Public Comment Summary Report

Project Title:

Development of Claims-Based and Hybrid Measures of 30-Day Mortality Following Acute Ischemic Stroke Hospitalization that Incorporate Risk Adjustment for Stroke Severity

Dates:

- The Call for Public Comment ran from July 27, 2015 to August 26, 2015
- The Public Comment Summary was made on September 1, 2015.

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with Yale New Haven Health Systems Corporation/Center for Outcomes Research and Evaluation (CORE) to develop two types of hospital-level measures of mortality following hospitalization for ischemic stroke. These measures include risk adjustment for stroke severity. The contract name is Development, Reevaluation, and Implementation of Hospital Outcome/Efficiency Measures. The contract number is HHSM-500-2013-13018I- T0001 Modification 000002. As part of its measure development process, CMS has requested interested parties to submit comments on the candidate or concept measures that may be suitable for this project.

Project Objectives:

To develop two types of hospital-level measures of risk-standardized mortality for ischemic stroke patients that include an assessment of stroke severity, as measured by the first captured National Institutes of Health Stroke Scale (NIHSS) score. One type of these measures is an updated claims-based stroke mortality measure that utilizes only Medicare administrative claims data. The other type is "hybrid," which utilizes both claims data and clinical data extractable from electronic health record (EHR) data. We developed two hybrid measures, with two different risk-adjustment models both of which include the NIHSS as a risk factor. One risk-adjustment model is hybrid and includes additional risk factors derived from claims and EHR data; the other risk-adjustment model is EHR data-only and includes additional risk factors only from clinical EHR data.

Information About the Comments Received:

- Public comments were solicited by email notifications. The request for comments was also posted on the CMS Call for Public Comment website (http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html)

Eight responses were received on this topic in total:

- 1 comment from a healthcare company (VHA-UHC Alliance NewCo)
- 1 comment from a not-for-profit accreditation/certification organization and measure developer (The Joint Commission)
- 2 comments from clinical researchers (Veterans Affairs Health Services Research and Development Stroke Quality Enhancement Research Initiative, University of Maryland School of Medicine)
- 2 comments from professional societies/physician associations (American Medical Association, American Association of Neurological Surgeon and Congress of Neurological Surgeons)
- 2 comments from medical/hospital associations (America's Essential Hospitals, American Heart Association/American Stroke Association)

Stakeholder Comments—General and Measure-Specific

Summary of general comments

The vast majority of commenters stated support for the inclusion of stroke severity as a risk factor in the stroke mortality measures. Many comments stated support for the incorporation of clinical EHR data into the measure. A few comments indicated support for the soundness of the methodology.

Proposed action: We thank you for your comments. See CMS's responses and proposed actions under the comment summaries below.

Measure Methodology

Cohort

One comment questioned the generalizability of the measures due to the sample used for development. They posited that the hospitals and patients included in the AHA/ASA registry and used in the development sample may not be representative of the general measure population. Additionally, the commenter expressed concern over the low match rate of the registry and claims datasets.

Response: We thank you for your comment. The Get With The Guidelines (GWTG) – Stroke registry is currently the largest database of stroke patients in the United States that includes both the NIHSS and a wide range of clinical risk factors, with data from over 1,700 hospitals. The hospitals that participate in GWTG-Stroke registry cover over 75% of the total strokes discharged from hospitals in the US. Although the GWTG-S registry was the best source of clinical data for measure development, further measure testing will occur if the measures are implemented and data becomes available.

Regarding the match rate of the datasets, there are multiple possible explanations for mismatch, including key differences such inclusion of only ischemic strokes or a broader set of strokes, all of which are detailed in section 3.4 of the Claims-Based and Hybrid Measures of 30-Day Mortality Following Acute Ischemic Stroke Hospitalization Incorporating Risk Adjustment for Stroke Severity Technical Report (Version 1.0).

One comment voiced a concern regarding the transfer scenarios described in the technical report, which the commenter deemed inconsistent. In these measures, for cases in which the patient is transferred from the emergency department of one hospital and admitted for inpatient care at a different hospital, the mortality outcome is attributed to the hospital that admitted the patient for inpatient care. Additionally, for cases in which the patient is admitted for inpatient care at one hospital and then transferred to a different hospital for inpatient care, the mortality outcome is attributed to the hospital where the patient was first admitted for inpatient care.

Response: We thank you for your comment. The intent of the measure, and all of CMS's 30 day mortality measures, is to attribute the mortality outcome to the index hospitalization, where the patient was first admitted for inpatient care. Actions taken at the admitting hospital, during the transfer, and at the receiving hospital all can affect outcomes, but it is the first admitting hospital that sets the course for care and determines if a transfer is important. Moreover, this attribution strategy avoids creating an incentive for hospitals to transfer patients who are critically ill and at high risk of dying to other institutions. Although it is unlikely that hospitals would act on such an incentive, it is important that the measures do not create incentives for actions that may not be in the best interest of the patient.

