

A STUDY OF **Primary Stroke Center Policy** RECOMMENDATIONS FOR POLICY IMPLEMENTATION

National Center for Chronic Disease Prevention and Health Promotion
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A STUDY OF PRIMARY STROKE CENTER POLICY: Recommendations for Policy Implementation

Introduction

Stroke is the fourth leading cause of death in the United States. The development of new treatment strategies for stroke has improved the care of hospitalized stroke patients receiving the recommended treatment in the critical early hours following symptom onset. Yet there is still room for improvement. Some states have responded by adopting a certification process and criteria for primary stroke centers (PSCs) as part of improving the state's stroke system of care. A stroke system of care is one that coordinates patient access to a full range of coordinated services necessary for all aspects of stroke management, including prevention, notification and response of emergency medical service (EMS), acute treatment in the hospital emergency department, and rehabilitation.¹ PSC hospitals have the infrastructure and organizational elements, including staff, equipment, and protocols, to treat stroke patients quickly and efficiently.^{2,3} However, wide variation exists among and within states on procedures for PSC certification and designation, regulatory authority and responsibility, available resources, and quality improvement and assurance initiatives. Some states accept The Joint Commission PSC certification; others have their own certification process based on American Heart Association/American Stroke Association (AHA/ASA) and Brain Attack Coalition guidelines. Additionally, some states have built levels of certification into their PSC policies.

A collaborative project by the Centers for Disease Control and Prevention's Division for Heart Disease and Stroke Prevention, the National Association of Chronic Disease Directors, and the University of Georgia Department of Public Administration and Policy looked at the implementation of PSC policies.⁴ The project focused on four early adopter states—Florida, Massachusetts, New Mexico, and New York—with varying experience in PSC policy implementation. The project team reviewed a variety of public documents and reports, visited each state, and observed a large meeting of stakeholders or providers in each of the case study states. The project team spoke with a wide range of stakeholders on a broad range of topics relating to acute stroke care. Stakeholders included academics, public health advocates, AHA/ASA representatives, emergency department physicians and nurses, EMS staff and administrators, hospital administrators, insurance payers, neurologists and other medical specialists, hospital stroke coordinators, state health department managers and regulatory representatives, and stroke survivors. Interviewees spoke specifically about their professional interaction in the PSC system of care.

¹ Schwamm LH, Pancioli A, Acker JE 3rd, Goldstein LB, Zorowitz RD, Shephard TJ, et al. Recommendations for the establishment of stroke systems of care: recommendations from the American Stroke Association's Task Force on the Development of Stroke Systems. *Circulation*. 2005;111(8):1078–1091.

² Alberts MJ, Hademenos G, Latchaw RE, Jagoda A, Marler JR, Mayberg MR, et al. Recommendations for the establishment of primary stroke centers. *JAMA*. 2000;283(23):3102–3109.

³ Alberts MJ, Latchaw RE, Jagoda A, Wechsler LR, Crocco T, George MG, et al. Revised and Updated Recommendations for the Establishment of Primary Stroke Centers. *Stroke*. 2011;42:2651–2665.

⁴ O'Toole LJ Jr, Slade CP, Brewer GA, Gase LN. Barriers and facilitators to implementing primary stroke center policy in the United States: results from 4 case study states. *Am J Public Health*. 2011;101(3):561–566.

In general, stakeholders:

- Supported some level of state policy to promote developing and managing a state stroke system of care, including PSCs.
- Recognized the need to consider the successes of other states in policy implementation.
- Had first-hand understanding of the complexity of policy processes.
- Were able to identify several barriers and facilitators to implementing PSC policy.

Because states have a continued interest in adopting PSC policies, these findings, combined with published policy implementation literature, were translated into key components for policy implementation. Considering the key components, barriers, and contextual facilitators identified in this study may guide the development of policy language and help states move toward successful policy adoption and implementation. Although the key components described here do not assure improvements in health outcomes, they do support successful implementation of PSC policy. Many of the key components described in this document center on engaging stakeholders, cohesiveness, communication, and clarity of roles and responsibilities. By considering these issues during policy formulation and throughout the legislative process, states can avoid some of the challenges experienced by early adopters of PSC policy.

