AHA/ASA Presidential Advisory

Stroke Outcomes Measures Must Be Appropriately Risk Adjusted To Ensure Quality Care of Patients

A Presidential Advisory From the American Heart Association/American Stroke Association

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This statement was approved by the American Heart Association Science Advisory and Coordinating Committee on January 24, 2014. A copy of the document is available at http://my.americanheart.org/statements by selecting either the “By Topic” link or the “By Publication Date” link. To purchase additional reprints, call 843-216-2533 or e-mail kelle.ramsay@wolterskluwer.com.


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(Stroke. 2014;45:000-000.)

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Stroke is available at http://stroke.ahajournals.org

DOI: 10.1161/STR.0000000000000014
Abstract

Because stroke is among the leading causes of death, disability, hospitalizations, and healthcare expenditures in the United States, there is interest in reporting outcomes for patients hospitalized with acute ischemic stroke. The American Heart Association/American Stroke Association, as part of its commitment to promote high-quality, evidence-based care for cardiovascular and stroke patients, fully supports the development of properly risk-adjusted outcome measures for stroke. To accurately assess and report hospital-level outcomes, adequate risk adjustment for case mix is essential. During the development of the Centers for Medicare & Medicaid Services 30-day stroke mortality and 30-day stroke readmission measures, concerns were expressed that these measures were not adequately designed because they do not include a valid initial stroke severity measure, such as the National Institutes of Health Stroke Scale. These outcome measures, as currently constructed, may be prone to mischaracterizing the quality of stroke care being delivered by hospitals and may ultimately harm acute ischemic stroke patients. This paper details (1) why the Centers for Medicare & Medicaid Services acute ischemic stroke outcome measures in their present form may not provide adequate risk adjustment, (2) why the measures as currently designed may lead to inaccurate representation of hospital performance and have the potential for serious unintended consequences, (3) what activities the American Heart Association/American Stroke Association has engaged in to highlight these concerns to the Centers for Medicare & Medicaid Services and other interested parties; and (4) alternative approaches and opportunities that should be considered for more accurately risk-adjusting 30-day outcomes measures in patients with ischemic stroke.
**Key Words:** AHA Scientific Statements; stroke; acute ischemic stroke; mortality; outcome measures; health policy
Introduction

There is increasing emphasis given to defining and improving the quality and value of health care through reporting of process and outcome measures. National quality profiling efforts have begun to report hospital-level performance for Medicare beneficiaries, including 30-day mortality and 30-day rehospitalization rates, for common medical conditions including acute myocardial infarction (AMI), heart failure (HF), and community-acquired pneumonia with the Centers for Medicare & Medicaid Services (CMS) incorporating these outcome measures into its inpatient quality reporting (IQR) program and hospital value-based purchasing programs. The CMS states that, in the interest of promoting high-quality, patient-centered care and accountability, the purpose of having publicly reported outcome measures is to “increase the transparency of hospital care, provide useful information for consumers choosing care, and assist hospitals in their quality improvement efforts.” These measures are currently reported on the Hospital Compare Web site. Additionally, the 30-day HF, AMI, and pneumonia mortality measures are used in the CMS’ hospital value-based purchasing program, and both the 30-day mortality and readmission measures for these 3 disease states are used in the IQR program; the rehospitalization measures are part of the readmission reduction program. Because stroke is among the leading causes of death, disability, hospitalizations, and healthcare expenditures in the United States and worldwide, there has been growing interest in also reporting outcomes for patients hospitalized with acute ischemic stroke.

Risk adjustment for case mix is considered essential for accurately assessing and reporting hospital-level outcomes. The risk-adjustment models currently used by the CMS incorporate data exclusively from administrative claims. Although claims data risk models for
AMI, HF, and community-acquired pneumonia were validated against clinical data adequate case-mix adjustment for acute ischemic stroke by claims data may be particularly difficult as it is essential for acute ischemic stroke models to include adjustment for stroke severity. Numerous studies demonstrate that initial stroke severity, as indexed by the National Institutes of Health Stroke Scale (NIHSS), is the dominant predictor of mortality in acute ischemic stroke. Recent studies have highlighted the importance of including a valid specific measure of stroke severity in hospital risk models for mortality after acute ischemic stroke for Medicare beneficiaries and found adjustment for stroke severity to be essential for optimal ranking of hospital with respect to 30-day mortality.

Since the adoption of the HF, AMI, and pneumonia outcome measures, the CMS stated its interest to develop additional 30-day outcome measures and placed a focus in developing measures for stroke. As a result, the CMS engaged Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE) to develop a claims-based 30-day stroke mortality measure and a 30-day stroke readmission measure. The American Heart Association/American Stroke Association (AHA/ASA) fully supports the development of appropriately risk-adjusted outcome measures for stroke and cardiovascular disease. However, during the course of the development of the 30-day stroke mortality and the 30-day claims-based stroke readmission measures, concerns were expressed by the vast majority of stroke stakeholders that these measures were not adequately designed because these measures did not include a valid measure of presenting stroke severity, such as the NIHSS. Efforts were made to identify other available variables that could function as a proxy for stroke severity but were of limited success. Both stroke measures, as constructed, may therefore be prone to
mischaracterizing the quality of stroke care being delivered by hospitals and have the potential to ultimately harm patients requiring acute stroke treatment. Despite the efforts of AHA/ASA and other professional organizations to advocate for adoption of more appropriately risk-adjusted measures, the CMS ultimately decided to go forward and implement these 2 stroke outcome measures for use in the IQR and for public reporting purposes for 2014. Furthermore, based on recent activities by the Measures Application Partnership (MAP), it is likely that the 30-day readmission measure will be used in the readmission reduction program. The AHA/ASA advocates that these 2 measures be revised to avoid unintended consequences that may ultimately affect stroke patient care. It is unclear how many stroke stakeholders, including payers, state bodies, accrediting organizations, regional policy makers, emergency medical services (EMS) agencies, hospital associations, patient support groups, and other interested stakeholders, are fully aware of the limitations of the currently constructed measures and the potential adverse impact of the use of these measures for public reporting.