The rationale for not attributing the outcome to a hospital that only cared for the patient in their emergency department is that this hospital may have had less influence on the patient's outcome than the accepting hospital. However, such patients are often at higher risk of mortality, so the measure adjusts for that risk.

Risk factors

One comment identified endovascular treatment and tPA administration as potential additional risk factors. The commenter noted that both procedures are becoming more commonly performed.

Response: We thank you for your comment. The measures seek to adjust for case mix differences among hospitals based on the clinical status of the patient at the time of the index admission. Accordingly, only comorbidities and other characteristics that convey information about the patient at that time or in the 12 months prior, and not actions taken by the hospital during the hospitalization, are included in risk adjustment.

A couple of comments suggested risk-adjusting for socio-demographic status (SDS) factors. One commenter cited a study that posited that SDS factors were associated with more severe

strokes. The National Quality Forum currently requests the examination of SDS factors for risk adjustment.

Response: We thank you for your suggestions. The presented stroke mortality measures, like CMS's other risk-standardized outcome measures, do not currently adjust for socioeconomic status or other socio-demographic factors such as race, ethnicity, primary language, and insurance status. CMS has not included socio-demographic factors in the risk model as differences in health outcomes can be due, in part, to differences in quality of health care across groups.

The National Quality Forum is currently undertaking a two-year trial period in which new measures will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate for each measure. Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. CMS will closely examine the findings of the ASPE reports and related Secretarial recommendations when they are available and consider how they apply to quality programs at such time.

In regards to the commenter's reference to the study linking low SES with increased stroke severity, CMS acknowledges that the inclusion of a stroke severity scale may not account for all SDS factors that may be related to stroke. However, the inclusion of NIHSS scores in the risk-adjustment models is designed to account for differences in the severity of strokes experienced by patients.

Feasibility and Testing

A few comments questioned the feasibility of the extraction of EHR variables used in the hybrid risk models. One commenter indicated that "it is still unclear whether EHR data can capture and submit in a manner comparable to the registry testing." Commenters suggested that the clinical variables from the registry data used in development may not be equivalent to clinical variables available in EHR systems, since some hospitals manually abstract data for registry submission. One commenter was concerned that testing the measure with data from one organization was not representative of other hospitals.

Response: We thank you for your comments and understand your concerns. All clinical variables included in the final hybrid risk models have been previously shown to be consistently and reliably collected on all inpatients during clinical workflow, and entered into a standard EHR field in a standardized way. Although many variables were available in the registry database, only variables previously identified as meeting this strict feasibility criteria were considered during the development of these measures. For a detailed list of all the clinical variables available, and rationale for exclusion, please see Table B 2 in the Claims-Based and Hybrid Measures of 30-Day Mortality Following Acute Ischemic Stroke Hospitalization Incorporating Risk Adjustment for Stroke Severity Technical Report (Version 1.0).

In response to the concern regarding submitting EHR data, CMS is considering conducting a pilot to test the submission of clinical data and possibly administrative linking variables from hospitals. If implemented, CMS would use the linking variables to match clinical data to their respective claims data for claims-based outcome measures.

A few comments favored using the NIHSS, but questioned the feasibility of collecting the NIHSS from the majority of EHR systems. One commenter specifically favored using the hybrid risk model, but mentioned the challenge and burden of collecting three years of NIHSS and EHR data from 'two sources'. They specifically asked for EHR extraction to be streamlined and automated in the future.

Response: We thank you for your comments and suggestions. The NIHSS was selected as the stroke severity assessment to be incorporated into the measures based on current clinical guidelines for stroke care, review of the literature, and stakeholder feedback. We developed multiple measures to obtain the NIHSS from either ICD-10 or from EHRs. As one commenter mentioned, it is already used in electronic quality clinical quality measures (STK-4). The NIHSS could be obtained electronically from EHRs because it is collected with a standard definition and entered in structured fields, which indicates that it can be feasibly extracted. Clinical guidelines suggest the NIHSS be performed on every stroke patient upon arrival at a hospital, so it is expected to be widely performed and recorded. As for extracting data from 'two sources', we assume this to be in reference to hospitals using modular EHR systems. CMS is aware of this burden, and is working with stakeholders to streamline this process.

A few comments encouraged CMS to do additional testing of the measures with actual ICD-10-CM and EHR data. Commenters suggested the need to test the model with the exact data sources envisioned for potential use in implementation, as the registry data used for measure development may not be equivalent to EHR data.

Response: We thank you for your comments. A challenge in the development of these measures was the lack of national data currently that includes ICD-10 reported or EHR extracted NIHSS scores. We therefore used registry data as a surrogate for these sources. CMS plans to examine any measure that goes into implementation further once the data from these sources are available.

One comment requested to see the differences in hospitals' performance categorization between the measures; specifically, the commenter was interested in whether the same hospitals would be identified as outliers among the different measures. Additionally, the commenter stated the clinical-only risk model was more parsimonious and less susceptible to gaming, but wondered if this would be more acceptable to the clinical community and stakeholders despite its slightly lower c-statistic.

