program as >4 units of packed red blood cells in the 72 hours before operation) but were not more likely to require preoperative mechanical ventilation.

Table 4 shows the intraoperative characteristics of all patients included in the study. Although there is no indication in the American College of Surgeons National Surgical Quality Improvement Program about the extent to which a patient's ultimate surgical diagnosis might be known preoperatively, DNR patients were more likely than non-DNR patients to receive a postoperative diagnosis of intestinal obstruction, intestinal ischemia, gastroduodenal ulcer disease, or complications of colorectal malignancy. Overall, operative time and total work relative value units (which we considered a marker of procedure complexity) were significantly greater in DNR patients than in non-DNR patients. When compared individually for each of the 10 postoperative diagnosis classifications included in our analysis, median operative time differed between the 2 groups only in patients with colorectal malignancy (with DNR patients having a shorter median operative time than non-DNR patients; data not shown). Conversely, the median total work relative value units associated with index operation did not differ between the 2 groups for 7 of the diagnoses and was greater in the DNR group for 3 of the diagnoses (intestinal obstruction, acute appendicitis, and gallbladder disease; data not shown). Finally, DNR patients were significantly more likely than non-DNR patients to require intraoperative transfusion of blood products.

Table 5 shows the primary and secondary postoperative outcomes for all elderly DNR patients from the overall American College of Surgeons National Surgical Quality Improvement Program study sample. Thirty-day postoperative mortality rate ranged from 9.4% (for operations related to a ventral hernia complication) to 55.6% (for operations related to intestinal perforation), whereas the major complication rate ranged from 26.0% (for operations related to gallbladder disease) to 60.0% (for operations related to gastroduodenal ulcer disease). The overall failure-to-rescue rate (defined as mortality in the setting of 1 or more major postoperative complications) was 57.0%, with diagnosis-specific rates ranging from 22.7% (for operations related to a ventral hernia complication) to 65.8% (for operations related to diverticular disease).

Propensity score matching was performed to adjust as much as possible for known and potentially unknown differences between DNR and non-DNR patients when comparing the outcomes of these

TABLE 3. Acute Physiological Characteristics for All Elderly NSQIP Patients Undergoing Emergency General Surgery, Stratified by Preoperative DNR Status

	DNR (N = 1,061)	Non-DNR (N = 24,497)	*P*
Acute coma or impaired sensorium	130 (12.3%)	1,271 (5.2%)	<0.0001
ASA physical status class ≥4	558 (52.6%)	6,546 (26.7%)	<0.0001
Preoperative mechanical ventilation	68 (6.4%)	1,264 (5.2%)	0.07
Preoperative infected wound	78 (7.4%)	973 (4.0%)	<0.0001
Preoperative transfusion	49 (4.6%)	622 (2.5%)	<0.0001
Prior operation within 30 d	49 (4.6%)	1,334 (5.5%)	0.24
Preoperative albumin			<0.0001
Normal (≥3.5 mg/dL)	259 (24.4%)	10,310 (42.1%)	
Low (<3.5 mg/dL)	626 (59.0%)	8,574 (35.0%)	
Not checked	176 (16.6%)	5,613 (22.9%)	
Preoperative sepsis classification			<0.0001
None	482 (45.4%)	13,699 (55.9%)	
SIRS	297 (28.0%)	6,268 (25.6%)	
Sepsis	148 (14.0%)	2,779 (11.3%)	
Septic shock	134 (12.6%)	1,751 (7.2%)	

NSQIP indicates National Surgical Quality Improvement Program; ASA, American Society of Anesthesiologists; SIRS, systemic inflammatory response syndrome.

TABLE 4. Intraoperative Characteristics for All Elderly NSQIP Patients Undergoing Emergency General Surgery, Stratified by Preoperative DNR Status

	DNR (N = 1,061)	Non-DNR (N = 24,497)	*P*
Diagnosis			<0.0001
Intestinal obstruction	310 (29.2%)	5,380 (22.0%)	
Acute appendicitis	50 (4.7%)	4,736 (19.3%)	
Gallbladder disease	104 (9.8%)	2,510 (10.3%)	
Intestinal ischemia	144 (13.6%)	2,196 (9.0%)	
Ventral hernia	53 (5.0%)	1,930 (7.9%)	
Intestinal perforation	72 (6.8%)	1,796 (7.3%)	
Diverticular disease	77 (7.3%)	1,751 (7.2%)	
Groin hernia	65 (6.1%)	1,597 (6.5%)	
Gastroduodenal ulcer	90 (8.5%)	1,420 (5.8%)	
Colorectal malignancy	96 (9.1%)	1,181 (4.8%)	
Operative time			<0.0001
<50 min	187 (17.6%)	5,726 (23.4%)	
50–79 min	302 (28.5%)	7,052 (28.8%)	
80–119 min	319 (30.1%)	6,132 (25.0%)	
≥120 min	253 (23.9%)	5,587 (22.8%)	
Contaminated/dirty incisional wound	535 (50.4%)	12,920 (52.7%)	0.14
Intraoperative transfusion	139 (13.1%)	2,168 (8.9%)	<0.0001
Total work relative value units			<0.0001
<12	118 (11.1%)	6,003 (24.5%)	
12–22	272 (25.6%)	6,295 (25.7%)	
23–36	304 (28.7%)	6,122 (25.0%)	
≥37	367 (34.6%)	6,077 (24.8%)	

NSQIP indicates National Surgical Quality Improvement Program.

2 groups. Such adjustment seemed particularly necessary, given the many aforementioned differences that resulted between these groups upon analysis of the overall study sample. As shown in Table 6, the propensity-matching algorithm that we used resulted in a smaller cohort of non-DNR patients that seemed to be very well matched to DNR patients for all of the patient- and operation-related variables that were available for risk adjustment. A comparison of the postoperative outcomes of this matched cohort is shown in Table 7. Although 30-day postoperative mortality was significantly greater in DNR patients [36.9% vs 22.3%, odds ratio for mortality in DNR group = 2.07 (95% confidence interval, 1.69–2.55)], there was no significant difference between the 2 groups in the incidence of major postoperative complications [42.1% for DNR patients vs 40.2% for non-DNR patients, odds ratio for major postoperative complication in DNR patients = 1.08 (95% confidence interval, 0.91–1.29)]. Among those patients who did sustain 1 or more complications, subsequent mortality (ie, failure-to-rescue) was significantly higher in the DNR group than in the non-DNR group. Furthermore, DNR patients were significantly less likely than non-DNR patients to undergo reoperation within 30 days after index operation. Preoperative DNR status did not have a significant effect on postoperative length of hospitalization.

Figure 1 shows the mortality rates of patients from the propensity-matched cohort who suffered specific postoperative complications. Several complications (such as stroke, coma, or

TABLE 5. Postoperative Outcomes After Emergency General Surgery for All Elderly NSQIP Patients With a Preoperative DNR Order, Stratified by Postoperative Diagnosis

Postoperative Diagnosis (No. Patients in "DNR" Group)	30-Day Mortality	30-Day Major Complication	Failure –to Rescue	Reoperation	Postoperative LOS (Among Survivors), d
Intestinal obstruction (n = 310)	100 (32.3%)	127 (41.0%)	9 (54.3%)	24 (7.7%)	9 (6–14)
Acute appendicitis (n = 50)	9 (18.0%)	18 (36.0%)	8 (44.4%)	3 (6.0%)	5 (3–8)
Gallbladder disease (n = 104)	24 (23.1%)	27 (26.0%)	17 (63.0%)	4 (3.9%)	5 (3–8)
Intestinal ischemia (n = 144)	89 (61.8%)	72 (50.0%)	49 (68.1%)	18 (12.5%)	12 (8–16)
Ventral hernia (n = 53)	5 (9.4%)	22 (41.5%)	5 (22.7%)	8 (15.1%)	8 (5–14.5)
Intestinal perforation (n = 72)	40 (55.6%)	39 (54.2%)	23 (59.0%)	5 (6.9%)	10.5 (8–17)
Diverticular disease (n = 30)	30 (39.0%)	38 (49.4%)	25 (65.8%)	7 (9.1%)	9 (7–13)
Groin hernia (n = 65)	18 (27.7%)	19 (29.2%)	11 (57.9%)	6 (9.2%)	5 (3–8)
Gastroduodenal ulcer (n = 90)	48 (53.3%)	54 (60.0%)	30 (55.6%)	5 (5.6%)	13 (9–17)
Colorectal malignancy (n = 32)	32 (33.3%)	30 (31.3%)	17 (56.7%)	7 (7.3%)	8 (6.5–10)
Total (N = 1061)	395 (37.2%)	446 (42.0%)	254 (57.0%)	87 (8.2%)	8 (6–13)

NSQIP indicates National Surgical Quality Improvement Program; LOS, length of stay.

cardiac arrest) were associated with high mortality rates in both the DNR and non-DNR groups. Other complications (such as renal insufficiency, myocardial infarction, organ/space surgical site infection, or pneumonia) were associated with significantly higher mortality rates for DNR patients than for non-DNR patients.

DISCUSSION

Our analysis of more than 25,000 patients in the American College of Surgeons National Surgical Quality Improvement Program database shows that elderly patients who undergo emergency general surgical procedures suffer very high mortality and morbidity and that they are more likely to die within 30 days of the operation if they carried DNR orders preoperatively. Although the alternative for many of these patients should they have refused operation would have been likely death, the findings of our study nevertheless serve to underscore the ominous outcomes associated with emergency general surgical intervention in the elderly population. To our knowledge, this is the most detailed description of early postoperative outcomes among elderly DNR patients requiring emergency general surgery to be published. Our specification of diagnosis-specific postoperative mortality and morbidity rates will enable general and acute care surgeons to use objective data rather than anecdotal observation when advising elderly DNR patients about the anticipated risks of emergency operation. Although a better understanding of these outcomes may not alter a patient's decision to undergo operation, it will nevertheless provide surgeons with greater confidence in their ability to provide unbiased counsel to patients and/or their health care proxies. Alternatively, receiving a more objective presentation of potential postoperative outcomes may dissuade some patients from pursuing emergency operation, depending on their particular goals of care.[3] Either way, studies drawn from the oncology literature clearly demonstrate that the quality of prognostic information can have a significant effect on patient treatment decisions.[4,5] Therefore, any resource that adds to the ability of surgeons to predict postoperative outcomes in the elderly population must necessarily be viewed as useful.

In addition to its practical utility, the findings of our study may also help to elucidate potential causes for the independent association between preoperative DNR status and postoperative mortality that we and others have demonstrated.[6,7] Specifically, we believe that the major contributing factor for the higher mortality among DNR patients in our propensity-matched cohort was their greater likelihood (compared with non-DNR patients) of succumbing to major postoperative complications. Although "failure to rescue" is the traditional term that is used to describe death in the setting of postoperative complications, such a moniker is potentially misleading when used to describe mortality among patients who undergo emergency operation.[13,14] "Failure to rescue" implies that patient death due to postoperative complications has occurred despite every and all attempts to prevent such death. A close examination of the findings of our analysis suggests "failure-to-pursue rescue" as a more accurate descriptor of the excess mortality suffered by elderly DNR patients who experience major postoperative complications, as this term better reflects the possible disinclination among such patients to accept aggressive management of these complications.

