Variable Impact of State Legislative Advocacy on Registry Participation and Regional Systems of Care Implementation

A Policy Statement From the American Heart Association

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Regionalization, systems of care design, and quality improvement (QI) registry participation all promote the widespread dissemination of guideline-based evidence into actual practice. As a result, policy statements from the American Heart Association/American Stroke Association (AHA/ASA) advocate for the creation of regional systems of care for various time-critical diagnoses, including ST-elevation myocardial infarction (STEMI), out-of-hospital cardiac arrest resuscitation, and acute stroke.1-3 Creation of these regional networks requires multidisciplinary collaboration to implement 5 mutually reinforcing core elements4 that build each system: (1) Designation of certain hospitals with special treatment capabilities as Receiving Centers for STEMI, resuscitation, or stroke; (2) emergency medical services (EMS) destination protocols that allow for direct transport of certain patients identified by explicit triage criteria to a designated Receiving Center, thus allowing for bypass of closer hospitals if they lack the needed specialty service; (3) organized interhospital transfer and transport protocols to a Receiving Center for appropriate patients who initially self-present or are mistreated at a Referral Hospital; (4) communication or telemedicine options to provide real-time expert consultation as needed from a Receiving Center to its associated Referral Hospitals or EMS providers; and (5) participation in a regional and/or national QI registry to track relevant process-of-care metrics and meaningful risk-adjusted clinical outcomes.

Within each of the 50 states, unique challenges exist for stakeholders attempting to implement the 5 aforementioned core elements of regional or statewide systems of care. In particular, substantial variation exists with regard to the starting point for these initiatives. For example, some states already have sufficient regulatory authority within their EMS agency or state department of health (DOH) to regionalize care of time-critical diagnoses, whereas other states require new legislation to create coordinated systems.

In October 2011, the Advocacy Coordinating Committee of the AHA convened a multispecialty task force to assess the effects of state legislative activity on regional systems of care. The resulting AHA policy statement reflects a combination of expert consensus and mixed methods5 research. Semiquantitative analyses were used to study various state legislative efforts and evaluate their subsequent impact on QI registry participation, because this provided a practical and objective surrogate marker for the magnitude of regional systems implementation. In some states, existing regulatory authority allowed for avoidance of de novo legislation. Qualitative analyses were used to explore various supporting themes and lessons learned from each state’s experience with de novo legislation versus existing regulatory authority in promoting regional systems of care development and QI registry participation. Qualitative study methods are particularly useful when investigating the most relevant real-world factors in complex nonlinear processes.5

Methods

The AHA/ASA Office of State Advocacy continually monitors legislative activities in all states across the nation. At the time the

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present task force was convened (2011), 5 “case” states existed that had passed systems-of-care legislation that was also designed to encourage QI registry participation. These included Maryland, New Jersey, North Dakota, Rhode Island, and Tennessee during the years 2008 and 2009. For New Jersey, the 2009 law built on an initial hospital designation regulation from its Stroke Center Act of 2004. The fifth state, Maryland, instituted both stroke (2006) and STEMI (2010) registries via regulation under broad EMS authority from a prior trauma systems law that permitted the designation of hospitals as specialty centers and the development of clinical registries to monitor performance.

Two illustrative “control” states, Pennsylvania and Indiana, were chosen because they lacked a legislative mandate to create a statewide stroke or STEMI registry, had not created a system of care via other mechanisms, and were not the recipients of federal monies aimed at the creation of voluntary registries. Pennsylvania and Indiana thus provided a comparison for registry participation in states without targeted AHA/ASA advocacy efforts.

The semiquantitative analysis in the present study evaluated both the number of participating hospitals and the number of patient records submitted to state registries, stratified by key time points in system development: Prelegislation (2 years and 6 months prior), at legislation enactment (date of passage), at implementation date (effective date of legislation), and postimplementation (6 months, 1 year, and 2 years later). Simple unadjusted descriptive statistics were used to show trends over time. For stroke, the cross-sectional data queries for each time point were performed on the basis of data submitted by hospitals participating in the AHA’s Get With The Guidelines (GWTG)-Stroke program* in each of the 5 case and 2 control states. In these states, participation in GWTG-Stroke is voluntary and represents a convenience sample of hospitals. Although the New Jersey state system officially uses its own registry platform modified from the Coverdell QI registry, many New Jersey hospitals also continue to use GWTG-Stroke for collection and reporting of these data. For STEMI, a cross-sectional query of the ACTION (Acute Coronary Treatment and Intervention Outcomes Network) Registry–Get With The Guidelines (ACTION-GWTG) was performed for Maryland only, because it was the only state in the present study that had a STEMI registry. The rationale and registry design of both GWTG-Stroke and ACTION-GWTG have been described previously.6,7 Also, for each state, the ratio of registry-participating hospitals to total number of hospitals per a Medicare Web site8 was determined.