Response: We thank you for your comment. The development team will take this recommendation for additional analysis under consideration. We developed a more parsimonious clinical-only risk model to be responsive to stakeholders, and to allow CMS flexibility around implementation. Feedback received from previous public comment periods on

other hybrid measures mentioned the desire for a small number of clinical variables, to reduce any burden to hospitals in extracting and submitting data.

Implementation

One comment suggested using Systematized Nomenclature of Medicine--Clinical Terms (SNOMED CT) codes instead of ICD codes for measure calculation, particularly if the measure may be transitioned into an electronic clinical quality measure in the future. The commenter noted that NIHSS scores already exist as a data element in some inpatient quality measures and recommended using the same value set.

Response: We thank you for your comment. The development team will take this recommendation into consideration. The development of multiple measures allows CMS different implementation options, and NIHSS scores could potentially be obtained from EHR data (such as SNOMED CT codes) or from claims data (ICD-10-CM codes), depending on feasibility and CMS's future directions. The electronic specifications for the hybrid measures have not yet been developed, but CMS would plan to align value sets and harmonize with other outcome measures.

Several comments had concerns regarding how CMS would handle missing NIHSS scores or other EHR data. A large proportion of missing variable values would increase the number of values that need to be imputed in order to calculate the measure. One commenter asked if a minimum threshold of data completeness would be set to avoid this. One commenter specifically asked how many patients were missing the NIHSS, and if this had an impact on hospitals' performance.

Response: We thank you for your comments and understand your concerns. If required, hospitals will be expected to accurately and reliably report NIHSS scores for stroke patients, which will reduce the number of missing NIHSS. As to other variables, the final hybrid and clinical-only risk models only include variables previously shown to be consistently and reliably collected on all inpatients during clinical workflow.

The hospitals in the GWTG-Stroke registry cover over 75% of the total strokes discharged from hospitals in the US, although it is unknown how many patients have a recorded NIHSS nationwide. We did not investigate the impact of missing NIHSS scores on hospital performance. CMS is not yet able to provide further implementation details, as the measures are still currently under development.

One comment requested clarification on whether CMS will require hospitals to report NIHSS scores as the measurement of stroke severity. If the NIHSS will be required, commenter urged CMS to provide early warning and education around how to administer NIHSS, as some hospitals might lack the expertise. They also wondered what additional steps and resources would be necessary to collect the NIHSS and other data.

Response: We thank you for your comments and suggestions. If implemented, hospitals will be expected to accurately and reliably report NIHSS scores for stroke patients. CMS will work with stakeholders to provide educational resources on how to find information on administering the NIHSS, and detailed measure specifications. If implemented, guidance will be given on how hospitals will submit data as part of an outcome measure. For more information on the NIHSS, we urge providers to visit the AHA/ASA, here: www.heart.org.

One comment was concerned about the burden on smaller hospitals, and asked if CMS had considered providing incentives or resources for EHR data collection, which could also be used for other hybrid outcome measures.

Response: We thank you for your comments and understand your concern. We will take your suggestion under consideration.

A few comments questioned the generalizability of the models to an all-payer population. Commenters cautioned that the measure models may not be generalizable to younger patients, and therefore inappropriate for use in an all-payer population.

Response: We thank you for your comments. The initial development of these measures was for this 65+ Medicare population; however, CMS is considering further testing in an all-payer population and would reassess the model to ensure that it was appropriate for a younger population as a part of such testing.

A few comments requested details on an implementation timeline. One commenter noted that the measures will need to be reassessed annually, as EHRs evolve over time.

Response: We thank you for your comments. The development team will take stakeholder input into consideration while developing an implementation timeline. As a part of regular measure maintenance, all measures are reevaluated annually.

Model Preferences

One commenter suggested first implementing the updated claims-based measure, then to transition over time to the hybrid measure with the hybrid risk-adjustment model by requiring the collection of EHR data from hospitals.

Response: Thank you for your comment. CMS will take this recommendation into consideration.

A few commenters indicated favor for the hybrid measure with the hybrid risk-adjustment model. One commenter explained that each data source could provide different risk factors, and likely the best model discrimination. Another commenter noted that this measure could provide more standardization than the other measures.

Response: Thank you for your comment. CMS will take this recommendation under consideration.

Preliminary Recommendations

We do not plan on making further changes to the measures' methodology in the immediate future. However, we will take under consideration suggestions for further testing. To the extent possible, we will also incorporate suggestions received during public comment on the implementation of these measures. Specifically, we will plan to:

- Continue measure testing and development
- Submit measures to the MAP for inclusion in the rulemaking cycle;
- Submit measures to NQF for review and endorsement; and
- Conduct a pilot test, to assess roadblocks for clinical data submission.

Overall Analysis of the Comments and Recommendations

Comments overall were positive. The comments and feedback received provided useful input for the development and implementation of the stroke mortality measures.

