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Recommendations for the Implementation of Telemedicine Within Stroke Systems of Care. A Policy Statement From the American Heart Association

Lee H. Schwamm, Heinrich J. Audebert, Pierre Amarenco, Neale R. Chumbler, Michael R. Frankel, Mary G. George, Philip B. Gorelick, Katie B. Horton, Markku Kaste, Daniel T. Lackland, Steven R. Levine, Brett C. Meyer, Philip M. Meyers, Victor Patterson, Steven K. Stranne, Christopher J. White and on behalf of the American Heart Association Stroke Council; Council on Epidemiology and Prevention; Interdisciplinary Council on Peripheral Vascular Disease; and the Council on Cardiovascular Radiology and Intervention

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Recommendations for the Implementation of Telemedicine Within Stroke Systems of Care

A Policy Statement From the American Heart Association

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In 2005, the American Stroke Association formed a task force on the development of stroke systems to propose a new framework for stroke care delivery that would emphasize linkages rather than silos in the chain of stroke survival and provide a blueprint for large organizations or state and federal agencies on how to implement a more coordinated approach to stroke care.¹ The stroke systems of care model (SSCM) recommends implementation of telemedicine and aeromedical transport to increase access to acute stroke care in neurologically underserved areas, as do the latest American Stroke Association guidelines for the early management of adults with ischemic stroke.² The present report was commissioned by the American Heart Association to address how telemedicine might help address current barriers to improved stroke care delivery in the United States within the framework of the SSCM.

Telemedicine has been defined broadly as “the use of telecommunications technologies to provide medical information and services” (p 483).³ Technically, this encompasses all aspects of medicine practiced at a distance, including use of telephone, fax, and electronic mail technology, as well as

the use of interactive full-motion integrated video and audio, that brings together patients and providers separated by distance.⁴ In the early part of the twentieth century, electrocardiograms and electroencephalograms were transmitted over ordinary analogue telephone lines, and in 1920, medical advice service for sea craft via Morse code and voice radio was established. Expensive and cumbersome 2-way closed-circuit television systems used in the 1960s to transmit radiographs and evaluate patients have been replaced by low-cost, personal computer-based solutions for videoconferencing and transmission of physiological data from clinics or patient homes or from inaccessible sites such as ships, aircraft, and geographically remote regions.⁵

Telemedicine has been proposed as an alternative means of managing many different diseases and conditions over the past few decades, and a review of the barriers to implementation and the challenges to sustainability in general is useful in the consideration of telemedicine for stroke (*telestroke*). For telemedicine to transform the world of health care as the Internet has transformed the world of commerce, several barriers must be overcome. These include (1) defining the

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types of specialties suited to telemedicine practice, (2) addressing licensure and liability laws that traditionally have been regulated at the state level, (3) developing acceptable policies relating to the privacy and confidentiality of information exchanged over telemedicine, (4) simplifying the process of requesting and delivering telemedicine consultations while also improving the training and education of the end users (eg, patients and providers), (5) developing financial models for reimbursement of provider time spent on consultation via telemedicine (*teleconsultation*), and (6) gaining acceptance of the practice by patients, providers, and payers.⁶⁻⁹

Licensure and liability laws may result in the most formidable barriers to the expanded use of telemedicine, while at the same time failing to provide sufficient protection for consumers. Mutual recognition of licensing laws across state medical boards coupled with a universal standard of care for teleconsultation may be necessary to erode the barriers to full implementation.¹⁰ Health services research suggests that telemedicine applications can be cost-effective and improve continuity of care for patients within organizations that can adapt to new technology easily. New management priorities and organizational structures may be necessary for the benefits of telemedicine to be realized, including substantial investments in training in these new technologies for physicians and nurses.¹¹ The 2 factors that may be the biggest barriers to provider adoption and utilization are inadequate provider training (especially when the equipment installed includes features that are more complex and sophisticated than necessary) and the role of the provider as the gatekeeper to telemedicine access.⁹

The direct involvement of providers in the development of disease-specific telemedicine systems greatly enhances their acceptance and adoption, but there are few published studies of failed telemedicine implementations to quantify the extent to which provider buy-in may be essential.¹² Although it seems clear that the benefits of such a systematic implementation of telestroke could be readily generalized to the care of patients with other diseases, the lessons learned from prior telemedicine implementations suggests that adoption in one area does not necessarily lead to rapid and simple adoption in other areas. Careful attention to the barriers listed above will be needed to successfully implement crossover applications of the telestroke model.

Use of interactive full-motion audio and video for acute stroke care was first reported in the early 1990s, but Levine and Gorman¹³ were the first to coin the term *telestroke* for the use of high-quality interactive telemedicine in acute stroke intervention. Over the past 2 decades, this model has been adopted and implemented by multiple different types of healthcare organizations across the United States and abroad.¹⁴ As technology matures, systems that today require dedicated high-bandwidth telecommunications networks (eg, speeds in excess of 300 kilobits per second of synchronous duplex communication) and dedicated external video processor chips will soon be able to perform high-quality videoconferencing (HQ-VTC) with inexpensive, commercially available portable computers with standard integrated software and hardware options.

The core steps of an acute stroke clinical encounter include rapid neurological assessment, review of brain imaging, and clinical formulation (eg, exclusion of stroke mimics and assessment of patient eligibility for intravenous thrombolytic therapy, investigational stroke clinical trials, or more advanced stroke services). Telemedicine-enabled acute stroke consultation supports the remote review of transmitted medical images at appropriate resolution with the industry standard DICOM (digital imaging and communications in medicine) digital format, established in 1982 by the American College of Radiology and the National Electric Manufacturers Association.¹⁵ The clinical evaluation is performed over interactive full-motion integrated video and audio (videoconferencing) with common industry standards for far-end camera control, video transmission, and compression such as MPEG (Motion Picture Experts Group) and CIF (common intermediate format) to define resolution and frame rates of projection. Audio transmission incorporates algorithms to reduce the echo and distortion that are common to medical environments.

With the potential to facilitate each of these steps, telemedicine technology provides specialists with the data necessary to assist clinicians at the bedside in stroke-related decision making for patients presenting at distant or under-equipped facilities. There are now a growing number of telestroke programs established in the United States and Europe (Tables 1 and 2), ranging from small partnerships between individual campuses of a single hospital system to large multihospital affiliations in which nonprofit, academic medical centers or tertiary hospitals serve as the *hubs* (eg, centralized specialty care stroke centers) to a network of *spokes* (eg, rural or community hospitals that lack readily available stroke expertise around the clock). The reported numbers of telestroke consultations overall and those that lead to thrombolysis show that the use of telemedicine is feasible and has already impacted local stroke care; however, its use must be extended substantially to have a meaningful impact on reducing the burden of stroke disability in our society. Scalability is a challenge that has yet to be demonstrated definitively. Some of these networks began as externally grant-funded pilot programs, whereas others relied on internal institutional capital investments to get started. As the number of states with stroke center certification requirements has increased and the financial viability of telestroke has been demonstrated, third-party stand-alone vendors who are not affiliated with academic institutions have begun to offer services outside of a hub-and-spoke model of care delivery. Because the evidence that supports the practice of telestroke is derived from published experiences of hub-and-spoke networks, they will form the basis of the recommendations in the present report. Because of the evidence that stroke care delivery is improved when delivered in a systematic fashion, the recommendations will focus on the implementation of telestroke within the context of the SSCM for acute stroke care delivery. Further research is warranted to demonstrate whether alternative models of telestroke care delivery can achieve the same positive results.

Although the most-studied encounters in telestroke have been those that involve thrombolysis eligibility for patients

Table 1. Survey of US Telestroke Projects

	CO-DOC	Detroit Medical Center Systemwide Stroke Initiative	Methodist Hospital Telestroke Program	Michigan Stroke Network	Montana Stroke Initiative	MUSC Reach Stroke Network	Nevada Telemedicine Program	New York State Rural Telemedicine Initiative
Name of institution(s)	Colorado Neurological Institute	Wayne State University/ Detroit Medical Center	Methodist Hospital-Park Nicollet Clinic	St Joseph Mercy Oakland Hospital	St Vincent Healthcare, Benefis Healthcare, Billings Clinic	Medical University of South Carolina Hospital	Renown Institute for Neurosciences	Bassett Healthcare, Catholic Health System, Millard Fillmore Gates Circle Hospital, SUNY Upstate Medical University
Primary location of hub	Denver, Colo	Detroit, Mich	St Louis Park, Minn	Pontiac, Mich	Billings and Great Falls, Mont	Charleston, SC	Reno, Nev	Cooperstown, Buffalo, and Syracuse, NY
Primary contact* (name of person)	Christopher Fanale, MD	Ramesh Madhavan, MD	Sandra K. Hanson, MD	Richard Fessler, MD	Nicholas Okon, DO	Robert Adams, MD	Paul M. Katz, MD	John Morley, MD
No. of states served	1	1	1	1	1	1	1	1
No. of hubs	1	1	1	1	3	1	1	4
No. of spokes†	10	4	4	31	1	3	27	22
No. of telestroke consultations in 2007‡	84	25§	29	78	0§	0	20	85
No. of telestroke consultations‡ with tPA given in 2007	13	16§	10	20	0§	0	5	5
Challenges to the implementation of telemedicine								
Funding source (choose all that apply): A, institutional/ nonprofit; B, federal government; C, state government; D, third-party payer/commercial insurance; E, for-profit company; F, spoke membership fees	C, D, F	A	A, B, F	A	A, C	A, F	A, D	A, C, F
Hub state regulatory environment (choose all that apply): A, state-based stroke center designation; B, legislation addressing stroke telemedicine in place as of September 2008; C, stroke center self-designation; D, EMS triage to stroke centers	A	A, D	C	C	None	C	D	A
Reimbursement for telemedicine (choose all that apply): A, Medicaid; B, third-party payers	None	None	A, B	B	A	None	B	None
Hub hospital participation in stroke quality improvement registries (choose all that apply): A, The Joint Commission; B, CDC Paul Coverdell Stroke Registry; C, <i>Get With the Guidelines</i> ; D, other	A, D (state stroke registry)	A, B, C	A	A, C	A, C	A, C	A, C	A, C
Additional malpractice insurance for hub telestroke consultants required (yes/no)	Yes	No	No	No	No	No	No	No
Hub-and-spoke business relationship (choose all that apply): A, contract; B, grant; C, courtesy; D, other	A	A	C	C	D (stipend from Department of Public Health)	A	C	A, C
Spoke affiliation (choose all that apply): A, within hospital network; B, outside hospital network	A, B	A	B	A, B	B	B	B	A, B

(Continued)

CO-DOC indicates Colorado Digital Online Consultant; MUSC, Medical University of South Carolina; OSF, the Sisters of the Third Order of St Francis; STRoE DOC, Stroke Team Remote Evaluation using a Digital Observation Camera; STARR, Stroke Telemedicine for Arizona Rural Residents; UPMC, University of Pittsburgh Medical Center; SUNY, State University of New York.

This Table only includes a sample of the telemedicine programs that exist in the United States. All programs listed practice telemedicine using interactive, high-bandwidth, full-motion video and audio; include at least 1 hub and 1 spoke hospital; and were operational as of May 2008 (data accurate as of October 2008). Many pilot programs not currently active have been omitted from the Table. Data in this Table were provided by self-report of the program's primary contact or another representative of the program listed at the bottom of the Table.

*Additional data provided by REACH CALL, Inc.

†Spokes are defined as hospitals with which the hub hospitals have executed a signed letter of intent or other formal agreement to engage in consultations.

‡Includes only consultations that involved interactive videoconferencing. Telephone-only consultations are not included in this number.

§Program was in operation for only part of the year in 2007.

