Background—The Centers for Medicare and Medicaid Services is considering developing a 30-day ischemic stroke hospital-level mortality model using administrative data. We examined whether inclusion of the National Institutes of Health Stroke Scale (NIHSS), a measure of stroke severity not included in administrative data, would alter 30-day mortality rates in the Veterans Health Administration.

Methods and Results—A total of 2562 veterans admitted with ischemic stroke to 64 Veterans Health Administration Hospitals in the fiscal year 2007 were included. First, we examined the distribution of unadjusted mortality rates across the Veterans Health Administration. Second, we estimated 30-day all-cause, risk standardized mortality rates (RSMRs) for each hospital by adjusting for age, sex, and comorbid conditions using hierarchical models with and without the inclusion of the NIHSS. Finally, we examined whether adjustment for the NIHSS significantly changed RSMRs for each hospital compared with other hospitals. The median unadjusted mortality rate was 3.6%. The RSMR interquartile range without the NIHSS ranged from 5.1% to 5.6%. Adjustment with the NIHSS did not change the RSMR interquartile range (5.1%–5.6%). Among veterans ≥65 years, the RSMR interquartile range without the NIHSS ranged from 9.2% to 10.3%. With adjustment for the NIHSS, the RSMR interquartile range changed from 9.4% to 10.0%. The plot of 30-day RSMRs estimated with and without the inclusion of the NIHSS in the model demonstrated overlapping 95% confidence intervals across all hospitals, with no hospital significantly below or above the mean-unadjusted 30-day mortality rate. The 30-day mortality measure did not discriminate well among hospitals.

Conclusions—The impact of the NIHSS on RSMRs was limited. The small number of stroke admissions and the narrow range of 30-day stroke mortality rates at the facility level in the Veterans Health Administration cast doubt on the value of using 30-day RSMRs as a means of identifying outlier hospitals based on their stroke care quality.

Key Words: stroke ■ outcome assessment (health care) ■ hospital mortality

To evaluate hospital quality, the Centers for Medicare and Medicaid Services (CMS) have developed standardized methods using administrative data to report hospital condition-specific 30-day mortality rates.1–3 Currently, hospital data on 30-day mortality for patients with pneumonia, congestive heart failure, and acute myocardial infarction are available on the CMS hospital compare web site.4 One measure under consideration by CMS is a 30-day hospital-level acute ischemic stroke mortality measure using administrative data. However, serious concerns were raised against this proposal during the public comment period arranged by CMS.4 Both the American Academy of Neurology and the American Heart Association expressed their opposition to the development of a 30-day acute ischemic stroke mortality measure using only administrative data.5 These organizations and many physicians and hospital administrators expressed doubts over whether administrative data could be used to adequately risk-adjust differences in case-mix between hospitals. Chief among the concerns regarding risk adjustment was the absence of any validated measure of stroke severity in the administrative data or in the chart review.
data used as part of the measure development process. Many hospital administrators were concerned that patients with severe strokes would be more likely to be diverted to their hospitals because of regional specialization in stroke care, and a 30-day mortality model based on administrative data alone would make their hospital appear to have a higher standardized 30-day mortality rate compared with other hospitals. The National Institutes of Health Stroke Scale (NIHSS) is a widely used, validated measure of stroke severity and is a predictor of both poststroke functional outcomes and mortality. The development of a 30-day risk-adjusted mortality model without the inclusion of the NIHSS or other validated measure of stroke severity might constitute a systematically flawed measurement system leading to erroneous conclusions by policymakers and the public.

The development of 30-day mortality measures to compare the performance of hospitals has also been an area of interest to the Veterans Health Administration (VHA). In 2007, the VHA Office of Quality and Performance, in partnership with the VHA Stroke Quality Enhancement Research Initiative, undertook a comprehensive review of VHA ischemic stroke care quality; we used these national VHA data to assess the importance of including the NIHSS in a 30-day mortality model that generates adjusted mortality rates to compare Veterans Affairs (VA) hospital performance and to examine whether 30-day mortality could be used as a means of ranking hospitals based on their stroke care quality.

WHAT IS KNOWN?

- Many clinicians assume that stroke severity is an important, independent predictor of mortality.
- However, policymakers have proposed models for hospital-level comparisons of stroke care quality based on administrative data that do not include this variable.