Table 1 Public Comment Verbatim Report

Date Posted	Commenter	Type of Org.	Verbatim Comment	Recommendations / Actions taken
8/21/15	Linda Williams, MD Veterans Affairs Health Services Research and Development Stroke Quality Enhancement Research Initiative	Clinical Research	Can you tell us a little about the choice to describe the hybrid models as derived from EHR data when GWTG registry data was used as a "surrogate" for EHR data? From an informatics standpoint registry data would not equate to EHR data so I would postulate that the validity with which one could construct these models from EHR data remains unknown.	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses are provided above.
8/26/15	Maryellen E. Guinan, Esq. Beth Feldpush, DrPH America's Essential Hospitals	Medical/ Hospital Association	Thank you for the opportunity to submit comments on the technical report ("Technical Report") from the Centers for Medicare & Medicaid Services' (CMS') contractor tasked with developing a measure of 30-day mortality following acute ischemic stroke hospitalization incorporating risk adjustment for stroke severity. America's Essential Hospitals supports CMS' work to develop a stroke mortality measure that incorporates risk adjustment for stroke severity when assessing and reporting hospital-level outcomes. America's Essential Hospitals is the leading association and champion for hospitals and health systems dedicated to high-quality care for all, including the most vulnerable. Filling a vital role in their communities, our more than 250 member hospitals provide a disproportionate share of the nation's uncompensated care and devote about half of their inpatient and outpatient care to Medicaid or uninsured patients. Through their integrated health systems, members of America's Essential Hospitals offer primary through quaternary care, including trauma care, outpatient care in ambulatory clinics, public health services, mental health services, substance abuse services, and	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses are provided above.

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			wraparound services critical to vulnerable patients. Members of America's Essential Hospitals engage constantly in robust quality improvement initiatives - from preventing falls to reducing readmissions, patient harm events, and blood stream infections. Our members also include hospitals with primary and comprehensive stroke centers. These hospitals are valued for their expertise in caring for the sickest and most complex stroke patients within their communities and beyond. As such, America's Essential Hospitals supports appropriate risk adjustment for stroke severity and asks that CMS consider the following comments as it finalizes a 30-day hospital-level stroke mortality measure that incorporates stroke severity assessment. 1. CMS should incorporate stroke severity in a mortality measure to accurately assess and report hospital-level outcomes following acute ischemic stroke and to avoid mischaracterization of outcomes at essential hospitals. In recognition of and response to stakeholder comments, CMS proposes to incorporate a stroke severity assessment-specifically, the National Institutes of Health Stroke Scale (NIHSS)-in the measure of 30-day mortality following acute ischemic stroke hospitalization. The Technical Report sets forth two approaches to risk adjustment. The first would involve an updated, claims-only measure to include administrative claims data and NIHSS scores. The second approach would be a hybrid measure, relying on Medicare claims in addition to electronic health record (EHR) data and the NIHSS. Whatever approach CMS adopts, America's Essential Hospitals applauds and supports the agency's efforts to ensure hospitals are not disproportionately impacted by a stroke mortality measure that, in its current publicly reported form, does not account for stroke severity. Risk assessment for severity is essential for accurately assessing and reporting hospital-level outcomes. Studies have highlighted the importance of including a valid, specific measure of stroke severity in hospital risk models for mortality after acute ischemic stroke and have found stroke severity to be essential to optimally rank hospitals with respect to 30-day mortality. Additionally, analysis by the American Heart Association/American Stroke Association (AHA/ASA) of its Get With The Guidelines	

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			data set for stroke found that hospitals treating patients with greater stroke severity were substantially more likely to provide care for patients who were black, Hispanic, and transported by emergency medical services (EMS) rather than private vehicle. Essential hospitals, which care for a large number of these and other minority patients, are at risk of being disproportionately impacted by a measure that does not account for stroke severity. America's Essential Hospitals supports incorporating stroke severity assessment, such as the NIHSS, in risk adjustment of the stroke mortality measure. 2. CMS should adopt a risk adjustment model for stroke severity that includes sociodemographic information, and should seek input from hospitals on how to implement the model without undue administrative burden. The current stroke mortality measure, publicly reported on Hospital Compare as part of the Inpatient Quality Reporting (IQR) program, uses only administrative claims data for risk adjustment and does not include an assessment of stroke severity. The Technical Report states various benefits of incorporating clinical data from EHRs into hospital outcome measures, including that EHRs are recorded by clinicians who interact with patients and capture data in real time, which can make the data less susceptible to variations in billing practices compared with an administrative claims-only approach. A hybrid approach to risk adjustment for stroke severity-combining the NIHSS with Medicare claims and EHR data-would allow for use of more than one data source. However, this approach will require hospitals to take additional steps and expend additional resources to collect and report the data. Irrespective of the approach CMS adopts, America's Essential Hospitals urges the agency to capture sociodemographic data in the stroke severity risk adjustment. Currently, neither method proposed by CMS would incorporate important demographic variables in the methodology. Once a new stroke measure methodology is adopted, the agency should provide robust guidance to providers to ensure uniform collection and reporting across hospitals. a. CMS should account for sociodemographic factors among the risk adjustment variables for stroke severity.	