The results of our analysis do not suggest that increased presence and/or severity of comorbid illnesses are responsible for the greater postoperative mortality rates experienced by DNR patients. Although DNR patients in our overall study sample did seem to be more acutely and chronically ill than non-DNR patients, our use of propensity matching seemed to adequately adjust for this baseline difference in health status. Specifically, the non-DNR patients who were included in our smaller, propensity-matched cohort were uniformly well matched to DNR patients with respect to incidence and severity (when severity is known) of all of the preoperative variables included in our analysis. In addition, preoperative DNR status did not seem to influence the incidence of major postoperative complications in our matched cohort (40.2% for non-DNR patients vs 42.1% for DNR patients, $P = 0.38$). We would have expected to find a higher rate of major postoperative complications in DNR patients if they were in some way "sicker" than the non-DNR patients who were included in our matched cohort. In the absence of such a finding, we cannot conclude that disparate degrees of comorbid illness explain the discrepancy in surgical mortality that we describe.

Similarly, our findings do not support the existence of an overt bias among physicians against aggressive preoperative or intraoperative management of elderly DNR patients. Our inclusion of markers of aggressiveness of preoperative/intraoperative care in our propensity-matching algorithm theoretically adjusts for such differences. Even before this adjustment, however, a comparison of the unmatched study sample suggests that DNR patients were managed just as aggressively as non-DNR patients in the preoperative period. For example, DNR patients were as likely or more likely to receive packed red blood cell transfusion and/or mechanical ventilation before operation. Similarly, a review of diagnosis-specific operative times and total work relative value units suggests that the operations performed in DNR patients were just as complex as those performed in non-DNR patients. Taken together, these findings argue against less aggressive preoperative or

TABLE 6. Perioperative Characteristics of Propensity-Matched Cohort of Elderly Patients Undergoing Emergency General Surgery, Stratified by Preoperative DNR Status

	DNR (N = 1053)	Non-DNR (N = 1053)	*P*
Female	693 (65.8%)	690 (65.5%)	0.89
Body mass index			0.38
Underweight (<20 kg/m^2)	357 (33.9%)	376 (35.7%)	
Normal (20–24 kg/m^2)	220 (20.9%)	220 (20.9%)	
Overweight (25–29 kg/m^2)	290 (27.5%)	289 (27.5%)	
Obese (≥ 30 kg/m^2)	186 (17.7%)	168 (16.0%)	
Patient age, yr			0.14
65–69	70 (6.7%)	56 (5.3%)	
70–74	86 (8.2%)	88 (8.4%)	
75–79	153 (14.5%)	172 (16.3%)	
80–84	250 (23.7%)	255 (24.2%)	
85–89	269 (25.6%)	273 (25.9%)	
≥90	225 (21.4%)	209 (19.9%)	
Nonindependent functional status	328 (31.2%)	321 (30.5%)	0.71
Decreased physical mobility	60 (5.7%)	57 (5.4%)	0.77
Chronic obstructive pulmonary disease	204 (19.4%)	206 (19.6%)	0.91
Congestive heart failure	92 (8.7%)	98 (9.3%)	0.65
Renal dysfunction	91 (8.6%)	95 (9.0%)	0.76
Chronic steroid use	94 (8.9%)	81 (7.7%)	0.30
Bleeding disorder	246 (23.4%)	250 (23.7%)	0.84
Known malignancy	87 (8.3%)	93 (8.8%)	0.64
Cerebrovascular disease	261 (24.8%)	270 (25.6%)	0.65
Acute coma or impaired sensorium	126 (12.0%)	114 (10.8%)	0.40
ASA physical status class ≥4	550 (52.2%)	575 (54.6%)	0.24
Preoperative mechanical ventilation	68 (6.5%)	82 (7.8%)	0.24
Preoperative infected wound	77 (7.3%)	70 (6.7%)	0.54
Preoperative transfusion	49 (4.7%)	50 (4.8%)	0.92
Preoperative albumin			0.88
Normal (≥ 3.5 mg/dL)	259 (24.6%)	257 (24.4%)	
Low (< 3.5 mg/dL)	618 (58.7%)	627 (59.5%)	
Not checked	176 (16.7%)	169 (16.1%)	
Preoperative sepsis classification			0.74
None	480 (45.6%)	482 (45.8%)	
SIRS	294 (27.9%)	278 (26.4%)	
Sepsis	148 (14.1%)	148 (14.1%)	
Septic shock	131 (12.4%)	145 (13.8%)	
Operative time			0.60
<50 min	187 (17.8%)	204 (19.4%)	
50–79 min	298 (28.3%)	291 (27.6%)	
80–119 min	317 (30.1%)	305 (29.0%)	
≥120 min	251 (23.8%)	253 (24.0%)	
Intraoperative transfusion	139 (13.2%)	145 (13.8%)	0.92
Total work relative value units			0.97
<12	118 (11.2%)	112 (10.6%)	
12–22	270 (25.6%)	271 (25.7%)	
23–36	302 (28.7%)	308 (29.3%)	
≥37	363 (34.5%)	362 (34.4%)	
Diagnosis			0.98
Intestinal obstruction	308 (29.3%)	313 (29.7%)	
Acute appendicitis	50 (4.8%)	42 (4.0%)	
Gallbladder disease	103 (9.8%)	109 (10.4%)	
Intestinal ischemia	143 (13.6%)	155 (14.7%)	
Ventral hernia	53 (5.0%)	46 (4.4%)	
Intestinal perforation	72 (6.8%)	74 (7.0%)	
Diverticular disease	76 (7.2%)	77 (7.3%)	
Groin hernia	65 (6.2%)	60 (5.7%)	
Gastroduodenal ulcer	90 (8.6%)	84 (8.0%)	
Colorectal malignancy	93 (8.8%)	93 (8.8%)	
Preoperative admission status			0.95
Not admitted	355 (33.7%)	351 (33.3%)	
Admitted to surgical service	336 (31.9%)	333 (31.6%)	
Admitted to Nonsurgical service	362 (34.4%)	369 (35.0%)	
Intraoperative resident participation	602 (57.2%)	621 (59.0%)	0.39

ASA indicates American Society of Anesthesiologists; SIRS, systemic inflammatory release syndrome.

TABLE 7. Postoperative Outcomes of Propensity-Matched Cohort of Elderly Patients Undergoing Emergency General Surgery, Stratified by Preoperative DNR Status

	DNR (N = 1053)	Non-DNR (N = 1053)	Odds Ratio (95% CI)
30-d mortality	388 (36.9%)	235 (22.3%)	2.07 (1.69–2.55), $P < 0.0001$
Major complication	443 (42.1%)	423 (40.2%)	1.08 (0.91–1.29), $P = 0.38$
Failure-to-rescue	251 (56.7%)	175 (41.4%)	2.07 (1.30–3.38), $P = 0.001$
Reoperation	87 (8.3%)	126 (12.0%)	0.67 (0.50–0.90), $P = 0.006$
Postoperative length of stay	8 (6–13)	9 (6–15)	0.12

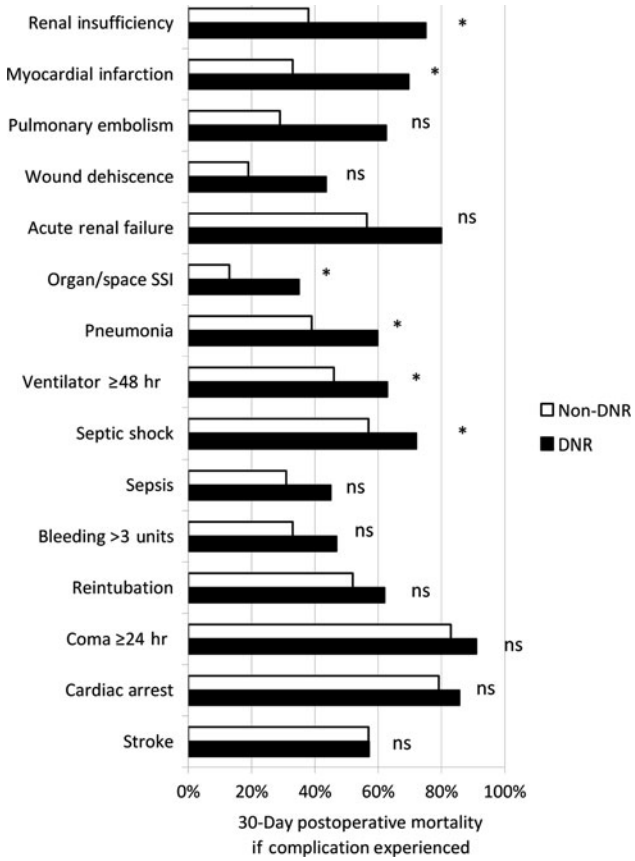

FIGURE 1. Postoperative mortality rates associated with specific complications for propensity-matched cohort, stratified by preoperative DNR status. Asterisk (*) indicates $P < 0.05$ in univariate comparison of complication-specific mortality rates of DNR versus non-DNR patients from propensity-matched cohort; "ns," $P > 0.05$.

intraoperative care as a reason for the higher postoperative mortality experienced by elderly DNR patients.[12,15,16]

The reason for increased mortality among DNR patients that is best supported by the findings of our study is that such patients are less likely than non-DNR patients to receive aggressive therapy for major postoperative complications. Approximately 57% of DNR patients from our matched cohort died after developing a major postoperative complication compared with 41% of non-DNR patients, despite the fact that the 2 groups had no detectable difference in their physiological ability to withstand such complications. Further evidence of failure-to-pursue rescue as the primary reason for the association between preoperative DNR status and postoperative mortality is the finding that DNR patients from the matched cohort were significantly less likely than non-DNR patients to undergo reoperation in the postoperative period. Although the American College of Surgeons National Surgical Quality Improvement Program does not provide information on the indication for reoperation, we have no reason to expect this indication to differ between the 2 groups of our matched cohort. Therefore, we believe that the lower reoperation rate among DNR patients from our matched cohort reflects the fact that they are less likely to consent to such intervention when it is indicated.