Key Components

- Identify and Support Policy Champions
- Clarify Legislation into Regulations and Rules
- Clarify Roles and Responsibilities
- Designate Lead Agencies
- Ensure Availability of Resources
- Establish and Use Advisory Groups
- Communicate with Key Stakeholders
- Support Communication between Implementing Organizations
- Coordinate Elements in the Overall System of Care
- Clarify Implications for Insurers, Medicare, and Medicaid
- Establish and Maintain Data for Quality Improvement
- Focus on Factors that Support Quality
- Support Stroke Care in Isolated and Rural Areas
- Create Policy Feedback Opportunities

Facilitators

- American Heart Association/American Stroke Association Resources
- Locally Driven Health Care Needs
- Hospital Competition

Barriers

- Lack of a State Stroke System of Care
- Use of Tissue Plasminogen Activator (tPA)
- Complex Roles of Government
- Financial and Regulatory Disincentives
- Emergency Response Challenges
- Intrastate and Interstate Barriers of Telemedicine
- Data Use Challenges

Key Components of Primary Stroke Center Policy Implementation

Identify and Support Policy Champions

Policy champions are key individuals in a state's stroke system of care and are well regarded professionally. These individuals can make a substantial difference in the implementation process because they are skilled at motivating others, inspiring cooperative action across public health agencies, and identifying and resolving interorganizational and other gaps in the system. They also understand the sticking points in health care regulation and health care reimbursement. Policy champions:

- May have varying backgrounds, with experience in such areas as politics, public administration, and clinical expertise.
- Are able to gain widespread support for improved stroke care and have knowledge of the policy process.
- Can be neurologists, stroke care coordinators, or nonclinicians working in hospitals or state agencies.

Clarify Legislation into Regulations and Rules

Translate general policy objectives often found in legislation into specific and operational regulations, interpretations, or administrative rules.

- Plain language and clear steps and requirements facilitate interpretation and implementation.

Clarify Roles and Responsibilities

The roles and responsibilities necessary for policy implementation need to be clarified if they are not documented in the policy.

- Clarify through operational policies or rules how oversight, assistance, and encouragement of PSC development will be managed if PSC policy does not provide the specific roles and responsibilities of implementers.
- Specify roles and responsibilities for regulatory compliance and quality improvement. These functions may be housed in one state agency or handled by separate coordinating agencies.
- Identify institutions with primary responsibility for development and oversight of telemedicine services if these services are integral to the policy.

Designate Lead Agencies

If the law designates one or more institutions as responsible for policy implementation, all involved parties must have a clear understanding of who is responsible for implementation or aspects of implementation, and the decision-making chain.

Ensure Availability of Resources

Resources are necessary to establish and support a well-functioning system of stroke care (e.g., basic funding, trained specialists, information systems, hardware). Resources may be authorized in the policy or require a separate appropriation action.

- At a minimum, regular support should be available for the personnel and process expenses involved with stroke center designation and review and the expenses of improving care throughout the system. In addition to one-time funding at the initiation of a state stroke policy, some states have provided grants, incentives, cost-sharing for certification, and other forms of support.
- Resources are necessary to advise and assist hospitals and other providers on specific legal and regulatory processes, as well as to assist hospitals with achieving PSC administrative standards.

- Stakeholders indicated that pre-hospital provider training and updates on the changing science of stroke care support more timely access to treatment for stroke patients.
- Resources may be available through public or private sources or foundations, legislated, or may be agency discretionary funds.

Establish and Use Advisory Groups

Ensure that policy is informed by the medical community and other advisors. Stroke treatment options and practical stroke care result from a constantly evolving science, based on rigorous studies and quality improvement initiatives.

- Having the medical community (including stroke neurologists, hospital medical staff, hospital stroke coordinators, and EMS medical directors) continually advise state policy efforts supports policy implementation and better coordination between state agencies and providers.

The implementation process benefits from the advice and recommendations of a stakeholder committee or council that has clear responsibilities, meets regularly, considers how the stroke system of care is operating, and considers improvements.

- Advisory groups may consist of clinicians and a broad array of organizations and relevant stakeholders (e.g., emergency responders, survivors, researchers).
- AHA/ASA or the state health office may convene such a group.
- Publicizing the committee's efforts can encourage broader discussion of state policy and the stroke system of care.

Communicate with Key Stakeholders

Stakeholders involved in the implementing policy for PSCs need to stay informed about policy requirements and challenges to implementation.

