

## REVIEW

## Telestroke: the promise and the challenge. Part two: expansion and horizons

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Acute ischemic stroke remains a major public health concern, with low national treatment rates for the condition, demonstrating a disconnection between the evidence of treatment benefit and delivery of this treatment. Intravenous thrombolysis and endovascular thrombectomy are both strongly evidence supported and exquisitely time sensitive therapies. The mismatch between the distribution and incidence of stroke presentations and the availability of specialist care significantly affects access to care. Telestroke, the use of telemedicine for stroke, aims to surmount this hurdle by distributing stroke expertise more effectively, through video consultation with and examination of patients in locations removed from specialist care. This is the second of a two part review, and is focused on the challenges telestroke faces for wider adoption. It further details the anticipated evolution of this novel therapeutic platform, and the potential roles it holds in stroke prevention, ambulance based care, rehabilitation, and research.

**INTRODUCTION**

Despite significant advances in primary prevention, acute ischemic stroke (AIS) remains a major public health burden, the fourth leading cause of mortality in the USA and the top cause of chronic disability.<sup>1 2</sup> Acute disease modifying treatment is founded on the recanalization hypothesis; recanalization of the occluded cerebral artery results in penumbral salvage, if accomplished early enough. Telestroke offers a mechanism for increasing patient and provider access to stroke expertise and therefore appropriate stroke treatment. In the first part of this two part review, we assessed the growth and current practice of telestroke in the USA, including the role of telestroke with emergent large vessel occlusion (ELVO) patients. This second portion focuses on expansion of the service, and horizons for telestroke in the years to come.

**EXPANDING ACCESS TO TELESTROKE**

Despite a wealth of data demonstrating safety and efficacy, millions of people in the USA continue to lack access to appropriate AIS care.<sup>3</sup> Rules and regulations surrounding healthcare delivery continue to lag behind the pace of modernization in telestroke, constraining widespread adoption of a proven modality. In a recent survey of 38 USA telestroke programs, the majority of respondents reported significant barriers to the creation or expansion of a telestroke network.<sup>4</sup> These barriers include medicolegal ambiguity, financial

sustainability, technological infrastructure, and practice based agreements. With many of the clinical concerns addressed over the history of this technology, the widespread expansion of telestroke will now likely hinge on overcoming practical barriers to care.

**Legal and administrative barriers**

Unlike most traditional healthcare delivery encounters, remote consultations in telestroke frequently cross state lines. For example, in a Boston based telestroke network, an on-call neurologist covers 32 hospitals in 3 different states,<sup>5</sup> while in Colorado, a telestroke network covers over 60 hospitals in 5 neighboring states. Clearly, the variable geography of telestroke poses novel legal questions regarding the licensing, credentialing, and liability of remote physicians.

In the American federalist model, each state grants and regulates medical licenses for clinical practice within that state. While licensing requirements can vary from state to state, they are largely similar.<sup>6</sup> In spite of this near uniformity in licensing requirements, there is enormous state to state variability in telestroke specific licensing.<sup>7</sup> For instance, Louisiana and Minnesota are two of nine total states that permit clinicians with an out of state license to practice telemedicine within their state.<sup>8 9</sup> Conversely, eight states specifically require telemedicine physicians to obtain an in-state medical license.<sup>7</sup> Six states do not address telemedicine at all, while most other states have acknowledged telemedicine but made few provisions for its practice.<sup>7</sup> Ultimately, the administrative burden of securing multiple state licenses per provider was recently cited as one of the biggest barriers to expanding a telestroke network.<sup>4</sup> In an attempt to break down barriers to telemedicine, the federal government has attempted to coordinate a national compact standardizing reciprocal telemedicine licensing.<sup>10 11</sup> In addition, the federation of state medical boards recently released a model policy for the appropriate use of telemedicine technologies in the practice of medicine for promoting cross state telemedicine practice, but few if any boards of registration have adopted it.<sup>12</sup> This challenge stands in stark contrast to the Nursing License Compact, where 24 states have adopted a national licensing standard to permit nurses to practice across state lines.<sup>13</sup> In the absence of such a compact, recent efforts have focused on working within regional cooperative programs to facilitate telemedicine in geographically related areas.<sup>14</sup> Regional programs

already exist to facilitate interstate cooperation. Within this framework, state lawmakers are attempting to develop reciprocal licensing agreements to facilitate telestroke across state lines.