An elderly patient's decision to undergo emergency operation is time sensitive and often made in the setting of severe physical discomfort. Our findings suggest that although many such patients will consent to emergency surgery, they will be more likely to decline aggressive medical intervention in the postoperative period if they had established DNR directives in place before the procedure. Although such behavior may seem paradoxical (accepting maximally invasive treatment in the form of emergency operation but declining less invasive treatment in the form of management of major complications), it seems more logical when viewed within the framework of "patient's goals of care."[3] Patients may be willing to undergo emergency operation for a life-threatening disease process knowing that they will be provided general anesthesia during the operation and that there is a reasonable chance that surgery will immediately improve their pain and definitively treat the cause of that pain. Upon further reflection in the postoperative period (especially in the setting of a major complication), they may discover that the procedure has left them more debilitated or that the postoperative discomfort is worse than they had hoped. As a result, their willingness to undergo continued aggressive management becomes more closely aligned with the reality of their postoperative course. Support for the impact of complications of medical care on patient preference for such care comes from a multicenter study by Nathens et al[17] of predictors of patient DNR status after severe traumatic injury. These authors found that the development of postinjury complications that resulted in end-organ dysfunction was independently associated with a patient being designated as DNR during his or her postinjury hospitalization.

Our analysis does indicate certain specific postoperative complications for which the discrepancy in subsequent mortality between non-DNR and DNR patients is relatively large. For example, we found DNR patients to be significantly more likely than non-DNR to die in the setting of postoperative renal insufficiency, myocardial infarction, organ/space surgical site infection, and pneumonia. If these discrepancies in complication-specific mortality are in fact due to a higher rate of failure-to-pursue rescue among DNR patients, then such patients may benefit from knowing that there is a possibility of improved survival should they accept aggressive management of these specific complications. Whether this improved understanding will alter the decision to forego such management will ultimately depend on a variety of factors, including individual goals of care and the perceived invasiveness of the management needed to treat the complication.

Our analysis has several important limitations. First, we lack the necessary patient-level information to conclusively determine context in which patient deaths occurred Prospective survey analysis will ultimately be required to confirm the extent to which failure-to-pursue rescue explains the excess mortality that elderly DNR patients experience after emergency general surgery. Second, the contribution that attending surgeon input has on a patient's decision to reject aggressive management of postoperative complications also cannot be assessed using information from data sources such as the American College of Surgeons National Surgical Quality Improvement Program. Third, the results of our analysis do not necessarily extend to nonelderly patients or to patients who undergo elective surgical intervention. Fourth, because the American College of Surgeons National Surgical Quality Improvement Program includes only patients who underwent an operation, we do not know the outcomes of elderly DNR patients who present with acute surgical disease but who do not receive an operation. It may be that less invasive interventions (such as percutaneous cholecystostomy drain placement or intravenous antibiotics) may adequately alleviate the symptoms of such patients while enabling their short-term survival. However, a comparison of outcomes for the full spectrum of treatment options (operation intervention vs nonoperative intervention vs comfort care) is not possible using the American College of Surgeons National Surgical Quality Improvement Program.

Despite these limitations, our study demonstrates that emergency general surgery is associated with significant morbidity and mortality in elderly patients. Furthermore, our findings suggest that one reason for the excess mortality experienced by that subgroup of elderly patients who have preoperative DNR orders is their failure-to-pursue rescue when major postoperative complications occur. Although confirmation of this finding will require prospective survey analysis, it is nevertheless reasonable to expect that the results of our study will enable general surgeons to provide more accurate and therefore more useful prognostic information to elderly patients who develop emergency general surgical conditions.

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DISCUSSANT

DR. RONNIE ROSENTHAL (West Haven, CT): The population of the United States is clearly aging, and the most rapidly growing segment is those over age 85. It is estimated that by 2050, 20 million Americans will be 85 years old or older. How we as a nation will be able to provide cost-effective care to our oldest patients as they approach the end of life, within the context of the individual's goals and preferences, is a central issue in the current, contentious healthcare reform debate.

Recently, attention has focused on the large geographic variation in the rates of utilization of aggressive medical and surgical interventions at the end of life. This variability indicates that healthcare decisions at the end of life are complex and not likely governed by patient preference alone, but rather by a combination of factors, including availability of services and physician/surgeon practice patterns and attitudes.

I want to congratulate Dr. Scarborough and his colleagues on their efforts to shed some light on the surgical decision making process at the end of life by examining the factors that contribute to poor outcomes of emergency general surgery in DNR (Do-Not-Resuscitate) patients. This is a well-done study, using data from the ACS-NSQIP, which is a reliable, well-defined database with a large number of patients.

Dr. Scarborough, you demonstrated that patients with the clinical characteristics of DNR patients (that is, older and sicker than others) have a high complication rate whether or not they have a DNR. Both groups also had very high mortality and "failure to rescue from a complication" rates, although these rates were clearly significantly higher in the DNR patients.

In your conclusions, you state that the increase in mortality and "failure to rescue" in DNR patients is attributable to the patient (or, more likely, the surrogate) declining further intervention once a complication occurs.

If that is the case, how do suggest we use these data on "failure to rescue" to counsel the individual patient and his or her family who come to the ER in the middle of the night with an acute abdominal emergency? Do you think that this counseling should be substantively different in similarly ill patients who do not have a DNR order?

CLOSING DISCUSSANT

DR. JOHN E. SCARBOROUGH: You asked how we use this data to counsel patients prior to their operations. We hope that our findings will provide general and acute care surgeons and their elderly emergency surgical patients with an objective resource for determining anticipated postoperative outcomes. These patients need to know that their expected incidence of major postoperative complications

will be as high as 50%, and if they sustain one or more such complications their mortality will also approximate 50%. Whether this prognostic information will influence a patient's decision to proceed with emergency surgical intervention cannot be known.

There is evidence from the oncology literature that a better understanding of a patient's prognosis will affect his or her treatment decisions, particularly with regard to aggressive treatments, or treatment options that are associated with high morbidity or serious morbidity. Whether this extends to emergency surgery is unclear, since in most cases the alternative to operative management is a high likelihood of death.

Your second question was whether this discussion should differ between DNR patients and non DNR patients. DNR patients and their surrogates should be informed that they may develop postoperative complications that require aggressive or invasive management. Our findings suggest that many such patients decline aggressive management in the postoperative period, and this does need to be discussed preoperatively with DNR patients. However, a similar "failure-to-pursue-rescue" scenario is also probably likely to occur among elderly emergency surgery patients who do not have a preoperative DNR order. These patients also carry relatively high morbidity and mortality. Therefore, I do not think that the discussion should differ too much between DNR patients and non-DNR patients.

DISCUSSANT

DR. NORMAN ESTES (Peoria, IL): In the early 1990s, the JCHO required hospitals to include an advance directive on the chart of all patients being admitted. To accomplish this, most hospitals elected to have a nurse talk with the patient and create the advance directive or place it if it had previously been completed. I do not know that surgeons are doing this in many hospitals.

At our last M&M, we saw three patients, aged 90 or older, who died, and it appeared that most of the care was withdrawn from them because of the advanced directives. Do you think that surgeons should be more involved in the decision for advanced directive, and discuss this with patients prior to admission? The surgeon signs it, but does not have the discussion with the patient most frequently.

CLOSING DISCUSSANT

DR. JOHN E. SCARBOROUGH: Of note, NSQIP defines the DNR order, it requires the order to be signed or cosigned by the attending physician, with regards to your first comment.

As far as whether a surgeon should be more involved in conversations about advanced directives with patients, we do not know from NSQIP who has the conversation with the patient, but you are certainly correct that it is probably not the attending surgeon. Ideally, the surgeon should be more engaged in that conversation, although it does depend on the surgeon. It is a very delicate conversation that requires a fair amount of time. Conveying an accurate portrayal of likely postoperative outcomes is the most important contribution that the surgeon can provide to the conversation, though whether the surgeon or a geriatrician or palliative care physician leads the conversation is subject to debate. It is certainly important that the surgeon know a patient's intent in signing a DNR order, since as we know from the number of DNR patients in our study who received emergency surgery, DNR does certainly not mean "do not treat."

DISCUSSANT

DR. ANNA M. LEDGERWOOD (Detroit, MI): I think what you miss getting out of the NSQIP data is the little old lady who comes in with a back problem, has her operation, and postoperatively the family sees her and says, no, grandma would not want this, and recommends care be terminated., and that is what is happening, would be my interpretation of your data. I do not know how you get that out of the NSQIP data.

CLOSING DISCUSSANT

DR. JOHN E. SCARBOROUGH: That is a very important point, and our inability to define the context of patient deaths in our study is just one of its many limitations. We could actually spend ten minutes alone on the limitations of our study, but I do not think that particular abstract was accepted by the Program Committee. Further prospective evaluation of the effect of preoperative DNR status on surgical outcomes should clarify the context of patients' deaths, specifically whether they occurred before or after complications and whether "failure-to-pursue rescue" was the patient's decision or the surrogate's. I will say that a majority of patients who died postoperatively in the absence of identifiable major complications did so within the first few days of their operation. Some of these patients are likely the ones to which you refer, Dr. Ledgerwood.

DISCUSSANT

DR. MICHAEL ZENILMAN (Bethesda, MD): Your data is very similar to a recent paper published in *Annals of Surgery* eight months ago about abdominal surgery in nursing home patients (Finlayson et al, 254:921-6 2011). The authors noted very similar death and complication rates. I wonder if your cohort is similar-DNR patients and nursing home patients who undergo surgery- and whether DNR status can be used as a marker for risk.

Regarding Dr. Estes' question, there was an article in *Annals of Surgery* three months ago (Redmann et al 255:418–423, 2012) which showed that surgeons talk about advanced directives only 50% of the time. So, we really are not very good at talking about this with the patients in real time.

Lastly, the American College of Surgeons has a position statement on DNR in the OR, and they state that advanced directives should be suspended in the perioperative period. We all know that most complications that happen in the perioperative period are reversible. Were you able to isolate when the complications occurred in the postoperative period? Specifically, those that occur within two or three days of surgery are likely reversible and the ones that occur a week or so later are likely not; this could help explain your observations.

CLOSING DISCUSSANT

DR. JOHN E. SCARBOROUGH: We do know the date for diagnosis of complications, but did not look specifically at that data. We only looked at the date on death for those patients who suffered no complications and found that it tended to be very early postoperatively.

Appeal Submitter
The Johns Hopkins Hospital
Rebecca Aslakson
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Summary of Appeal:
This metric has unintended consequences that negatively impact patients, families, and providers. This metric implies that death is the worst possible perioperative outcome. However, for some, suffering instead may be far worse than death. Even with good surgery and attentive care, some patients have unforeseen perioperative consequences that leave them in a state of high suffering that the patient and/or family feel is clearly worse than death. At that point, patient-centered care compels the cardiac surgical team to adjust care to pursue comfort-related goals. Yet, with this metric, providers are penalized for such action. I've had palliative care colleagues explicitly told by surgical providers to "not come until 30 days after surgery", so that 30-day mortality rates are not impacted should the patient choose to pursue comfort-related goals. This metric perpetuates such non-patient-centered care and should be either modified to be sensitive to patient-reported goals or removed.