Table 1. Continued

OSF Stroke Network	Partners TeleStroke Center	REACH MCG	Sacred Heart Regional Stroke Center	STRoKE DOC	STARR Network	Swedish Medical Center TeleStroke Program	Texas Telephysicians	University Healthcare Telestroke Program	UPMC Telestroke Network
Sisters of Third Order of Saint Francis Healthcare System	Massachusetts General Hospital/Brigham & Women's Hospital	Medical College of Georgia	Sacred Heart Regional Stroke Center	University of California, San Diego Stroke Center	Mayo Clinic Arizona	Swedish Medical Center	University of Texas-Houston	University of Utah	University of Pittsburgh Medical Center
Peoria, Ill	Boston, Mass	Augusta, Ga	Pensacola, Fla	San Diego, Calif	Phoenix, Ariz	Seattle, Wash	Houston, Tex	Salt Lake City, Utah	Pittsburgh, Pa
David Z. Wang, DO	Lee Schwamm, MD	David Hess, MD	Terry Neill, MD	Brett C. Meyer, MD	Bart Demaerschalk, MD	Tammy Cress, RN, MSN	James C. Grotta, MD	Elaine Skalabrin, MD	Lawrence Wechsler, MD
1	3	1	1	1	1	1	1	1	1
1	2	1	1	1	1	1	1	1	1
25	21	11	1	3	2	2	13	6	13
177	97	171	40	10§	4§	2§	180	38	151
45	40	32	2	3§	2§	0§	16	4	44
A	A, F	A, F	A	A, B	A, C	A	A, E	A, B, C, F	A, F
None	A, D	B	A	C, D	A, D	None	A, D	C, D	None
A	None	A, B	B	A	None	None	A	None	B
A	C	A, B, C	C	A	A, C	A, C	A	A, C	C
No	No	No	No	No	No	No	No	No	No
A, D	A	A, C	C	B, C	A	C	A	B, C	A
A, B	A, B	A, B	A	B	B	A	A, B	B, C	A

presenting within the first few hours of stroke onset, telestroke may offer substantial benefits to many patients presenting with stroke symptoms regardless of the timing in relation to stroke onset or the phase of care they require at the time of consultation. These benefits are explored in the context of each domain of the SSCM, preceded by an overview of the relevant barriers and potential solutions offered by telestroke.

Burden of Stroke

Stroke is a major public health problem worldwide.¹⁶ A major challenge will be to increase access to appropriate

interventions for stroke among patients in more remote or underserved regions. The United States has approximately 4.0 neurologists per 100 000 persons, caring for more than 700 000 acute strokes per year,¹⁷ although many parts of the United States are without access to acute stroke services entirely.¹⁸ Across the United States, a growing number of neurologists are opting out of call coverage for acute stroke and other neurological emergencies, thereby increasing the number of patients who could be described as neurologically underserved. State and local regulations requiring hospitals to provide this emergency call coverage if they wish to be licensed or recognized as acute stroke-

Table 2. Survey of European Telestroke Projects

	RUN-FC	TRUST-TPA	TELESTROKE-FINLAND	(Unnamed)	Telestroke GSTT
Country/region	France/Besançon	France/Paris	Finland	UK/Northern Ireland	UK/London
Name of coordination institution		Bichat University Hospital	Helsinki University		St Thomas' Hospital
Primary contact (name of person)	Thierry Moulin	Pierre Amarengo	Turgut Tatlisumak	Victor Patterson	Heinrich Audebert/ Antony Rudd
Special focus (eg, prehospital)	In-hospital	In-hospital, thrombolysis	In-hospital	In hospital, post-acute	In-hospital, on-call
No. of hubs	1	1	1	1	1
No. of spokes*	11	10	5	3	On-call service from home
Average distance of spoke hospitals to hubs	76 km	50 km	409 km	75 km	
Estimated stroke patients in spoke hospitals per year	3500	3000	1000	150	400
No. of telestroke consultations in 2007†	175	50	40‡	40	18‡
No. of telestroke consultations† with tPA given in 2007	20	30	21‡	0	7‡
Used bandwidth	1–2 Mb	360 kB	1–2 Mb	384 kbs	G3 (UMTS)
Videocommunication	2-way	2-way	2-way	2-way	1-way video, 2-way audio
Setup of stroke wards in spokes	Yes	No	Yes	No	
Hospital participation in stroke quality improvement registries	Yes	No	Yes/no	No	
Continuous stroke education program	Yes	Yes	Yes	No	Yes
Funding source (choose all that apply): A, institutional/nonprofit; B, federal government; C, state government; D, health insurances; E, for-profit company	B, C	B	B, A	C	A
Reimbursement for telemedicine (choose all that apply): A, health insurances; B, spoke hospitals; C, third-party payers; D, none			D	C	D
Data source, other than primary contact					

(Continued)

RUN-FC indicates Réseau des Urgences Neurologiques en Franche Comté; TRUST-TPA, Therapeutic Trial Evaluating Efficacy of Telemedicine (TELESTROKE) in Patients With Acute Stroke; GSTT, Guy's and St Thomas' NHS Foundation Trust; TEMPiS, Telemedic Pilot Project for Integrative Stroke Care in Bavaria/Germany; STENO, Stroke Network of University of Erlangen; TESS, Telemedicine in Stroke in Swabia; SOS, Stroke Ost-Sachsen; UK, United Kingdom; UMTS, universal mobile telecommunications system; and GPRS, general packet radio service.

This Table only includes a sample of the telemedicine programs that exist in Europe. All programs listed practice telemedicine using interactive, high-bandwidth, full-motion video and audio; include at least 1 hub and 1 spoke hospital; and were operational as of May 2008. Many pilot programs that not currently active have been omitted from the Table. Data in this Table were provided by self-report of the program's primary contact or another representative of the program listed at the bottom of the Table.

*Spokes are defined as hospitals with which the hub hospitals have executed a signed letter of intent to engage in consultations.

†Includes only consultations that involved interactive videoconferencing. Telephone-only consultations are not included in this number.

‡Program was in operation for only part of the year in 2007.

capable facilities or primary stroke centers are further exacerbating this gap between supply and demand for on-site acute stroke expertise. Direct and indirect costs of stroke are estimated to be \$62.7 billion annually in the United States, with 15% to 30% of stroke survivors being permanently disabled and 20% requiring institutional care at 3 months after stroke.

Rapid recognition and accurate diagnosis are critical to optimize outcomes in patients with acute stroke. A variety of

conditions can mimic acute stroke,¹⁹ and the ability to rapidly and accurately differentiate among these can be challenging for physicians without neurological expertise. The misdiagnosis rate by primary care and emergency physicians is substantial and may be as high as 30% when preimaging initial diagnoses by primary care and emergency physicians are compared with stroke team final diagnoses.²⁰ Delays in diagnosis, misdiagnosis, and complete failure to diagnose acute stroke limit the use of proven therapies such as

Table 2. Continued

TEMPIS	STENO	TESS	Stroke Angel	HELIOS NEURONET	Teleneurology Heidelberg	SOS-NET/Saxonia
Germany/Bavaria	Germany/Bavaria	Germany/Swabia	Germany/North Bavaria	Germany - Saxony, Berlin-Brandenburg, Turingia, Westfalia	Germany/Heidelberg	Germany
Klinikum Munich Harlaching	University of Erlangen	Bezirksklinikum Günstzburg	Neurologische Klinik Bad Neustadt/Saale	Klinikum Aue	University of Heidelberg	University of Dresden
Johannes Schenkel	Rene Handschu	Andrej Schleyer	Volker Ziegler	Guntram Ickenstein	Christoph Lichy	Georg Gahn
In-hospital	In-hospital	In-hospital	Prehospital	In-hospital	In-hospital	In-hospital
2	3	1	1	4	1	1
15	11	5	0	9	3	5
77 km	80 km	80 km	20 km	80 km	45 km	40 km
4000	4000	1500	700	1700	500	1200
1406	55‡	166	0	130‡	60	58
266	0‡	17	0	11‡	6	16
500 kB–2 MB	760 kB–2 MB	UMTS/ISDN	GPRS	2 Mb	10 MB/s	2 MB/s
2-way	2-way	2-way	Not yet	2-way	2-way	2-way
Yes	Yes	Yes	No	(Yes)	1 out of 3	Yes
Yes	Yes	Yes	No	Yes	No	Yes
Yes	Yes	Yes	Yes	Yes	No	No
B, C, D	B, C, D	D	A, B	A	C	A, C, D
A via C	A	A	D	D		A
www.tempis.de	http://steno-netz.de/		www.strokeangel.de	www.helios-neuronet.de		http://www.neuro.med.tu-dresden.de/sos-net/

thrombolysis that improve outcomes and substantially lower the long-term costs of stroke.^{21,22}

Barriers to Improved Stroke Outcomes and Proposed Telestroke Solutions Within the Stroke Systems of Care Framework

Primary or Primordial Prevention and Community Education

In geographically remote areas, lack of access to specialty care may hinder timely assessment and receipt of primary or secondary prevention. Community education is vital to the achievement of improved outcomes for acute stroke patients. Community outreach may be less frequent or effective in small or remote communities that have fewer resources. Remote clinical assessment has the potential to be of use in primary prevention of stroke. Currently, risk factors for stroke such as obesity, diabetes mellitus, and hypertension are increasing,^{23–26} and fewer patients in rural areas receive preventive services such as cholesterol testing.²⁷

For example, the Indian Health Service addresses the health needs of more than 1.6 million American Indians and Alaskan Natives in a network of 48 hospitals, more than 230 clinics, and a system of tribal and urban programs across the United States. Acute stroke services are limited in Indian Health Service hospitals because of the geographically remote regions in which they are located. The establishment of a telestroke network for these hospital systems would provide them the opportunity to be a provider of primary stroke services for their American Indian and Alaskan Native patients. Concurrent emphasis on outreach to the tribal communities with health promotion and stroke prevention education is of paramount importance.

Telemedicine infrastructure may help experts provide up-to-date medical education about best practices for primary prevention of stroke to patients, primary care providers, and emergency physicians. In addition, access to subspecialty expertise via teleconsultation might be beneficial for challenging cerebrovascular cases, such as patients with asymptomatic carotid disease and several comorbid features, refrac-

tory hypertension, atrial fibrillation (in a patient with fall risk), or cerebral venous thrombosis presenting as pseudotumor cerebri. There is currently not enough evidence to provide any concrete recommendation for telemedicine implementation in this area. Research is needed to evaluate whether telemedicine is safe and effective in supporting stroke prevention clinics and enhancing patient/provider stroke education and whether it is comparable or superior to alternative methods.

Notification and Response of Emergency Medical Services

Only two thirds of stroke patients arrive by emergency medical services, and those who do receive faster evaluation and treatment than those arriving by private transportation.^{28,29} In rural areas with limited emergency medical services vehicles, prehospital provider uncertainty about stroke diagnosis for patients at the initial receiving hospital can lead to delays or reluctance to dispatch limited ground or aeromedical resources for interfacility transport. Telemedicine has been used in pilot studies of prehospital diagnosis and scoring of symptom severity and has the potential to increase prehospital diagnostic accuracy in acute stroke and support the deployment of advanced resources (eg, aeromedical evacuation) directly at the scene.³⁰ Although telemedicine may be useful for early recognition of stroke symptoms, on-the-scene triage of stroke patients for referral to adequate treatment facilities, and prearrival notification of emergency departments about transport of suspected stroke patients, there is not yet sufficient evidence for a specific recommendation.

Acute Stroke Treatment, Including the Hyperacute and Emergency Department Phases

The most effective treatment for acute ischemic stroke is rapid reperfusion. Current recommendations and drug labeling limit the use of intravenous tissue plasminogen activator (tPA) in the United States to within 3 hours of the time the patient was last seen well (or had witnessed onset of symptoms). Although a large, risk-adjusted pooled analysis of intravenous tPA-treated patients has suggested that intravenous tPA may be effective up to 5 hours after onset,³¹ current practice generally adheres to this 3-hour limit. It has also been convincingly shown that the benefit from intravenous tPA decreases as a function of time from onset to treatment and that systems should strive to deliver tPA within 60 minutes of hospital arrival. The main barrier to increasing treatment among those patients arriving within 3 hours is physician reluctance to deliver the therapy in the absence of available acute stroke expertise around the clock.

Much of the reluctance to use intravenous tPA in acute stroke has been related to physician fears of side effects and liability.³² In one survey, 40% of emergency physicians indicated they would not use intravenous tPA, most citing the risk of intracerebral hemorrhage as the reason.³³ Reluctance to administer tPA at hospitals that have not made an institutional commitment to acute stroke care, including the rapid provision of neurological and radiological expertise on demand, is reasonable, because several reports suggested that complication rates may be higher in inexperienced facili-

ties.^{34,35} Reassuringly, studies have shown that with training and implementation of stroke teams, complication rates return to expected and acceptable levels.³⁶ National guidelines from the American College of Emergency Physicians recommend that hospitals alert local emergency medical systems regarding their stroke treatment readiness so that optimal routing of patients with suspected stroke to appropriate facilities may be implemented.