Therefore, this paper serves to provide a summary of:

- Why the CMS acute ischemic stroke outcome measures, in their present form, may not provide adequate risk adjustment;
- Why the measures, as currently designed, may lead to inaccurate representation of hospital performance and the potential for serious unintended consequences;
- What activities the AHA/ASA has engaged in to highlight these concerns to the CMS and other interested parties; and
Alternative approaches and opportunities that should be considered for more accurate, risk-adjusting 30-day outcomes measures in patients with ischemic stroke.

Summary of Efforts to Date by the AHA/ASA Regarding to the 30-Day Mortality and 30-Day Readmission Stroke Outcome Measures

Background

Stroke is the fourth leading cause of death in the United States and the second leading cause of death globally. It is most common cause for long-term disability. It is estimated that 6.8 million Americans ≥20 years of age have had a stroke. Each year, approximately 795,000 people experience a new or recurrent stroke. In 2010, the direct cost of stroke alone was estimated at $36.5 billion with a total cost of >$75 billion. Because of the high incidence rate and cost involved, the CMS’ decision to focus substantial efforts into the development of 30-day stroke outcome measures for mortality and readmission is admirable, but its execution needs to be remedied.

YNHHSC/CORE had previously been engaged by the CMS to develop the HF, AMI, and pneumonia 30-day outcome measures for mortality and readmission that are currently used by the CMS and are publicly reported on the Hospital Compare Web site. Once awarded the stroke measures contract, YNHHSC/CORE developed a technical advisory panel to review the stroke measures. A select number of AHA/ASA stroke experts were consulted through the development process and conveyed to YNHHSC/CORE and the CMS the critical importance for any models to adjust for initial stroke severity. In developing the stroke outcome measures, YNHHSC/CORE
adapted and applied the prior approach used for other disease states for models of 30-day mortality and 30-day readmission measures in acute ischemic stroke. Both the 30-day mortality and readmission stroke measures were constructed to utilize exclusively administrative data set-derived risk adjustments.

Medical conditions vary widely to the degree to which outcomes are determined by specific variables, such as presenting disease severity. However, most of these severity variables are not currently captured in administrative claims data. Previous studies demonstrated that risk-standardization models for nonstroke conditions, adjusting for demographics and comorbid conditions based on administrative claims data, are sufficient for public reporting despite not adjusting for indicators of disease severity, laboratory test results, and diagnostic studies at time of presentation. In acute ischemic stroke, stroke severity has been documented to be a key mortality risk determinant in acute ischemic stroke. Prior analyses demonstrated that stroke severity, as quantified by the NIHSS, was the strongest predictive variable for in-hospital and 30-day mortality and substantially improved the performance of a model based on clinical variables without stroke severity. It logically follows that a measure of stroke severity would be essential for optimal discrimination of hospital-level mortality risk. Such adjustments are particularly relevant to stroke because of the extreme heterogeneity in stroke severity and outcomes even among one well defined stroke subtype, namely ischemic stroke. Clinical deficits caused by an ischemic stroke are largely dependent on the location and size of the ischemic lesion. For example, an ischemic stroke 1 cm in diameter might be largely asymptomatic if it occurred in the nondominant frontal or temporal lobes; yet a similar-sized lesion could produce coma and/or quadraparesis if it occurred in the brainstem. Although the underlying
pathophysiology of most ischemic strokes is atherothrombosis or thromboembolism, the specific vessel involved and territory affected are highly variable and lead to a broad array of clinical syndromes and disability.

Research has confirmed that a hospital risk model for acute ischemic stroke, based on national CMS claims data alone without adjustment for stroke severity, has substantially worse discrimination compared with the same model to which stroke severity using the NIHSS has been added. Further ranking of hospitals could be confounded if the risk-adjustment models do not account for the severity of the acute ischemic stroke at initial presentation. Similarly, an analysis of 2 administrative data prediction models used to assess New York hospitals found that, in the absence of a measure of index stroke severity, the mortality prediction models were noncongruent and yielded hospital rankings that agreed only slightly more often than expected by chance. Although 30-day mortality that uses claims data only may adequately discriminate mortality risk at the hospital level for Medicare patients with conditions such as HF, AMI, and pneumonia, this is not the case for acute ischemic stroke. In marked contrast to these other conditions, 30-day mortality models using claims data only do not adequately discriminate mortality risk at the hospital level for acute ischemic stroke.

**Initial 30-Day Measures Posted for Public Comment**

In 2010, the draft measure specifications were posted on the CMS Web site for public comment. The AHA/ASA submitted comments to the CMS on the proposed measures, as did >30 organizations or individuals. The AHA/ASA suggested that applying the standard cardiovascular risk-adjustment strategy developed for cardiac conditions to stroke outcomes
assessment was inappropriate given that stroke is a distinct neurovascular disease, thus the need
to include stroke severity was reinforced.\textsuperscript{18} Although most administrative data sets currently do
not collect stroke severity information, capturing these data within administrative data sets is
feasible given the high frequency of documentation in the medical record in current clinical
practice and the increased documentation that would be expected if risk-standardized measures
explicitly incorporated this variable. Reliable tools for documenting presenting severity are
widely available, such as the NIHSS, a 15-item neurological examination scale with scores from
0 to 42, with higher scores indicating more severe stroke. The NIHSS is endorsed in national
guidelines, has high use in clinical practice, and is explicitly linked to medical practice by federal
drug labeling.\textsuperscript{15,22} Although the YNHHSC/CORE measure is an attempt to risk adjust the
measures without access to stroke severity variables, the adjustment technique developed does
not account for the wide variations in stroke severity among hospitalized patients observed at
various hospitals across the United States. For example, in the case of 30-day mortality, safety-
et hospitals that provide care to underserved minority populations are at a disadvantage,
because these patients typically have more severe presenting deficits.\textsuperscript{23} Similarly, evolving
stroke systems of care often triage or concentrate the most severely disabled stroke patients at
regional stroke referral centers, and this may result in a disproportionate concentration of more
severe strokes at these centers. If these claims-based models do not account for this case mix of
increased stroke severity, then these models will generate higher than expected mortality at
stroke referral centers.