Appeal Submitter
University of Wisconsin
Margaret Schwarze
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Summary of Appeal:
Please reconsider addition of 30-day post CABG all-cause mortality as a quality metric. Surgeons often struggle to withdraw life supporting treatments on postoperative patients despite patient or family preferences. While this conflict genuinely stems from deep notions of responsibility our data demonstrate that surgeons who report concern about profiling are more likely to refuse to withdraw life support before POD 30. This game-able metric harms patients and families, the surgeon patient relationship and fails to capture important safety information. Consider the patient who spends 24 hours in ICU and is discharged to home post-operative day 5 versus the patient who has the same operation, spends 20 days in ICU, is transferred to an LTAC and then palliative care on POD 32. These vastly different outcomes are not captured by the equivalent 30-day survival assigned to both episodes which fails to capture what is truly valuable to patients who don't want to live to just 30 days.

The Role of Surgeon Error in Withdrawal of Postoperative Life Support

Margaret L. Schwarze, MD, MPP, Andrew J. Redmann, BA, BS,† Karen J. Brasel, MD, MPH,‡ and G. Caleb Alexander, MD, MS§‖*

Background: Surgeons may be reluctant to withdraw postoperative life support after a poor outcome.

Methods: A cross-sectional random sample was taken from a US mail survey of 2100 surgeons who routinely perform high-risk operations. We used a hypothetical vignette of a specialty-specific operation complicated by a hemiplegic stroke and respiratory failure. On postoperative day 7, the patient and family requested withdrawal of life-supporting therapy. We experimentally modified the timing and role of surgeon error to assess their influence on surgeons' willingness to withdraw life-supporting care.

Results: The adjusted response rate was 56%. Sixty-three percent of respondents would not honor the request to withdraw life-supporting treatment. Willingness to withdraw life-support was significantly lower in the setting of surgeon error (33% vs 41%, $P < 0.008$) and elective operations rather than in emergency cases (33% vs 41%, $P = 0.01$). After adjustment for specialty, years of experience, geographic region, and gender, odds of withdrawing life-supporting therapy were significantly greater in cases in which the outcome was not explicitly from error during an emergency operation as compared to iatrogenic injury in elective cases (odds ratio 1.95, 95% confidence intervals 1.26–3.01). Surgeons who did not withdraw life-support were significantly more likely to report the importance of optimism regarding prognosis (79% vs 62%, $P < 0.0001$) and concern that the patient could not accurately predict future quality of life (80% vs 68%, $P < 0.0001$).

Conclusions: Surgeons are more reluctant to withdraw postoperative life-supporting therapy for patients with complications from surgeon error in the elective setting. This may also be influenced by personal optimism and a belief that patients are unable to predict the value of future health states.

(*Ann Surg* 2012;256:10–15)

When the patient of an internist dies, his colleagues ask, "What happened?," when the patient of a surgeon dies, his colleagues ask, "What did you do?"

—Charles Bosk, Forgive and Remember[1]

Surgeons embrace an ethos of personal responsibility for the surgical patient. This strong history and tradition contribute to more than a century of success prolonging and improving patients' quality and length of life through operative intervention. However, despite a record of impressive surgical success, not all patients have good operative outcomes. Surgeons, arguably more than their nonsurgical colleagues, are acutely aware and personally sensitive to the risks and complications inherent in the treatments they provide, given the active role they assume in the provision of surgical therapy.[1–4]

Although this commitment to the surgical patient may be an essential component of care, in some settings, surgeons' personal responsibility may conflict with patients' autonomy. For example, before the policy of required reconsideration, do not resuscitate (DNR) orders were routinely suspended in the operating room, suggesting that patient autonomy would not be honored if a cardiac arrest was the direct result of surgery or anesthesia.[5–7] Our work[8] and that of others[9,10] suggest that this surgical paternalism is linked to the issue of error and responsibility and is founded in the unique relationship between surgeon and patient. Most of what is known about this reluctance to withdraw life-support in surgery is based on qualitative studies[1,2,11] and anecdotal reporting.[12,13] It is unknown how frequently surgeons will override a patient's or surrogate's request for withdrawal of aggressive care and what factors influence this decision.

We used clinical vignettes to examine potential conflict between surgeon error and patient autonomy in the context of high-risk operations where unfortunate outcomes are not uncommon. Our use of vignettes allowed us to experimentally examine the role that operative timing and surgeon error may play in surgeons' decisions to withdraw life-supporting therapy after an unwanted clinical outcome. We explicitly tested the association between surgeons' personal responsibility and decisions to withdraw life-supporting therapy in the setting of a postoperative complication.

METHODS

Participants and Incentives

We administered our survey to a randomly selected sample of Vascular, Cardiothoracic, and Neurosurgeons derived from membership lists of regional vascular surgery societies, the Society of Thoracic Surgeons, and the Cerebrovascular Section of the American Association of Neurological Surgeons. We selected these subspecialties to maximize the likelihood that participants routinely performed high-risk operations. We defined "high risk" throughout the survey as an operation with a procedural mortality greater than 1% or significant morbidity such as renal failure, major stroke, paralysis, or ventilator dependence.

In March 2010, we sent 2100 surveys, 700 per subspecialty group, to potential respondents. Each survey was packaged with a

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stamped return envelope and a laser-pointer pen valued at $2.85 as an incentive to encourage participation. A follow-up survey with stamped return envelope was sent to all nonrespondents. Because of a low response rate, a third survey was sent to nonresponding neurosurgeons after verifying addresses through Internet searches. We then added 180 members of the American Association of Neurological Surgeons to replace individuals from the first cohort whose addresses could not be verified.

We used the American Association for Public Opinion guidelines to calculate our response rate.[14] First, all surveys that were returned to sender without survey response and all surveys completed by ineligible respondents such as junior residents and nonsurgeons were removed. Next, we used an Internet search to estimate the percentage of nonrespondents who were ineligible due to faulty contact information by verifying the contact information of 60 respondents—20 from each subspecialty group—and 60 nonrespondents. We combined this eligibility information according to the American Association for Public Opinion standards to calculate the adjusted response rate.

Survey Design

We designed a survey to elicit factors that may influence a surgeon's decision to withdrawal life-supporting therapy postoperatively after a life-altering complication. We first conducted a qualitative study to identify themes and trends regarding surgeons' practices around the use of advance directives and withdrawal of life-supporting therapy. We used semistructured interviews of surgeons and other physicians who routinely care for patients having high-risk operations. This study identified the importance of preoperative discussions, the influence of error and responsibility, and personal investment in the surgical patient as important factors for postoperative decisions about life-supporting therapy.[8,15] Next, we developed survey questions to validate and generalize the results of our qualitative investigation.

We designed a vignette to assess surgeon response to a patient's request to withdraw life-supporting therapy after a difficult postoperative complication (see Supplemental Appendix, Supplemental Digital Content 1, http://links.lww.com/SLA/A251). The vignette featured a specialty specific operation and we used a 2 × 2 between-subject factorial design to assess the associations of interest (Table 1). Thus, each surgeon received 1 of 4 vignette versions that modified the timing of the case (elective vs emergent) and the nature of the surgical complication (surgeon error vs happenstance). Our primary variable of interest was the surgeon's response to the patient's request to withdraw life-supporting therapy. We asked respondents how likely they would be to withdraw therapy using a 4-point Likert scale response frame ("Not at all Likely," "Somewhat Unlikely," "Somewhat Likely," and "Very Likely"). We also examined respondents' likelihood of asking the patient to wait for a short period of time (3 days) or for a prolonged period (10 days) to revisit the question of withdrawal of life-support. To understand factors that contributed to the surgeon's decision, we directly assessed the influence of 10 distinct factors on the surgeon's management of the patient's request to withdraw aggressive therapy. These factors include surgeon factors such as impact on performance measures and fear of litigation, institutional factors such as hospital resources invested in the patient's care, and patient factors such as the patient's ability to accurately predict the value of future health states.

The hypothetical vignette was piloted and pretested with 2 vascular surgeons, 1 neurosurgeon, and 1 cardiac surgeon for technical clarity and plausibility. In addition, all survey items were iteratively tested and modified using cognitive interviews with 6 surgeons who routinely perform high-risk operations but did not practice vascular, cardiac, or neurosurgery. The study was approved as exempt by institutional review boards at the University of Wisconsin and the University of Chicago and included a waiver of written consent.

Analysis

We entered data using Microsoft Excel with a 10% audit confirming that the accuracy of data entry was greater than 99%. We used descriptive statistics to examine the distribution of each variable. We defined our primary outcome as the surgeon's response to the patient's request for withdrawal of life-supporting therapy. For this analysis, we dichotomized responses by comparing "Not at all Likely" and "Somewhat Unlikely" with "Somewhat Likely" and "Very Likely." In sensitivity analyses, we examined the effect of different methods of categorizing this outcome variable, and findings were substantively unchanged using other methods of categorization. Next, we examined the bivariate association between the timing of the case, the nature of the surgical complication, surgeon-cited factors, and the surgeon's likelihood of honoring the patient's request to withdraw life-supporting therapy. Finally, we conducted stepwise multivariate logistic regression to identify factors independently associated with surgeons' decision to withdraw care. Our final models included the

TABLE 1. Characteristics of Clinical Vignettes Administered to Surgeons

	Vascular	Cardiothoracic	Neurosurgical
Elective	Thoracoabdominal aneurysm repair	Ascending aortic aneurysm repair	Calcified right MCA aneurysm clipping
Emergent	Ruptured thoracoabdominal aneurysm repair	Emergency ascending aortic aneurysm repair for dissection	Calcified right MCA aneurysm clipping with a Fischer 3, Hunt and Hess grade II subarachnoid hemorrhage
Surgeon error	During the operation, surgeon inadvertently places the proximal clamp so that it occludes the left carotid artery and the patient has weakness in her right arm and leg when she awakes from anesthesia	During the operation, surgeon inadvertently dislodges arterial cannula and patient has weakness in her right arm and leg when she awakes from anesthesia	Postoperative angiogram demonstrates that during the operation surgeon inadvertently caused ischemia from a third MCA branch that was accidently occluded by the clip tines
Not clearly surgeon error	Patient has an intraoperative stroke and weakness in her right arm and leg when she awakes from anesthesia	Patient has an intraoperative stroke and has weakness in her right arm and leg when she awakes from anesthesia	Patient has a dense left hemiparesis when she awakes from anesthesia; MRI confirms nonhemorrhagic stroke in the right internal capsule

experimental variables of interest, basic demographic characteristics of respondents, and factors surgeons reported as influential in guiding their decision making that were of at least borderline significance ($P < 0.10$) on bivariate analysis. All analyses were conducted using SAS version 9.1 (SAS Institute Inc, Cary, NC).

RESULTS

Participants

A total of 912 completed surveys were returned. The adjusted response rate was 56% for vascular surgeons, 54% for cardiac surgeons, and 56% for neurosurgeons. A similar number of surveys were returned for each of the 4 randomly distributed vignettes. We found no significant difference in the willingness to withdraw life-supporting therapy between the early responders and the late responders to this survey, suggesting the absence of response-wave or nonresponse bias.