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			Whichever approach it ultimately takes, CMS should incorporate sociodemographic factors in its selection of variables for severity risk adjustment so that results are accurate and reflect differences in stroke patients. Under the proposed risk adjustment for stroke severity, the measure developers applied a series of exclusion criteria to the available clinical variables and excluded demographic variables of race and ethnicity "to align with CMS policy regarding risk adjustment for socioeconomic variables at the time of measure development." A recent study found that patients living in impoverished areas have more severe strokes-in fact, they are twice as likely to have a severe stroke. Without proper risk adjustment, an essential hospital that serves many of the most complex stroke patients, who also have low incomes and other confounding sociodemographic factors, might appear through public reporting to have poorer outcomes than other hospitals. But this is an inaccurate and misleading picture created by factors outside the control of the hospital and its providers. CMS should include sociodemographic factors in its development of the stroke mortality measure with stroke severity risk adjustment so that results are accurate and reflect differences in patients across hospitals. b. CMS should clarify if the NIHSS will be required as the assessment for stroke severity and seek input from stakeholders on the most feasible approach to using it. The NIHSS, as an assessment of stroke severity, has been noted as the one of the most important indicators of 30-day outcomes for acute ischemic stroke, having more discriminatory power than all other variables combined." Many hospitals already collect and voluntarily report NIHSS scores to patient registries. However, as noted by CMS' contracted developers, hospitals do not always collect and record NIHSS scores for all patients. Certain hospitals that are not primary stroke centers or comprehensive stroke centers might lack experience administering the NIHSS or might not perform a stroke assessment at all. All three measures under development use patient information for risk adjustment in the statistical models, specifically with the NIHSS as an assessment of stroke severity. If CMS intends to require that hospitals use the NIHSS to assess stroke severity, we urge the agency to give them extensive guidance and adequate time before the start of public reporting to become familiar with it. We	

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			ask that CMS clarify whether the NIHSS will be the required assessment for stroke severity. If CMS adopts a hybrid measure-using both claims and EHR data-hospitals will be required to take additional steps due to the need to collect data from two sources. It is unclear from the Technical Report what steps will be required of hospitals and the resources required for adoption of an assessment for stroke severity and collection of related data. We urge CMS to seek further stakeholder input on the necessary steps that would be required for stroke severity assessment and allow hospitals adequate opportunity to become familiar with the collection and reporting of this new measure.	
8/26/15	David Levine, MD, FACEP VHA-UHC Alliance NewCo Vice President Advanced Analytics & Informatics/ Medical Director	Healthcare Company	VHA-UHC Alliance NewCo, Inc. (NewCo) appreciates the opportunity to submit comments on the 30-day risk adjusted mortality models presented in the technical report (Version 1.0). NewCo supports efforts by CMS and the Yale New Haven Service Corporation, Center for Outcomes Research & Evaluation (CORE) to introduce clinically relevant risk variables into the publicly reported 30-day risk-adjusted stroke mortality measure in order to increase the representation and utilization of clinically pertinent and relevant risk factors. In 2012, UHC embarked on a similar National Institute of Health Stroke Scale (NIHSS) risk variable evaluation into UHC's inpatient mortality stroke risk model per information gathered during a UHC Stroke Mortality Imperative for Quality Performance Improvement Initiative across several Academic Medical Centers across the country. As part of the stroke scale risk variable development, UHC created a similar process of patient identification, verification and missing data management between the UHC administrative claims-based data and NIHSS clinically abstracted data in order to develop the necessary modeling population. While NewCo supports CORE's described approach regarding patient linking, exclusion criteria and missing data imputation techniques, NewCo has concerns regarding the number of patients and hospitals excluded in model development and the predicted and expected value application. While the missing imputation methods described are statistically viable, having such a large number of excluded patients and hospitals from	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses are provided above.

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			the model building and application limit CMS's ability to provide clear and actionable performance improvement direction for the range of hospitals currently within the pay for performance program. Regarding the risk model performance, given that the NIHSS, plus administrative claims data outperforms the current 2013 CMS 30-day stroke mortality model (c-statistic of 0.81 vs 0.73 respectively), UHC acknowledges and supports efforts to incorporate the NHISS data with the administrative claims model. UHC found similar improved results when incorporating the NIHSS data with the administrative claims data versus the administrative only claims data model. While the presented hybrid models, in particular the EHR-only model, perform slightly better with improved significant variable parsimony than the claims-only model, NewCo recommends using the presented claims-based only model (NIHSS + administrative claims) at this time for the following reasons: 1) As mentioned previously, not all hospital organizations included in the IQR payment reduction program currently have the ability or resources to participate and extract the clinically relevant data elements needed for the EHR risk model; and 2) The impeding administrative claims data transition from version 9 of the international clinical classification of diseases (ICD- 9) to version 10 (ICD- 10), which incorporates the NIHSS into the administrative claims capture, not only improves both model performance but also clinical viability compared to the currently utilized CMS administrative claims-based only model. In turn, NewCo recommends starting 2016, that CMS expand the current 30-day mortality stroke model to include the administratively captured NIHSS stroke scale through ICD-10 in order to capture, as complete as possible, all hospital and patient performance within the IQR program. In parallel, NewCo supports a future CMS-proposed rule to begin requiring the collection of EHR information into publicly reported metrics and risk adjustment variables in order to improve model performance, increase clinical acceptability and drive performance improvement efforts. This will also allow hospitals the time needed to prepare for data collecting and reporting.	