Ironically, the available evidence concerning litigation involving stroke therapy with tPA indicates liability is predominantly associated with failure to provide tPA rather than with adverse events associated with its use. The greatest risk of malpractice litigation for providers comes not from adverse outcomes after tPA administration but rather from failure to document appropriate reasons as to why the therapy was either withheld or not mentioned. In 29 (88%) of the cases reviewed in this report, patient injury was claimed to have resulted from failure to treat with tPA. Emergency physicians were the most common physician defendants. Defendants prevailed in 21 cases (64%), and among the 12 with results favorable to the plaintiff, 10 (83%) involved failure to treat, whereas 2 (17%) claimed injury from treatment with tPA.³⁷

Catheter-based reperfusion (eg, chemical thrombolysis, thromborehexis, clot retrieval, angioplasty, and/or stenting) may confer benefit in carefully selected patients with acute ischemic stroke who are not eligible for intravenous tPA thrombolysis or who have failed to respond to it. Although the window for initiation of catheter-based mechanical clot retrieval may be up to 8 or 9 hours after symptom onset, there are currently only 385 interventional neuroradiologists in the United States, practicing in 238 hospitals in 45 states.³⁸ The ability to increase the proportion of ischemic stroke patients who are transported to centers that can provide reperfusion therapy will rely on increased training of appropriate specialists, although it might result in significant cost savings for the healthcare system that could potentially offset the initial capital costs associated with improved diagnostics or interfacility transport.³⁹

A growing number of centers in the United States and abroad have initiated telestroke programs to support rapid evaluation of patients for intravenous- or catheter-based thrombolytic therapy.^{40–51} Work from these and other centers has convincingly demonstrated the feasibility and reliability of performing validated clinical stroke severity scales^{52–55} and supervising the remote administration of intravenous tPA by use of telestroke, which has resulted in thousands of acute stroke evaluations and significantly increased numbers of tPA administrations.^{40–42,44–46,48–51} Large-scale telemedicine reports have shown good functional outcome and mortality comparable to other case series and trials of conventionally treated patients.^{45,49} It has recently been shown that the accuracy of decision making by stroke neurologists via telestroke is superior to that via telephone for patients with acute ischemic stroke when assessing their suitability for treatment with thrombolytics. Correct treatment decisions were made more often when telemedicine was used rather than telephone only (108 [98%] versus 91 [82%], odds ratio [OR] 10.9, 95% confidence interval [CI] 2.7 to 44.6;

$P=0.0009$). There was no difference in the rates of intravenous tPA use (28% versus 25%, $P=0.43$) or 90-day functional outcomes, mortality, or intracerebral hemorrhage after treatment with thrombolytics (7% versus 8%; $P=1.0$).⁵⁶

With the increasing use of hub-and-spoke telestroke models to support patient evaluation and tPA administration, it is imperative that minimum standards be developed and implemented to ensure that the previously documented safety and efficacy of telestroke consultation can be replicated. These should include technical and procedural standards. Technical standards include minimum thresholds for video and audio signal quality and latency, timeliness of system access and response, required documentation of medical decision making, availability for review of the full data set of acquired brain images in DICOM format, and bidirectional interactive videoconferencing capability (Table 3, sections G4 and G5). Procedural standards include the use of protocols and training for tPA administration and postthrombolysis care at the spoke facilities (Table 3, sections 1b and 1c). Further research is warranted to demonstrate whether alternative models of telestroke care delivery, outside of the traditional hub-and-spoke model, can achieve similar positive results at equivalent or reduced costs.

For spoke facilities without the infrastructure to care for patients after tPA administration, intravenous tPA should be started at the remote hospital under expert supervision from the hub hospital before transfer to the hub hospital. This drip-and-ship model ensures early delivery of reperfusion therapy, with the complex follow-up care delivered at better-resourced centers. Because it has been shown that favorable outcomes decrease substantially with increasing time from symptom onset to treatment, tPA should be administered before transport rather than delaying treatment until after transfer; however, because data on the safety of interhospital transport during thrombolysis are limited, more research is needed in this area. Telestroke can satisfy requirements for around-the-clock acute stroke coverage⁵⁷ and allow for highly efficient dissemination of expertise to neighboring and distant communities for acute stroke treatment and education.

Given the supportive evidence in the current literature and the likely continued exponential evolution in telecommunication technology, telestroke has the potential to facilitate increased access to the expertise necessary for safe initiation of thrombolytic therapy for stroke. It may also help to detect high-risk patients who require hospitalization and specific care, such as those with suspected basilar artery occlusion or aneurysmal subarachnoid hemorrhage.

Subacute Stroke Treatment and Secondary Prevention

Many small hospitals do not have specialists with training and expertise to treat patients with stroke or transient ischemic attack (TIA) effectively, and yet they continue to admit and treat these patients.⁵⁸ This includes specialists from all disciplines, such as medical subspecialties, nursing, physical, occupational and speech therapy, and rehabilitation medicine. All stroke patients, including those treated with thrombolysis during the acute stage, benefit from prevention of in-hospital complications and early initiation of secondary prevention.

Care in dedicated stroke units reduces the risk of death and the need for institutional care and improves the functional outcome of patients.^{2,59–61} General medical care of the stroke patient is available in smaller hospitals, and the resources and procedures necessary to augment care to the level of a stroke unit may be available through alternative means.

Organization of stroke care with proper access to vascular neurology expertise is an important component of stroke prevention, because it provides an opportunity for proper identification of stroke subtype followed by individualized, evidence-based secondary stroke prevention.⁶² In many areas of the world, including both developed and developing regions, access to vascular neurologists, general neurologists, or other healthcare clinicians with special training in acute stroke treatment and prevention is sorely lacking.⁶³

The Veterans Administration Stroke Study (VAST) showed that neurologist care for acute stroke patients was associated with lower in-hospital mortality and less long-term disability.⁶⁴ When neurological expertise is lacking locally, telemedicine can become a useful substitute by providing remote expertise. Stroke call centers may be effective in selecting patients with a TIA for prompt, around-the-clock evaluation and treatment. Patients who wait days to weeks to receive treatment for TIAs may experience a stroke while waiting to see a specialist. Telemedicine might be useful to remotely staff community-based stroke prevention clinics by providing access to specialized personnel for patients with known risk factors for stroke and might allow more rapid treatment for TIA patients in underserved areas.⁶⁵ In one study of rapid TIA management, a specialized clinic discharged 75% of TIA patients the same day and had a lower-than-expected 3-month stroke-event rate based on a standard risk prediction model, the ABCD² score (Age, Blood pressure, Clinical features, symptom Duration, and Diabetes).⁶⁵

A telestroke system has been effective in providing acute and subacute stroke care, as well as prevention of poststroke complications, in the TEMPiS project (Telemedic Project for Integrative Stroke Care).⁴⁸ As part of a 24-hours-per-day/7-days-per-week telestroke service, this program includes the implementation at each spoke facility of specialized local stroke units, standardized treatment protocols, continuing medical education, and a comprehensive quality management program. In a prospective nonrandomized study, 3122 patients with acute stroke were admitted to 10 general hospitals; 63% were admitted to 5 hospitals with telestroke plus augmented stroke units, and the remaining 37% were admitted to 5 control regional hospitals without telemedicine support or stroke units. At 3 months after stroke, fewer telestroke patients were dead, institutionalized, or disabled (44% versus 54%), with a 38% lower probability of poor outcome in multivariable analysis (OR 0.62, 95% CI 0.52 to 0.74, $P<0.0001$). Five percent ($n=80$) of patients in the networked hospitals and 0% ($n=4$) in the control hospitals received intravenous tPA.

A higher proportion of patients in the telestroke hospitals had an indicated procedure, such as rapid brain imaging (74% versus 32%), carotid ultrasonography (83% versus 62%), or a standardized test for dysphagia (73% versus 48%). This study clearly showed the benefits of telestroke plus augmented

Table 3. Recommendations for Implementation of Telemedicine With Stroke Systems of Care

General recommendations:

- G1. Whenever local or on-site acute stroke expertise or resources are insufficient to provide around-the-clock coverage for a healthcare facility, telestroke systems should be deployed to supplement resources at participating sites. This should be done within the context of an SSCM framework wherever possible. This includes the local adoption of the structural components necessary for stroke center capability, including stroke units, the use of standardized evidence-based stroke management and collection of state or national stroke quality measures, and the implementation of effective clinical and educational collaborations between spoke and hub facilities. Wherever this integration is not feasible, alternatives such as a transfer to adequately equipped facilities of patients who exceed the care capabilities of the spoke facility should be considered. Continuous quality improvement activities should include assessment of adoption and use of the technology, rates of technical and human failures related to the system, and needs for training and maintaining competency, and the results of these activities should be shared across the network. Training of end users and physicians should occur at regularly scheduled intervals, and the equipment should be used or tested at least monthly to ensure its proper functioning when needed.
- G2. Organizations providing or requesting telestroke services should operate under rules and principles governed by contractual agreements between the parties. Areas to be explicitly addressed include (a) assignment of the costs of developing and maintaining the telemedicine network, (b) compliance with relevant federal, state, and local statute boundaries and any existing noncompete relationships, (c) assessment of medicolegal risk and provision of adequate malpractice coverage, (d) compliance with relevant regulations for the sharing of protected health information, (e) administrative and licensing/credentialing requirements for all providers, (f) methods and nature of reimbursement for professional services at fair market value or under safe harbor from government statutes related to fraud and abuse, and (g) explicit delineation of roles and responsibilities of all providers during and after stroke consultation.
- G3. Medical advice should be provided during telestroke consultation in a manner similar to that which occurs during on-site consultation, and documentation of the recommendations should be made available to the originating site within a reasonable time after completion of the consultation. Patients and/or their families should be made aware that telestroke consultation will occur and should grant permission for this activity. A copy of the recommendations produced should be kept in the spoke-site medical record in a manner accessible to the telestroke consultant at a later date. For patients who are subsequently transferred to the hub hospital or other institution, this documentation should be made available to the subsequent receiving facility. Procedures should facilitate easy access by the referring physician to the acute stroke consultant.
- G4. Technology providers should adhere to widely accepted industry standards. Technological approaches using widely accepted industry standards such as MPEG or DICOM should be developed and preferentially adopted to promote interoperability of systems across institutions and alternative uses, and compatibility with legacy systems should be maintained for reasonable periods of time to reduce the need for frequent replacement of costly hardware and software.
- G5. Technology solutions should include easy-to-use standard features to ensure an adequate visualization of the patient and surrounding environment, examination of the patient, and the opportunity to interact with others at the bedside, including providers and caregivers. The following recommendations apply to hospital-based acute care settings: The camera at the spoke facility should permit independent operation by the telestroke consultant. Audio transmission should incorporate algorithms to reduce echo and distortion common to medical environments. Transmission of sufficient quality to support standard video resolution parameters (eg, fractional CIF or SiF) at ≥ 20 frames per second of bidirectional synchronized audio and video at a resolution capable of being accurately displayed on 13-inch monitors (or more) is recommended, although it is recognized that some healthcare facilities or provider locations may not always achieve this level of quality for an entire encounter. It is recommended that each site have a mechanism for documenting circumstances of inadequate technical quality and predetermined mechanisms to address these scenarios and other equipment failures. This should include prespecified "fail-safe" methods for consultation when technology failures impact patient interactions. Rapid, secure transmission or remote viewing of brain images in DICOM format is recommended to permit adjustment of the imaging data for optimal interpretation and recognition of subtle findings. The device used to view the DICOM images should be set at a resolution that supports accurate grayscale display.
- G6. New models and codes for reimbursement of telestroke services should be developed to reflect the increased upfront costs to providers and reduced long-term healthcare costs to insurers. Increased reimbursement under Medicare for tPA delivery in the United States under stroke thrombolysis DRGs (MS-DRG 61, 62, and 63) should be available to hospitals that supervise the initiation of intravenous tPA via telestroke consultation and then accept these patients in transfer for admission to the hub hospital. This rate should reflect the full reimbursement to the hub hospital for MS-DRG 61, 62, and 63 minus the drug costs that are already being paid to the spoke facility via the outpatient prospective payment system. A similar cost-sharing model should be considered for hospitals that receive patients after tPA delivery but that did not participate in the decision to deliver tPA via telestroke. Medicaid and private payers should adopt similar payment policies. In addition, there should be increased professional reimbursement for telestroke services that reflects the increased burden this coverage places on acute stroke providers. Reimbursement for telestroke services by Medicare, Medicaid, and other insurers should occur regardless of whether the originating site is a spoke hospital in a rural or metropolitan census tract, because the shortage of acute stroke-capable providers is a growing problem that affects patients cared for at both rural and metropolitan hospitals. On-call stipends or other incentives should be provided to encourage broad participation by acute stroke consultants and increase the available pool of physicians who can provide this much-needed telestroke expertise.
- G7. A mechanism for a uniform national US licensure process limited to telemedicine practice should be adopted by state medical boards, and a uniform streamlined credentialing and privileging process for telestroke providers should be adopted by hospitals. This reduced administrative burden will allow telestroke programs to focus on the task of decreasing disparities and facilitating increased access to acute stroke care for the greatest number of individuals. For broad implementation of telestroke networks to be successful, it is essential to reduce the administrative burden posed by multiple licensures and credentialing requirements across each state.
- G8. Telestroke networks should be deployed wherever a lack of readily available stroke expertise prevents patients in a given community from accessing a primary stroke center (or center of equivalent capability) within a reasonable distance or travel time to permit access to specially trained stroke care providers. The use of telemedicine should be adopted within all stroke systems of care components to eliminate geographic disparities in care that may occur as a result of limited resources, manpower shortages, and long distances to specially trained providers.
- G9. Institutions seeking to develop hub-and-spoke telestroke networks should attempt to include key stakeholders from the beginning of the process to ensure successful adoption and sustainability. These would include multidisciplinary representation of physicians, nurses and allied health professionals from the emergency medicine, neurology, neurosurgery, hospitalist medicine, radiology, administration, information technology, and inpatient departments at both the spoke and hub sites. For larger-scale networks that will cover state or regional service areas, additional stakeholders might include members of regulatory agencies with jurisdiction over the practice of telemedicine, state stroke task force or stroke advisory panel members, Department of Health officials, legislative staff, and state and private health insurance payers.