For the qualitative evaluation, a 2-person policy research team conducted in-depth telephone interviews in each of the 5 case states and the 2 control states. Researchers interviewed at least 3 individuals in each state, selecting representatives from regulatory agencies, hospitals, and local AHA staff to assess how the QI registry data were being collected and used, barriers to implementation, and the overall impact on systems of care across each state. Table 1 provides more detail on those interviewed and demonstrates the equal distribution of categories for all studied states. The interviews focused primarily on stroke registries, because Maryland was the only state in the

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**Table 1. Qualitative Evaluation: Details on Study Interviewees**

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*AHA indicates American Heart Association; DOH, Department of Health; and QI, quality improvement.*

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**Figure 1.** Maryland: GWTG-Stroke. Participation by hospital and number of patient records by month before regulation enactment, after regulation enactment, and after regulation implementation. GWTG indicates Get With The Guidelines.

**Figure 2.** New Jersey: GWTG-Stroke. Participation by hospital and number of patient records by month before regulation enactment, after legislation enactment, and after legislation implementation. GWTG indicates Get With The Guidelines.
present study with a STEMI system. As per standard qualitative methodology,5 the conversations were dynamic yet organized around 7 key themes from a predetermined discussion guide (listed below); distinct concepts were cataloged by the constant comparative method; and interviews continued until theoretical saturation (the point at which no new concepts emerged):

1. Pathway to legislation in each state
2. Designation of “centers” and organization of regional systems
3. Registry implementation
4. Current use of registry data
5. Keys to successful implementation of registry
6. Challenges to implementation
7. Next steps

**Results of Semiquantitative Analyses**

Figures 1 through 7 illustrate trends over time for stroke in the 5 case states and 2 control states. Both the number of participating hospitals and total number of patient records are displayed and span the period from 2 years before legislation (or regulation) enactment for the case states to December 2011 (except Rhode Island). For the 2 control states, the graphs span January 2007 to December 2011.

For all 5 case states, participation by hospitals (blue line) and the total number of patient records (red line) in the registries increased consistently over time. The upward slope of both lines began before legislation enactment, but the positive trend in hospital participation (blue line) accelerated around the time of legislation for all case states except Rhode Island. Specifically, for Maryland and Tennessee, it occurred during the legislation period, whereas it accelerated in New Jersey during the 6 months before legislation enactment and accelerated in North Dakota ≈6 months after legislation implementation began. Although analysis of the 2 control states also demonstrated a positive trend for both hospital participation and number of patient records, the slope was consistently gradual and without any obvious inflection point. Across all 7 graphs, minor slope changes may be seen around the beginning of the year, indicative of the annual contract renewal cycle that occurs within the GWTG program.

Table 2 summarizes the maximum number of stroke registry–participating hospitals in each state during the study
period. Most states had ≈50% of hospitals voluntarily participating in the stroke system of care when the denominator was the total number of both acute care hospitals and critical access hospitals (CAHs) on the Medicare Web site (Veterans Health Administration hospitals excluded). Among the case states, Tennessee had the lowest proportion (11%) and New Jersey had the highest proportion (69%). For the 2 control states, Indiana had a 28% and Pennsylvania a 47% rate of participation.

Maryland (using existing regulatory authority) was the only state in the present study to implement a STEMI system, with 25 (56%) of 45 hospitals participating in ACTION-GWTG by the end of the study period. In Figure 7, a particularly steep upward slope (blue line) reflects the rapid response by hospitals in the 2-month period after regulation enactment and leading up to regulation implementation.

Results of Qualitative Analyses
Table 3 provides a summary of recurrent themes and key findings. Section 1 highlights important clinical registry policies, and section 2 lists supportive state policies. The narrative below provides a more in-depth discussion of each item in Table 3.