The AHA/ASA specifically endorsed the NIHSS as a measure of severity in its comments to the
CMS. Although there are many different methods of gauging the severity of stroke, multiple
publications have shown that the baseline NIHSS is well-validated, highly reliable, and an extremely strong predictor of both mortality and short- and long-term functional outcomes.\textsuperscript{7,8,14,24-26} Use of a standardized assessment and stroke scale, such as the NIHSS, is endorsed in national guidelines as a Class I recommendation,\textsuperscript{27,28} because the assessment ensures that the major components of a neurological examination are performed in a timely and uniform manner, quantifies the degree of neurological deficits, facilitates communication among practitioners, helps identify the location of arterial occlusion, provides early prognosis, helps select patients for various interventions, and identifies the potential for complications.\textsuperscript{27,28} The NIHSS is widely used in current clinical practice.\textsuperscript{29} These baseline differences in NIHSS scores can affect the response of stroke patients to intravenous tissue plasminogen activator, which is the only FDA-approved medical therapy to reduce disability after acute ischemic stroke. Moreover, federal drug labeling for intravenous tissue-type plasminogen activator incorporates the NIHSS. Because the risk of hemorrhage is considerable among patients with high NIHSS scores, FDA labeling indicates the decision to treat with intravenous tissue-type plasminogen activator in patients with NIHSS scores $>22$ should be made with caution. Therefore, the AHA/ASA advocates that efforts continue to focus on how to collect and incorporate the NIHSS into a revised version of the 30-day measures.

The CMS could, at very little cost, require NIHSS data collection, making this important covariate available for risk adjustment in all eligible patients and hospitals. There is growing evidence that supports the feasibility of collecting NIHSS data in all acute ischemic stroke patients with little or no missing data, at the hospital level and across hospital systems level.\textsuperscript{23,30,31} These data are routinely and voluntarily reported by the 1702 hospitals currently
participating in the AHA’s Get With The Guidelines-Stroke (GWTG-Stroke). The AHA/ASA advocated that a stroke severity variable can be reliably abstracted and reported via clinical disease registries and can be required by the CMS for all stroke admissions by creating a new coded variable for this value. Although there were concerns about requiring hospitals to collect such data (baseline NIHSS), such data would benefit the hospitals by allowing them to risk adjust their outcomes.

Finally, the AHA/ASA expressed its concerns that both the 30-day mortality and 30-day readmission measures were not well validated, because these measures were not published in a peer-reviewed journal that could serve to critique what limitations, if any, were identified through data analysis.

30-Day Stroke Measures Are Submitted to the National Quality Forum for Potential Endorsement

Despite feedback on these measures by the AHA/ASA and other organizations, these measures were submitted to the National Quality Forum (NQF) for possible endorsement. The 30-day stroke outcome measures were submitted to NQF during a call for neurology measures. These measures are referred to as Measure #2026: Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following an acute ischemic stroke hospitalization and Measure #2027: Hospital 30-day, all-cause, risk-standardized readmission rate following an acute ischemic stroke hospitalization in the NQF measure documentation. The NQF Neurology Committee met and started the review of these measures during the summer of 2012.
The NQF held a first open comment period for all measures that were submitted for consideration on July 13, 2012. Through the public comment period, the AHA/ASA and other professional societies reiterated the comments previously provided in this document, and highlighted 2 recent papers that demonstrated that, in the case of the mortality measure, the NIHSS is highly correlated with outcome.\textsuperscript{15,16} Indeed, baseline NIHSS was demonstrated to be the most important clinical factor in predicting short-term stroke outcomes.

In the first study,\textsuperscript{15} researchers established the relationship, optimal categorization, and risk discrimination with the NIHSS for predicting 30-day mortality among Medicare beneficiaries with acute ischemic stroke. Researchers analyzed data from 33,102 fee-for-service Medicare beneficiaries treated at 404 GWTG-Stroke hospitals between April 2003 and December 2006 with NIHSS scores documented. The 30-day mortality rates according to the NIHSS as a continuous variable and by risk tree determined or prespecified categories were analyzed, with discrimination of risk quantified by the c-statistic. In this cohort, mean age was 79.0 years and 58% were female. The median NIHSS score was 5 (25th to 75th percentile, 2 to 12). There were 4496 deaths in the first 30 days (13.6%). There was a strong graded correlation between increasing NIHSS score and higher 30-day mortality (Figure). The 30-day mortality rates for acute ischemic stroke by NIHSS categories were as follows: 0 to 7, 4.2%; 8 to 13, 13.9%; 14 to 21, 31.6%; and 22 to 42, 53.5%. A model with NIHSS alone had better discrimination than a clinical model including demographic, clinical characteristics, and comorbid conditions but not adjusting for stroke severity. A model with the NIHSS alone also provided excellent discrimination whether included as a continuous variable (c-statistic 0.82 [0.81–0.83]), 4 categories (c-statistic 0.80 [0.79–0.80]), or 3 categories (c-statistic 0.79 [0.78–0.79]). The
researchers concluded that the NIHSS provides substantial, prognostic information regarding 30-day mortality risk in Medicare beneficiaries with acute ischemic stroke and that the NIHSS is a strong discriminator of mortality risk, even in the absence of other clinical information, whether used as a continuous or categorical risk determinant.