(Continued)

Table 3. Continued

Specific recommendations organized by SSCMs (when sufficient evidence exists to support recommendations):

1. Telestroke for acute stroke treatment (emergency phase)

(a) Telestroke networks should be deployed wherever a lack of readily available stroke expertise prevents patients in a given community from accessing a primary stroke center (or center of equivalent capability) within a reasonable distance or travel time to permit eligibility for intravenous thrombolytic therapy.

(b) Organizations providing telestroke services should reliably provide access to personnel with an appropriate level of expertise in stroke care and experience with the relevant telemedicine technology. All telestroke physician consultants must have training and experience in diagnosing and treating acute cerebrovascular disease, at or above the level expected for primary stroke centers. Consultation should be readily and rapidly available during agreed upon hours of operation, with mutually agreed upon targets for initial response time. Prespecified protocols should be in place for patient disposition after consultation or thrombolytic treatment, including contingency plans when transfer is not feasible or practical. These protocols should be standardized across network sites whenever possible, and staff should receive periodic training relevant to these protocols.

(c) Organizations requesting telestroke services need to provide the elements of emergency stroke diagnosis and treatment as defined in the primary stroke center recommendations and maintain competency in telestroke procedures. Hospitals that wish to provide care beyond the initial life-threatening period and thrombolytic delivery should have access to an organized stroke unit or equivalent where patients can receive specialized monitoring and care. Hospitals that cannot provide these extended services after the emergency room phase of care should stabilize patients and transfer them to the telestroke provider or another appropriate facility.

2. Telestroke for subacute stroke treatment and secondary prevention

Telestroke networks should be deployed wherever a lack of readily available stroke expertise prevents patients in a given community from accessing a primary stroke center (or center of equivalent capability) within a reasonable distance or travel time to permit admission to an organized stroke unit. Providers and recipients of these telestroke services should follow the general guidelines described in the acute stroke treatment section. Telemedicine is useful for providing stroke consultation for patients hospitalized with stroke or TIA to support the establishment of stroke unit care. This includes initiation of the appropriate diagnostic evaluations and early secondary stroke prevention interventions, as well as prevention of in-hospital complications.

SSCM indicates stroke system of care; MPEG, moving pictures expert group; DICOM, Digital Imaging and Communications in Medicine; CIF, common intermediate format; and SIF, standard interchange format.

local resources for the prevention of complications and for early initiation of secondary prevention in patients with acute stroke at hospitals. The TESS (Telemedicine in Stroke in Swabia) project suggests that relevant contributions could be made in >75% of the telestroke cases with regard to completeness or appropriateness of the diagnostic workup, computed tomographic (CT) assessment, and therapeutic recommendations.⁴⁷ Telemedicine is useful for providing stroke consultation for patients hospitalized with stroke or TIA to support the establishment of stroke unit care (Table 3). In addition, teleconsultation may be useful for rapid access to neurointensivist expertise to guide intensive care management and prevent complications in patients with hemorrhagic and ischemic stroke, including medical management of raised intracranial pressure, management of ventricular drainage rates, timing of decompressive surgery, or interpretation of continuous electroencephalograms and therapy for status epilepticus.

Rehabilitation

Assessment of the need for rehabilitation services and access to the appropriate level of those services after stroke plays a critical role in achieving optimal stroke recovery. Stroke rehabilitation involves coordinated implementation of medical, social, educational, and vocational interventions for retraining individuals to reach their maximal physical, psychological, social, vocational, and avocational potential and should be provided by an appropriately trained and staffed multidisciplinary team that follows established practice guidelines.^{1,66–68} Unfortunately, many patients do not receive a level of care that is consistent with published guidelines for poststroke rehabilitation.^{69,70} Vulnerable populations are at greater risk for impaired recovery due to limited geographic or financial access to appropriate rehabilitation services.⁷¹

Telemedicine-enabled delivery of rehabilitation services may help to address manpower shortages and reduce the costs of care delivery, especially for patients with limited mobility due to poststroke disability. Research is needed to establish which rehabilitation services (eg, physical, occupational, or speech therapy or physiatrist services) can best be delivered via telemedicine at a level comparable or superior to traditional methods. As in acute stroke management, the use of telemedicine in stroke rehabilitation should be focused on facilitation of evidence-based strategies that have been shown to improve outcomes. Case reports and a small series of patients suggest that telemedicine for rehabilitation (telerehabilitation) may be a practical and valuable approach to delivering poststroke care when limited resources, manpower shortages, long distances, or limited patient mobility prevent or limit access to indicated rehabilitation therapies.

Additional Research in the Application of Telemedicine in Stroke Care Is Needed

Further scientific evaluation is urgently needed to assess the risks, benefits, and costs of different implementations of telemedicine in stroke, especially in the areas of primary prevention/community education, prehospital care, and rehabilitation. In addition to traditional variables, economic analysis models in telestroke should consider diverse sources of costs, such as those of the full-network implementation and maintenance, access to care, increased reimbursement due to increased thrombolytic use, redistribution of acute stroke call coverage requirements, and reduced energy consumption and emissions associated with fewer interfacility patient transfers.

Studies are needed to define a set of minimum technical quality standards for telestroke. Wherever possible, randomized and controlled trial designs should be used to test the

efficacy of telestroke on clinical outcomes, with the recognition that cluster randomization may be an appropriate alternative to randomization of individuals in studies involving multiple sites. Other end points to consider measuring are user satisfaction, pace and rate of technology adoption, and changes in physician knowledge and behavior. The role of telestroke in facilitating enrollment into stroke clinical trials should be explored.

Challenges to the Implementation of Telemedicine Within Stroke Systems of Care

This section reviews the frequently encountered challenges to telestroke implementation and provides a summary of lessons learned by examining a few of the currently active telestroke programs in the United States and western Europe, as well as the methods these telestroke programs have used to address the challenges.

US Experience

Telestroke programs that focus on delivering acute stroke care are maturing throughout the United States. The programs reviewed herein are not intended to be comprehensive but rather to capture examples of successful strategies adopted in a range of political, geographic, and economic environments. The selection of these programs for detailed review should not be construed in any way as an endorsement of these programs or their business models or as an assertion of the superiority of these programs over the many other successful high-quality programs that are not listed here. An additional selection of telestroke programs in the United States is listed in Table 1, characterized according to the challenges they faced in implementation. Detailed descriptions of the following 3 telestroke systems are provided in the Appendix:

- One of the oldest telestroke programs was established in 2001 and comprises 2 urban academic medical centers that provide emergency stroke consultation to more than 18 community-based hospitals located in 3 states. In this example, the state department of health promulgated regulations that fostered the interest of hospitals in satisfying the requirements to be designated as a stroke hospital, although almost all of the funding and direction arose from the stroke community and individual hospitals.
- A rural telestroke program established in 2003 is a collaboration organized by a rural teaching hospital that provides acute telestroke consultation to 10 rural community hospitals located in surrounding areas.
- A state-led telestroke initiative established in 2006 by a department of health works to provide a statewide system linking hospitals via telemedicine for the purpose of providing rural and urban community hospitals with access to real-time acute telestroke consultations. In this instance, the state government has provided start-up funding and direction to the initiative, and policymakers view the telestroke effort as an initial phase in establishing access to comprehensive telemedicine services not limited just to the area of acute stroke.

Many other successful programs exist and are expanding their service areas as acceptance increases. In addition, several sites are engaged in government-funded research to establish the scientific validity and reliability of various aspects of telestroke practice (eg, the National Institutes of Health-funded US study Stroke Team Remote Evaluation Using a Digital Observation Camera [STRoKE DOC] at the University of California, San Diego and the Ministry of Health-funded European studies TRUST-TPA [Therapeutic Trial Evaluating Efficacy of Telemedicine (TELESTROKE) in Patients With Acute Stroke] in Paris and RUN-FC [Emergency Neurology Network in Franche-Comte] in Besançon, France). Telestroke programs in the United States have made concerted efforts to focus on the affordability of the start-up and maintenance costs of these programs while working to ensure access to the technology and other services necessary to provide high-quality acute stroke care.

An Overview of the European Experience

Although telestroke programs are well developed in regions of some European countries, they do not yet exist in most. By the end of 2007, there were approximately a dozen telestroke programs operating in Germany (7), France (2), Finland (1), and the United Kingdom (2), with additional telestroke programs expected in the coming years (see Table 2 for additional details regarding the existing telestroke programs in Europe).

As in the United States, the European telestroke programs generally have adopted the hub-and-spoke model. In aggregate, the 12 existing European telestroke programs reviewed include 18 hub and 77 spoke hospitals (with more than 20 000 stroke patients evaluated in these hospitals). These existing programs currently provide approximately 2200 telestroke consultations per year, with approximately 400 telestroke patients (18%) receiving systemic thrombolysis.

In a majority of the systems, the national government provided funding to establish the telestroke programs. In several cases, funding for program infrastructure was provided by some combination of the national government, insurers, hospitals, and charitable foundations. In Bavaria/Germany, 2 telemedicine projects have gained annual support from regional health insurers after their analysis determined that providing greater access to specialized stroke therapy improved clinical outcomes and resulted in cost savings due to decreases in morbidity and chronic care. These networks provide good coverage of large rural areas with specialized stroke care, and the latest figures indicate a thrombolysis rate of up to 10% of all admitted ischemic stroke patients in one of these networks, with outcomes comparable to those of patients treated with tPA by conventional methods.^{45,72–75}

The 2006 World Health Organization Helsingborg Declaration on European Stroke Strategies declared that all European stroke patients should have access to a continuum of care, including organized acute stroke units, appropriate rehabilitation, and secondary prevention measures.⁷⁶ A recently published survey by the European Stroke Initiative revealed that there is significant need for improved access to such services for stroke care throughout the European Union.⁵⁸ Telestroke systems represent an important strategy

for helping to achieve these objectives, particularly in rural areas. Fortunately for Europe, there appear to be fewer bureaucratic barriers to the development and operation of telestroke programs than in the United States in areas such as reimbursement, licensure, credentialing, and medical liability.

Addressing Common Implementation Issues

The experiences of existing programs in the United States may be instructive for other organizations seeking to develop new telestroke programs. Common challenges include (1) infrastructure funding, (2) regulatory changes to promote development of acute stroke-capable or primary stroke centers, (3) reimbursement for services, (4) promoting physician adoption and participation, (5) physician licensure and credentialing, (6) technology assessment and deployment, (7) medical liability, (8) compliance with privacy and security laws, and (9) compliance with fraud and abuse statutes.

Infrastructure Funding

The development of telemedicine programs for the treatment of stroke requires capital investment in infrastructure, including the purchase and maintenance of computer hardware and related software, as well as a secure means of transmitting stroke-related data that is compliant with current federal privacy standards. Additional costs involve ensuring access to appropriate professionals, particularly the costs of recruiting and providing around-the-clock access to stroke experts at hub hospitals and the costs of providing training and support services for spoke-hospital physicians and staff.