Nearly all surgeons reported performing at least one high-risk procedure per month (mean = 10.8, median = 8). The respondents were evenly split between private practice and academic practices and represented a broad range of practice experience (Table 2). In response to the vignette featuring a patient requesting withdrawal of life-supporting therapy, 63% of surgeons reported they were "Not at all" or "Somewhat unlikely" to withdraw life-supporting therapy in this setting; 57% reported they were "Very Likely" or "Somewhat Likely" to wait 10 days to see if the patient's condition improved.

Factors Influencing the Decision to Withdraw Life-Supporting Therapy

On bivariate analysis, surgeons who were told the patient's complication was the result of surgeon error were significantly less likely to withdraw support than their colleagues who encountered a noniatrogenic complication (33% vs 41%, $P = 0.008$) (Figure 1). Similarly, surgeons who had an elective operation were less likely to withdraw life-supporting therapy than those operating in an emergent setting (33% vs 41%, $P = 0.01$) (Table 3). There were also differences in the likelihood of withdrawal of life-support based on several other surgeon characteristics. For example, cardiothoracic and neurosurgeons were significantly less likely to withdraw life-support than vascular surgeons (30 vs 37 vs 45%, respectively, $P = 0.0006$). In addition, surgeons who were less likely to withdraw life-supporting therapy were more likely to report personal optimism about the patient's future quality of life than their counterparts (79% vs 62%, $P < 0.0001$). There was no difference in reported concern about performance measures between surgeons who withdrew and did not withdraw life-supporting therapy (25% vs 27%, $P = 0.54$) (Table 4).

On multivariate analyses, a strong and statistically significant association persisted between surgical timing, the surgeon's role in the poor outcome, and willingness to withdraw life-support. The odds of withdrawing life-sustaining therapy were nearly twofold as great among surgeons who encountered a complication that was not clearly the result of surgeon error during an emergency operation than among surgeons encountering a complication from surgeon error in the elective setting (odds ratio [OR] = 1.95, 95% confidence intervals [CIs] 1.26–3.01). In addition, the odds of withdrawing life-support were greater among those who did not express optimism about the patient's future quality of life (OR = 1.75, CI 1.11–2.50) and among those who were less concerned that the patient did not accurately value her future health state (OR 1.59, CI 1.11–2.27) than among their counterparts (Table 5).

TABLE 2. Respondent Characteristics (N = 912)

	No. (%)
Male gender	850 (94)
Specialty	
Vascular	327 (36)
Neurological	273 (30)
Cardiovascular	312 (34)
Practice setting	
Private practice	376 (42)
Academic practice	328 (37)
Private practice with academic affiliation	182 (20)
Other	8 (1)
Years in practice	
<10	187 (22)
11–20	208 (25)
21–30	229 (27)
>30	216 (26)
No. of high-risk operations performed each month	
0	34 (4)
1–5	311 (34)
6–10	256 (31)
11+	238 (29)

DISCUSSION

In this national study of surgeons, those faced with complications from surgical error during an elective operation were substantially less likely to withdraw life-supporting therapy than those managing a patient in whom a complication was not clearly from error and occurred in the setting of an emergency operation. Optimism about the patient's future quality of life and concern for the patient's ability to accurately predict her future health state were both associated with a surgeon's decision to delay withdrawal of postoperative life-support.

These findings are important because high-risk operations are performed frequently and little is known about the complex factors that influence the management of complications and requests for withdrawal of life-supporting therapy. Surgeons who feel responsible for the life of their patient and the role that they played in an unwanted outcome have difficulty relinquishing the goal of patient survival. Patients and other providers unaware of the surgeon's error and feelings of responsibility may then struggle to understand the surgeon's inability to change course and reconsider clinical goals. In *The Silent World of Doctor and Patient*, Jay Katz notes that " . . . physicians and patients bring their own vulnerabilities to the decision-making process. Both are authors and victims of their own conflicting motivations, interests and expectations."[16] Our findings demonstrate that in the setting of an unwanted postoperative outcome, a surgeon's emotion and accountability have inevitable clinical consequences for both surgeons and patients.

For surgeons, these data suggest that nonclinical factors may influence decision making about withdraw of life-supporting therapy. Ours is not the first study to suggest the importance of nonclinical factors that influence clinical decision-making; there is a large body of literature demonstrating how nonclinical patient characteristics, as well as features of physicians and structural aspects of care, may affect health care delivery.[17–20] However, our study is unique in its examination of high-risk operations and the role that technical performance may play in guiding the management of postoperative life-supporting therapies. Iatrogenic complications that clearly derive from technical error during elective operations may pose considerable guilt and emotional burden upon surgeons.[21–23] It is understandable that such factors should weigh on the surgeon. However, our findings call into question the degree to which these factors may unduly interfere with a patient's ability to control his or her health care decisions.[24,25]

For patients and their families, these data suggest that surgeons who prognosticate in the setting of an elective operation complicated

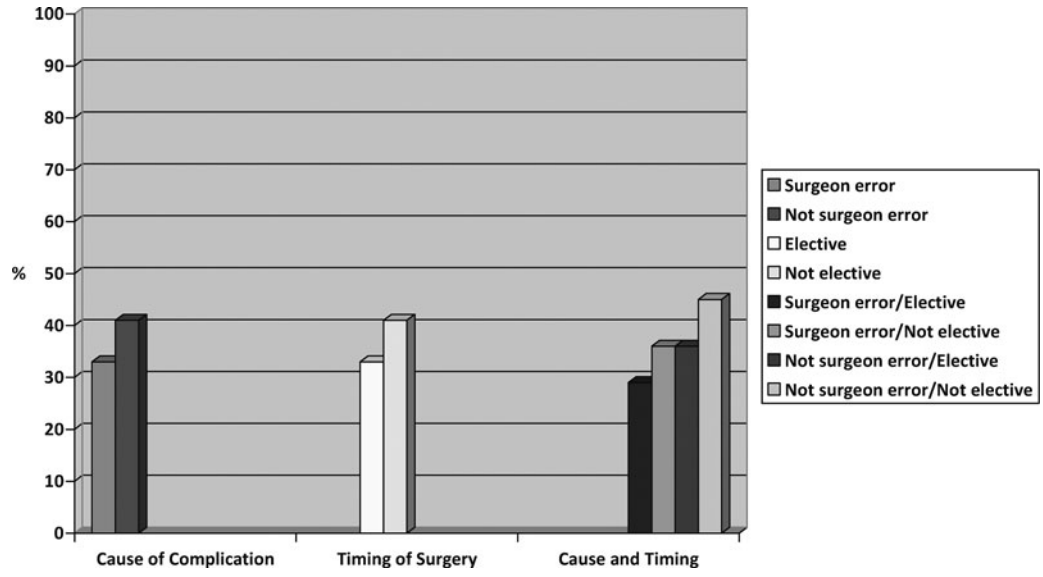

FIGURE 1. Percentage of surgeons who would withdraw life support at the time of patient request as influenced by vignette characteristics.

TABLE 3. Bivariate Association Between Respondent and Vignette Characteristics and Withdrawal

Characteristic	N	Percent Withdrawing Life Supporting Therapy	Bivariate *P*
Sex			
Male	830	38	0.90
Female	49	37	
Subspecialty			
Cardiothoracic	307	30	
Neurosurgery	264	37	0.0006
Vascular	317	45	
Years of experience			
0–10	193	42	
11–20	213	39	0.22
21–30	228	36	
31–40+	214	33	
Region			
Midwest	226	36	
Northeast	245	43	0.03
South	234	30	
West	158	40	
Cause of complication			
Surgeon error	427	33	0.008
Not surgeon error	461	41	
Timing of surgery			
Elective	429	33	0.01
Not elective	459	41	
Cause and timing			
Surgeon error/Elective	208	29	
Surgeon error/Not elective	221	36	0.004
Not surgeon error/Elective	219	36	
Not surgeon error/Not elective	240	45	

by technical error may be providing information that is overly influenced by an emotional response to the clinical situation rather than an unbiased interpretation of the relevant clinical data. Indeed physicians' *subjective* impressions about survival may have more impact on the decision to withdraw support in the critically ill patient than validated predictive models[26,27] and physicians' tendency to be overly optimistic regarding the prognosis of terminally ill patients has been well described.[28] Our data suggest that commission of an error in surgical technique and prognostic optimism may present a challenge to patient autonomy. Particularly in settings in which there is disagreement between patients and their families and the treating physician, our findings highlight the importance of frank discourse and, when needed, consultation with other disinterested parties in order to navigate what may be difficult postoperative decision-making.

Recognition that the surgeon's emotional state may have a significant impact on patients' postoperative management also suggests the importance of efforts to alleviate surgeons' emotional strain while simultaneously respecting the fierce ethic of responsibility that surgeons possess for patients' outcomes.[1] While surgical Morbidity and Mortality (M&M) Conferences may be a forum for catharsis and education surrounding technical error, there are few, if any, other formal venues for surgeons to express the emotional burden of caring for the surgical patient.[22,29–31] Furthermore, although efforts to improve quality and outcomes in surgery are essential, the goals of quality improvement should be distinct from the intrinsic goals of surgical therapy and from the value of the surgeon–patient relationship. The performance of an operation to save or improve quality of life is valuable to patients and their families even when the patient does not survive.

Our study had several limitations. First, as with all surveys, our findings may be subject to nonresponse bias. However, we did not find any evidence of response wave bias, and since our hypothetical vignette used an experimental design, it is unlikely that our main findings would be substantively affected by such bias. Second, we focused on Vascular, Cardiothoracic, and Neurosurgeons because of how commonly they perform high-risk operations. Although our findings may not be generalizable to surgeons in other fields such as general surgery or nonthoracic surgical oncology, we have no reason to believe otherwise. Third, our study design necessarily used a hypothetical vignette so that operative characteristics could be experimentally altered. Although vignettes cannot capture the complexity present in a real clinical case, evidence supports their use to examine physicians' clinical decision-making.[32]

TABLE 4. Association Between Factors Impacting Decisions to Withdraw Life Supporting Therapy

Factors "Somewhat" or "Very Important" Influencing Management of Vignette Patient	Response to Hypothetical Vignette Regarding Whether or Not Life Supporting Therapy Should Be Withdrawn: Favor Withdrawing Therapy (N = 329), %	Favor Not Withdrawing Therapy (N = 557), %	*P*
Preoperative discussion with family	97	94	0.08
Impact on performance measures	25	27	0.54
Personal time and emotional commitment	50	52	0.66
Hospital resources invested in patient	19	16	0.25
Patient's unknown prognosis	70	70	0.97
Personal optimism regarding patient's future QOL	62	79	<0.0001
Concern patient is unable to accurately predict value of future health state	68	80	<0.0001
Personal feelings about morality of WD of LST	16	31	<0.0001
Fear of litigation	16	16	0.99
Belief that as the patient's surgeon you are ultimately responsible for her death	31	33	0.54

QOL indicates quality of life; LST, life supporting treatment; WD, withdraw.