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8/26/15	Michael S. Phipps, MD, MHS Assistant Professor Department of Neurology Department of Epidemiology and Public Health University of Maryland School of Medicine	Clinical Research	Thank you for the opportunity to comment on the proposed updated stroke mortality measure for hospitals. To those that do not know, I will disclose that I assisted Yale CORE on the original stroke mortality measurement development for CMS. I have reviewed the proposed updates to the stroke risk-adjusted mortality measure, and let me first comment that I believe that the inclusion of the stroke severity measure NIHSS will only strengthen the measure and help to insure that hospitals with overall more severe strokes are appropriately evaluated by this measure. So I am in complete support of inclusion of the NIHSS in the stroke mortality measure by CMS. I also commend CMS for agreeing to include an ICD-10 code for completion of the NIHSS, which I supported along with the AHA/ASA and AAN. This change will hopefully increase the number of patients that have documented stroke severity, which as noted is part of the AHA/ASA guidelines, but I believe also will be useful for quality improvement and research. There are three proposed updates for this measure, and although I realize that none will be able to be implemented immediately, I think that Yale CORE and CMS are appropriately thinking ahead to the use of clinical data acquired from electronic health records (EHR). After reviewing the proposed models, I think that the models that incorporate EHR data would be preferred, and that the hybrid model that included administrative data and EHR data would be most preferred— primarily because each data source might identify items that would be most useful for risk adjustment, and seemed to provide the best discrimination in the presented models. Items such as cancer would not be captured in the EHR, and items such as glucose level or blood pressure will not be captured in the admin data. I realize that this will require additional quality data to be entered by hospitals and captured by CMS, so implementation might not be feasible in the short term, but should continue to be a goal by CMS. I have 2 concerns about the proposed updates:	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses are provided above.

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			1) The amount of missing variables. If there are hospitals with a large amount of missing data for NIHSS or other EHR data, the amount of imputation goes up as does the possibility of error. Is there a minimum threshold of completeness of this data? 2) As noted, there were discussions with the working group about implementation challenges and burden to hospitals. These issues, I think, would be even more difficult for smaller hospitals than larger ones with more infrastructure. Are there thoughts about incentives or resources for hospitals that would assist in this EHR data collection? I assume this could be used for multiple measures (i.e. for more than just stroke measures).	
8/26/15	Lisa Anderson, MSN, RN-BC The Joint Commission Associate Project Director eClinical Department of Quality Measurement Division of Healthcare Quality Evaluation	Not-for-Profit Accreditation/ Certification Organization, Measure Developer	Please see below comments from The Joint Commission pertaining to the Development of Claims-Based and Hybrid Measures of 30-Day Mortality Followign Acute Ischemic Stroke Hospitalization that Incorporate Risk Adjustment for Stroke Severity. The Yale group has had much experience developing risk models and I believe their statistical methodology in building the models is sound. I also applaud their efforts to incorporate a clinical measure of severity in the risk models rather than just depending on administrative data for risk adjustment. As the study authors pointed out, clinical data are less susceptible to gaming, coding drift, and variations in billing practices compared with administrative data used for billing purposes. My main issues have mostly to do with the data sources used and the applicability of the models developed to the general US population if the measure ever goes beyond the Medicare population. The importance of this is illustrated by the fact that almost half of the data in the Stroke Registry are non-Medicare patients. The three models in this report were developed for the Medicare population and are generally only applicable to this population. A major question that needs to be resolved is how generalizable these models are to the general US population and whether risk factors identified for Medicare patients tend to be the same as those that are not Medicare patients. Similarly, there is a question of how applicable the models would be to a population of patients whose clinical data is obtained from another source other than the GWTG-Stroke Registry. Are patients in the registry comparable to the general population?	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses are provided above.