The telestroke programs reviewed for the present report minimize infrastructure costs while maximizing the level of care available to patients with acute strokes. In addition, the programs collaborate with government officials to provide or encourage investment in infrastructure. For example, public officials in New York State reprogrammed unspent budgeted health dollars to support the initial infrastructure costs of its statewide program.⁷⁷

In Massachusetts, state officials promote investment in telestroke infrastructure indirectly through a stroke-designation program for hospitals.⁷⁸ The Massachusetts Primary Stroke Service regulations require that emergency medical services providers transport suspected acute stroke patients to the nearest designated hospital. In part because state officials recognize telemedicine as a means to meet the requirements of the stroke designation program,⁷⁹ community hospitals throughout Massachusetts invest in infrastructure for telestroke as a cost-effective means to secure and maintain designation. This effort is encouraging widespread patient access to acute stroke treatment that meets established clinical guidelines for stroke care.

There are also potential resources for infrastructure funding that local communities or states can access from the federal government. These include the Telehealth Network Grant Program administered by the Health Resources and Services Administration,⁸⁰ the Rural Health Care Pilot Program administered by the Federal Communications Commission,⁸¹ and the Distance Learning and Telemedicine Loan and

Grant Program administered by the US Department of Agriculture.⁸²

There may be additional federal resources available in the future. The STOP Stroke Coalition, a group of more than 25 major health organizations, was formed to support the STOP Stroke Act, a piece of legislation first introduced in the 107th Congress in 2002 and reintroduced every session since. The proposed legislation aims to maintain a national stroke registry and clearinghouse of information and best practices, promote telemedicine solutions to reduce stroke care disparity, standardize emergency medical services triage and response, and support regional consortiums and stroke systems development through grants to states. On March 27, 2007, it passed the House of Representatives of the 110th Congress. It was later integrated into a package of bills, called the Advancing America's Priorities Act, and proposed for consideration by the Senate on July 28, 2008. Unfortunately, the package did not get the 60 votes needed to advance to actual consideration of the bill by the full Senate for reasons unrelated to the stroke policy provisions, so the bill remains unaddressed.

Regulatory Changes to Promote Development of Acute Stroke-Capable or Primary Stroke Centers

Clearly, implementation of public health regulations or legislative action requiring hospitals that receive acute stroke patients to be acute stroke-capable or primary stroke centers is a tremendously important lever in accelerating adoption of telestroke networks. This is because it is increasingly difficult for community hospitals to retain on-call coverage for emergency stroke care by neurologists, as well as because the economics strongly favor the use of teleconsultation to staff for these low-frequency, high-impact events. In the absence of regulations that compel hospitals to provide these acute stroke services or risk loss of patient referrals, it is uncommon to observe hospitals spending additional capital or operating resources to secure these services.

Reimbursement for Services

Adequacy of ongoing reimbursement for professional and other services provided to acute stroke patients is essential. Lack of adequate physician and hospital reimbursement has played a critical role in delaying the development of sufficient acute stroke call coverage capability and may have had a more profound effect on smaller, nonacademic hospitals. Reimbursement for telemedicine services and acute stroke treatment has been improving in the United States, although there are at least 2 primary reimbursement issues of current interest to US telestroke programs.

The first issue involves whether and how professional reimbursement is provided for telestroke consultation and for on-call coverage in general. Reimbursement policies differ depending on the payer, and the policies promulgated by various payers continue to evolve. Medicare is a public federal health insurance program that covers the majority of individuals 65 years of age or older in the United States and some patients with disabilities. Medicare currently provides reimbursement for telemedicine consultations, including acute telestroke consultations, provided that the system uses an interactive audio and video telecommunications system.

Reimbursement is provided to both the consulting and referring practitioners. However, Medicare coverage is limited to patients who are located at an originating facility (ie, the facility at which the patient is physically located) within a rural health professional shortage area, within a county located outside of a metropolitan statistical area, or within a telemedicine demonstration project.⁸³ The federal Department of Health and Human Services defines health professional shortage areas as those areas with a shortage of primary medical care, dental, or mental health providers.⁸⁴ The number of facilities that qualify as originating sites under these definitions can be limited, especially in greater metropolitan areas that may be neurologically underserved despite having adequate primary care and municipal services.

Medicaid is the public health insurance program that targets low-income families and is a shared financial responsibility for both the state and federal governments. Some state Medicaid programs provide reimbursement for telemedicine consultations that involve stroke care. Since September 2006, the New York Medicaid program recognizes “medically necessary emergency room and inpatient hospital consultation services as payable to physicians with a specialty designation providing consultations via an interactive audio and video telecommunications system.”⁸⁵ These communications must meet the Medicare standard of interactive audio and video. The consulting physician is reimbursed for a telemedicine consultation at the same payment level that applies to in-person consultations through the use of a telemedicine modifier code.

Many private sector health plans provide reimbursement for telemedicine consultations. The American Telemedicine Association conducted a survey of telemedicine programs in 2005. The survey had a 56% response rate, and the data indicate that of those respondents who provide potentially billable telemedicine services, 57% were receiving reimbursement from private payers, up from 4% in 2003.⁸⁶

The second reimbursement issue of interest to telestroke programs involves inpatient hospital reimbursement for stroke patients treated with thrombolytic therapy. The adequacy of reimbursement for the inpatient care of stroke patients has been a longstanding issue of concern. In 2006, Medicare and many other payers implemented a new code for stroke admissions that include the delivery of tPA (diagnosis-related group [DRG] 559, now subdivided into Medicare severity DRG [MS-DRG] 61, MS-DRG 62, and MS-DRG 63), which provided a significant increase in reimbursement that nearly doubled the payment for patients who receive intravenous tPA compared with those who do not. This reimbursement reflects the significant hospital costs attributable mainly to the increased professional and monitoring services that must be provided to stroke patients after they receive tPA, rather than just the cost of the drug.⁸⁷

The current issue for telestroke programs is whether hospitals in a telemedicine network can receive reimbursement under new policies that became effective in 2006 under a model of care often called *drip and ship*. This term refers to cases in which thrombolytic therapy for stroke is initiated in a spoke hospital during a telestroke consultation, and the patient is then transferred from the spoke hospital’s emergency depart-

ment to another hospital (typically the hub hospital) for the remainder of the course of therapy. This is considered an important strategy to ensure that telestroke programs can provide meaningful access to thrombolytic therapy for patients in rural and remote areas (Table 3, section G6).

Under this drip-and-ship scenario, current Medicare policy does not permit either hospital to obtain the enhanced payment under the new coding, even if the tPA is still infusing on arrival at the hub hospital. Instead, the spoke hospital is paid on an outpatient basis for the drug costs and services provided (ie, Outpatient Prospective Payment System). The admitting (hub) hospital currently does not receive the enhanced Medicare payment under the codes for stroke patients requiring thrombolytic therapy unless further new dosing is provided (eg, as part of an endovascular procedure). Instead, the admitting hospital is paid the traditional inpatient payment rate for stroke care that applies to patients who do not receive thrombolytic therapy.⁸⁸ Clinical experts have argued to expand these Medicare coverage rules, pointing in particular to the high-intensity services needed at the receiving hospital to closely monitor patients after thrombolytic treatment, costs that far exceed those attributable to the tPA itself. The Centers for Medicare and Medicaid Services recently acknowledged this issue, suggesting that drip-and-ship patients are a unique category of patients and that modification to the reimbursement system may be warranted. However, the Centers for Medicare and Medicaid Services requires information regarding frequency, distribution, length of stay, and charge data before it can determine whether a change is necessary. To help the Centers for Medicare and Medicaid Services identify these patients and collect the necessary data, a new diagnostic code, V45.88 (status after administration of tPA in a different facility within the past 24 hours before admission to the current facility), has been established. The new code is available for use for drip-and-ship patients who were discharged on or after October 1, 2008.⁸⁹

The New York Medicaid program has addressed reimbursement concerns expressed by spoke hospitals. Under the New York Medicaid program, emergency room fees were deemed inadequate to support tPA administration to treat stroke. Under new rules, if tPA is begun in a spoke hospital and transfer of a patient is medically necessary from that community hospital to an academic medical center or other designated stroke center, the spoke hospital is now eligible for a transfer fee. New York initiated this policy change to encourage rural hospitals to participate in its telestroke initiative.

Although it is beyond the scope of this policy statement to provide a balance sheet for the costs and revenues, a set of commonly encountered typical costs required and potential resources available for establishing a hub-and-spoke telestroke system is presented in Table 4. It is critical to recognize that there is tremendous variability in the United States regarding financial incentives given to stroke specialists for providing acute stroke coverage for hospitals. Telestroke networks obviously increase the demand for acute stroke services, although they may allow for more effective sharing of individual coverage by several providers across a network of hospitals.

Table 4. Typical Costs Required and Potential Resources Available for Establishing a Hub-and-Spoke Telestroke System

Type of Cost or Resource	Comments
Costs required	
On-call stroke specialists	Often, the on-call specialists are neurologists, but sometimes, emergency physicians or others with special expertise in acute stroke care play this role. In some programs, there is an additional stipend paid to physicians who take acute telestroke calls. In other programs, incentives or financial bonuses are paid to reward physicians who take calls. Other programs do not provide any additional payments or incentives for taking calls.
Videoconferencing technology	In the United States, spoke hospitals must reimburse hub hospitals for the fair market value of this and any other equipment received.
Image-sharing technology	Image-sharing technology may be stand-alone or incorporated into the telestroke system.
Legal guidance	As with all relationships in the healthcare arena, legal guidance is necessary for contracting and for ensuring compliance with federal, state, and local regulatory requirements.
Provider education	Typically, spoke hospitals will require education and training with respect to acute stroke management, equipment use, and activation of the acute stroke system.
Ongoing equipment maintenance and information technology support	The need for such support will vary depending on the capabilities of both the hub and the spoke hospitals.
Information transmission	These fees include ISDN, Internet access, or other modes of transmission.
24–7 Method for activating the acute stroke team at the hub hospital	This may rely on the current hospital paging system at the hub hospital or additional means of reaching consultants.
Credentialing and licensure	Credentialing and licensure efforts will be more significant in programs operating across state lines.
General administration	General administrative costs will vary depending on the number of providers and the number of spoke hospitals served.
Program development	These costs involve the initial development of the program and subsequent resources for expansion.
Quality assurance	Quality assurance initiatives are important and should be incorporated into the program from the outset.
Potential resources available	
Institutional funds	Some hospitals will view the increased rate of admission of stroke patients or the increased reputation and visibility associated with the hub hospital affiliation as a valuable offset to the costs of running the program. In addition, clinical and research revenues associated with patients who are transferred may be available to support the telestroke program.
State and federal support	Some states offer incentives for rural or community hospitals to participate in such programs or discounted access to equipment or bandwidth. In addition, state and federal grant programs are available.
Philanthropy	Philanthropic organizations working at the national, state, and local levels may provide funding to help provide patients with access to evidence-based health services for acute stroke.
Spoke-hospital fees	For most hospitals, paying a fee to be a part of the telestroke network is a much less expensive alternative to paying for 24–7 emergency in-person coverage. This approach is especially desirable given that the number of stroke specialists available to take calls is diminishing rapidly. In the United States, spoke hospitals must pay fair market value for any equipment or services provided by the hub hospital.
Public and private health insurance programs	These programs already provide reimbursement for telemedicine consultations when performed in accordance with regulatory requirements, although most require the originating site to be a rural hospital or critical access facility.

24–7 indicates 24 hours per day, 7 days per week; ISDN, Integrated Services Digital Network.

Promoting Physician Adoption and Participation

Physicians are important gatekeepers in telemedicine adoption and diffusion,¹² and local physician endorsement is an important prerequisite for the success of telestroke programs. In the Massachusetts and Georgia programs, physician champions at the hub hospitals engaged key stakeholders and other physicians to promote the development and ongoing operations of the programs.⁹⁰ Although the subject has not been studied in a systematic way, there are indications that spoke-hospital physicians are more likely to become enthusiastic participants in a telestroke program if they play active roles in the implementation of the program at the hospital and if ongoing professional and educational interactions occur among the hub and spoke physicians (Table 3, section G9).

The relationship between the telestroke consultants and local referring physicians is crucial to the success of any telestroke service. In the German telestroke experiences, referral rates of eligible patients from participating hospitals ranged from 2% to 86%⁴⁷ and from 20% to 53%.⁷⁵ This pattern was also reported in a series of 657 consecutive multispecialty teleconsultations from California.⁹¹ Methods that promote physician-to-physician interaction, build trust among providers, and increase awareness of successful treatments via telestroke and of mutually agreed indications for teleconsultations all help to change attitudes and increase utilization.