TABLE 5. Multivariate Logistic Regression of Surgeon and Operative Factors Associated With Withdrawal of Life-Supporting Therapy

	OR (95% CIs)
Case factors	
Iatrogenic/Elective	Ref
Iatrogenic/Emergent	1.34 (0.86–2.11)
Not iatrogenic/Elective	1.37 (0.88–2.12)
Not iatrogenic/Emergent	1.95 (1.26–3.01)
Surgeon factors	
Specialty	
Cardiothoracic	Ref
Neurosurgery	1.29 (0.87–1.90)
Vascular	1.72 (1.81–2.52)
Years of experience	
30+	Ref
21–30	1.05 (0.68–1.61)
11–20	1.43 (0.92–2.20)
0–10	1.50 (0.96–2.36)
Region	
South	Ref
Midwest	1.23 (0.79–1.91)
Northeast	1.64 (1.07–2.54)
West	1.47 (0.92–2.35)
Somewhat or very important factors influencing decision making	
Preoperative conversations	2.00 (0.91–4.4)
Optimism about patient's future quality of life	0.57 (0.40–0.80)
Concern patient cannot accurately predict value of future health state	0.63 (0.44–0.90)
Morality of withdrawing life supporting therapy	0.51 (0.35–0.75)

In conclusion, when a patient suffers a life-threatening complication and requests withdrawal of life-supporting therapy postoperatively, surgeons may be unlikely to withdraw life-supporting therapy without delay. These decisions are influenced by both the timing of surgery and whether the complication was the result of explicit technical error. In addition, these nonclinical factors may be associated with surgeons' optimism about the patient's postoperative quality of life. Future efforts to enhance shared decision making for critically ill surgical patients need to address nonclinical biases that influence decision making in the setting of surgical complications.

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Appeal Submitter
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Summary of Appeal:
Please reconsider addition of 30-day post CABG all-cause mortality as a quality metric. Surgeons often struggle to withdraw life supporting treatments on postoperative patients despite patient or family preferences. While this conflict genuinely stems from deep notions of responsibility our data demonstrate that surgeons who report concern about profiling are more likely to refuse to withdraw life support before POD 30. This game-able metric harms patients and families, the surgeon patient relationship and fails to capture important safety information. Consider the patient who spends 24 hours in ICU and is discharged to home post-operative day 5 versus the patient who has the same operation, spends 20 days in ICU, is transferred to an LTAC and then palliative care on POD 32. These vastly different outcomes are not captured by the equivalent 30-day survival assigned to both episodes: it fails to capture what is truly valuable to patients who don't want to live to just 30 days.

VIEWPOINT

Beyond 30-Day Mortality
Aligning Surgical Quality With Outcomes That Patients Value

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Because of their strong sense of responsibility for the lives of patients, surgeons frequently struggle to withdraw postoperative life-supporting treatments when patients or their families request it.[1] Although surgeons experience this as therapeutic optimism or the emotional pull of error and responsibility, these forces are accentuated by the increasing emphasis on 30-day mortality reporting. The recent expansion of outcomes profiling imposes an unconscious bias in these critical decisions: surgeons who report concern about physician profiling are more likely to decline to operate on a patient who prefers to limit life support, or are more likely to refuse to withdraw life support postoperatively, than surgeons who perceive less pressure from outcomes reporting.[2,3]

Public reporting of 30-day mortality may motivate surgeons and hospitals to improve outcomes and theoretically empowers patients to make informed choices.[4] However, use of this single metric unintentionally fails to accommodate patients who might benefit from palliative surgery, or patients who would prefer death to prolonged postoperative treatment in the intensive care unit or long-term chronic care after a major complication. Surgeons should be able to offer informed patients a risky but potentially beneficial surgical option and then allow patients to refuse aggressive treatments if they have become overly burdensome or when patients' goals for surgery are no longer possible.

Reconciling the effects of an approach designed to ensure high-quality surgical care with the needs of vulnerable patients is challenging, particularly for high-risk operations in which hard outcomes, such as mortality, are easily observed and other important outcomes are more difficult to assess. Strategies to mitigate the impact of 30-day mortality reporting through consideration of alternative quality metrics are required to protect the needs of surgical patients and the practices of surgeons who could make a valuable contribution to their patients' quality of life.

Alternative Outcomes to 30-Day Mortality

A system that prioritizes one metric, 30-day mortality, above all others is unlikely to produce outcomes that are desirable for all stakeholders. The purpose of reporting 30-day mortality is to assess surgical safety, but patients desire surgical safety only to the degree that it predicts efficacy (longer-term survival and quality of life). Although most patients wish to survive for 30 days after their operation, the notion that surgery has intrinsic value to patients if they could live just 30 days is outdated, as if additional survival time is an unexpected luxury. Reporting mortality statistics at other time points, including 60 days and 6 months, would help align patients' and surgeons' goals at concordantly valuable touch points and would de-emphasize the singular importance of 30-day survival. By broadening the time horizon, this strategy could reduce the external pressure to achieve a specific target with limited impact on safety assessment as postoperative complications are tightly linked to longer-term postoperative survival.[5]

Other safety metrics that matter to patients should be elevated to the current status of mortality: intensive care unit days, prolonged mechanical ventilation (longer than 96 hours), and discharge destination. There is a clear distinction between the patient who has an extended hepatectomy, spends 24 hours in the intensive care unit and 5 days in the hospital, and is discharged to home with physical therapy and the patient who has the same operation, spends 14 days in the intensive care unit on a ventilator and 33 days in the hospital, and is discharged to a long-term acute care hospital with a tracheostomy. Although the differences between these 2 outcomes are striking, this distinction is not well captured by the equivalent 30-day survival assigned to both episodes.

Report Patient-Centered Outcomes

The collection of data on patient-centered outcomes in quality improvement programs and surgical registries for all operations would help both patients and surgeons. In addition to procedure-specific morbidity, reported outcomes should match the goals of surgery. For example, a 3-month measurement of fatigue and bone pain after parathyroidectomy or the ability to eat solid food after gastrectomy should be reported along with surgical site infection and postoperative readmission. Although these additional metrics focus on efficacy, rather than safety, surgical quality should be judged by both. Patients will undertake significant risk in pursuit of a specific goal; measuring and reporting these outcomes will improve their ability to evaluate the trade-offs inherent in surgical treatment and will provide clarity about what is a realistic postoperative goal.

Emphasize Process Measures for Palliative Operations

For patients who have operations with palliative intent, quality of care should not be judged by mortality but by robust reporting of outcomes that reflect high-quality palliative care. This would include clear delineation and postoperative measurement of the symptoms the operation is intended to address. For example, re-

porting for an enteric bypass for obstructing cancer should measure relief of nausea and vomiting. Other metrics of high-quality palliative care include documentation of a preoperative goals-of-care conversation, pain scores, family meetings, and even time between a do-not-resuscitate order and death. Although the collection of survival rates after palliative operations might help inform future patients about the value of an operation, the 30-day mortality rates for these operations should not be interpreted or publicly reported as a quality metric.

Attend to the Needs of Poor-Risk Patients

Targeting surgical mortality likely decreases the number of operations on poor-risk candidates, as it has for percutaneous coronary interventions.[6] However, when 30-day mortality reporting influences the decision making for poor-risk patients, this can result in mistrust, inconsistency, and discriminatory practices. To promote quality and reduce ineffective or marginally beneficial care, it is necessary to delineate both upper and lower boundaries around the patients who are appropriate operative candidates. Expansion of guidelines, such as those for lung volume reduction surgery, that define indications for the performance of surgery, including a clear description of patients who are not surgical candidates because of unlikely long-term survival and prohibitive morbidity, would lead to consistent practices about who should be refused surgery based on defined prognostic features and would reduce concern that the decision was influenced by performance metrics.

Patients frequently proceed with surgery because they perceive no other option, even though surgery is unlikely to meet their needs. Preoperative conversations typically stress risks and benefits, rather than a detailed discussion of patient preferences and goals. Often, the postoperative care required is not consistent with patients' desires, even if all goes well. Although penalties for high 30-day mortality would reduce the number of operations on high-risk patients, such penalties do not consider whether the treatment received was aligned with the patient's values.[7] Although difficult to operationalize, incentives that reward patient engagement rather than a specific outcome would credit surgeons for identifying both the patients who are unlikely to value risky surgery and the patients who would value surgical intervention and be accepting of the necessary postoperative life support.

The benefits of detailed reporting of surgical outcomes, specifically highly visible mortality statistics, will be limited unless we focus on results that are valuable to patients. It is time for surgical quality metrics to evolve because there is much at stake for both patients and surgeons. The way forward requires (1) an alignment of the goals of surgery with the outcomes that are measured and (2) a more sophisticated and nuanced approach in order to value the full range of outcomes that surgeons have to offer patients beyond 30-day survival.

ARTICLE INFORMATION

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Role of the Sponsor: The funding agencies had no role in the design and conduct of the study; collection, management, analysis, or interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Additional Contributions: We thank Justin Dimick, MD, MPH, from the Department of Surgery at the University of Michigan, Ann Arbor; Diane Meier, MD, FACP, from the Center to Advance Palliative Care at the Icahn School of Medicine at Mount Sinai in New York; James Tulsky, MD, from the Center for Palliative Care at Duke University School of Medicine in Durham, North Carolina; and the Qualitative Research Group at the University of Wisconsin Institute for Clinical and Translational Research in Madison for their valuable input on earlier versions of this article. All of these people read the manuscript and offered comments on or a critique of the manuscript. No financial compensation was received for this input.

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VIEWPOINT

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Additional Contributions: We thank Justin Dimick, MD, MPH, from the Department of Surgery at the University of Michigan, Ann Arbor; Diane Meier, MD, FACP, from the Center to Advance Palliative Care at the Icahn School of Medicine at Mount Sinai in New York; James Tulsky, MD, from the Center for Palliative Care at Duke University School of Medicine in Durham, North Carolina; and the Qualitative Research Group at the University of Wisconsin Institute for Clinical and Translational Research in Madison for their valuable input on earlier versions of this article. All of these people read the manuscript and offered comments on or a critique of the manuscript. No financial compensation was received for this input.