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			That would need to be demonstrated for the risk models to be used generally. Also of concern is the low match rate of potential cases to include in the population. Only about half (55%) of the hospitalizations in the Medicare claims database matched with those in the registry. There is a question of how comparable (in terms of severity) the matches are to the general stroke population, even though they roughly match on other risk factors used in the study. The methodology used imputation methods to replace missing NIHSS values in the analysis, but it was not clear what percentage of cases had missing NIHSS scores. Was this common? It would have been good to see how different the models would be from those using only the complete data. Are those with missing NIHSS scores different from the general population? I would have liked to see more comparisons of the three models. For example, is there a difference in the number of hospitals that would have been identified as outliers using the three models? Would the same hospitals be identified as outliers? The EHR-only data was the most parsimonious, but had the lowest C-statistic. What would be the implications of using the EHR-only models compared to the other models for public reporting? The EHR-only model has the considerable advantage of being less susceptible to gaming. Would it be more acceptable to the clinical community and other stakeholders? When discussing the NIHSS score, it is stated that this will soon be included in claims data for ICD-10. As an electronic clinical quality measure (eCQM) developer, this is interesting, as there is a push to stop using ICD codes, and use SNOMED CT instead. The drive being to use real time EHR data instead of claims data. This data element is already included in inpatient quality measures, such as STK-4, and uses value set National Institute of Health Stroke Scale (OID 2.16.840.1.113883.3.117.1.7.1.269). If the move forward includes eCQM specification development, we would suggest re-using this value set. With regards to the eCQM path, this report used the AHA/ASA's GWTG-Stroke registry as a proxy for EHR data. We feel that this may not be a very good proxy, as many	

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			times people are manually abstracting data for the registry, and this does not mean that the data is available from an EHR as structured and codified data.	
8/26/15	Susan K. Bishop, MA American Heart Association Senior Regulatory Affairs Advisor	Medical/ Hospital Association	The American Heart Association (AHA) and its division, the American Stroke Association (ASA), appreciate the opportunity to submit comments on the three new stroke mortality risk-adjustment models developed by the Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE). We would first like to applaud CMS for its responsiveness to stakeholder concerns regarding the inadequacy of the administrative claims-based risk-adjustment model that is now in use in the 30-Day Mortality Following Acute Ischemic Stroke Hospitalization measure and the need to incorporate a clinical measure of initial stroke severity such as the National Institutes of Health Stroke Score (NIHSS.) CMS listened to the serious concerns expressed by AHA/ASA and numerous other organizations regarding the potential unintended consequences related to misclassification of hospital performance using this model, which does not adjust for stroke severity. A measure of stroke severity is essential for optimal discrimination of hospital- level mortality risk, given the great variability in stroke severity and outcomes for patients hospitalized with ischemic stroke. We strongly believe that all three of the new models, each of which incorporates the National Institutes of Health Stroke Score (NIHSS) as a measure of initial stroke severity, represents a significant improvement over the claims-based risk model that is currently in use. Although there are many different methods of measuring the severity of stroke, the NIHSS is well- validated, highly reliable, and an extremely strong predictor of both mortality and short- and long-term functional outcomes. It is recommended in national guidelines and widely used in clinical practice. The approval last year of a new ICD-10 code for initial NIHSS should also improve the feasibility of using it in the proposed risk models. We are very supportive of the efforts of CMS to refine the risk model by exploring the use of new data sources to create a hybrid model that incorporates the anticipated new ICD-10 code combined with clinical data from EHRs. We also appreciate that this	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses are provided above.

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			work is taking place well in advance of the expected implementation of the new ICD-10 code for initial NIHSS in October 2016, rapid uptake of which we intend to facilitate by working closely with hospitals. The forward-thinking approach that YNHHSC/CORE has taken in offering three alternatives should allow CMS greater flexibility and we hope this will help minimize any delays in transitioning to the improved risk model. All three of the models offered as options should greatly enhance CMS' ability to accurately classify hospital performance and to limit the risk of unintended adverse effects on patient care. We leave it to CMS' discretion to select the best alternative for its programs based on a careful evaluation of each model and look forward to revalidating the models once the ICD‐10‐derived NIHSS data are available. The AHA/ASA is very pleased that the data collected by our GWTG‐Stroke registry was useful in developing the updated risk models and we appreciate the opportunity to collaborate with CMS on this important effort. We look forward to other opportunities to collaborate in the future. Thank you for consideration of our comments. AHA/ASA would be happy to work with CMS and YNHHSC/CORE as you work to revise the measures. If you have any questions or require any additional information, please contact Melanie Shahriary, RN, BSN, Manager, Performance Measures, Quality and HIT, at 301‐651‐7548 or melanie.shahriary@heart.org.	
8/26/15	Koryn Rubin, MHA American Medical Association	Professional Society/ Physician Association	The AMA is glad to see the measure developer incorporate the NIHS scale into the three models, which has increased the c-stat. The AMA would like to point out that the developer does not prove whether it is feasible to collect stroke severity within the majority of EHRs across institutions as the developer only tested the measure within a registry. Testing the measure at Kaiser is insufficient since it is a closed system and not representative of the vast majority of institutions across the country.	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under