1. Clinical Registry Policies

1A. Hospitals Are Most Likely to Submit Data to a Stroke Clinical Registry When State Policies Require Mandatory Data Collection as Part of Stroke Center Designation

Four of the 5 case states evaluated have a mandatory registry policy: By law or regulation, each hospital in the state that voluntarily decides to become stroke center certified must submit data to the state stroke clinical registry. Interviewees observed that the mandatory nature of a state’s stroke registry policy serves 2 important functions: (1) Mandatory registries ensure robust data submission from certified stroke centers, and (2) these policies tend to signal to hospital administrators that the state is taking stroke QI seriously. As a result, many hospitals in these states have become more motivated to focus on stroke within their institutions, often giving them the impetus to become stroke center certified in the first place. In the case states where a mandatory reporting policy is in place, >50% of eligible hospitals in the state are certified as stroke centers. By contrast, in Tennessee (the only case state where reporting to the stroke clinical registry is voluntary), only 11% of hospitals in the state have sought stroke center certification.

1B. Initial State Funding to Assist Hospitals in Registry Participation Is Often a Determining Factor of Hospital Engagement With a Stroke Registry

In all case states, interviewees described the challenges for hospitals to submit data to the state stroke clinical registry, including the cost of purchasing stroke registry software and salaries for data-entry personnel. To address some of these cost concerns, most states implemented regulations that selected the GWTG-Stroke registry as the official clinical registry platform, given that many hospitals were already familiar with the program and its relatively low annual subscription cost.

New Jersey is unique because the state’s legislation requires registry reporting through a state-specific stroke clinical registry, the New Jersey Acute Stroke Registry. Many hospitals initially found it difficult to adapt to the alternative registry format and had to dedicate more staff resources to the submission process.
of new data points. Interestingly, many New Jersey hospitals also continued to participate in GWTG-Stroke because they wanted to compare their performance against national trends. Despite these burdens, 69% percent of hospitals in New Jersey participate in the New Jersey Acute Stroke Registry. In addition to waiving any data submission fees for registry participation, the state has established a grant-making program to assist some hospitals with developing the infrastructure necessary to become stroke center certified and registry-submission ready.

Other case states implemented smaller funding programs with similar success. For example, North Dakota has established a grant program to assist CAHs in the state to purchase GWTG-Stroke, train staff, and receive reimbursement for data entry activities. Before the grant program, no CAHs were submitting data to a stroke registry; today, the majority of CAHs submit stroke registry data to the state. Interviews in several states revealed that when hospitals do not receive supportive funding from their state, stroke coordinators face greater challenges convincing their hospital administrators to promote stroke improvement initiatives.

1C. DOH Management Over the Stroke Clinical Registry and Adequate Resources for Data Analysis Are Important for Full Registry Implementation and Continued Stakeholder Engagement

The experience from Maryland and New Jersey highlights that developing a stroke clinical registry with robust data analysis requires DOH leadership and dedicated resources. Both of these states have the capacity to evaluate stroke data and issue quarterly reports, largely because of the considerable resources each state DOH devotes to the stroke effort.

Other case states have struggled to implement their stroke registries because of a lack of dedicated resources or prioritization at the DOH. For example, insufficient DOH resources in Rhode Island have delayed the state’s implementation of its stroke registry by almost 4 years. In North Dakota, although hospitals were able to submit data to the registry relatively soon after passage of the implementing law, the DOH has not yet had the ability to conduct a comprehensive analysis of incoming data, because it lacked sufficient funds to hire a full-time employee dedicated to the stroke registry. The Tennessee DOH determined that operation of a stroke registry was cost-prohibitive, so the registry was placed within one of the state’s universities; however, some interviewees are now apprehensive about the university-model registry because it does not appear sufficiently responsive to stakeholder or DOH needs.

1D. Engaging CAHs in the Stroke Clinical Registry Is Important for Rural States

Given the rural nature of North Dakota, CAHs (small, rural hospitals with <25 beds) dominate the state’s healthcare landscape. The state has 36 CAHs compared with just 8 acute care hospitals. Although individual CAHs encounter few cases of stroke, collectively, North Dakota’s network of CAHs sees a significant number of stroke patients. Accordingly, regulations implementing the stroke registry in North Dakota allow CAHs to voluntarily submit data, and interviewees anticipate that CAH registry data will be critical in understanding and improving the stroke system of care for the state’s rural residents.