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December 19, 2014

Cristie Upshaw Travis, Chair
Lee Fleisher, MD, Vice Chair
Consensus Standards Approval Committee
National Quality Forum
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Washington DC 20005

RE: Response to Appeals Letters regarding 0119 Risk-Adjusted Operative Mortality for CABG

Dear Ms. Upshaw Travis and Dr. Fleisher:

We are writing in response to letters requesting reconsideration of the 30-day (NQF 2558, CMS) and operative (NQF 0119, STS) CABG mortality measures recently endorsed by NQF. The similarity in these measures, which in many instances are nearly identical, allows us to address them as a group. These are the facts from our perspective:

1. Neither STS nor CMS suggest that CABG mortality should be the sole metric to assess quality in cardiothoracic surgery. To the contrary, STS has strategically and persistently worked to evolve cardiac surgery quality measurement beyond its historical focus on one procedure, CABG, and one outcome, risk-adjusted mortality [1-7]. Our composite measures include not only mortality but also risk-adjusted occurrence of ANY of five major complications (stroke, renal failure, sternal infection, prolonged ventilation, reoperation for bleeding). These are the major morbidities most commonly responsible for the lengthy and difficult postoperative courses described in the letters to NQF. Furthermore, we have also moved beyond a focus solely on CABG and now have similar composite measures for aortic valve replacement (AVR), AVR + CABG, mitral repair/replacement, and mitral repair/replacement + CABG. Thus, we have purposely evolved our quality measurement enterprise to be much more expansive, both in terms of the adverse outcomes measured and the procedures covered.

   To further expand our quality measurement portfolio, we have also developed a 30-day readmission measure for CABG (NQF 2514) [8], recommended by the CSAC for endorsement, which will further enhance our ability to identify non-fatal but serious postoperative complications, as these are the most common causes for readmission.

   STS has also nearly completed a study of failure to rescue as another potential component of our quality metrics portfolio and we expect to submit this for NQF endorsement next year. We are

also exploring the addition of patient satisfaction (e.g., HCAHPS) data to our measures portfolio, and we have applied for several grants to study patient-reported outcomes using the PROMIS instrument.

2. Notwithstanding our determined evolution towards more expansive and patient-centered outcomes, we cannot ignore the most important and longstanding metric in all complex operations—patient survival. As long as there is still substantial variability among providers in this archetypal outcomes measure, this must continue to be part of our measurement armamentarium. Patients are interested in the many other outcomes mentioned in the various letters you have received, but none of these outcomes can be evaluated unless the patient survives.

   There are three currently used time frames for measuring CABG mortality: in-hospital, 30-day, and STS operative mortality. In-hospital mortality is the least desirable. It is a non-standardized ascertainment period that results in bias against hospitals that do not have nearby extended care facilities to which they can discharge patients early in their postoperative courses. Thus, their results will appear worse than those of other institutions that do have the ability to transfer patients to post-acute care facilities; the subsequent deaths of such patients may not be captured by in-hospital mortality metrics.

   Thirty-day mortality (e.g., NQF 2558) is superior to in-hospital mortality as a quality metric, as it uses a standardized time frame for endpoint ascertainment [9,10]. This is preferred by statisticians and is used in virtually all government accountability programs. It also mitigates the bias resulting from differential access to post-acute care facilities. However, as noted by the letter authors, it can have unintended negative consequences. Some providers may use supportive care measures in very ill patients until the 30-day threshold is reached, and only then discuss withdrawal of care. Despite anecdotes describing such occurrences, there are no hard data on their prevalence. Local hospital ethics committees are best positioned to identify and mitigate such questionable practices.

   Although STS still has 30-day mortality measures, in virtually all of our current performance composites we preferentially use operative mortality instead of in-hospital or 30-day mortality [11,12]. Operative mortality is defined in all components of the STS National Database as (1) all deaths, regardless of cause, occurring during the hospitalization in which the operation was performed, even if after 30 days (including patients transferred to other acute care facilities); and (2) all deaths, regardless of cause, occurring after discharge from the hospital, but before the end of the 30th postoperative day. It is this metric that is used in NQF 0119. This measure combines the other two metrics (in-hospital mortality and 30-day mortality), and, therefore, includes all in-hospital deaths regardless of timing, and all 30-day deaths regardless of venue. We believe this is the most comprehensive mortality measure, and it specifically addresses the objections raised in the recent letters to NQF. There is no incentive to discharge patients prematurely, as their out-of-hospital deaths will still be recorded out to 30 days (by which time most early outpatient deaths will have occurred). There is also no incentive to keep the patient alive using extraordinary

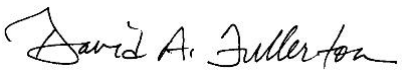
means until day 30, then to remove life-sustaining support. Because the patient is still hospitalized, their death is recorded, regardless of how long postoperatively it has occurred.

3. STS also has been actively developing strategies to longitudinally measure late mortality (after the time interval measured with operative mortality), using linkages of the STS National Database to both Medicare Data and data from national registries of death [13-17].

In summary, STS supports the sentiments expressed in the recent letters to NQF which suggest that mortality is not the only metric we should use in cardiothoracic surgery. We have proven our commitment to this by relentlessly expanding our measure portfolio with numerous multidimensional composites, readmission measures, and in the near future, failure to rescue, patient satisfaction, patient-reported outcomes, and possibly long-term survival. However, we cannot ignore the continued importance of survival as an extremely important metric for complex surgery, as long as it occurs with measureable frequency and variability. Among the available risk-adjusted mortality metrics, we believe operative mortality (as used in NQF 0119) is the most comprehensive, and that 30-day mortality (NQF 2558) should also be retained as it provides a standardized time frame for ascertainment and is used in almost all governmental and commercial accountability programs.

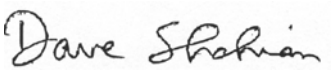
We appreciate the opportunity to respond to the appeals letters. Thank you for your thoughtful consideration.

Respectfully yours,



David A. Fullerton, MD
STS President

Richard L. Prager, MD
Chair, STS Quality, Research and Patient Safety Council Operating Board



David M. Shahian, MD
Chair, STS Workforce on National Databases
Chair, STS Quality Measurement Task Force

Jeffrey P. Jacobs, MD
Chair, STS Public Reporting Task Force
STS Surgeon Representative for NQF Surgery Project Phase 1 & 2

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CENTER FOR OUTCOMES RESEARCH AND EVALUATION

MEMORANDUM

TO: NQF Consensus Standards Approval Committee
CC: The Centers for Medicare and Medicaid Services;
The Society of Thoracic Surgeons
FROM: YNHHSC Center for Outcome Research and Evaluation
DATE: Monday, December 29, 2014
SUBJECT: Response to Surgery Standing Committee Phase 1 Project Appeals letters regarding Measure 2558: Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery

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We deeply appreciate the concerns expressed in the submitted appeal letters. In brief, the stated concerns are that:

- a performance measure of 30-day mortality might influence providers to withhold comfort care or fail to appropriately transition patients to comfort care during the post-operative period, and
- focusing solely on mortality may perpetuate non-patient-centered care and CMS should consider additionally measuring patient-reported outcomes.

We appreciate these concerns and the recommendation to measure alternate outcomes such as patient-reported outcomes. However, we believe there is current benefit achieved by measuring 30-day mortality following CABG surgery. Mortality rates following CABG surgery are not insignificant and vary across hospitals. For example, in January 2009 – September 2011 Medicare FFS data, the median hospital-level risk-standardized mortality rate after CABG was 3.1% and ranged from 1.5% to 9.3%. Even within a single state (New York),[1] the observed in-hospital/30-day all-cause, hospital-level mortality rate was 1.81% and ranged from 0.0% to 5.6% among patients who were discharged after CABG surgery (without any other major heart surgery earlier in the hospital stay). The risk-adjusted mortality rate in New York ranged from 0.0% to 8.2%. These rates suggest wide variation and that there is room for improvement. An all-cause mortality measure for patients who undergo CABG surgery will provide hospitals with an incentive to reduce mortality through improved coordination of perioperative care and discharge planning. This is further supported by the success of registry-based mortality measures in reducing CABG mortality rates. For example, California reports that CABG mortality in that state has steadily declined from 2.9% in 2003, the first year of mandatory reporting of their state registry measure, to 2.2% in 2008.[2] The Society of Thoracic Surgeons has also documented decreasing 30-day mortality rates after isolated CABG among their registry participants.[3]

Not only does NQF Measure #2558: Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following CABG Surgery provide an important and patient-centered signal of care quality reflected by the mortality outcome itself, but it is harmonized with the paired readmission measure, NQF Measure #2515: Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following CABG Surgery,

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1 New York State Department of Health. Adult Cardiac Surgery in New York State 2006-20082010:54.
2 California CABG Outcomes Reporting Program. The California Report on Coronary Artery Bypass Graft Surgery: 2007-2008 Hospital and Surgeon Data2011:119.
3 Shahian DM, O'Brien SM, Sheng S, et al. Predictors of Long-Term Survival Following Coronary Artery Bypass Grafting Surgery: Results from The Society of Thoracic Surgeons Adult Cardiac Surgery Database (The ASCERT Study). *Circulation* 2012; 125(12):1491-500.

to ensure that the full spectrum of perioperative care and care coordination can be assessed while simultaneously ensuring CMS can monitor for unintended consequences of measurement. To our understanding, published data are mixed regarding whether measurement will, in fact, influence physician behavior to withhold comfort care. In the appeal from Dr. Margaret Schwarze is an article,[4] authored by Dr. Schwarze and colleagues, that states "there was no difference in reported concern about performance measures between surgeons who withdrew and did not withdraw life-supporting therapy (25% vs 27%, *P* = 0.54)". We also note that a recent Cochrane review concluded "Evidence that the public release of performance data may have an impact on the behaviour of healthcare professionals or organisations is lacking."[5]

Regarding Ms. Rebecca Aslakson's and others' recommendation to use patient-reported outcomes to replace or supplement mortality measurement, at this time patient-reported outcomes are not routinely collected and thus cannot currently be used in a reliable manner for national measurement programs. Further, process measures unfortunately do not correlate closely with clinical outcomes and thus cannot fully supplant outcome measures. Until appropriate patient-reported outcome metrics are widely available, we believe there is greater good achieved by measuring CABG mortality than by not measuring this outcome at all. We also note that The Society of Thoracic Surgeons' Measure #0119: Risk-Adjusted Operative Mortality for CABG has been reporting CABG mortality for several years without apparent harm.[6]

Overall, according to our clinical expert consultants and Technical Expert Panel, patients who are undergoing CABG surgery likely have a reasonable expectation of surviving more than 30-days beyond their surgery or physicians would not offer such an invasive procedure nor would patients likely consent to this procedure if their primary goal of care was comfort and not survival. According to The Society of Thoracic Surgeons data, more than 95% of isolated CABG patients are alive at one-year.[7]

CMS has heard the concerns voiced in the appeals letters and takes these concerns under consideration throughout the lifecycle of the measures. As with all of its measures, CMS reevaluates measures on an annual basis, including annual and comprehensive reevaluations through the NQF. This ongoing reevaluation provides an opportunity for continued monitoring for potential unintended consequences of measurement, including increases in post-30-day mortality or hospice enrollment. In their response to the appeals letters, The Society of Thoracic Surgeons has made a similar commitment.