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	Assistant Director		The developer also makes the assumption that registry data is comparable to claims data when the measure will be coded in ICD-10 since ICD-10 will include stroke severity. Historically, though, claims data is less than ideal for capturing information. The developer also has not proven whether the overall performance will improve with the ability to capture stroke severity within ICD-10. The AMA is also concerned that the developer and/or CMS will not actually re-test the measure with EHR data and coded in ICD-10 to account for stroke severity. It is false to assume that EHR data will produce the same results as what has been found with the registry data. Essentially, all we know from the developer's results is that clinical data is needed to improve the measure and registry data improves the measure, but we still don't know whether EHR data can capture and submit and comparable to the registry testing.	consideration. Responses are provided above.
8/26/15	Rachel Groman, MPH American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) Vice President, Clinical Affairs and Quality Improvement Hart Health Strategies	Professional Society/ Physician Association	On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), we appreciate the opportunity to comment on the Claims-Based and Hybrid Measures of 30-Day Mortality Following Acute Ischemic Stroke Hospitalization Incorporating Risk Adjustment for Stroke Severity Technical Report, which was developed by the Yale New Haven Health Systems Corporation/Center for Outcomes Research and Evaluation (CORE). The 30-day stroke mortality measures document attempts to derive an algorithm to determine hospital performance (i.e., mortality outcome) for stroke admissions, accounting for stroke severity in a risk- adjusted model. The AANS and CNS view this as an important endeavor and appreciate Yale/CORE's ongoing efforts to incorporate the input of relevant stakeholders. The measure developers present three possible models based on Medicare administrative claims data, EHR data and a hybrid between the two. The developers present various factors that strengthen each of these models over past algorithms. Most importantly, all of these models include the presenting NIHSS score, which the AANS and CNS believe is among the most important exposure variables. The addition	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses are provided above.

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	H. Hunt Batjer, MD President, AANS Nathan R. Selden, MD, PhD President, CNS		of the NIHSS score is a positive step forward in that it does provide an additional layer of standardization. Each of the three models also has a fairly strong c-statistic and r2 coefficient, which should make them more accurate and predictive than existing models. The authors also state that the models are more parsimonious, increasing statistical efficiency. In each of the models, NIHSS, age and transfer appear to perform strongly in terms of association. The "EHR only" model seems to perform the least favorably, perhaps because it eliminates administrative variables (such as transfer). This model has substantially less input variables than each of the other models (9 vs. 20 and 21). Since the claims model alone may result in some lack of standardization, the utilization of the hybrid model (claims and EHR) will likely provide a more standardized way moving forward. However, even the hybrid model will be challenging. For one, it will require more time investment to gather the data since there will be more variables from two sources. The developer's state that it will likely take three years of ICD-10 coding to generate the relevant NIHSS data and three years of EHR use to generate data in the EHR model. We have concerns that extraction from multiple different EHRs could be difficult and potentially a burden on clinicians, coordinators and hospitals if not centralized. If the EHR extraction can be streamlined and automated, we would favor inclusion of these variables, but we seriously question whether this is feasible in a short to medium time frame. Similarly, the developers do not present any evidence to prove that it is feasible to collect stroke severity within the majority of EHRs across institutions as the measure was only tested using the AHA's Get with the Guidelines (GWTG) stroke registry. The GWTG registry risks some selection bias as noted in the document. It appears that the organizations utilizing the registry are usually located in a metropolitan area, large hospitals, and usually teaching facilities. We are also concerned that the developer and/or CMS will not actually re-test the measure with EHR data and coded in ICD-10 to account for stroke severity. We cannot assume that EHR data will produce the same results as what has been found with the	

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			registry data. Essentially, all we know from the developer's results is that clinical data is needed to improve the measure and registry data improves the measure, but it is still unclear whether EHR data can capture and submit in a manner comparable to the registry testing. For all of these reasons, it is critical that CMS continue to closely monitor the implementation of whichever model(s) it adopts. For instance, as EHRs continue to mature, the models will need to be revisited to determine if EHR alone would be sufficient to provide all the needed information. A timeline to reassess this probably needs to be included in the original document, as well. The AANS and CNS also have general concerns that apply to all three models. If the intent of the document is to ultimately generalize the findings of patient age >65 to all stroke patients for outcomes measures, none of these models are adequate, because all patients younger than age 65 were excluded. These models are only applicable to patients age >65, which may impact model generalizability. It would be worthwhile for the sake of generalizability as to whether younger patient outcomes can also be tracked with these models. There are a reasonable number of patients in this category with significant care implications. We are also concerned about the handling of transferred patients in these models. It appears that a patient sent from an emergency room at one hospital and admitted at another hospital is counted for the admitting hospital. This seems reasonable, if indeed the case. By contrast, it appears as if patients transferred from one hospital (inpatient) to another get counted toward the first (transferring) hospital. This seems inconsistent and may bias the data. It also does not appear that procedural codes for endovascular treatment or tPA administration are entered into the model. As these procedures are rapidly increasing in frequency, this could have a significant effect. Finally, the developers did not examine any socio-demographic (SDS) factors in the risk adjustment methodology, which is now requested by National Quality Forum (NQF)	

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			under its new SDS trial period. The NQF asks that developers analyze performance measures with and without these factors in their measure submission. The AANS and CNS once again thank you for the opportunity to provide feedback on these various models for capturing 30-day mortality following acute ischemic stroke hospitalization. We look forward to working closely with you to further refine these models. If you have any questions or need further information, please feel free to contact us.	