Indiana (a control state) engages CAHs in stroke registry participation through the use of “telestroke” consultations with tertiary hospitals. In addition to building telestroke capacity, the program provides support to Indiana CAHs to enable them to submit data to GWTG-Stroke. Even in less rural states, engaging smaller community hospitals is critical to program success, because ideally all hospitals in the state will participate in some manner within the stroke systems-of-care model.

1E. Strong Data Confidentiality Policies Are Critically Important to Drive Hospital Participation in Stroke Registries

Nearly every hospital employee interviewed emphasized the importance of data confidentiality, because hospitals want to be assured that any publicly reported stroke registry data are only reported in the aggregate. This QI approach fosters a truthful, accurate, and comprehensive evaluation of each hospital’s strengths and weaknesses. Case states vary in how they address registry data privacy. Maryland regulations outline specific standards for how the DOH can use any data collected through the registry and set strong protections that limit public reporting of hospital-identifiable data. New Jersey does not have a formal
registry privacy policy, but the DOH has stated that it does not intend to publicly report hospital stroke registry data.

In contrast, the first report from the Tennessee stroke registry contained hospital-specific information, even though the state’s statute specifically precluded reporting of hospital-identifiable data. The lapse in privacy protection has since been resolved, but some hospitals have dropped out the registry and are hesitant to rejoin without stronger privacy regulations. Similarly, in Pennsylvania, hospitals have been reluctant to support state efforts to implement a stroke clinical registry because respondents believed that the state had a history of reporting hospital-identifiable stroke information publicly.

2. State Policies That Reinforce Clinical Registry Participation
A stroke clinical registry is just 1 of the 5 major components (described in the introduction to this statement) needed to create a statewide system of care. Interviews were rich with information on other aspects of the stroke system of care that contribute to (or detract from) clinical registry efforts. The following discussion outlines several findings on supportive state stroke system-of-care policies.

2A. Leadership and Consensus From an Independent or State-Sponsored Stroke Task Force Were Often Integral to the Establishment of a State’s Stroke Registry
Before implementation of stroke center designation, EMS protocols, or clinical registry policies, all of the case states depended on leadership from a statewide stroke task force. The Rhode Island and North Dakota task forces were established officially by law; in New Jersey, the state’s task force was convened by the DOH; and in Maryland and Tennessee, the task forces convened informally with leadership from the AHA and other stakeholders. Formal or informal, each of these stroke task forces is generally composed of state DOH officials and voluntary stakeholders from across the spectrum of stroke care (eg, healthcare providers, stroke survivors, and EMS personnel). Interviewees in the case states generally agreed that recommendations that came out of these consensus-driven multidisciplinary task forces carried weight with decision makers (state legislatures, DOH officials, and others) and were a pivotal part of getting legislative and regulatory stroke system reforms implemented.

However, the existence of a stroke task force does not guarantee success. For example, Indiana has a stroke task force mandated by its general assembly and operated within the DOH. The task force has a similar makeup and goals as other stroke task forces in other states, yet Indiana has not been able to introduce legislation to implement a stroke registry in the state. The different outcome in Indiana (despite task force engagement) appears to be the task force’s limited ability to issue and enforce recommendations, as well as the Indiana DOH’s relative lack of resources put toward stroke QI efforts compared with case states.

2B. State Leadership on Designating Primary Stroke Centers May Be Important
In 4 of the 5 case states examined, a formal statewide primary stroke center designation process forms the foundation of the state’s stroke clinical registry. Although it is voluntary for hospitals to apply to the state to become a designated primary stroke center, all hospitals that become designated stroke centers in Maryland, New Jersey, North Dakota, and Rhode Island must submit data to the state stroke registry and participate in QI activities. In each of the case states with a stroke center designation process, more than half of all hospitals have become designated. In contrast, Tennessee does not have a state designation program, and very few hospitals in the state have independently sought certification.

2C. A State-Operated Primary Stroke Center Designation Process May Reduce Barriers to Hospital Participation Compared With Joint Commission Accreditation
Criteria for primary stroke center designation differ between states. Although New Jersey conducts its own designation process through the state DOH, North Dakota and Rhode Island recognize hospitals as primary stroke centers only if they have obtained designation from The Joint Commission. Hospitals in Maryland can achieve designation either using their existing certification from The Joint Commission or by undergoing the state’s certification process. Interviewees described the cost of certification by The Joint Commission as a major barrier to participation in the stroke system in states that did not offer a DOH designation option. Hospitals in New Jersey and Maryland, however, noted that they still sought certification from The Joint Commission because it allowed national comparisons.

