The Current State and Future of Stroke

Measuring and Changing the Quality of Care via National Registries

Lee H. Schwamm, MD

There is abundant evidence that in-hospital and postdischarge interventions can reduce the complications of stroke and can prevent future events.1 Despite ready access to published guidelines and widespread health provider awareness, guidelines are often poorly implemented in in-hospital and postdischarge environments, and risk factors are poorly controlled. The effort to close the gap between what is known and what is practiced has been the focus of several initiatives in the past decade, spearheaded by the Institute of Medicine. After large-scale quality improvement (QI) programs in cardiovascular disease demonstrated the power of a patient-focused QI registry to increase rates of adherence to national guidelines, a series of stroke QI prototypes were developed and pilot-tested.2

The original criteria for stroke performance measurement were developed through expert consensus and review of the available evidence, undertaken independently by multiple health care societies and government agencies, including the Joint Commission, Centers for Disease Control and Prevention, American Heart Association/American Stroke Association, American Medical Association, Physicians Consortium for Performance Improvement, American Academy of Neurology, Veterans Administration, National Committee for Quality Assurance, and Centers for Medicare and Medicaid Services.3 Ultimately, these measures were incorporated into the Joint Commission Primary Stroke Center certification program and the American Heart Association/American Stroke Association Get with the Guidelines-Stroke (GWTG-Stroke) program. Many of these were endorsed by the National Quality Forum (Table). Although the Centers for Disease Control and Prevention, the Joint Commission, and American Heart Association/American Stroke Association have pursued harmonization of measures in their programs, the Veterans Administration has developed parallel efforts integrated into a broader Veterans Administration framework of QI.4

These programs have shown that a hospital-based stroke QI program can lead to clinically meaningful and statistically significant improvements in measures derived from established care processes (Table). Defying the conventional wisdom, they have demonstrated that these improvements do not need to be limited to a single focused intervention, but hospitals working as teams can successfully tackle multiple measures simultaneously.5 The American Heart Association/American Stroke Association GWTG-Stroke registry has emerged as the dominant national US registry for stroke QI, with >2 million subjects enrolled at >2000 hospitals as of February 2012. The aggregation of such a large number of records in 1 registry brings with it the possibility of evaluating (1) disparities in care delivery across a wide range of real-world care settings with respect to age, race, sex, or geographic region; (2) changes over time in care practices related to timeliness of care or the incorporation of new scientific information released in clinical trial publications or professional society advisories; (3) the risk factors associated with rare events, such as symptomatic hemorrhage after thrombolysis in patients using subtherapeutic warfarin anticoagulation; and (4) the construction and validation of risk prediction models of important outcomes, such as inpatient mortality.6

Because these registries are focused on QI and deidentified, they avoid the need for patient consent under current privacy regulations. Because they avoid patient consent for follow-up assessment, they generally lack longer-term postdischarge patient outcomes. Although viewed by some as a crucial limitation, this approach avoids the bias introduced when written consent is required. When the Canadian government began requiring written consent for a national stroke registry, the registry of the Canadian Stroke Network reported that this requirement created a consent election bias such that the patients in the registry were no longer representative of the stroke patients in their target population. The in-hospital mortality rate was much lower among patients who were enrolled than among those who were not enrolled (6.9% vs 21.7%; P<0.001).7

What QI registries like GWTG-Stroke lack in outcomes they make up for in sample sizes approaching administrative datasets, but with much greater fidelity for key variables (eg, case validity and stroke subtype, stroke severity, date/time elements in care delivery, and accurate classification of complications versus conditions present on admission).8 Fortunately, linkage with Medicare fee-for-service (FFS) claims data and other external datasets that contain postdischarge information has been successfully implemented.9 The patients in GWTG-Stroke have been compared with those in Medicare FFS, both among those
records that were linked by probabilistic matching and those that were not linked; it has been shown to be representative of the US population hospitalized with ischemic stroke. Among 144 344 GWTG-Stroke patients linked to Medicare FFS patients with ischemic stroke from the same period, differences in patient characteristics, including age, race, sex, and comorbidities, compared with an unlinked Medicare cohort were minimal. Length of stay and rate of discharge home were almost identical, and in-hospital mortality was lower in the linked Medicare cohort compared with the unlinked cohort (6.3% vs 7.0%). These data support that Medicare-eligible GWTG-Stroke ischemic stroke admissions are representative of the national Medicare FFS ischemic stroke population.19

This successful linkage to Medicare FFS claims data has enabled the creation of 30-day and 1-year mortality prediction models, comparing hospital variation19 in these important outcomes of interest. Recent work has shown that initial stroke severity is the single most important determinant of 30-day and 1-year postdischarge mortality,20 and that risk-standardized models based on claims data that do not contain stroke severity likely misclassify hospitals on their mortality rates.21 These data were a central part of the vigorous health policy debate on the appropriateness of stroke mortality measures when the National Quality Forum recently evaluated proposed measures related to stroke care quality in October 2012.