- Hospitals, voluntary agencies, The Joint Commission, medical specialists (including neurologists and emergency physicians), stroke coordinators, and emergency response partners are among the key stakeholders who need to be included in a communication network.
- Establishing information systems, regular channels of communication, well-designed Web sites, periodic regional or statewide meetings, or a clearly designated communications office or staff person will keep stakeholders informed and engaged.

Support Communication Between Implementing Organizations

In addition to communication among stakeholders about policy developments, successful policy implementation requires regular and well-established communication between the organizations engaged in implementation or oversight. Rapid and accurate transmission of information, and the smooth transfer of patients for diagnosis, testing, and treatment, are essential among these participating organizations. Key organizations include:

- Emergency medical dispatch systems (EMD) and EMS. EMS needs to have real-time information regarding whether a particular stroke center has the capacity to admit and treat additional patients and a full description of patient symptoms.
- EMS and hospitals. Transfer protocols and practices need to be in place and regularly used to foster timely care.
- Emergency medicine and neurology. Sometimes these functions are within the same hospital and sometimes cross organizational boundaries, for instance via telemedicine.

Communication between implementers includes sharing stroke treatment protocols among hospitals, sharing current science about treatment among providers, and organizing regular meetings of diverse stakeholders to discuss best practices, issues, and problems in stroke care.

Coordinate Elements in the Overall System of Care

Although acute care for stroke in the hospital setting is vitally important, it is not the only component of an overall system of care. Policy implementation and health outcomes are improved when the pre-hospital, hospital, and rehabilitation systems are linked and coordinated.

- Coordination of stroke care policy and trauma system policy is important, while maintaining an understanding of how they differ in terms of patient needs and provider resources.
- Coordination improves when systems of stroke care leverage existing systems of care such as trauma networks or neonatal systems.
- The primary advantages of coordinating pre-hospital care for stroke patients include using preexisting resources and leveraging the availability of early responders.

Clarify Implications for Insurers, Medicare, and Medicaid

State policies on health insurance influence how systems of care develop. Costs, charges, and incentives within and between stakeholder organizations also are very important in determining how organizations involved in stroke systems of care operate and work together. For instance, PSC designation affects the bottom line for hospitals because it may affect where patients—both paying and uninsured—are taken.

- Policy implementation is supported when those responsible for reimbursement, insurance, and health care coverage understand state policy on PSCs and are given an opportunity to address barriers and disincentives as they arise.

Establish and Maintain Data for Quality Improvement

Participation in a stroke registry (e.g., Paul Coverdell National Acute Stroke Registry), a state-organized quality improvement program for acute stroke, or AHA/ASA's Get with the Guidelines program can support PSC policy implementation.

- Registries can assist in identifying implementation problems through data analysis, allowing their resolution and improvement in quality of care over time.
- Gathering data about pre-hospital care and relating those data to hospital care are important for stroke care given the time-sensitive nature of diagnosis and treatment.
- States that participate in the National EMS Information System (NEMSIS) expect benefits from collecting and analyzing standardized pre-hospital data on stroke patient diagnosis and transport.
- Where resources exist for state stroke registries that collect data on quality of care and sharing of best patient care practices, evidence suggests that stroke patient care improves.

Focus on Factors that Support Quality

It is important to have hospital certification and inspection processes that are focused on quality of care, cost-effective, consistent with current science, and reasonable. One example is physician licensure regulations that support flexible credentialing across a multihospital system of care to facilitate telemedicine and improve access to quality care in rural areas.

Support Stroke Care in Isolated and Rural Areas

Given the time-dependent nature of acute stroke care, providing access for rural stroke patients to PSCs presents a challenge in many states. Although EMS air transport can help, telemedicine is the most promising strategy for rural acute stroke patients.⁵

- Telemedicine can provide the necessary support and diagnosis for many patients.
- Addressing telemedicine in PSC policy supports implementation and coordination of care.
- Basic questions about access to participating neurologists, reimbursement, and credentialing of physicians in multiple states must be addressed.
- Funding requirements for hardware and adjustment of physician and hospital routines to accommodate consultation from a distance need to be considered if telemedicine is to reach its full potential in reducing or eliminating urban-rural disparities in acute stroke care.

Create Policy Feedback Opportunities

The creation and implementation of PSC policy is not a one-time event—opportunities exist to modify and improve the policy over time. States that adopt policy may learn from experience about how and why their policies might be changed to improve health outcomes.