2D. Efforts to Address Complex Stroke Cases Are a Critical Component in the Stroke System of Care
Two case states, New Jersey and Maryland, have promulgated regulations for designating comprehensive stroke centers. Comprehensive stroke centers are highly specialized facilities capable of delivering the full range of care needed for complex stroke patients, including advanced neuroimaging capabilities, a neurosurgical team, and onsite rehabilitation services. Since its inception in 2006, the natural distribution of primary and comprehensive stroke centers in New Jersey has formed a network in which each primary stroke center is linked to a comprehensive stroke center in a hub-and-spoke arrangement. Maryland is working toward a similar goal of comprehensive stroke center distribution across the state.

2E. EMS Bypass Policies Likely Reinforce the Initial Stroke Center Designation Process, Thereby Increasing Stroke Clinical Registry Participation
Three of the case study states (Maryland, New Jersey, and Rhode Island) have formal EMS bypass policies in place. These policies state that potential stroke patients identified by EMS via prehospital triage protocols must be transported to the nearest designated primary stroke center, thereby bypassing closer hospitals without stroke center designation (with certain exceptions). For patients, these destination protocols ensure a consistently high level of care. However, with the loss of EMS-transported patients, some small-volume nondesignated hospitals will find it difficult to ever gain the skills and expertise needed for future stroke center designation. Nevertheless, EMS bypass policies are generally viewed favorably by most stakeholders and provide a strong driving force for hospital...
participation in stroke regionalization and QI efforts, especially in healthcare markets with more intense hospital competition.

2F. A Statewide Stroke Coordinator Network May Be Important for Stroke Registry Participation

All 5 case states have an active statewide stroke coordinator network, whereas the 2 control states lack this feature. Connecting these coordinators allows for “rising water to elevate all boats” in each state’s system by providing forums (both in-person and via the Internet) to convene individual hospital stroke coordinators, increase knowledge of current issues in cerebrovascular treatment, foster collaboration between small and large hospitals, share best practices, and benchmark themselves against peer hospitals. Moreover, the stroke coordinators collectively keep both hospital administrators and state regulators focused on optimizing stroke care delivery across the state.

2G. Broad Regulatory Authority May Be Helpful for Implementation but May Not Be Feasible in All States

The scope of legislation authorizing the DOH to address stroke quality determines the degree to which states can collect and analyze comprehensive registry data, implement primary stroke center certification, and adopt EMS bypass protocols. For example, acting from broad regulatory authority rather than specific statutory language has proven to be advantageous in Maryland and New Jersey, because these states have been able to build on stroke improvement efforts over time rather than struggle to implement a comprehensive law all at once. By contrast, in Rhode Island, where more detailed statutory language specifies the elements of the stroke clinical registry and surrounding system of care, the DOH is still struggling to implement the clinical registry portion of their comprehensive stroke law.

Interviewees also revealed that it is not always feasible to pass a broad legislative mandate. The history of the stroke effort in Pennsylvania provides a good example, wherein on several occasions, a comprehensive stroke law has failed to pass the state legislature because of fiscal concerns, state politics, and other pressures. Similarly, in Tennessee, the legislature was only willing to pass a very narrow law; the statute allows for the development of a clinical registry without granting the DOH authority to develop other elements of a stroke system.

2H. Registry Data Collection and Dissemination Promotes Continuous QI Activities

Maryland has been collecting and analyzing stroke data through its registry since 2006, New Jersey and Tennessee since 2010, and North Dakota since 2011. Many interviewees observed that the stroke clinical registry has already had a positive impact on quality of care in their region. For example, stroke registry data have been used at various hospitals to address system delays and implement new protocols to increase the number of eligible patients receiving thrombolytic therapy within an appropriate time frame. Registry findings have also increased the focus and resources that hospitals and providers are putting toward stroke care, generated more training for emergency department providers to address delays in care, and fostered more open communication between hospitals and the EMS. Disparities between stroke care in rural and urban communities have led to increased investment in telemedicine and other support for smaller rural hospitals. Lastly, registry reports have helped stakeholders make a more persuasive argument to their legislators for continued stroke registry funding and added focus to the state’s stroke system of care.