The ease of use of telemedicine technology is vital to the success of the program. In practice, ease of use of telemedicine technology may be more important to the end-user

physician than the quality of the technology.⁹² Most successful telestroke programs have hosted more sophisticated technology at the hub sites and emphasized low-cost, easy-to-use systems at the spoke sites, where technical support and training capabilities are limited.

Physician Licensure and Credentialing

In the United States, each state establishes its own rules and governs the practice of medicine within its own borders. Under current law, a physician typically is considered to be practicing medicine in the state where the patient is located. The implication for telestroke programs is that in general, both the on-site treating physician and the remote consulting physician need to be licensed to practice medicine in the state where the patient is located, as well as being credentialed and privileged at the originating site. Some have contended that licensure and credentialing are 2 of the most significant barriers to the broad implementation of telemedicine.

In existing telestroke programs, the hub hospitals have addressed the licensure issue by assuming the full administrative burden of ensuring that all consulting physicians are licensed to practice in all applicable jurisdictions. For example, the Massachusetts Partners Telestroke Center Network operates in Massachusetts, New Hampshire, and Maine. Each of these states requires full medical licensure and primary source verification of credentials for any physician who seeks to diagnose and treat patients within its borders. The hub hospitals have devoted substantial administrative resources to assist all consulting physicians in securing and maintaining the required licenses to practice medicine in all 3 states.

Policymakers have considered potential solutions to reduce this administrative burden while also ensuring that necessary safeguards remain in place to protect patients. For example, both the Southern Governors Association and the Western Governors Association have considered regional approaches to licensure in response to the growth of telemedicine.⁹³

Some states already have taken specific steps to diminish the administrative burden placed on physicians who consult via telemedicine. In 1996, the Federation of State Medical Boards developed the Model Act to Regulate the Practice of Medicine Across State Lines (Model Act).⁹⁴ The Model Act calls for the issuance of special purpose licenses to any applicant holding a full and unrestricted license to practice in any state or US territory, provided that there have not been previous disciplinary or other actions taken against the applicant by any state or jurisdiction. Such a special purpose license entitles the licensee to use telemedicine to provide written (or otherwise documented) medical opinions or to render treatment for patients located within the state.⁹⁴ The Model Act has been adopted in 11 jurisdictions (Alabama, California, Minnesota, Montana, New Mexico, Nevada, Ohio, Oregon, South Dakota, Tennessee, and Texas).⁹⁵

In February 2008, the State Alliance for E-Health (a committee of the National Governors Association operating under contract from the federal Office of the National Coordinator for Health Information Technology) proposed reform of the physician licensure system to allow for a licensure option that works in a uniform way across state lines. The group further urged medical boards to work with

the National Governors Association to create this system. The Alliance recommendations will be sent to the full governors association for further consideration.^{85,85a}

Credentialing is the process by which hospitals review the education, background, experience, training, and character of physicians to ensure that each provider is qualified to perform professional services.⁹⁷ In practice, the credentialing requirements that must be followed arise from multiple sources, including state law, accreditation requirements (such as the requirements of the Joint Commission), and the hospital-specific rules adopted by the spoke hospital.

As a general rule, credentialing requires primary source verification, in which the hospital must verify information directly with each contact listed by the prospective provider on the application. Although credentialing requirements usually share similarities among hospitals, there are currently no standardized processes or requirements for credentialing.

For telemedicine programs, consulting physicians at hub hospitals must be credentialed at all spoke hospitals in the telestroke network. This process can be time-consuming and cumbersome. In many instances, the hub hospitals of existing telestroke programs have devoted substantial administrative resources to assist individual consulting physicians and to ensure that all credentialing requirements at the spoke hospitals are met.

Some states and accreditation bodies are taking steps to diminish the administrative burden of primary source verification for physicians providing telestroke consultations. For example, New York recently clarified that as long as the hub-and-spoke hospitals have a contractual relationship, the hub hospital can collect the credentialing information on the spoke hospital's behalf. Specifically, with the physician's permission, the information collected for accreditation by the physician's home hospital can be shared with the spoke hospital for purposes of credentialing, provided a contract exists between the 2 entities.⁹⁸

Similarly, the Joint Commission allows for spoke hospitals to credential consulting providers directly. Alternatively, spoke hospitals may use information from the hub hospital if the hub hospital is a Joint Commission-accredited facility and meets certain conditions.⁹⁷

Technology Assessment and Deployment

Technical problems with telemedicine technology, including nonconnecting or malfunctioning devices, can be major barriers to successful telestroke programs.⁹⁹ Poor technical execution of applications typically results in distrust by users and low levels of satisfaction. Lack of interoperability also delays adoption because of fears of rapid obsolescence and wasted capital. Major corporations and smaller companies that manufacture telemedicine equipment should follow the lead of cellular telephone manufacturers and adhere to open standards that permit all devices to communicate seamlessly across different brands and information architectures.

There should be effective information technology systems and supporting infrastructure in place to initiate a telemedicine program for stroke treatment. For example, the mode of data transmission must provide adequate bandwidth to transmit large amounts of data quickly, accurately, and securely.

With appropriate bandwidth, CT scans can be sent to the hub hospital for simultaneous viewing by the spoke's emergency department physician and the hub's stroke expert.¹⁰⁰ Ideally, stroke consultants can access these data from both the hub hospital facility and from remote workstations throughout the hospital or at home.

In terms of telemedicine-directed stroke care, there have been 3 different methods used for interaction: (1) Plain old telephone service (POTS) or cellular telephone assistance; (2) HQ-VTC with an on-call stroke team using an Internet-based wireless or high-speed landline connection; and (3) a combination of telephone and video methods.¹⁰⁰ Each of these methods has strengths and weaknesses, and several trials are seeking to determine whether videoconferencing is superior to exclusively telephonic interaction.¹⁰⁰

Videoconferencing allows the patient, the patient's caregivers, and the spoke and hub physicians to interact visually and audibly, which enables a more comprehensive communication. In addition, CT scans can be made available for simultaneous viewing by spoke hospital personnel and the telestroke consultant, which reduces the number of individuals required to make definitive recommendations regarding thrombolytic therapy or other time-critical interventions.¹⁰⁰

However, many rural areas (as well as some urban and suburban areas) do not have access to consistent low-latency, high-speed bandwidth sufficient to support reliable, high-quality video transmission and reception over open, standards-compliant networks. The presence of essential infrastructure (telephone lines, wireless broadband) must be assessed for hospitals participating in the exchange of telemedicine data as part of an SSCM implementation. This need for enhanced connectivity to rural regions should be addressed in part by the Federal Communication Commission's Rural Health Care Pilot Program, which offers steep discounts (up to 85%) to collaboratives of rural health facilities that install commercial fiber optic cabling for access to high-speed Internet. There should be improved economies of scale in future service and information delivery in rural areas.

The advent of telemedicine holds great potential to educate physicians in both spoke hospitals and hub hospitals and can provide patients with a fuller range of therapeutic options in an efficient manner.¹⁰⁰ Overall, telemedicine-directed stroke care can increase communication between providers and elevate the overall quality of care provided in remote hospitals through education provided in the form of active consultation recommendations.

Medical Liability

As with much of the practice of medicine in the United States, medical liability concerns are occasionally expressed regarding telemedicine, including telestroke. The term *medical liability* refers to the potential that patients experiencing adverse clinical outcomes will sue the treating physician or healthcare facility for malpractice, asking the court to require the provider to pay the patient monetary damages. In the context of telestroke programs, the issue involves whether telemedicine services provided in the care of stroke patients serve to increase or decrease the risk of malpractice litigation. To date, there is no specific evidence to suggest that provid-

ing telemedicine consultations increases the risk of malpractice claims compared with providing local consultations for the treatment of acute stroke patients. In cases of cross-border telestroke consultation, providers may be vulnerable to legal action in both the originating state where the patient was located at the time and the state from which they provided teleconsultation.

In 2006, Weintraub¹⁰¹ published a review based on a series of cases involving the general use of thrombolytic therapy in the treatment of acute stroke. He concluded that neurologists, emergency room physicians, and hospitals are at increased liability risk when the use of thrombolytic therapy is considered, whether or not the decision is made to administer tPA.¹⁰¹ Weintraub found that treatment decisions concerning tPA, including clinical decisions not to administer the therapy, require detailed documentation, informed consent discussions (although not necessarily formal written informed consent), and timely transfer to help reduce the threat of legal action.¹⁰¹ Because recent evidence suggests that failure to provide tPA is the disproportionately largest cause of malpractice actions against physicians, interventions that increase the safe and appropriate use of tPA therapy may help address this vulnerability. Telestroke services that extend the ability to offer tPA where indicated to more facilities and support the proper documentation of appropriate reasons not to give tPA when not indicated are likely to reduce medicolegal liability exposure for local spoke-hospital providers.³⁷

Effective communication among providers, timely evaluation of patients, well-documented decision making, and access to experienced stroke specialists will improve patient outcomes and diminish the risk of adverse patient outcomes and possible litigation in telestroke systems. These processes are typically integrated into the day-to-day operation of existing telestroke programs.

Compliance With Privacy and Security Laws

Although concerns about complying with federal and state privacy laws are sometimes expressed in the context of telestroke programs, most hospitals have access to professionals who are well versed in how to comply with these important patient protections. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a federal law that permits healthcare providers to share patients' protected health information for routine healthcare operations, including activities such as quality improvement and consultations between healthcare providers relating to a patient.¹⁰² This type of information exchange is essential to the day-to-day operation of telestroke programs.

Telemedicine also involves the transmission of HIPAA-protected health information, and participating hospitals are required to put safeguards in place to secure the privacy of these data. Telestroke programs need to have processes in place to ensure the security of live HQ-VTC transmissions between hospitals, the security of data storage associated with the consultations, and the security of the network technologies that consulting physicians may use to access this information remotely. Documentation of the policies and procedures for using and securing protected health information is important to ensure HIPAA compliance.¹⁰³

In general, the telestroke programs reviewed for this policy statement have built the required safeguards into the design and technology used in their programs. Compliance with these requirements can be burdensome at times and usually benefits from integration into other hospital-based HIPAA compliance activities.

Compliance With Fraud and Abuse Statutes

Hospitals and physicians engaged in providing telestroke services should be aware of the applicable federal and state laws designed to prevent fraud and abuse, especially in the Medicare and Medicaid programs. There are 2 primary federal statutes, the Antikickback Statute and the statute governing physician self-referral, commonly known as the Stark Law, that govern the allowable relationships between hospitals, including the sharing of information technology.

The federal antikickback statute prohibits payment or receipt of remuneration in return for referrals (or for encouragement of referrals) for services that are payable under a federal healthcare program such as Medicare or Medicaid.¹⁰⁴ In this context, the term *remuneration* refers to any cash or in-kind payment, whether direct, indirect, overt, or covert.¹⁰⁵ Most states have comparable laws, although these laws may differ from the federal statute in important ways. Specifically, in telestroke relationships, the antikickback statute may arise as a potential issue for consideration if the hub hospital provides services or equipment at less than fair market value to the community hospital in establishing or maintaining the spoke telestroke program, because a community hospital physician may subsequently refer patients to the hub hospital for services reimbursed under Medicare or Medicaid.

Violations of this statute can result in significant criminal and civil penalties, including imprisonment, exclusion from participation in federal healthcare programs, and civil monetary penalties.¹⁰⁶ The statute's prohibitions are extremely broad, including not only relationships between physicians and healthcare entities (even between affiliated hospitals within the same corporate network) but also all relationships that involve items or services potentially subject to federal reimbursement.¹⁰⁶ There are certain safe harbors to protect relationships and activities that might otherwise technically violate the statute but that present little risk of abuse to federal healthcare programs¹⁰⁷; however, it can be difficult for many common and nonabusive arrangements to qualify for safe harbor protection.

The federal Stark Law prohibits a physician from ordering certain health services for Medicare or Medicaid patients from entities with which the physician has an ownership, investment, or financial relationship.¹⁰⁸ The Stark Law also prohibits a hospital from billing for any services that result from a prohibited referral.¹⁰⁹ The Stark Law does not require intent; that is, it is possible to violate the statute, and become subject to its penalties, in the absence of any intention to do so.