WHAT THIS STUDY ADDS

- This study confirmed that stroke severity was an important predictor of 30-day mortality.
- However, inclusion of this variable in a hospital-level model that included age and measures of comorbid conditions did not substantially impact hospital-level comparisons of risk standardized mortality rates in the VA.
- However, the limited number of strokes admitted to each VA hospital and the consistently low mortality rates across VA hospitals limited the use of 30-day mortality as a measure to compare hospital performance.

Methods

Sample
A sample of 5000 veterans admitted to a VA hospital in the fiscal year 2007 (FY07) with a primary discharge diagnosis of ischemic stroke was identified from VHA administrative data using a modified high-specificity algorithm of the International Classification of Disease Codes (9th revision). The sample included all veterans at small volume centers (≤55 patients in FY07) and an 80% random sample of veterans at high volume centers (>55 patients in FY07). Data were collected through retrospective chart review of medical records performed by abstractors from the West Virginia Medical Institute who were specially trained for this study. A total of 1013 patients were excluded because they had a carotid endarterectomy during the stroke hospitalization, the stroke occurred after admission, they had a transient ischemic attack rather than a stroke, or they were admitted only for poststroke rehabilitation. To be consistent with current CMS measure specifications for 30-day acute ischemic stroke mortality, the sample was further restricted to exclude hospitals with >25 stroke patients and patients transferred from other hospitals, leaving a final sample of 2562 patients from 64 hospitals. In a secondary analysis, we excluded veterans <65 years of age to attain a sample that is more relevant to CMS policymakers, providing 543 veterans across 17 hospitals for this analysis.

Variables

Our main dependent variable was the 30-day stroke mortality, defined as death from any cause within 30 days after the index admission date. Mortality was assessed from the VA Vital Status Files, which identifies VA beneficiary deaths from a variety of VA and non-VA sources (eg, CMS). Previous reports indicate that the VA Vital Status Files are relatively complete and accurate when compared with information contained in the National Death Index, the typical gold standard for death ascertainment. More than 98.3% of deaths in the VA Vital Status Files were confirmed with deaths in the National Death Index. Our main independent variable was the NIHSS, which was retrospectively constructed from physician notes within 24 hours of admission using trained abstractors. Similar to prior work, we used the following cutoffs for the NIHSS (0–2, 3–5, 6–10, 11–15, 16–20, 21–25, >25). Covariates included age, sex, and comorbid conditions available for each veteran. Comorbid conditions abstracted from the medical record included a past history of hypertension, hyperlipidemia, diabetes mellitus, coronary artery disease, acute myocardial infarction, coronary artery bypass graft, percutaneous transluminal coronary angiography, transient ischemic attack or ischemic stroke, intracerebral hemorrhage or prior hemorrhagic stroke, any intracranial surgery or carotid intervention, congestive heart failure, atrial fibrillation, chronic obstructive pulmonary disease, peripheral vascular disease, kidney disease, dialysis, dementia, depression, deep venous thrombosis, HIV, cancer, liver disease, any rheumatologic disorder, and a history of gastrointestinal or genitourinary hemorrhage.

Analyses

Patient-Level Analysis
Although the focus of this study was to compare 30-day hospital-level mortality rates, we first verified that the NIHSS was an important, independent patient-level predictor of 30-day mortality rates in our sample of patients using logistic regression and adjusting for age, sex, and comorbid conditions. We also determined the incremental impact of adding the NIHSS on the C-statistic of the model that included only age, sex, and comorbid conditions.

Hospital-Level Analysis
We examined the distribution of patient demographic and clinical characteristics at the hospital level, reporting the median and range across hospitals. We calculated the mean, median, and interquartile range for the observed unadjusted mortality rates across the 64 hospitals. Using the approach developed by CMS and endorsed by the National Quality Forum, we calculated hospital-specific risk standardized mortality rates (RSMRs) for each hospital. The CMS method estimates hospital-level, 30-day, all-cause RSMRs using a hierarchical logistic regression model to account for the clustering of patients within hospitals and sample size variations among hospitals. The model calculates the RSMRs by producing a ratio of the
number of predicted deaths to the number of expected deaths and multiplying the value by the national unadjusted mortality rate.\textsuperscript{1,4} Hospitals are then classified as better, worse, or no different from the national average based on whether the 95% confidence interval (CI) is higher, lower, or overlaps the mean national unadjusted rate. Using this method,\textsuperscript{7} we calculated RSMRs for each hospital and examined the mean, median, and interquartile range across the VHA. We then developed not only 2 hierarchical models, one that included age, sex, and comorbid conditions and another that included these variables, but also included the NIHSS and then used these models to calculate the RSMRs for each hospital.