The organization of large numbers of diverse hospitals into a dynamic, networked cluster of hospitals with multidimensional relationships to one another. Christakis et al22 have analyzed the impact of clusters on patient and physician behavior, and within the GWTG-Stroke network we see evidence of what seems to be bidirectional flow of information. Not only are sites entering information and comparing their performance with peers, benchmarking their adherence to evidence-based practice, and competing for awards and recognition at national conferences, they are also highly attuned to new evidence that is transmitted to them via webinars, in-person meetings, and online communities. Rapid behavior change after dissemination of clinical trial results was observed regarding dual antiplatelet therapy for stroke prevention12 and

Table. Performance Measures Used by the Major Stroke Quality Improvement Organizations and Whether or Not They Are Endorsed by the National Quality Forum

<table>
<thead>
<tr>
<th>Performance Measures</th>
<th>CDC</th>
<th>AHA/GWTG</th>
<th>TJC</th>
<th>NQF</th>
</tr>
</thead>
<tbody>
<tr>
<td>DVT prophylaxis: Nonambulatory patients should start receiving</td>
<td>Ischemic</td>
<td>Ischemic</td>
<td>Ischemic</td>
<td>Ischemic</td>
</tr>
<tr>
<td>DVT prophylaxis by end of hospital day 2</td>
<td>Hemorrhagic</td>
<td>Hemorrhagic</td>
<td>Hemorrhagic</td>
<td>Hemorrhagic</td>
</tr>
<tr>
<td>Discharged on antithrombotic therapy: Patients prescribed antithrombotic therapy at discharge</td>
<td>Ischemic</td>
<td>Ischemic*</td>
<td>Ischemic</td>
<td>Ischemic</td>
</tr>
<tr>
<td>Discharge on anticoagulation for patients with atrial fibrillation:</td>
<td>Ischemic</td>
<td>Ischemic*</td>
<td>Ischemic</td>
<td>Ischemic</td>
</tr>
<tr>
<td>Patients with atrial fibrillation discharged on anticoagulation</td>
<td>TIA</td>
<td>TIA*</td>
<td>Ischemic</td>
<td>Ischemic</td>
</tr>
<tr>
<td>Thrombolytic therapy administered: Acute ischemic stroke patients who arrive at the hospital within 120 min (2 h) of time last known well and for whom IV tPA was initiated at this hospital within 180 min (3 h) of last known well</td>
<td>Ischemic*</td>
<td>Ischemic</td>
<td>Ischemic</td>
<td>Ischemic</td>
</tr>
<tr>
<td>Antithrombotic therapy by the end of hospital day 2: Patients who receive antithrombotic therapy by the end of hospital day 2</td>
<td>Ischemic</td>
<td>Ischemic</td>
<td>Ischemic</td>
<td>Ischemic</td>
</tr>
<tr>
<td>Discharged on cholesterol-reducing medication: Patients with LDL &gt;100, or LDL not measured, or on cholesterol-reducer before admission, who are discharged on cholesterol-reducing drugs</td>
<td>Ischemic</td>
<td>Ischemic*</td>
<td>Ischemic</td>
<td>Ischemic</td>
</tr>
<tr>
<td>Dysphagia screening: Patients who undergo screening for dysphagia with a simple valid bedside testing protocol before being given any food, fluids, or medication by mouth</td>
<td>Ischemic</td>
<td>Ischemic</td>
<td>Ischemic</td>
<td>Ischemic</td>
</tr>
<tr>
<td>Stroke education: Patients or their caregivers who were given education or educational materials during the hospital stay addressing all of the following: personal risk factors for stroke; stroke warning signs; activation of EMS; need for follow-up after discharge; and medications prescribed</td>
<td>Ischemic</td>
<td>Ischemic</td>
<td>Ischemic</td>
<td>Ischemic</td>
</tr>
<tr>
<td>Smoking cessation: Patients with a history of smoking cigarettes who are, or whose caregivers are, given smoking cessation advice or counseling during hospital stay. A smoker is defined as someone who has smoked cigarettes anytime during the year before hospitalization</td>
<td>Ischemic</td>
<td>Ischemic</td>
<td>Ischemic</td>
<td>Ischemic</td>
</tr>
<tr>
<td>Assessed for rehabilitation: Patients who are assessed for rehabilitation</td>
<td>Ischemic</td>
<td>Ischemic</td>
<td>Ischemic</td>
<td>Ischemic</td>
</tr>
</tbody>
</table>