We would also like to bring to the attention of the Committee that that our response applies to the Society of Thoracic Surgeons' Measure #0119: Risk-Adjusted Operative Mortality for CABG, with which Measure 2558: Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following CABG Surgery is harmonized to the extent possible given their different data sources and their complementary but distinct goals to assess mortality throughout different post-operative settings and time periods. We continue to support the endorsement of both CABG mortality measures in order to provide any stakeholder who implements the measures scientifically rigorous instruments to continue progress towards clinical data-based measurement and ultimately to achieve better patient care and outcomes.

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Appendix D – Measure Evaluation Summary Tables

LEGEND: Y = Yes; N = No; H = High; M = Moderate; L = Low; I = Insufficient

0119 Risk-Adjusted Operative Mortality for CABG

Specifications

Description: Percent of patients aged 18 years and older undergoing isolated CABG who die, including both 1) all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and 2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure

Numerator Statement: Number of patients undergoing isolated CABG who die, including both 1) all deaths occurring during the hospitalization in which the operation was performed, even if after 30 days, and 2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure

Denominator Statement: All patients undergoing isolated CABG

Exclusions: N/A

Adjustment/Stratification: Statistical risk model

Level of Analysis: Facility, Clinician : Group/Practice

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Electronic Clinical Data : Registry

Measure Steward: The Society of Thoracic Surgeons

STANDING COMMITTEE MEETING [05/28/2014-05/29/2014]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: **Y- 20; N- 0**; 1b. Performance Gap: **H- 15; M- 5; L- 0; I- 0;** 1c. Impact: **H- 19; M- 1; L- 0; I-0**

Rationale:

- The Committee agreed that there is a strong rationale and evidence base indicating that mortality rates for patients undergoing CABG surgery can be affected through a variety of well-established healthcare interventions and approaches.
- Data provided by the developer show that for the measurement period of July 2012 to June 2013, providers' risk-adjusted CABG mortality rates ranged from 1.65% in the highest performance decile to 2.5% in the lowest performance decile.
- The Committee considered there to be a significant opportunity for improvement on this measure.
- The Committee agreed that the measure addresses a high-impact and high-priority area.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H- 16; M- 5; L- 0; I-0**; 2b. Validity: **H- 19; M- 2; L- 0; I-0**

Rationale:

- The developer noted that the clinical nomenclature around CABG procedures allows for precise identification of the target population as well as fairly sophisticated risk-adjustment.
- Committee members asked what percentage of CABG surgeries are captured by the STS Adult Cardiac Surgery Database

0119 Risk-Adjusted Operative Mortality for CABG

- The developer estimated that approximately 95% of CABG procedures are captured, noting that 90-95% of all programs in the country doing CABG surgery participate in the STS Database, and that non-participants are likely to be lower-volume programs.
- In response to questions from Committee members, the developer clarified that any death within 30 days of a CABG procedure is counted as an operative death, in an effort to capture the fullest possible picture of postoperative mortality.
- The developer noted that the data element indicating mortality (vital status) is examined closely as part of the STS audit process, and estimated that 30-day mortality is captured with 98-99% accuracy.
- To demonstrate reliability of the measure, the developers presented information on the STS database audit process, through which participants are randomly selected on an annual basis to undergo an evaluation of the accuracy, consistency, and comprehensiveness of data collection activities.
- Data submitted by the developer show that in the 10% of STS Adult Cardiac Surgery Database participants subjected to an audit, there was 96.6% agreement between information submitted to the registry by participants and information re-abstracted by independent auditors.
- The Committee generally found the reliability information submitted by the developers to be adequate.
- To demonstrate measure validity, the developers tested the stability of measure results over time. Because providers are unlikely to have significant fluctuations in performance from year to year, stability of measure scores over time may indicate that the measure is capturing an accurate signal of provider performance.
- Testing results submitted by the developer showed that registry participants rated as 'low' in one performance period (July 2011-June 2012) were more likely than other participants to receive that same rating in the following performance period (July 2012-June 2013). No providers were given 'high' ratings in either performance period, and 'mid'-level performers were highly likely to remain in that category across time.
- Committee members found the measure's risk adjustment approach to be sound and well-supported.
- The Committee was satisfied with the measure's validity.

3. Feasibility: H- 10; M- 11; L- 0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- Committee members noted that there are substantial costs associated with registry participation, including a significant data collection burden.
- The developer highlighted a collaborative effort between STS and leading EHR vendors to develop an infrastructure allowing for direct importation of data from EHRs, potentially reducing the data entry burden significantly.
- The Committee was generally satisfied with the measure's feasibility.

4. Use and Usability: H- 12; M- 11; L- 0; I-0

(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)

Rationale:

0119 Risk-Adjusted Operative Mortality for CABG
• The developer confirmed that CABG mortality rates have decreased consistently over time, suggesting that this speaks to the benefits of participation in a multi-institutional clinical registry. • The developer clarified that measure performance is reported at both the hospital and practice group level, noting that there is a small degree of overlap between these groups. • Committee members asked whether the measure could also be stratified to provide performance information on individual physicians. • The developer responded that there are issues related to small sample size at the individual physician level, and noted that, to-date, STS has chosen to pursue a strategy of measuring outcomes that reflect the performance of entire teams, as opposed to individual providers. • However, the developer also reported that STS is actively working to develop a method for reporting cardiac surgical performance stratified by individual physician. • Committee members noted that acceptance of measurement efforts by specialty societies is an important factor in increasing clinician buy-in and measure use. • Some Committee members expressed concern about the difficulty of discerning between practices or providers based on publicly-reported measure results, which show little variation and high levels of performance across providers, noting that this is due in part to the low incidence of the outcome in general. • The developer pointed out that this measure is part of the STS's overall CABG composite, which achieves a larger sample size by combining a number of outcomes into a single measure, thereby allowing for clearer differentiation between providers. • The Committee was generally satisfied with the use and usability of this measure.
5. Related and Competing Measures • This measure directly competes with 2558 Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery, the measure estimates a hospital-level, risk-standardized mortality rate (RSMR) for patients 18 years and older discharged from the hospital following a qualifying isolated CABG procedure. Mortality is defined as death from any cause within 30 days of the procedure date of an index CABG admission. The measure was developed using Medicare Fee-for-Service (FFS) patients 65 years and older and was tested in all-payer patients 18 years and older. An index admission is the hospitalization for a qualifying isolated CABG procedure considered for the mortality outcome.
Standing Committee Recommendation for Endorsement: **Y- 23; N-0**
6. Public and Member Comment: July 3, 2014 – August 4, 2014 Comments received: • Commenters generally expressed support for the measure and the Committee's recommendation for endorsement.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-16; N-0; A-0
8. Board of Directors Vote: Yes
9. Appeals

2558 Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery

Specifications

Description: The measure estimates a hospital-level, risk-standardized mortality rate (RSMR) for patients 18 years and older discharged from the hospital following a qualifying isolated CABG procedure. Mortality is defined as death from any cause within 30 days of the procedure date of an index CABG admission. The measure was developed using Medicare Fee-for-Service (FFS) patients 65 years and older and was tested in all-payer patients 18 years and older. An index admission is the hospitalization for a qualifying isolated CABG procedure considered for the mortality outcome.

Numerator Statement: The outcome for this measure is 30-day all-cause mortality. Mortality is defined as death for any reason within 30 days of the procedure date from the index admission for patients 18 and older discharged from the hospital after undergoing isolated CABG surgery.

Denominator Statement: This claims-based measure can be used in either of two patient cohorts: (1) patients aged 65 years or older or (2) patients aged 18 years or older. We have tested the measure in both age groups.

The cohort includes admissions for patients who receive a q

Exclusions: Hospitalizations are excluded if they meet any of the following criteria. Hospitalizations for:

1) Patients with inconsistent or unknown vital status or other unreliable data.

Rationale: We exclude these because the outcome cannot be adequately measured in these patients.

2) Patients who leave the hospital against medical advice (AMA)

Rationale: We exclude hospitalizations for patients who are discharged AMA because providers did not have the opportunity to deliver full care and prepare the patient for discharge.

3) Patients with qualifying CABG procedures subsequent to another qualifying CABG procedure during the measurement period

Rationale: CABG procedures are expected to last for several years without the need for revision or repeat revascularization. A repeat CABG procedure during the measurement period very likely represents a complication of the original CABG procedure and is a clinically more complex and higher risk surgery. We, therefore, select the first CABG admission for inclusion in the measure and exclude subsequent CABG admissions from the cohort.

Adjustment/Stratification: Statistical risk model

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Administrative claims

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING [05/28/2014-05/29/2014]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: **Y- 23; N- 0**; 1b. Performance Gap: **H- 16; M- 6; L- 0; I-0;** 1c. Impact: **H- 21; M- 1; L- 0; I-0**

Rationale:

- Evidence provided by the developer displays a direct relationship between the outcome of mortality and processes of care, including timing of procedure in relation to cardiac events and various peri-operative strategies.
- The developer provided data from 2009-2011 showing that risk-adjusted mortality rates ranged from 1.5% to 9.3%, demonstrating a gap in performance.

2558 Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery

- The Committee agreed that an opportunity for improvement remains on this measure.
- In 2007, there were 114,028 hospitalizations for CABG surgery and 137,721 hospitalizations for combined surgeries for CABG and valve procedures ("CABG plus valve" surgeries) among Medicare FFS patients in the United States, suggesting that this is a high priority.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H- 12; M- 10; L-1; I-0;** 2b. Validity: **H- 14; M- 9; L- 0; I-0**

<u>Rationale</u>:

- Reliability testing was conducted at both the performance measure score and data element level. A test-retest approach was performed with the correlation coefficient being 0.32 which the Committee stated was sufficient for reliability.
- Validity was conducted at both the data element and measure score level. Face validity was also assessed by a Technical Expert Panel using a six-point scale obtained from the mortality measure as specified, provide an accurate distinction between good and bad quality of care.

3. Feasibility: H- 21; M- 2; L- 0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

<u>Rationale</u>:

- The Committee had no concerns regarding measure logic feasibility based on the feasibility assessment using administrative claims.

4. Use and Usability: H- 8; M- 12; L- 3; I-0

(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)

<u>Rationale</u>:

- The Committee discussed no concerns regarding usability and use. Although this measure is not being currently reported, the developer stated plans for future use.

5. Related and Competing Measures

- This measure directly competes with 0119 Risk-Adjusted Operative Mortality for CABG, Percent of patients aged 18 years and older undergoing isolated CABG who die, including both 1) all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and 2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure.

Standing Committee Recommendation for Endorsement: **Y- 22; N-1**

6. Public and Member Comment: July 3, 2014 – August 4, 2014

Comments received:

- Commenters generally expressed support for the measure and the Committee's recommendation for endorsement.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-16; N-0; A-0

8. Board of Directors Vote: Yes

9. Appeals