To examine the impact of the NIHSS as an additional adjuster, we performed several analyses comparing the RSMRs estimated with and without inclusion of the NIHSS. First, we plotted the RSMR and the associated 95% CI for each hospital in all patients with and without the inclusion of the NIHSS to examine whether mortality rates significantly changed for each hospital and relative to other hospitals. We did not examine the impact of NIHSS on hospital rankings in patients >65 years of age because the small volume prohibited any meaningful comparisons. Second, we calculated Pearson $r$ and Spearman $\rho$ to assess correlation between the RSMRs estimated from the 2 models. Third, to determine whether the stroke severity of patients accounted for some additional variation in facility mortality rates, we examined the correlations between facility mean NIHSS scores and their observed mortality rates and RSMRs, excluding NIHSS and RSMRs with NIHSS as an adjuster.

### Sensitivity Analysis in Estimating 30-Day RSMRs

The RSMR methodology is meant to deal with statistical estimation error as well as case-mix differences between hospitals.\textsuperscript{1} Given the relatively small patient volume at each hospital, a statistical estimation error is of potential concern. We conducted a sensitivity analysis to assess the incremental impact of the adjuster variables of age, sex, and comorbid conditions by comparing the RSMRs estimated with the hierarchical models after adjusting for the covariates of interest with alternative 30-day hospital mortality rates estimated with the RSMR methodology but without the adjuster variables. All analyses were conducted using SAS Software, version 9.2 (SAS Institute, Inc, Cary, NC).

### Results

#### Patient-Level Characteristics and Model

A total of 2562 patients met the inclusion criteria. The median age for the entire sample of veterans was 66 years (patient-level data not included in tables). About half the population (53.5%) had an NIHSS of 2 suggesting low stroke severity for most of the patients. Only 8.2% of the population had an NIHSS of ≥11. The mean NIHSS in the sample was 2 with an interquartile range of 1 to 5. Among veterans ≥65 years of age, the mean NIHSS was 3 with an interquartile range of 2 to 6.

We first demonstrated in our sample that at the patient level, the NIHSS was an important independent predictor of 30-day mortality. Patients older than 65 years of age had more than a 2-fold increased odds in 30-day mortality compared with patient under 65 (odds ratio, 2.4; 95% CI, 1.5–3.8), and patients with NIHSS ≥25 had a 59-fold higher odds of mortality compared with patients with an NIHSS ranging from 0 to 2 (odds ratio, 59.2; 95% CI, 26.2–133.5). Two other patient factors that were associated with 30-day mortality: a history of coronary artery disease and acute myocardial infarction (odds ratio, 1.7; 95% CI, 1.1–2.5) and a history of cancer (odds ratio, 2.2; 95% CI, 1.3–3.6). None of the remaining comorbid conditions was significantly associated with 30-day stroke mortality. The addition of the NIHSS to the CMS model increased the C-statistic from 0.75 to 0.83 (patient-level data not shown).

### Population Characteristics Across Different Hospitals

A total of 2562 patients across 64 hospitals met the inclusion criteria outlined by CMS. The hospital-level median age for the entire sample of veterans was 67.6 with a range of 61.5 to 75.4 (Table 1). The majority of the sample was

<table>
<thead>
<tr>
<th>Hospital Sample</th>
<th>Hospital Sample Includes Veterans ≥65 Years of Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of hospitals</td>
<td>64</td>
</tr>
<tr>
<td>No. of patients</td>
<td>2562</td>
</tr>
<tr>
<td>Hospital median age, y (range)</td>
<td>67.6 (61.5–75.4)</td>
</tr>
<tr>
<td>Male, median % (range)</td>
<td>98 (88–100)</td>
</tr>
<tr>
<td>Comorbid conditions</td>
<td>Median % (Range)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>79 (52–98)</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>50 (11–72)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>41 (9–66)</td>
</tr>
<tr>
<td>Coronary artery disease, acute myocardial infarction, coronary artery bypass graft, or percutaneous transluminal coronary angiography</td>
<td>33 (6–62)</td>
</tr>
</tbody>
</table>