AHA/GWTG indicates American Heart Association/Get With The Guidelines; CDC, Centers for Disease Control and Prevention; DVT, deep vein thrombosis; EMS, emergency medical services; IV tPA, intravenous tissue type plasminogen activator; LDL, low-density lipoprotein; NQF, National Quality Forum; TIA, transient ischemic attack; and TJC, the Joint Commission.

For each measure, the stroke subtypes eligible for inclusion are listed.

*One of 7 GWTG achievement measures used for hospital recognition.

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intravenous alteplase 3 to 4.5 hours after stroke onset\textsuperscript{13} within GWGT-Stroke hospitals.

Another powerful aspect of these registries is the ability to create new knowledge about previously unrecognized risk factors and to recruit sites into investigations of these factors. Findings about the increasing rates of adherence at discharge led investigators to speculate about the factors that might promote continued adherence at 1 year after discharge. The Adherence Evaluation After Ischemic Stroke Longitudinal (AVAIL) registry was an observational cohort study to which GWGT-Stroke registry–participating hospitals were invited to join.\textsuperscript{23} Sites collected baseline data in GWGT-Stroke and then submitted additional study-specific data after written informed consent through a parallel data channel. The study was executed at a lower cost and reached a cadre of sites that usually do not participate in clinical trials. The AVAIL study showed that 65.9\% were regimen-persistent at 1 year after discharge. Independent predictors of 1-year medication persistence included fewer medications prescribed at discharge, adequate income, an appointment with a primary care provider, and greater understanding of why medications were prescribed. These registry communities represent an important avenue into the conduct of comparative effectiveness research in diverse hospital settings.\textsuperscript{23}

Finally, these registries have prompted recent efforts at the National Institutes of Health to promote alignment and harmonization of data elements across various clinical studies to enhance our ability to compare findings across studies and over time and to support the pooling of data. The Common Data Element project is designed to standardize harmonization of data elements across various clinical studies to support the pooling of data. \textsuperscript{24} Wherever possible, the Common Data Elements harmonized with existing registry elements to reduce the burden of collecting a substantial amount of this baseline demographic and clinical data for both research and QI registry purposes. However, trivial differences in large datasets of baseline characteristics can be statistically significant, and therefore additional hypothesis testing and a priori thresholds for clinically meaningful differences are needed. Multivariate models must account for clustering of cases within hospitals, and commonly used methods include generalized estimating equations or hierarchical linear models to account for within-hospital correlation of observed outcomes.\textsuperscript{21,25} Prespecified variables are often selected a priori for model inclusion based on established associations from the literature or the exposures of interest. Because there is often a lack of documentation of certain important variables, such as initial stroke severity, sensitivity analyses can be conducted within and without the patients in whom these variables are present to explore the impact of their inclusion on the study findings. Finally, large hospital-based registries usually lack information on patient-centered functional outcomes, such as cognition and quality of life. This emphasizes the value of linking registries to Medicare FFS or other data sources from which measures, such as time spent at home in the first 90 days, can be derived.

In summary, national stroke QI registries\textsuperscript{26} have the power to improve the quality of care delivery through measurement, comparison with peers, and real-time point-of-care access to high-quality, up-to-date guidelines. They are limited by voluntary participation, potential selection bias, unmeasured confounders, and lack of concurrent controls or long-term outcomes. However, despite these limitations, they can be very useful in measuring adoption of efficacious interventions or comparative effectiveness across various real-world populations. They can serve as powerful tools for hypothesis generation or validation and, when linked to existing large datasets, can add substantial value and sustainability. Future integration of data from claims, drug or service use, and geospatial information systems will enable further creation of new and intriguing knowledge.

**Disclosures**

Dr Schwamm serves as the Chair of the American Heart Association Get With the Guidelines Steering Committee (unpaid) and has served as a stroke systems and measurement consultant to the Massachusetts Department of Public Health (paid), Centers for Disease Control and Prevention, Paul Coverdell Acute Stroke Registry (unpaid), and the Joint Commission (paid).

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