Violations of the Stark Law automatically subject a provider to various penalties, including denial of payment for the services provided; exclusion from Medicare and state healthcare programs, including Medicaid; and payment of civil penalties of up to \$100 000 for each attempt to circumvent the Stark Law, among others.¹⁰⁸ Similar to the antikickback

statute's safe harbors, the Stark Law establishes exceptions for certain arrangements. Exceptions have been developed, for example, for personal electronic health records items and services, as well as for community-wide health information systems. For both the antikickback statute and the Stark Law, many relationships may be permissible under an applicable safe harbor or exception. Whether a safe harbor or an exception applies and which safe harbor or exception might protect a properly structured relationship may only be determined by competent legal counsel considering all the facts and circumstances of the particular relationship proposed.

Existing telestroke programs have been diligent in ensuring compliance with state and federal laws governing these relationships and have identified practical ways to develop telestroke networks. The individuals working to establish telestroke programs should review the proposed telemedicine network relationships with legal counsel to ensure compliance with the antikickback and Stark laws and regulations.

General Recommendations for Telestroke Implementation

Telestroke, when defined as consultations that involve a physician stroke expert using a high-quality bidirectional audio and videoconferencing system to interact with a bedside provider and/or patient/caregiver for the purposes of delivering stroke care or advice, is not a new medical therapy per se. Rather, it is a method used to overcome barriers to the delivery of proven, evidence-based therapies that might otherwise be unavailable for stroke patients. In this context, telemedicine can help to establish an organized SSCM and increase utilization of intravenous thrombolysis and stroke unit care.

Telestroke can enable the initiation of cost-effective interventions proven to reduce complications and stroke recurrence and can identify and facilitate transfer of patients in the community for specific tertiary care interventions such as neurointensive care; decompressive surgery for life-threatening, space-occupying cerebral infarction; and prompt surgical or endovascular repair of ruptured cerebral aneurysms. The Working Group's recommendations are presented in Table 3, organized by global considerations and then within each component of the SSCM for which sufficient evidence for recommendations exists.

Appendix

Lessons Learned

This appendix provides a detailed review of some examples of state and community efforts to implement telestroke programs for the treatment of acute stroke, reviews the frequently encountered challenges to telestroke implementation, and provides a summary of lessons learned by examining 3 representative telestroke programs in the United States and the methods these telestroke programs have used to address the challenges. As described below, these stroke telemedicine programs in eastern Massachusetts, east-central Georgia, and New York State are enabling participating hospitals to access expertise in the acute treatment of stroke 24 hours a day, 7 days a week. To help inform policy considerations and practical implementation decisions for new telestroke systems, the authors conducted an in-depth analysis of several representative telestroke programs.

The firm of Health Policy R&D reviewed the relevant literature, interviewed key informants, and selected 3 programs as examples on the basis of a set of predetermined criteria. These criteria included:

- Programs that demonstrate leadership in the area of telemedicine policy issues, especially with respect to telestroke services;
- Programs that have successfully implemented a telestroke initiative;
- Programs that have addressed various policy challenges in implementing telestroke initiatives that could provide helpful lessons learned for other programs;
- Programs that have evolved in different state and local policy environments that could provide perspectives on how to collaborate with government officials or otherwise overcome policy challenges; and
- Programs that represent different approaches that might be instructive to other telestroke initiatives.

The selection of these programs for detailed review should not be construed in any way as an endorsement of these programs or their business models or as an assertion of the superiority of these programs over the many other successful high-quality programs that are not listed here. Simply put, they are meant to be useful lessons for other individuals, organizations, or state or federal agencies that may wish to implement telemedicine within their own systems of care.

The history of these initiatives demonstrates the importance of integrating clinical teams at partner hospitals throughout the continuum of the educational, clinical, and quality improvement functions necessary to provide patients with effective stroke care. In this way, the establishment of stroke telemedicine programs has served as an important focal point for the development of an integrated SSCM, consistent with the recommendations published previously for such systems.¹

Example 1: Eastern Massachusetts: Partners TeleStroke Center

Overview

Through the Partners TeleStroke Center, stroke specialists from 2 Boston-area academic medical centers (Massachusetts General Hospital and Brigham and Women's Hospital) provide emergency stroke treatment consultations to a network of 21 community-based hospitals throughout eastern Massachusetts, New Hampshire, and Maine.¹¹⁰ The Partners TeleStroke Center began with physician innovators seeking to improve access to time-sensitive interventions for the treatment of acute stroke and to reduce disparities in stroke care. With the advent of thrombolytic therapy for the treatment of acute ischemic stroke, tertiary academic medical centers began receiving calls on a case-by-case basis from community hospitals requesting telephonic consultation to help determine whether such therapy was appropriate.

Neurologists at Massachusetts General Hospital, seeking to improve these consultations by making more data directly available to the consulting physician, began experimenting with technology to connect Martha's Vineyard Hospital in Oak Bluffs, Mass, to Massachusetts General Hospital via a secure high-speed telecommunications link for high-quality videoconferencing and CT image transmission. This collaboration began testing the reliability of assessing stroke severity with the National Institutes of Health Stroke Scale.¹¹¹ In 1999, Shafiqat et al⁵³ published an assessment of the feasibility and reliability of conducting a National Institutes of Health Stroke Scale assessment via telestroke and found that although remote assessments took slightly longer than bedside assessments, total scores obtained by bedside and telestroke methods were strongly correlated.

Legal and Regulatory Environment

A major catalyst for the expansion to 18 Massachusetts community hospitals was an initiative by the Massachusetts Department of Public Health to designate appropriate acute care hospitals as primary stroke services providers. Concerned about the disparities in acute stroke outcomes between large urban areas and nonurban and

rural areas, the Massachusetts Department of Public Health issued regulations in 2004 intended to improve stroke care. The regulations, which became effective on March 12, 2004, allow hospitals in Massachusetts to seek voluntary designation as a provider of primary stroke services.

To secure such designation, the regulations require that the hospital provide access to appropriate expertise 24 hours a day, 7 days a week. Specifically, Massachusetts' regulations define primary stroke services as "emergency diagnostic and therapeutic services provided by a multidisciplinary team and available 24 hours per day, 7 days per week to patients presenting with symptoms of acute stroke" (p 4).⁷⁸ The Department of Health also issued guidance for emergency medical services regions in Massachusetts that required direct transport of patients experiencing acute stroke symptoms to hospitals designated as providers of primary stroke services.

As part of the state-level commitment to addressing disparities in care, the Massachusetts Department of Public Health pursued an inclusive approach to the designation, encouraging a large number of facilities to participate as providers of primary stroke services. At the same time, community hospitals began to assess the potential impacts if patients were diverted to other facilities. Together, these factors stimulated the interest of community-based hospitals to seek practical and cost-effective solutions to allow hospitals to be designated as primary stroke services providers. Telestroke consultation provided a solution.

The regulations and the application for primary stroke services designation reflect Massachusetts' openness to using telemedicine to achieve the objective of improving acute stroke care. For example, the regulatory definition of an acute stroke team does not require all team members be on-site. Instead, the definition requires that physicians and other healthcare professionals with acute stroke expertise be "available for prompt consultation" (p 2).⁷⁹

Furthermore, the application to seek designation as a provider of primary stroke services requires that neuroimaging interpretation services be staffed 24 hours per day, 7 days per week but allows neuroimaging interpretation to occur either by a staff physician at the hospital or by contractual arrangement with consultant physician(s) either in the hospital or through remote access.⁷⁹ As of October 2007, 68 hospitals in Massachusetts have been designated as primary stroke services providers, including 15 hospitals in the TeleStroke network.¹¹²

Operations

In the Partners TeleStroke Center, Massachusetts General Hospital and Brigham and Women's Hospital function as the hubs that connect to each of the community hospitals or *spokes* in the network. If the on-site stroke team at a participating spoke community hospital seeks remote consultation from an acute stroke expert, a brain image is performed, and the patient is asked to sign a consent form that permits evaluation over an HQ-VTC system.

With the assistance of the on-site physician, the stroke specialist conducts both a brief neurological examination of the patient and an assessment of the brain imaging studies over a secure Internet connection. The consulting expert discusses the findings with the on-site physician, and together, the hub and spoke physicians collaborate to decide on a plan of care. The acute stroke evaluation and recommendations are placed on a secure Web site. This document can be printed and placed in the patient's medical record at the spoke site.¹¹⁰ Follow-up consultation is also available for further treatment decisions.

Because the Partners Telestroke Center operates in Massachusetts, New Hampshire, and Maine, each hub physician must be licensed to practice medicine in all 3 states. Each of these states considers the diagnosis of a patient located within the borders of the state to be practicing medicine within the state. Accordingly, each requires full medical licensure for any physician who seeks to diagnose and treat patients within the state's borders. Each hub physician also must be credentialed to provide services at each spoke hospital.

Furthermore, to successfully implement the program, spoke hospitals are required to acquire commercially available off-the-shelf equipment at their own expense, including an HQ-VTC device that

supports industry-standard videoconferencing protocols, including a pan/tilt/zoom camera and encryption (eg, H.320, H.323, H.263/4 families), typically mounted on a portable cart. They also need an IP (Internet Protocol) or ISDN (Integrated Services Digital Network) connection for HQ-VTC, high-bandwidth access (typically 384 kilobits per second), and CT/brain image transfer capability.¹¹⁰ Although leaders of the initiative sought ways to make the program affordable to the spoke sites, the financial concerns of many spoke hospitals were offset by a keen interest in using a telestroke relationship to allow the hospital to be recognized as a provider of primary stroke services.

In addition, under a contractual arrangement between the spoke and hub hospitals, spoke hospitals are required to pay fees to the hub hospitals to share in the cost of supporting the operation of the network and for consultation services. The spoke hospitals are required to meet certain expectations with respect to equipment testing and maintenance. As academic medical centers, the hub hospitals already had some of the telemedicine infrastructure in place at the start of the program to facilitate multiparty HQ-VTC connections, and the hub hospitals can make enhancements to these tools over time with support from the spoke contracts.

Outcomes

In 2004, the team at Massachusetts General Hospital published the results of an assessment of the relationship with the initial spoke member of the Partners TeleStroke Network. Although the study was not blinded and had a small sample size, the authors concluded that the 27-month pilot study demonstrated an ability to “identify appropriate candidates for treatment with tPA, support the delivery of intravenous tPA without increasing protocol violations, and increase use of tPA when compared with prior years” (p 1195).⁵⁰ The authors also noted that this program “produced high levels of patient and physician satisfaction” (p 1195).⁵⁰

Lessons Learned

Leaders in the Partners TeleStroke Center point to educational efforts with policymakers as a key component of the successful development of this network. Advocates and clinical experts focused the attention of policymakers on the disparities in acute stroke treatment capability between urban and nonurban areas. Awareness led policymakers to advance telemedicine as an option for improving stroke treatment, as reflected in Massachusetts’ regulations on primary stroke services. With the Department of Public Health invested in solving the problem, the state became a partner in addressing barriers to implementation.

In addition, leaders of the initiative point to the local design and management of the network as an important feature. Hub-based consultants are integrated into the stroke teams of network hospitals, which provides an opportunity to build relationships with spoke-hospital emergency department physicians over multiple consultations and to collaborate in educational efforts.

Example 2: East-Central Georgia: Medical College of Georgia’s Remote Evaluation of Acute isCHemic stroke (REACH) Program

Overview

The Medical College of Georgia (MCG) is located in Augusta, Ga, at the nexus of rural east-central Georgia and rural central South Carolina. Located approximately 150 miles from Atlanta, Ga, and 70 miles from Columbia, SC, MCG is the major medical center for a large rural population.

In 2003, a Department of Neurology team at MCG initiated the REACH (Remote Evaluation of Acute isCHemic stroke) Program, now called REACH Call, Inc. The objective of the REACH program was to better assist rural community hospitals seeking telephonic consultations to help with acute stroke diagnosis and treatment. Many rural Georgia hospitals in MCG’s catchment area lacked neurology consultation capacity. Patients were presenting to the rural emergency departments with symptoms of acute stroke and subsequently being transferred to MCG. The time involved in transfer

often resulted in patients arriving at MCG outside of the therapeutic timeframe to initiate thrombolytic therapy.