In the second study, researchers evaluated the degree to which hospital outcome ratings and potential eligibility for financial incentives would be altered by adding initial stroke severity to a claims-based risk model for hospital 30-day mortality for acute ischemic stroke. Data were analyzed from 782 GWTG-Stroke participating hospitals on 127,950 fee-for-service Medicare beneficiaries with ischemic stroke who had a score documented for the NIHSS between April 2003 and December 2009. Performance of claims-based hospital mortality risk models (replicated using the published methods of the YNHHSC/CORE group) with and without inclusion of NIHSS scores for 30-day mortality was evaluated and hospital rankings from both models were compared (Tables 1 and 2). The net reclassification improvement (93.1%; 95% confidence interval, 91.6%–94.6%; \( P < 0.001 \)) and integrated discrimination improvement (15.0%; 95% confidence interval, 14.6%–15.3%; \( P < 0.001 \)) indexes both demonstrated significant enhancement of model performance after the addition of the NIHSS (Table 1). A net reclassification improvement can be interpreted as the percentage by which the net classification has improved with the addition of the NIHSS.\(^{16}\) As an integral, the integrated discrimination improvement grades performance in improving overall sensitivity and specificity. The value obtained as the integrated discrimination improvement grade can best be interpreted as the absolute increase in sensitivity given a constant specificity. Among hospitals ranked in the top 20% or bottom 20% of performers by the claims model without NIHSS scores, 26.3% were
ranked differently by the model with NIHSS scores. Of hospitals initially classified as having “worse than expected” mortality, 57.7% were reclassified to “as expected” by the model with NIHSS scores included (Table 2). Of the 782 hospitals in the study, the median absolute change in rank position was 79 (interquartile range 35–155) when hospitals were ranked with and without adjustment for stroke severity. Explained variance and model calibration was also improved with the addition of NIHSS scores. More than 40% of hospitals identified in the top or bottom 5% of hospital risk-adjusted mortality would have been reclassified into the middle mortality range using a model adjusting for NIHSS compared with a model without NIHSS adjustment. This study concluded that adding stroke severity, as measured by the NIHSS, to a hospital 30-day risk model based on claims data for Medicare beneficiaries with acute ischemic stroke was associated with considerably improved model discrimination and change in mortality performance rankings for a substantial portion of hospitals. Both of these studies demonstrated the value of including stroke severity in any stroke outcomes model. These studies also demonstrated that a substantial portion of hospitals will be misclassified if a 30-day mortality model is used that does not adjust for stroke severity.

When the data provided by YNHHSC/CORE to the NQF using the CMS measure were compared with a model that adjusts for stroke severity (using a similar but less accurate measure of stroke severity than the NIHSS), similar findings were demonstrated. In the Stroke Measure Methodology report, the YNHHSC/CORE CMS compared its claims model to a medical record model of a retrospective hospitalized cohort of Medicare beneficiaries from 1998 to 2001 that adjusts for presenting stroke severity using the National Stroke Project-Stroke Scale. The National Stroke Project-Stroke Scale is a measure of stroke severity with substantial limitations
in content validity and concurrent validity compared with the NIHSS. Despite the major limitations of the National Stroke Project-Stroke Scale, the YNHHSC/CORE reports demonstrated there is marked improvement in model discrimination when this severity measure is included. The claims model without stroke severity adjustment has a c-statistic of 0.71, whereas the medical record model has a c-statistic of 0.80. This large absolute difference in model discrimination, comparing the YNHHSC/CORE CMS administrative-only model to one that adjusts for stroke severity, reinforces the concerns about inadequate risk adjustment by the claims-only model. Further, there was no hospital-level comparison of the claims model to the clinical model. A state-level comparison of the 2 models showed the $R^2$ was 0.56. The figure provided in that report, plotting the RSMRs for claims versus medical record models (that included National Stroke Project-Stroke Scale stroke severity adjustment), showed that of the 8 states with the highest RSMRs by the claims model, only 2 of these states have the highest RSMRs using the medical record model. Thus, the YNHHSC/CORE data demonstrate that by using the CMS claims model, 75% of states classified as having the worst RSMR performance were misclassified compared with the output of a medical record model that adjusts for stroke severity.

Although studies on the need to adjust for stroke severity have focused on 30-day mortality rather than rehospitalization, the AHA/ASA did submit comments to the NQF stating that the stroke readmission model for measure #2027 had very poor discrimination in its current form (c-statistic 0.60). Therefore, most of the variances in hospital 30-day readmission are not captured by variables included in the YNHHSC/CORE CMS model. The stroke 30-day readmission measure also does not account for patients who die within the 30 days postdischarge, and
therefore, cannot be rehospitalized. The AHA/ASA further noted that there is a growing body of
evidence that suggests the primary drivers of the variation in 30-day readmission rates involve
variables that are not included in this model nor captured in administrative claims data, including
poor social supports, socioeconomic status, differential access to rehabilitation facilities, and
inadequate community resources.\textsuperscript{36} None of these are factors that a hospital can readily mitigate.
Each of these factors is especially important to ischemic stroke patients who are often disabled
and unable to care for themselves after their hospital stay.

Based on the first round of public comments that were submitted, the YNHHSC/CORE made
some changes to the specifications for stroke mortality and stroke readmission (measures \#2026
and \#2027).\textsuperscript{32} The changes that were made can be summarized as follows.

- For acute ischemic stroke mortality measure \#2026, the YNHHSC/CORE modified the
  measure to include all-payer patients ages \( \geq 18 \) years rather than limiting it to Medicare
  fee-for-service patient ages \( \geq 65 \) years.
- For acute ischemic stroke readmission measure \#2027, the YNHHSC/CORE modified
  the measure to:
  - Include all-payer patients ages \( \geq 18 \) years (rather than Medicare fee-for-service patient
    ages \( \geq 65 \) years only).
  - Incorporate an algorithm for identifying and excluding planned readmissions from the
    measure.
  - Revise the algorithm that identifies commonly planned readmissions for all types of
    patients, not just those who are planned as follow-up poststroke. Originally, the
    measure excluded readmissions that were planned for procedures related to follow-up
care after an ischemic stroke. The new planned readmission algorithm also attempted to harmonize the stroke readmission measures with other CMS/YNHHSC readmission measures.

These 2 measures were then released for a second comment period in September 12, 2013. The NQF Neurology Committee again received numerous concerns from public commenters that the 30-day mortality measures continued to lack adequate risk adjustment for stroke severity; other commenters voiced concern that the measure could not adequately demonstrate the quality of care without some sort of adjustment for stroke severity; still other commenters addressed the lack of exclusions for patients choosing palliative care. As a result of the AHA/ASA and other public feedback, the 30-day mortality measure was withdrawn from consideration by the measure developer to reevaluate its approach to risk adjustment, and therefore the measure was not endorsed by NQF. The NQF Neurology Committee reviewed the public comments received on the 30-day readmission measure and, after discussion, decided not to endorse this measure.