- Changes may relate to funding levels or the system of care, such as establishing or modifying a stroke registry, developing a bypass system for EMS, improving telemedicine coverage, or creating an oversight system for PSC compliance.
- State experience with other comprehensive systems of care (e.g., trauma, coronary care), may provide opportunities for improvement and policy change.

States can establish regular opportunities for policy improvement by establishing regular mechanisms for policy review and feedback.

- A state task force or advisory committee may be one such forum, especially if it is charged with making periodic recommendations.
- Regular hearings in the legislature, annual reports with recommendations by the state health office, partner-organized forums for discussion and review, and conducting assessments also may improve implementation.

Facilitators to State Primary Stroke Center Policy Implementation

American Heart Association/American Stroke Association Resources

AHA/ASA resources and staff, including quality improvement directors, advocacy directors, and regional vice presidents, support policy implementation. AHA/ASA also may offer a wide range of technical, administrative, and research supports for policy developers, advocates, and implementers. States with access to and understanding of these resources generally benefit in their policy implementation efforts.

Locally Driven Health Care Needs

Stakeholders indicated that flexibility to allow hospitals and physicians to provide care in line with local needs, resources, and policies facilitates policy implementation.

⁵ Schwamm LH, Holloway RG. A review of the evidence for the use of telemedicine within stroke systems of care: a scientific statement from the American Heart Association/American Stroke Association. *Stroke*. 40(7):2626–2634.

- A bypass and notification system that allows hospitals to opt in and out of readiness to provide stroke care makes sense so long as it is not used to avoid care of the indigent.
- Considering urban vs. rural vs. frontier area needs and resources and population demographics in implementation allows for a more responsive system.

Hospital Competition

In some markets, competition between hospitals for PSC designation can promote quality and gain hospitals an edge in the market.

- Representatives from hospitals in highly competitive markets reported efforts to compete on quality even without better reimbursement.
- State policies that promote emergency medical bypass to PSC-designated hospitals take hospitals' competitive strategies to a new and more complex level.

Barriers to Implementation of Primary Stroke Center Policy

Lack of a State Stroke System of Care

Without an intact system of care, states face the need to create or improve collaboration and communication between pre-hospital and hospital programs.

Use of tPA

Provision of tPA, a clot-busting drug, is a key competency of a PSC and used in PSC certification. When indicated by imaging tests, stroke patients should receive tPA as soon as possible after a stroke. Evidence suggests the earlier tPA or other appropriate treatment is begun, the greater the potential for stroke recovery.⁶ There are several challenges to the use of tPA:

- Hesitancy of emergency department doctors to administer a drug with potentially hemorrhagic results without a prior neurology consultation.
- Too many hospitals do not have neurologists and neurosurgeons to adequately assess stroke patients on an emergency basis. This is especially problematic in rural areas that lack computed tomography (CT) imaging resources and access to telemedicine.
- Stakeholders indicated that tension sometimes exists between emergency physicians, neurologists, and stroke neurologists on using tPA.

Complex Roles of Government

For stroke care, more than one agency may be involved in guidance and oversight. A unique and sometimes difficult relationship exists between public health and regulatory agencies. The potential issues include:

- Information sharing and data use can pose a conflict when the same or similar data are used for both quality improvement and to measure regulatory compliance.
- Lines between public health roles can be blurred when ensuring compliance with state policy and supporting hospitals in improving the quality of services and outcomes.
- The roles of ensuring policy implementation and administration of certification may be housed in one or more agencies and may evolve over time. Lines of authority at each stage of policy implementation and administration may not be clear.

⁶ Hacke W, Donnan G, Fieschi C, Kaste M, von Kummer R, Broderick JP, et al. Association of outcome with early stroke treatment: pooled analysis of ATLANTIS, ECASS, and NINDS rt-PA stroke trials. *Lancet*. 2004;363:768–774.

Financial and Regulatory Disincentives

Because hospitals and medical providers are required to follow existing guidelines, laws, billing practices, and regulations, adding a policy related to stroke care creates a new level of complexity and in some cases conflicts with existing policy.