Discussion

Collectively, using a mixed methods approach, this task force found that state-based legislative efforts are generally associated with desired large-scale changes and represent a reasonable strategy for AHA/ASA Office of State Advocacy to pursue to create regional systems of care. The present 7-state analysis demonstrated that efforts that led to the successful passage of state legislation resulted in the acceleration of hospital participation in QI registries for time-critical diagnoses. Specifically, semiquantitative analysis of stroke registry participation in 4 of the 5 case states (Maryland, New Jersey, North Dakota, and Tennessee) revealed a noticeable upward deflection (blue lines) with regard to the number of hospitals participating compared with a gradually increasing rate of participation in the 2 control states (Pennsylvania and Indiana). The data for Rhode Island remain inconclusive, and interpretation was limited by both the small number (n=10) of acute care hospitals and prolonged implementation delays despite existing legislation.

The qualitative analysis highlighted various overarching themes. Five mutually reinforcing core components (described in the introduction to this statement) are needed to create and sustain a statewide system of care, but their implementation can lead to multiple sources of resistance during or after the legislative process. For example, political forces can result in weak legislative mandates, including voluntary (rather than mandatory) registry participation. In an era of budgetary constraints, hospitals or hospital associations often resist unfunded mandates given the cost and personnel resources needed to participate in a QI registry. Cumbersome data forms or registry designs, problems with database confidentiality, and complex or costly accreditation to achieve stroke center designation can further exacerbate the reluctance of hospitals to join a system-of-care network. Similarly, a state’s DOH or EMS oversight agency may lack adequate resources, funding, enforcement strategies, or leadership to coordinate a multidisciplinary system designating specialty Receiving Centers that receive certain patients via EMS destination protocols. State-based legislative efforts should strive to provide funding to mitigate all of these barriers.

When available, existing regulatory authority (EMS or DOH) appears to be the preferred strategy by which to initiate regional systems of care with supporting QI registry participation. Most of the legislative efforts we evaluated spanned 5 to 10 years from inception to implementation, whereas regulatory authority pathways were generally more direct and rapid. For example, the Maryland Institute for EMS Systems was created in 1973 by a governor’s executive order and granted broad regulatory authority to coordinate a statewide EMS system focused on regionalizing trauma care. When new data emerged supporting stroke and STEMI systems of care 3 decades later, the Maryland Institute for EMS Systems invoked existing authority to rapidly enact and implement regulations for statewide QI registry participation, as reflected by the steep upward curves for both GWTG-Stroke and ACTION Registry-GWTG, respectively (Figures 1 and 8).
Coverdell grants, administered through the Centers for Disease Control and Prevention, represent another powerful stimulus to stroke systems development and are named in honor of Senator Paul Coverdell, who died in 2000 of a massive stroke. Although New Jersey’s funding came from its state Department of Health and Senior Services, it did modify the Coverdell registry in developing its own registry platform. Other states, outside those examined in the present 7-state study, have benefited from this national funding source. For example, Massachusetts initially used its 2001 grant to fund hospital infrastructure and registry participation, which then allowed the state DOH to use existing regulatory authority in 2005 to begin designating stroke centers and updating EMS destination protocols. At present, 69 of 70 acute care Massachusetts hospitals are designated as primary stroke centers and submit quality assurance data to the DOH.10 The state registry began with strict confidentiality policies but gradually evolved (with participating hospital consensus) into publicly reporting thrombolyis rates in a format that identified each hospital by name. Analogously, Georgia currently has 66 (48%) of 137 hospitals (acute care and critical access) voluntarily participating in the state’s Coverdell stroke registry. The registry began in 2001, reports QI data analyzed by the DOH only in aggregate, has successfully recruited and retained hospitals for the past 10 years, and has demonstrated improvements in the quality of care as measured by nationally accepted quality indicators.11 These early achievements led to passage of the Coverdell-Murphy Act by the Georgia legislature in 2008, which allowed the state DOH to designate hospitals as either primary stroke centers or remote stroke treatment centers and encourages (but does not mandate) EMS providers to bypass nondesignated hospitals when a stroke patient is identified.

Assisted by the efforts of the AHA and other advocacy organizations, a few other states have passed systems-of-care legislation, but QI registry infrastructure and participation were not part of the final law (thus excluding these states from the present study). For example, in 2008, Missouri12 passed time-critical diagnosis (STEMI and stroke) legislation, but regulatory and registry implementation has not yet occurred because of various impediments and funding issues. Similarly, in 2010, the state of Washington13 passed emergency cardiac and stroke system legislation, but hospital participation was voluntary, no funding was allocated, and QI registry participation mandates were removed from the final law.