Some of the concerns raised by the NQF Neurology Committee were noted in the final report and included conclusions from the committee that, among other concerns, there was a lack of information regarding the extent to which hospital-level factors influence readmission rates; thus, there was significant chance of potential unintended consequences.

**30-Day Stroke Measures to be Included in Inpatient Prospective Payment System Rule**

In 2013, the CMS proposed to include both measures for the Inpatient Prospective Payment System (IPPS). In this proposed rule, the CMS stated that they planned to include the non-NQF endorsed hospital 30-day, all-cause risk-standardized rate of mortality following an admission.
for acute ischemic stroke measure, and also planned to include the 30-day, all-cause risk-standardized rate of readmission following an admission for acute ischemic stroke measure in the Hospital IQR Program. According to the CMS, it was planning to include these measures despite lack of NQF endorsement. The CMS felt it was important to adopt these measures to address a prevalent and costly health problem in the nation and was using its discretionary authority. The CMS further noted that the measures aligned with its prior priority objectives to promote quality improvements leading to successful transition of care for patients from acute care to outpatient settings and reducing short-term, preventable mortality rates.\textsuperscript{16}

Multiple organizations have expressed concerns regarding the proposed inclusion of these measures in the IPPS rule. The commenting organizations that recommended these measures should not be adopted in their current form included: the America’s Health Insurance Plans, American Academy of Neurology, American Academy of Physical Medicine and Rehabilitation, American Association of Neurological Surgeons, American College of Physicians, Paul Coverdell National Acute Stroke Program, Premier, American Hospital Association, and Highmark.\textsuperscript{38}

In a public comment letter to the CMS, the AHA/ASA reiterated prior concerns and made the following 3 observations as to why the CMS should not adopt these measures into the IPPS. (1) In past IPPS proposed rules, the CMS has clearly moved toward adoption of measures that are NQF endorsed to ensure that the measures are consensus based, are widely supported, and, where possible, to reduce administrative burden. Although occasional measures have been adopted by the CMS without NQF endorsement, using its exception authority under section 1886(b)(3)(B)(IX)(bb) of the Act,\textsuperscript{39} the AHA/ASA voiced concerns about the CMS adopting an
outcome measure that was not endorsed. (2) The CMS has used this authority to adopt process measures, but this would be the first time that it would be adopting a measure that the NQF had explicitly declined to endorse or that was pending NQF endorsement.\(^{40}\) (3) The MAP, which is intended to provide input to the US Department of Health and Human Services on the selection of performance measures for public reporting and performance-based payment programs,\(^ {41}\) recommended against adoption for both of these measures. The CMS should not adopt these measures.

Ultimately, the CMS decided to go forward with implementation of the measures; however, it noted in the final rule\(^ {42}\) that it was committed to working with the stakeholder communities and to continuously refine the stroke outcome measures to seek feasible ways to incorporate additional severity adjustment as suggested. Because the CMS has decided to adopt both of these measures, it has stated that results for these outcome measures will be reported publicly in 2014 through Hospital Compare. To educate hospitals, the CMS provided hospitals with its 2013 Hospital-Specific Reports on August 12, 2013.\(^ {43}\) A national provider conference call was held on August 20, 2013, for hospitals, quality improvement organizations, and other stakeholders. The detailed measure specifications for these 2 measures were posted on Quality Net as a resource for interested parties\(^ {35}\)

### 2013 Review of Potential 30-Day Measures

On December 1, 2013, the NQF announced that the measures-under-consideration list to be reviewed and potentially recommended by the MAP had been developed and posted. Each year, the MAP meets to provide the CMS with guidance regarding which measures the CMS should
consider adopting or removing from the program for the next fiscal year. The MAP then assembled workgroups to identify which of the measures in the proposed list would be recommended by the MAP for inclusion in the US Department of Health and Human Services federal programs. Included in the list of measures under consideration were both the 30-day mortality and 30-day readmission stroke outcome measures. The hospital workgroup met on December 11, 2013, and discussed the 30-day stroke outcome measures. During this meeting, the workgroup acknowledged that the risk adjustment for these measures was not adequate. Nevertheless, the workgroup felt that it was better to have outcomes measures for stroke used by the CMS, rather than none. The hospital workgroup, therefore, voted that both these measures should be conditionally approved for IQR with the expectation that the measures would need to be refined to incorporate stroke severity in the future. The workgroup also recommended the 30-day hospital readmission measure.41

Although the final report has not been issued, the AHA/ASA will again raise concerns with the decision of the MAP to endorse these measures. In this case, the MAP is not following the recommendations made by the NQF Neurology Committee that specifically recommended against endorsing the 30-day readmission measure. Furthermore, because the measure developer pulled the 30-day mortality measure from consideration, the NQF was unable to make a recommendation on endorsement of this measure. The AHA/ASA and others are concerned that even provisional endorsement of these measures is inconsistent with the stated purposes of the CMS outcomes measure reporting program. Furthermore, in the case of the readmission, it has facilitated the ability of this measure to be used in another CMS program where payment is based on performance.
The Importance of Advocating for Revisions to the 30-Day Stroke Outcome Measures

Potential Unintended Consequences From Current 30-Day Outcome Measures

The AHA/ASA supports the creation and implementation of appropriately risk-adjusted outcome measures that have been tested and validated in peer-review literature. There are several concerns that the AHA/ASA hopes to mitigate through its current advocacy efforts on the 30-day mortality and 30-day readmission stroke measures. The unintended consequences that may occur are discussed below in more detail but can be summarized as follows. These measures may (1) mischaracterize hospital performance, (2) worsen health disparities, and (3) harm patient care by undermining stroke systems of care.