- Licensure of hospitals for stroke care sometimes conflicts with other state regulations or Medicare and Medicaid rules.
- A state stroke system of care assumes that neurologists and neurosurgeons can move easily between hospital facilities, especially for telemedicine support, yet this is unrealistic given current hospital credentialing.⁷
- A stroke system of care assumes that hospitals share equally in the burden of care for the indigent and uninsured, yet this is an unrealistic assumption. Academic and tertiary care centers often bear the burden of unreimbursed care. These and other hospitals, once designated as PSCs, may not be in a position to treat additional uninsured patients generated by EMS policies requiring bypass of non-PSC designated hospitals. If PSCs have less control over their indigent care obligation, it may adversely affect profitability and continued PSC designation.
- A state stroke system of care assumes that hospitals work together, but overlooks the fact that hospitals are often competing. Given the regulatory burden, interhospital networks are not always collegial unless they have financial incentives.
- A state stroke system of care assumes that PSC designation ensures comparable access, capacity, and quality across hospitals. However, hospitals have different bed, staffing, and facility capacities. Across PSCs, large and small alike, the number of services provided and the quality of care may still vary.
- Stroke is not a money maker for hospitals.^{8,9}
- Hospitals' focus on the efficient use of resources poses challenges to making available CT scanning and staffing for time-limited and unpredictable stroke diagnostic procedures.
- The science of stroke care is constantly changing and hospitals are challenged to maintain up-to-date protocols and by the costly training and retraining of staff on an ongoing basis.

Emergency Response Challenges

Proper stroke care depends on early recognition of sometimes subtle symptoms and rapid access to emergency departments capable of providing such care. Barriers to emergency response include:

- EMD is a complicated communication system often tied to fire and police department resources and is often organizationally and operationally distinct from EMS. For situations like stroke, the dispatch system operators might not be trained to recognize symptoms and direct EMS transport.
- Lack of integration of the EMD and EMS delivery systems makes communication, cross-training, and collaboration challenging.

⁷ Hospitals have many good reasons to be selective and cautious about providers within their system. Comments suggesting that credentialing is problematic in general come from stakeholder interviews that identified the issue as problematic in the context of a statewide system of stroke care.

⁸ Brinjikji W, Kallmes DF, Rabinstein AA, Lanzino G, Cloft HJ. Hospitalization costs for patients with acute ischemic stroke treated with endovascular embolectomy in the United States. *Stroke*. 2011;42:3271–3273.

⁹ Brinjikji W, Rabinstein AA, Cloft HJ. Hospitalization costs for acute ischemic stroke patients treated with intravenous thrombolysis in the United States are substantially higher than Medicare payments. *Stroke*. 2012;43:1131–1133.

- EMS transfer agreements and insurance reimbursement relationships may hinder a patient's access to the closest PSC hospital or result in the transfer of patients between hospitals.
- Local EMS system budget constraints may limit training to incorporate improving stroke care science.
- Challenges for local EMS providers to dedicate ambulances to out-of-area transports include crossing provider service areas and tying up vehicles for long periods of time. This is especially true in rural areas that have few EMS vehicles and crews.

Intrastate and Interstate Barriers of Telemedicine

Telemedicine is an important alternative because of the significant difficulties of providing rural area access to in-person neurology support. Challenges at the state level include:

- Rural hospitals lack connectivity.
- Credentialing at rural hospitals by numerous offsite neurologists providing diagnosis and treatment via telemedicine.¹⁰
- The complexity of billing and distributing the costs and revenues of telemedicine.¹¹
- Costs of equipment and hardware.

Data Use Challenges

- Limitations, including HIPAA¹² and potential Freedom of Information Act requests, make it challenging to share and use data for quality improvement.
- Concerns about potential adverse or malpractice claims.
- Data systems that track patients through the system of care are limited.

Conclusion

Adopting policies that affect health care settings can have a wide reaching effect on health outcomes. To have impact, successful policy implementation is critical. While planning policy action, taking into account the key components and barriers identified for primary stroke policy in this report can guide the development of policy language and support adoption and implementation strategies.

¹⁰ Patterson V, Wootton R. How can teleneurology improve patient care? *Nat Clin Pract Neurol*. 2006;2(7):346–347.

¹¹ Refer to Centers for Medicare and Medicaid Services documents on billing Medicare for these services Web site. Available at www.cms.hhs.gov/Transmittals/downloads/R790CP.pdf (page 7) and www.cms.hhs.gov/Transmittals/downloads/R43BP.pdf.

¹² The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule is designed to protect the privacy of individually identifiable health information, and the confidentiality provisions of the Patient Safety Rule protect identifiable information being used to analyze patient safety events and improve patient safety. Available at www.hhs.gov/ocr/privacy.

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