### Stroke Severity and 30-Day Hospital Mortality

The median NIHSS in the sample was 2 with an interquartile range of 2 to 6. Among veterans ≥65 years of age, ≥25 had a 59-fold higher odds of mortality compared with patients with an NIHSS ranging from 0 to 2 (odds ratio, 59.2; 95% CI, 26.2–133.5). Two other patient factors that were associated with 30-day mortality: a history of coronary artery disease and acute myocardial infarction (odds ratio, 1.7; 95% CI, 1.1–2.5) and a history of cancer (odds ratio, 2.2; 95% CI, 1.3–3.6). None of the remaining comorbid conditions was significantly associated with 30-day stroke mortality. The addition of the NIHSS to the CMS model increased the C-statistic from 0.75 to 0.83 (patient-level data not shown).
Impact of the NIHSS on Comparisons of 30-Day RSMRs Among All Hospitals

To examine whether there was any difference in 30-day RSMRs across hospitals and whether the inclusion of the NIHSS had an impact on these differences, we plotted the 30-day RSMRs estimated with and without the inclusion of the NIHSS in the model. Figure 2 demonstrates overlapping 95% CIs across all hospitals with no hospital significantly below or above the mean-unadjusted 30-day mortality rate. The 30-day mortality measure did not discriminate well among hospitals. The RSMRs from the 2 methods were highly correlated: the Pearson correlation was .940 (P<0.001), and the Spearman ρ was .933 (P<0.001). Finally, we found a modest correlation (r=.369; P<0.01) between facility mean NIHSS scores and their observed mortality rates. Before adjusting the RSMRs for the NIHSS, the correlation between facility RSMRs and their NIHSS scores remained modest (r=.371; P<0.01); after adjusting the RSMRs for NIHSS, the correlation became nonsignificant. Thus, the stroke severity of patients accounted for some additional variation in facility mortality rates, but the effect was not strong enough to make a substantive difference in the RSMRs.

Sensitivity Analysis

We assessed the incremental impact of the adjuster variables of age, sex, and comorbid conditions by comparing the 30-day hospital-level RSMRs with alternative 30-day hospital mortality rates. These alternative hospital mortality rates were estimated with the RSMR methodology but without the adjuster variables (null model; Figure 1). The CI and interquartile ranges from these alternative rates were different from the observed rates but very close to the RSMRs. The alternative 30-day hospital-level RSMR for the total sample had a mean of 5.3% and an interquartile range of 4.3% to 5.9%.

### Table 2. Distribution of Unadjusted and Risk Standardized Mortality Across Hospitals

<table>
<thead>
<tr>
<th>Hospital Characteristics</th>
<th>Hospital Sample Includes All Veterans</th>
<th>Hospital Sample Includes Veterans ≥65 Years of Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>2562</td>
<td>543</td>
</tr>
<tr>
<td>No. of hospitals</td>
<td>64</td>
<td>17</td>
</tr>
<tr>
<td>Median patients per hospital (range)</td>
<td>37 (25–97)</td>
<td>29 (25–52)</td>
</tr>
<tr>
<td>Observed (unadjusted) mortality rate</td>
<td>5.1 (4.0–6.2)</td>
<td>8.8 (5.4–12.1)</td>
</tr>
<tr>
<td>Mean mortality rate (%) and 95% CI</td>
<td>3.6% (2.4%, 7.5%)</td>
<td>8% (3.8%, 11.1%)</td>
</tr>
<tr>
<td>Range (min–max)</td>
<td>0%–17.8%</td>
<td>0%–21.2%</td>
</tr>
<tr>
<td>RSMR without inclusion of NIHSS in model</td>
<td>5.40 (2.65–9.60)</td>
<td>9.84 (3.09–21.9)</td>
</tr>
<tr>
<td>Mean RSMR (%) and 95% CI</td>
<td>5.35% (5.1%, 5.6%)</td>
<td>10.04% (9.24%–10.27%)</td>
</tr>
<tr>
<td>Median and (IQR, 25%–75%)</td>
<td>4.79%–6.82%</td>
<td>6.86%–12.09%</td>
</tr>
<tr>
<td>RSMR with inclusion of NIHSS in model</td>
<td>5.42 (2.52–9.92)</td>
<td>9.75 (3.16–21.38)</td>
</tr>
<tr>
<td>Mean RSMR (%) and 95% CI</td>
<td>5.24% (5.1%, 5.6%)</td>
<td>9.90% (9.40%, 10.04%)</td>
</tr>
<tr>
<td>Median and (IQR, 25%–75%)</td>
<td>4.72%–6.81%</td>
<td>7.53%–11.58%</td>
</tr>
</tbody>
</table>

CI indicates confidence interval; IQR, interquartile range; RSMR, risk standardized mortality rate; and NIHSS, National Institutes of Health Stroke Scale.