30-Day Stroke Mortality Measure May Mischaracterize Hospital Performance

As previously noted, a study published in 2012 used a risk model almost identical to the mortality measure proposed by the CMS and found that 58% of hospitals identified as having “better than” or “worse than” expected risk-standardized mortality would be reclassified to “as expected mortality” if the measure did not include an adjustment for stroke severity.16 This means that stroke centers, which are the most qualified to treat patients with severe strokes and treat more of them than other facilities, may be assigned a low performance rating simply because patients with severe strokes are more likely to die.44 This could result in significant financial penalties for these hospitals and could create adverse incentives for them to avoid treating or accepting in transfer the sickest patients for whom they are the most capable of providing treatment.
To further explore to what extent teaching hospitals and The Joint Commission–certified primary stroke centers will be impacted by being misclassified as having “worse than expected” 30-day mortality using a model that does not adjust for stroke severity, we examined the hospital characteristics of the hospitals evaluated in the *Journal of the American Medical Association* publication. We focused our analysis on those hospitals that were classified as “worse than expected” using the administrative model without the NIHSS but that were reclassified to “as expected” when using the administrative model with the NIHSS added. Among this cohort of misclassified hospitals, 46% were teaching hospitals, whereas among all hospitals in the overall sample only 28% were teaching hospitals. We then examined what proportion of teaching hospitals or primary stroke centers would be misclassified by the absence of the NIHSS. Among teaching hospitals classified as having “worse than expected” mortality by the claims-based measure, 58% will have been misclassified. Among primary stroke centers classified as having “worse than expected” mortality by the claims-based measure, 50% will have been misclassified. Therefore, primary stroke centers and teaching hospitals may be disproportionately negatively impacted by use of a model that does not adjust for stroke severity.

It has been shown that patients transported by EMS have greater stroke severity. Hospitals participating in stroke systems of care that include EMS diversion policies are also most likely to receive these patients with greater stroke severity. These hospitals may be unfairly penalized by an RSMR measure that does not account for stroke severity, which may lead to hospitals not participating in stroke systems of care. Some have suggested that differences across the hospital-level patient comorbidity codes can help distinguish high from low stroke severity and thereby adjust for the differences in case mix. There are, however, few differences in the demographics
and comorbid conditions that are used in the CMS risk-adjustment models among hospitals treating patients with greater or lesser stroke severity,\textsuperscript{35} suggesting that the hospital-level variation in case-mix severity could not be captured indirectly by current comorbidity codes and would require a direct measure of stroke severity.

All hospitals deserve to have their performance fairly and accurately rated. However, using the CMS model, hospitals that care for patients with greater stroke severity may be unfairly misclassified as having “worse than expected” 30-day mortality, with primary stroke centers, comprehensive stroke centers, and academic teaching hospitals particularly at risk for misclassification.

30-Day Mortality Measure and 30-Day Readmission Stroke Measures May Worsen Health Disparities

According to a recent study,\textsuperscript{23} patients living in impoverished areas have more severe strokes. In fact, they are twice as likely to have a severe stroke. In this study, researchers found that the poorest community socioeconomic status was associated with a significantly increased initial NIHSS score by 1.5 points (95% confidence interval, 0.5–2.6; $P<0.001$) compared with the richest category in the univariate analysis, which increased to 2.2 points after adjustment for demographics and comorbidities. In addition, in the GWTG-Stroke national registry, African American race and Hispanic ethnicity are associated with higher presenting stroke severity.\textsuperscript{44}

The AHA/ASA is concerned that safety-net hospitals that care for significantly larger numbers of poor and minority stroke patients are at risk of being disproportionally impacted by a measure that does not account for stroke severity. Analysis of the GWTG-Stroke dataset found that
hospitals treating patients with greater stroke severity were substantially more likely to provide care for patients who were African American (20.2% highest stroke severity hospitals versus 15.3% lowest stroke severity hospitals; \( P<0.0001 \)), were Hispanic (11.1% highest stroke severity hospitals versus 4.5% lowest stroke severity hospitals; \( P<0.0001 \)), and were transported by EMS rather than private vehicle (55.2% highest stroke severity hospitals versus 44.3% lowest stroke severity hospitals; \( P<0.0001 \)). Therefore, the nation’s safety-net hospitals that care for these disadvantaged groups are most likely to be unfairly penalized by RSMR measures that do not take stroke severity into account, depriving them of needed resources and unduly causing concerns in these communities of substandard care.

It is reasonable to expect that consumers viewing publicly reported government data on these measures may believe that safety-net hospitals deliver poorer quality of care, when in reality they may be delivering good or excellent quality of care to the sickest stroke patients, which often includes ethnic minorities. This mischaracterization may evoke unjustified mistrust in the medical system, the opposite of what consumer engagement should engender.

The 30-Day Mortality and 30-Day Readmission Stroke Measures May Harm Patient Care by Undermining Stroke Systems of Care Model

Stroke systems of care are designed to ensure that stroke patients receive timely, appropriate treatment; this includes transportation to the hospital or stroke center that is best equipped to care for the patient.\(^{46,47}\) The AHA/ASA has worked for more than a decade to promote the adoption of systems of care at the state and federal levels.\(^{46}\) These outcome measures have the potential to undermine these efforts. Within a stroke system of care, EMS will divert the sickest patients to
designated hospitals, while less ill patients will be transported to other facilities. The hospitals accepting the sickest patients have a real risk of being unfairly penalized if they report worse outcomes, as might be expected based on the above data. This has the potential to create powerful disincentives for some hospitals to accept the most severely affected stroke patients unless the results are adjusted for severity. Specifically, the proposed measures may encourage hospitals to select or “cherry pick” stroke patients with mild or moderate strokes and may discourage hospitals from accepting patients via transfer from referring emergency departments or hospital inpatient units who have the most severe strokes. This is of particular concern, because hospitals are aware that the resulting mortality and readmissions data will be publicly available on hospital comparison Web sites without the benefit of an adequate risk adjustment.

The AHA/ASA noted to the CMS during the IPPS comment period that there were few differences in the demographics and comorbid conditions that are used in the CMS risk-adjustment models among hospitals treating patients with greater or lesser stroke severity, suggesting that the hospital-level variation in case-mix could not be captured by current comorbidity codes and requires a direct measure of stroke severity.