After an initial attempt to address this problem through increased reliance on air ambulance transfers, the REACH team found that low-cost, secure Internet-based communications could provide the real-time data that remote physicians need to advise on-site physicians.¹¹³ By 2005, MCG had established itself as the hub of the REACH network, with 8 rural hospitals serving as the spokes. Only 1 of these hospitals had formalized acute stroke care guidelines at the start of the program, and only 2 of these hospitals had tPA available in the hospital pharmacy.⁴³ By 2007, the network had expanded to include 9 spoke hospitals.¹¹⁴

Legal and Regulatory Environment

Although there is no specific regulatory requirement for 24-hours-per-day, 7-days-per-week specialized stroke capacity in Georgia, hospital emergency departments are required to provide for staffing of both anticipated and unanticipated needs. To ensure access to expertise in the treatment of acute stroke, as of January 2008, 10 hospitals in Georgia have joined the program. In addition, legislation establishing a 2-level system of certified stroke centers in Georgia passed the state legislature in April 2008 and went into effect beginning in December 2008. The law provides for the designation of acute stroke treatment facilities as either primary stroke centers, which should be Joint Commission certified, or remote treatment stroke centers, in which patients are evaluated via telemedicine. All emergency services personnel in the state will be provided with a list of registered stroke treatment facilities at each designation level and a stroke triage assessment tool.¹¹⁵

Operations

The REACH system allows on-site medical staff to contact the hub hospital when evaluating an acute stroke patient for eligibility for thrombolytic therapy. The call center contacts the on-call consultant, who has portable, secure technology available to receive CT scans and to view the patient remotely to administer the National Institutes of Health Stroke Scale. The consultants emphasize the importance of portable videoconferencing technology to reduce the time to consultation.

Each spoke hospital must have a specialized mobile cart on-site that includes the following: A pan/tilt/zoom camera, an Internet-enabled personal computer workstation, a wireless bridge, and a port switch. The consultant evaluates the data and makes a recommendation regarding thrombolytic therapy, and this recommendation is communicated to the mobile cart in the spoke hospital and can be added to the medical record.⁴²

In designing the system, the MCG team and the initial rural community hospital partners focused on ease of use. MCG made site visits to the early partner spoke hospitals and consulted extensively with the rural hospital emergency department staff in the design of the program. MCG was particularly motivated to minimize costs in the development of its program given the limited resources of its rural spoke partners and because the initial cost of development was borne by MCG. Georgia Medicaid reimburses physician consultations furnished via interactive video teleconferencing. Payment is on a fee-for-service basis and is the same as the reimbursement for covered evaluation and management services furnished in conventional, face-to-face consultations.¹¹⁶

Outcomes

In 2003, the MCG team published an assessment of the reliability of the National Institutes of Health Stroke Scale using the REACH telestroke network. The authors conducted both a bedside and a remote evaluation for 20 patients who presented in rural community hospitals and found that the correlation between the 2 modalities was very strong.⁴²

In 2005, MCG researchers published data on 194 acute stroke patient consultations provided between March 2003 and May 2005, which included 30 patients treated with tPA.⁴³ The authors concluded that their system “permits the rapid and safe use of tPA in rural community hospitals” (p 2018) and that time and experience help reduce onset to treatment time.^{43,117}

Lessons Learned

Based on their experiences, leaders of Georgia's telemedicine initiative point to 4 major lessons for developing stroke and telemedicine programs in rural areas: (1) Work to keep the program and the technology as simple as possible while maintaining the highest standards of care; (2) keep the focus of the program on the local region, where referral and other relationships exist; (3) ensure that spoke-hospitals' participation in the program is affordable; and (4) develop the program with active participation from and consultation with the spoke-hospital partners.

Example 3: New York State: Stroke Telemedicine Initiative

Overview

Political leadership played a central role in the recent establishment of a telemedicine initiative in New York State for the treatment of acute stroke. The New York State Department of Health sought to reduce geographic treatment disparities and recognized telemedicine as a means of achieving this goal. The initial telemedicine efforts focused on acute stroke treatment; however, the Department of Health views the telemedicine platform being built for stroke as adaptable for other acute and ambulatory uses.

Legal and Regulatory Environment

In August 2004, the Department of Health initiated New York State's Stroke Center Designation Program. Among the requirements for hospital participation in the designation program were the use of written procedures to rapidly activate the acute stroke team so that team members are at the patient's bedside within 15 minutes of being notified and staffing of the acute stroke team by qualified healthcare professionals, including at a minimum a board-certified or board-qualified physician with special competence in caring for the acute stroke patient, as well as another healthcare provider who has experience caring for the acute stroke patient, such as a registered nurse, physician's assistant, or nurse practitioner.¹¹⁸ As part of the designation program, the state began working with the State Emergency Medical Advisory Committee and local emergency medical services providers on transport protocols to promote the use of stroke centers.

More than 100 hospitals have received Stroke Center Designation. However, the program highlighted the unequal distribution of neurology experts throughout New York State and the challenge many areas of the state face in delivering acute stroke experts to the bedside within 15 minutes. For example, New York City averages 6.4 neurologists per 100 000 people, whereas western New York averages 2.8 neurologists per 100 000 people, and the Mohawk Valley averages only 0.7 per 100 000.⁹⁸ In response to the disparities in access to specialized stroke care between urban and nonurban areas, in 2006, the Department of Health announced a new Stroke Telemedicine Initiative.

Operations

In September 2006, New York initiated the first phase of its Stroke Telemedicine Initiative. Under this initiative, a traditional telestroke hub-and-spoke network model was implemented with real-time consultation and review of CT scans through secure Internet transmissions. This includes the requirement that New York State-licensed neurologists be credentialed to practice in spoke hospitals and be available full time (24 hours per day/7 days per week) to remotely examine patients in rural emergency rooms and/or inpatient hospital settings, review CT scans and other patient information, and make recommendations regarding treatment, including the use of tPA when appropriate.

New York State estimates that the program costs for this initiative are \$60 000 per year for 3 years at the hub hospital and \$78 400 for 3 years or \$26 134 per year at each spoke.⁹⁸ The Department of Health reprogrammed unspent dollars to support the initial phase of the project. Phase 1 includes 2 networks: Bassett Hospital in Cooperstown is serving as the hub hospital to 4 community hospital spokes, and Millard Fillmore Gates Hospital in Buffalo is serving as the hub for 7 community hospital spokes, with additional spoke

hospitals in development.¹¹⁸ In the next phase, the State University of New York Upstate Medical University Hospital will begin to serve as a hub hospital in its region for a hub-and-spoke network that is under development.

As part of the implementation plan for the initiative, the state changed the payment policies in its Medicaid program. Effective September 2006, the New York State Department of Health Office of Health Insurance Programs recognizes "medically necessary emergency room and inpatient hospital consultation services as payable to physicians with a specialty designation providing consultations via an interactive audio and video telecommunications system."⁸⁵ The communication must be bimodal (ie, video and voice). Reimbursement is the same as it would be for in-person specialist consultations. Although reimbursement was approximately \$20 in 2006,¹¹⁰ advocates view the establishment of the code and the guidance for its use as an important foothold for future efforts to address the adequacy of reimbursement. With respect to administration of thrombolytic therapy, acute stroke care, and telemedicine, if it is medically necessary to transfer a patient to a hub hospital or other designated stroke center after administration of tPA, the spoke hospital receives a transfer payment, and the hub hospital is then eligible for reimbursement that does not reflect the costs of thrombolytic therapy.⁹⁸

The Department of Health also has engaged the private payer community to encourage coverage for telemedicine consultation services. For example, BlueCross BlueShield of Northeast New York has begun reimbursing for these consultation services, and other private payers are reportedly in the process of developing codes and methodologies for telemedicine reimbursement.

Consulting physicians in New York's hub hospitals must be credentialed in the spoke hospitals. To address the credentialing paperwork burden, the state clarified that provided the hub and spoke hospitals have a contractual relationship, the hub hospital can collect the credentialing information on the spoke hospital's behalf. Specifically, with the provider's permission, the information collected for the physician's home hospital can be shared with the spoke hospital for purposes of credentialing, provided a contract exists between the 2 entities. The New York Stroke Telemedicine Initiative also includes a data collection and reporting initiative that will collect data on hub-and-spoke hospital consultation and treatment steps to inform the science of acute stroke treatment and the design of future treatment protocols.

Outcomes

The New York initiative is too new to have reportable outcomes; however, one of the unique features of this initiative worthy of future study is the approach the state has taken in shaping the telemedicine networks. In Massachusetts and Georgia, the networks grew in parallel to the hub and spoke hospitals' needs and relationships. The New York State model is a more structured top-down approach that used political leadership to create access to acute stroke care across rural and other nonurban regions. Future evaluations of the New York model will help to answer whether this more systematic approach produces different outcomes and rates of adoption than those led by nonprofit organizations or physicians.

Lessons Learned

In New York, the major lesson learned has been that political leadership and commitment not only facilitate the development of stroke telemedicine but also help to create a key ally in conquering real and perceived barriers to implementation. For example, the New York State Department of Health has been the catalyst in streamlining the process for hub consultants to become credentialed in spoke hospitals, an issue other telemedicine systems have struggled to tackle. One of the motivations for the state's commitment has been its vision of telemedicine as a platform for more comprehensive telemedicine systems treating many conditions in addition to stroke in areas where access to specialty care has been an important barrier to care delivery. In this case, the policymakers' long-term goal is broader than the stroke initiative, but stroke care advocates were able to leverage stroke as the condition to prove the value of this methodology.

Disclosures

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Writing Group Member	Employment	Research Grant	Other Research Support	Speakers' Bureau/Honoraria	Expert Witness	Ownership Interest	Consultant/Advisory Board	Other
Lee H. Schwamm	Massachusetts General Hospital (MGH)† (MGH is a non-profit hospital that as part of its medical mission provides telemedicine services to the surrounding community for access to care in the fields of dermatology, critical care, stroke neurology, oncology and other specialties as needed); and Massachusetts Department of Public Health (contracted after open bidding process as a Stroke systems consultant to assist with design and implementation of MA DPH's Paul Coverdell Acute Stroke Registry funded by CDC)	None	None	None	Occasional review of medical records in cases of alleged malpractice in defense of neurologists. These cases often involve the use of IV tPA. None for telemedicine specifically†	None	None	None
Heinrich J. Audebert	Guy's and St Thomas' NHS Foundation Trust (London, UK)	None	None	Meytec GmbH, supplier of telemedicine equipment (Germany)*	None	None	None	None
Pierre Amarenco	Denis Diderot University (Paris, France)	Boehringer Ingelheim†	None	Pfizer†; Sanofi-Aventis*	None	None	Daiichi-Sankyo*; GE-Healthcare*; Pfizer*; Sanofi-Aventis*	None
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Michael R. Frankel	Emory University School of Medicine	Centers for Disease Control and Prevention†; Georgia Division of Public Health†; National Institutes of Health†	None	None	Expert witness for defense and plaintiff attorneys*	None	None	None
Mary G. George	Centers for Disease Control and Prevention	None	None	None	None	None	None	None
Philip B. Gorelick	University of Illinois	None	None	None	None	None	InTouch Health*	None

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Daniel T. Lackland	Medical University of South Carolina	None	None	Merck†; Novartis†; Sanofi-Aventis†	None	None	None	None
Steven R. Levine	The Mount Sinai School of Medicine	Gaisman Foundation Award for conduct of preliminary telestroke studies*; NIH grant support to institution for conduct of preliminary telestroke studies (ending August 2008)†	None	Honoraria for grand rounds on telestroke*; NCMC*; Medical Education Speakers Network*	Consulted on cases for both plaintiffs and physicians/hospitals related to stroke care. None related to telestroke†	None	National Stroke Association: Reimbursement for time reviewing NSA scientific content*	None
Brett C. Meyer	University of California, San Diego	Principal Investigator for the NIH-funded "Stroke Team Remote Evaluation using a Digital Observation Camera" (STROKE DOC) clinical trial. NIH (P50 NS044148)†	None	Speakers' Bureau for Boehringer Ingelheim (past)*	None	None	Advisory Board Meeting for Genentech*	None
Phillip M. Meyers	Columbia University	None	None	None	None	None	None	None
Victor Patterson	UK Limited Company, Synapse Teleneurology Ltd, which aims to promulgate the use of teleneurology (including telestroke) throughout the world	None	None	None	None	None	None	None
Steven K. Stranne	Bryan Cave LLP (Partner)	None	None	None	None	None	None	None
Christopher J. White	Ochsner Medical Institutions	None	None	None	None	None	Baxter Healthcare*	None

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*Modest.

†Significant.

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*Modest.

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KEY WORDS: AHA Scientific Statements ■ stroke ■ telemedicine ■ telestroke ■ stroke care ■ thrombolysis ■ video conferencing



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