The cohort included a sample of all veterans at small volume centers (≤55 patients in fiscal year 2007) and an 80% random sample of veterans at high volume centers (>55 patients in fiscal year 2007).
Discussion

We confirmed that the NIHSS is an important patient-level characteristic associated with 30-day mortality. The addition of the NIHSS to the CMS-like adjustment models increased model discrimination. However, we also found that the addition of the NIHSS to a model that includes age, sex, and comorbid conditions did not alter the hospital-level 30-day mortality rates in the VHA. The small number of stroke admissions and the narrow range of 30-day stroke mortality rates at the facility level in the VHA cast doubt on the value of using 30-day RSMRs as a means of identifying outlier hospitals in terms of stroke care quality. If the VA were to follow the same methodology used by CMS Hospital Compare to report 30-day ischemic stroke mortality, then all 64 VA hospitals would receive the same rank (“no different from national rate”) irrespective of whether NIHSS was included or not. However, data from the National Office of Quality and Performance Study on stroke care in the VA demonstrates that there are significant differences across the VA in stroke quality process of care. The power to detect differences in mortality in this study may not be adequate irrespective of risk adjustment methods used.

Our limited sample of patients ≥65 years of age precludes our ability to provide any insight on the relative importance of the NIHSS.
of including the NIHSS in the CMS 30-day acute ischemic stroke mortality model. We did observe a modest improvement in model discrimination that could suggest that NIHSS may be important to hospital-level comparisons. However, overall, our findings may not apply to clinical settings outside the VHA. There is less variation in 30-day stroke mortality among veterans, even those 65 years of age and older in the VHA compared with the Medicare population. The mean 30-day mortality rates reported in Medicare hospitals that participate in the Get-With-the-Guidelines Stroke Program is 13.9% and is higher than the mean 30-day mortality rate in veterans ≥65 years of age (8.8%).17 Among the 1036 hospitals that participated in the Get-With-the-Guidelines Stroke Program, the mean NIHSS among stroke patients was higher than our sample of patients ≥65 (mean NIHSS of 5 versus 3). However, hospitals that participate in the Get-With-the-Guidelines Stroke Program are particularly interested in stroke care and may serve a population that is not nationally representative either. The NIHSS may have a greater role in a system of care with greater variation in stroke severity such as the Medicare program. A larger study of a cross-section of different types of hospitals across the United States should be undertaken to conclusively evaluate the impact of the NIHSS when comparing facility performance in the Medicare program.

Our study has a number of important limitations that deserve comment. First, we used medical record data and not administrative data in our analysis of the impact of the NIHSS on hospital RSMRs. Any extrapolation of our results to models that use administrative data must be made cautiously. Second, our analysis is based on a predominantly male cohort that may limit the generalizability of our findings. Third, our main independent variable, the NIHSS, was constructed retrospectively from physician notes. However, previous studies have shown that the summed score of the retrospective NIHSS is very highly correlated with the prospective NIHSS.18 Finally, our small sample size and limited facility-specific volume, although in line with CMS guidelines on inclusion of facilities with ≥25 patients,11 may have diminished our ability to examine the impact of the NIHSS.

Conclusions
The limited influence of the NIHSS on 30-day mortality that we observed may be influenced by the sample size and the narrow range of variability in both 30-day mortality and stroke severity across the VHA. The NIHSS may have a greater role in adjusting facility-level mortality rates in a system of care with greater variation in stroke severity and mortality (such as the Medicare program) or in a system with more stroke admissions per hospital or in which mortality is reported over a longer time frame. A larger study of hospitals is needed to evaluate the impact of stroke severity on facility performance based on 30-day mortality.

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Disclosures
None.

References
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