These potential unintended consequences are magnified when one considers that these measures will be publicly reported on the Hospital Compare Web site beginning in 2014. The performance of hospitals will be available for comparison by patient, caregivers, payers other than the CMS, media, as well as other interested stakeholders. Consumers viewing this information may believe that safety-net hospitals or other teaching hospitals or stroke centers are poor performers, thus avoid these hospitals. Although these measures are not currently included in pay for
performance, it is foreseeable that these measures will eventually be incorporated into such a
model of payment by the CMS and potentially by other payers or in state initiatives.

**Activities the AHA/ASA Is Engaging in to Address These Measures**

Given that these measures will be reported in 2014 on the Hospital Compare Web site, it is
critical that hospitals, policymakers, payers, patients, and caregivers be aware of the potential
unintended consequences that may occur as a result of these measures. The AHA/ASA is
couraged by the CMS’ promise to work with interested stakeholders to refine this measure.
The AHA/ASA will work closely with the CMS to identify adequate mechanisms by which to
revise these 2 measures to be properly risk adjusted and integrate with the NIHSS. The
AHA/ASA also appreciates the CMS’ willingness to work with interested stakeholders to
develop better measures for stroke outcomes.

In the immediate future, there are some specific strategies that the AHA/ASA is interested in
exploring further. First, we ask that the CMS, the Administration, and the US Congress
reconsider the decision to use these specific outcomes measures for acute ischemic stroke that
have engendered such unprecedented controversy. This opposition should give pause to all
responsible for public health and result in reflection of the very real potential for these measures
to violate several of the domains of quality as defined by the Institute of Medicine. Namely,
these measures have the real potential to be unsafe, ineffective, or inequitable along with the
potential to do harm.
Opportunities to Provide More Accurate Risk Adjustment of Stroke Outcome Measures

Moving forward, there are important opportunities to help ensure adequate risk adjustment of stroke outcome measures. One method that should be explored is to develop electronic health record specifications of the 30-day stroke outcome measures that would include an index of stroke severity. The AHA/ASA acknowledges that developing electronic measures is labor intensive. However, we believe that timely creation of these measures is critical to mitigate any potential unintended consequences that may result from the claims based a measure that does not include the NIHSS. Given the length of time that can be required between the development, validation, and implementation of an electronic health record measure, the AHA/ASA sees the potential development of a code set that captures the NIHSS through administrative claims data as an interim step. There is precedence for the collection of severity data via *International Classification of Diseases, 9th Revision (ICD-9)* and *International Classification of Diseases, 10th Revision (ICD-10)* codes as is evidenced by the Glasgow Coma Scale and severity of renal disease. The AHA/ASA is interested in exploring the feasibility of developing NIHSS *ICD-9*/ICD-10 codes as a means by which to allow claims-based stroke outcome measures to include severity adjustment. Additionally, the AHA/ASA is planning to conduct additional research on data collected as part of its GWTG-Stroke program and other sources. Once the current CMS stroke measures are publicly reported, the AHA/ASA will analyze whether primary stroke centers and comprehensive stroke centers are more likely to be classified as having worse than national average 30-day outcomes using the CMS stroke measure. The AHA/ASA is collaborating with The Joint Commission on standardizing the collection of initial NIHSS data for patients hospitalized with acute ischemic stroke. In addition, the AHA/ASA will continue
offering a certification program for the NIHSS for US physicians, nurses, and allied health personnel at no or nominal cost, a program so far completed by 562,088 providers.49

In addition to our advocacy efforts, the AHA/ASA is committed to gaining further understanding of the unique complexity of stroke and the need for risk adjustment as evidenced in the recently released scientific statement entitled “Risk Adjustment of Ischemic Stroke Outcomes for Comparing Hospital Performance.”50

Lastly, we are committed to work with the CMS and other interested stakeholders to ensure that appropriate 30-day risk-adjusted stroke measures are created, which are fundamentally critical for the care of stroke patients in the United States. It is vital to work collaboratively to revise these measures, but also to identify and anticipate any unintended consequences that may be created by these measures and to help devise strategies to mitigate them.

Conclusion

The AHA/ASA fully supports the development of appropriately risk-adjusted outcome measures for stroke. However, we express concern that the current 30-day mortality and 30-day stroke readmission measures used by the CMS in its programs are not appropriately risk adjusted by failing to account for baseline stroke severity. Models for acute ischemic stroke without adjustment for stroke severity provides lesser discrimination, produces different rankings of hospital performance, and are biased in favor of hospitals treating less severe strokes. Rewarding or punishing hospitals on the basis of risk models that do not account for stroke severity will misalign incentives, as many hospitals identified as performing better than or worse than expected will have been misclassified. Primary stroke centers and safety-net and teaching
hospitals will be disproportionately and negatively impacted by the use of risk models not
directly adjusting for stroke severity. As a consequence, hospitals may consider turning away
patients with more severe strokes or transferring them to other hospitals after emergency
department assessment to avoid being misclassified as having worse risk-standardized outcomes,
undermining stroke systems of care.

The AHA/ASA is committed to partnering with others and providing the CMS with additional
data, expertise, and support in developing revised versions of these measures to promote truly
risk-adjusted outcome measures. We are pleased that the CMS has stated its intention to work
with organizations such as the AHA/ASA and others to revise future iterations of these
measures. We are, however, disappointed by the MAP hospital workgroup’s decision to
recommend these 2 measures. We recognize that revising the measures will take time; however,
during this interim period, unintended consequences could occur from the use of these measures
in their current form. Therefore, it is critical that interested stakeholders work with the
AHA/ASA to identify examples of unintended consequences that may occur, develop effective
strategies to mitigate any unintended consequences resulting from misclassification of hospitals,
and develop interim solutions to integrate stroke severity variables into the risk models. We
encourage all stroke stakeholders to share concerns and issues they have identified directly to the
CMS. It is through these mechanisms that we can ensure there is accurate and reliable
assessment and reporting of hospital-level outcomes for acute ischemic stroke.
Table 1. Performance of 30-Day Mortality Risk Models for Acute Ischemic Stroke Without and With the NIHSS