The present task force evaluation also revealed that state legislative efforts across the nation are primarily aimed at the creation of stroke systems. In contrast, STEMI and resuscitation systems have generally avoided legislative efforts (eg, Maryland) and instead proliferated in most regions of the United States via preexisting regulatory authority (often dating back to trauma system efforts in the 1970s). For example, California is covered by 31 local EMS agencies, each of which independently possessed broad authority within their county(s) jurisdiction to pioneer the creation of regional STEMI networks.14 Similarly, advocates in Minnesota15,16 and North Carolina17 have created statewide STEMI systems of care via existing EMS regulatory authority. Recognized resuscitation systems of excellence, including the King County (Seattle, WA, metropolitan area)18 and Arizona19 networks, were both led by their respective EMS agencies. The specific reason for this dichotomous approach (de novo legislation for stroke versus existing regulatory authority for STEMI and resuscitation) was not evaluated in the present study. Although speculative, one reason might be that stroke is quite heterogeneous in terms of prehospital diagnosis, pathophysiology, clinical presentation, and infrastructure required for treatment, whereas the principal focus of STEMI care is to route the majority of patients to a limited number of hospitals capable of timely reperfusion with percutaneous coronary intervention.

Finally, these state-based efforts have proven to be more fruitful than those to pass federal legislation. For example, the Stroke Treatment and Ongoing Prevention (STOP Stroke) US congressional bill introduced by Senator Edward M. Kennedy in 2001 was never passed into law despite attempts spanning 6 years. More recent proposals aimed at the federal level, such as Time-Critical Accountable Care Organizations,20 have focused on the potential for Medicare’s reimbursement strategies via regional pay-for-performance to accelerate systems of care development and QI registry participation. The Time-Critical Accountable Care Organization proposal, however, is still in the proof-of-concept stage.

Study Limitations

The present study has a number of important limitations. First, QI registry participation is a reasonable but imperfect surrogate marker of complete systems of care implementation. However, the mantra “you have to measure it to manage it” highlights the core role of QI registry participation in any regionalization effort. Second, the present semiquantitative data analysis is restricted to simple displays of trends over time, and statistical comparisons were not made. Third, a gradual trend in QI registry participation was also observed in both control states (ie, without successful legislative efforts), which suggests that a variety of other forces can positively influence registry participation (eg, financial incentives from Medicare or private insurers, local market competition, consumer demand, or corporate leadership mandates that affect multiple hospitals). Although we could not control for potential confounders, the purpose of our mixed methods’ study was to broadly inform real-world policy decisions at the advocacy level rather than detailed clinical decision making. Fourth, the true denominator of eligible hospitals in each state for Receiving Center designation for a particular time-critical diagnosis varied depending on both baseline assumptions (inclusion or not of CAHs) and chosen database source (Centers for Medicare & Medicaid Services or other). Fifth, our qualitative analysis is subject to selection bias and subjective recall, but this was mitigated by the use of multiple interviews per state, tape recording, a prospective outline of discussion topics, and a focus on independently reoccurring themes across multiple interviews. Lastly, the impact of registry participation is ultimately best determined at the patient level in terms of reduced morbidity and mortality. The gradually increasing ability to link state administrative databases with clinical stroke registries may enable future efforts to assess the true influence of legislation on public health.
Conclusions
Based on a combination of both semiquantitative and qualitative analyses involving 5 case states, 2 control states, and 2 AHA-affiliated registries, this mixed methods health policy evaluation suggests that efforts to pass state legislation for systems of care are generally associated with increased QI registry participation. However, because these legislative pathways may often be slow and nonlinear, states should first explore whether sufficient DOH or EMS agency regulatory authority exists when attempting to create systems of care for time-critical diagnoses.

Disclosures

This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the writing group are required to complete and submit. A relationship is considered to be “significant” if (1) the person receives $10,000 or more during any 12-month period, or 5% or more of the person’s gross income; or (2) the person owns 5% or more of the voting stock or share of the entity, or owns $10,000 or more of the fair market value of the entity. A relationship is considered to be “modest” if it is less than “significant” under the preceding definition.

*Modest.
†Significant.
**Reviewer Disclosures**

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**References**


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