<table>
<thead>
<tr>
<th>Risk model without NIHSS</th>
<th>c-Statistic (95% CI)</th>
<th>Generalized $R^2$</th>
<th>Predicted Event Rate by Decile of Predicted Risk, %</th>
<th>NRI, % (95% CI)</th>
<th>IDI, % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk model with NIHSS</td>
<td>0.864 (0.861–0.867)</td>
<td>0.335</td>
<td>4.81</td>
<td>—</td>
<td>27.7*</td>
</tr>
<tr>
<td>Difference</td>
<td>0.091 (0.088–0.094)</td>
<td>0.161 (0.155–0.167)</td>
<td>—</td>
<td>—</td>
<td>93.1 (91.6–94.6)</td>
</tr>
<tr>
<td>$P$ Value</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>—</td>
<td>—</td>
<td>&lt;0.0001</td>
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</table>

The NRI index compares the shifts in reclassified categories by observed outcome, resulting from the addition of NIHSS score to the model. A higher NRI index indicates a greater improvement in risk discrimination and improved reclassification. The IDI measures how the model that included NIHSS score reclassified patients compared with the model without NIHSS score. A higher IDI index indicates a greater improvement in risk discrimination and improved reclassification. Age, sex, past medical history of prior stroke/transient ischemic attack, and 84 condition codes are adjusted for in the modeling.

IDI indicates integrated discrimination improvement; NIHSS, National Institutes of Health Stroke Scale; NRI, net reclassification improvement.

*Discrimination slope defined as difference of estimated mean probability for events and estimated mean probability for nonevents.

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Table 2. Hospital Ranking Agreement Based on 30-Day Mortality Risk Models Without and With Adjustment for NIHSS

<table>
<thead>
<tr>
<th>Rank Based on Model Without NIHSS</th>
<th>Top 20%</th>
<th>Middle 60%</th>
<th>Bottom 20%</th>
<th>Total</th>
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<tr>
<td>Rank Based on Model With NIHSS</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Top 20%</td>
<td>110</td>
<td>55</td>
<td>1</td>
<td>156</td>
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<tr>
<td>Middle 60%</td>
<td>55</td>
<td>367</td>
<td>47</td>
<td>469</td>
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<tr>
<td>Bottom 20%</td>
<td>1</td>
<td>47</td>
<td>109</td>
<td>157</td>
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<tr>
<td>Total</td>
<td>156</td>
<td>469</td>
<td>157</td>
<td>782</td>
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<table>
<thead>
<tr>
<th>Rank Based on Model Without NIHSS</th>
<th>Top 5%</th>
<th>Middle 90%</th>
<th>Bottom 5%</th>
<th>Total</th>
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<tr>
<td>Rank Based on Model With NIHSS</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Top 5%</td>
<td>23</td>
<td>16</td>
<td>0</td>
<td>39</td>
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<tr>
<td>Middle 90%</td>
<td>16</td>
<td>668</td>
<td>19</td>
<td>703</td>
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<tr>
<td>Bottom 5%</td>
<td>0</td>
<td>19</td>
<td>21</td>
<td>40</td>
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<tr>
<td>Total</td>
<td>39</td>
<td>703</td>
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<table>
<thead>
<tr>
<th>Rank Based on Model Without NIHSS</th>
<th>Better Than Expected*</th>
<th>As Expected*</th>
<th>Worse Than Expected*</th>
<th>Total</th>
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<tr>
<td>Rank Based on Model With NIHSS</td>
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<tr>
<td>Better than expected*</td>
<td>13</td>
<td>9</td>
<td>0</td>
<td>22</td>
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<tr>
<td>As expected*</td>
<td>15</td>
<td>713</td>
<td>6</td>
<td>734</td>
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<tr>
<td>Worse than expected*</td>
<td>0</td>
<td>15</td>
<td>11</td>
<td>26</td>
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<tr>
<td>Total</td>
<td>28</td>
<td>737</td>
<td>17</td>
<td>782</td>
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</table>

NIHSS indicates National Institutes of Health Stroke Scale.

*Hospitals with the 95% credible intervals of the estimated random intercepts not covering the null point are considered to have performance that is significantly better or worse than the average hospital. These categories are analogous to the portions of hospitals identified in Hospital Compare as having better than expected, as expected, or worse than expected 30-day risk-standardized mortality rates.

From Fonarow et al. *JAMA*. 2012;308:257-264. Used with permission. Copyright © 2012 American Medical Association. All rights reserved.
The 30-day mortality rates by admission NIHSS for 33,102 fee-for-service Medicare beneficiaries with acute ischemic stroke. A model with the NIHSS alone, in the absence of any other clinical information provided excellent discrimination (c-statistic 0.82 [95% CI 0.81–0.83]) far exceeding that of administrative or clinical models that did not adjust for stroke severity (c-statistic 0.71 [95% CI 0.70–0.72]).

CI indicates confidence interval; NIHSS, National Institutes Stroke Scale.

## Writing Group Disclosures

<table>
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<tr>
<th>Writing Group Member</th>
<th>Employment</th>
<th>Research Grant</th>
<th>Other Research Support</th>
<th>Speakers’ Bureau/ Honoraria</th>
<th>Expert Witness</th>
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<td>AHA GWTG Stroke CWG (Chair - unpaid)*; Editorial board member of journal <em>Circulation: Cardiovascular Quality and Outcomes (unpaid)</em>; Editorial board member of journal <em>Stroke (unpaid)</em></td>
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*Modest.
†Significant.
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5. 42 CFR part 412 (§412.150 through §412.154).


29. Fonarow GC, Liang L, Smith EE, Reeves MJ, Saver JL, Xian Y, Hernandez AF, Peterson ED, Schwamm LH; on behalf of the GWTG-Stroke Steering Committee & Investigators.


37. 78 Fed Reg 27486 (May 10, 2013).


42. 78 Fed Reg 50496 (August 19, 2013).


Stroke Outcomes Measures Must Be Appropriately Risk Adjusted To Ensure Quality Care of Patients: A Presidential Advisory From the American Heart Association/American Stroke Association

Gregg C. Fonarow, Mark J. Alberts, Joseph P. Broderick, Edward C. Jauch, Dawn O. Kleindorfer, Jeffrey L. Saver, Penelope Solis, Robert Suter and Lee H. Schwamm

Stroke. published online February 12, 2014;

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