In addition to having a state medical license, physicians must obtain hospital credentials before being able to practice in a given inpatient or emergency department setting. Credentialing is a state mandated process by which each hospital verifies the qualifications and competency of potential practitioners before they are given privileges to practice in a given facility. There is no standard credentialing process, though there are competing requirements across various organizations such as Medicare, the Joint Commission, and individual state regulations, resulting in substantial hospital to hospital variation in required paperwork. This represents a further barrier to telestroke, because each remote neurologist must obtain and maintain credentials to practice at every facility within the telestroke network. In the absence of credentialing by proxy, telestroke networks expend an enormous amount of administrative effort to fulfill this legal requirement. The administrative burden is large enough that some large telestroke networks employ administrators whose sole responsibility is to facilitate medical licensing and credentialing.<sup>15</sup> In 2011, Centers for Medicare and Medicaid Services (CMS) attempted to streamline credentialing by allowing credentialing by proxy compacts between referring hospitals and teleconsultants in a telemedicine network.<sup>16</sup> In 2012, California was the first state to pass a law addressing hospital credentialing by proxy for physicians in a telestroke network, permitting local hospitals to credential remote physicians by proxy if they met practice requirements in their home facility.<sup>7 17 18</sup> Nonetheless, the overwhelming majority of state laws make no provisions for reciprocal credentialing in a telestroke network.<sup>7</sup>

Even after a remote physician navigates the licensing and credentialing process, the question of legal liability remains unclear. For instance, if a patient in Kansas is assessed by a teleconsultant physician physically located at the time of the consult in Ohio, is the governing jurisdiction for any litigation in Kansas, Ohio, or both? Which physician is ultimately responsible for the execution of the recommended management plan, the teleneurologist or the physician at the bedside in the originating site? These questions are largely unanswered by current state law. Currently, only two states have any statutes addressing malpractice liability in telemedicine.<sup>7</sup> Similarly, there are no major legal precedents for guidance in states without statutes defining malpractice liability in telemedicine. This ambiguity limits the growth of telestroke as providers, and networks remain unsure of their personal liability.<sup>19</sup> Since only cases that go to trial are indexed in case law, out of court settlements for alleged malpractice in telemedicine are of an unknown number and therefore cannot readily inform these decisions.

As telemedicine expands and various disciplines begin to leverage the advantages it offers, there will be increasing pressure to update legal and regulatory standards to reflect this novel delivery model. Many telestroke networks have navigated a complicated web of outdated, redundant, and or unpredictable legal hurdles. Nonetheless, these legal questions must be definitively addressed to promote nationwide adoption of telestroke and thereby realize the full potential of telestroke in optimizing AIS care.

### Financial barriers

Similar to the legal underpinnings of telestroke, the financial landscape remains uncertain. Financial considerations include both the cost of starting and maintaining a network, as well as the reimbursement for its services.

While telestroke networks leverage telecommunications to maximize the efficiency of medical resources, they require an investment to establish and maintain. Considerable efforts are required to develop these networks, including electronic medical record transfer, telecommunications equipment and support, interdisciplinary education, administrative support, and inter-hospital legal agreements. Coordinating these efforts requires an ongoing investment that, in the near term on an institutional level, can be more expensive than not treating AIS. The financial outlook of telestroke in a real world was recently assessed in a retrospective analysis of nearly 1300 AIS cases in a large German telestroke network.<sup>20</sup> The cost of treatment was compared for patients treated in hospitals with or without telestroke capabilities and tracked for 30 months post-stroke. Predictably, telestroke was associated with both improved functional outcomes and higher healthcare cost in the acute phase, but lower longer term costs. Patients treated at non-telestroke facilities had increased rates of ongoing care and institutionalization, requiring higher annual healthcare costs over the long term. Telestroke was cost neutral by 30 months, and for every year afterwards, cost effective by reducing lifelong costs of supportive care.<sup>20</sup> Similar results have been replicated in other American and European contexts, demonstrating long term cost savings generated from improved functional outcomes and decreased hospital transfers.<sup>21-24</sup> As a modality that increases the use of proven therapies such as thrombolysis, telestroke is a proven, cost effective delivery model.

Unfortunately there is a financial disconnect between the costs and benefits of telestroke, as the upfront costs are borne by the acute care providers while the savings are passed onto the broader healthcare system and society. Early adopters of telestroke have pioneered varying approaches to bridging the upfront costs in order to generate system wide benefits. For instance, in Georgia and Massachusetts, the initiation of certification criteria for stroke centers and accompanying diversion of patients to stroke capable facilities led to a financial incentive for community hospitals to enroll in a telestroke network.<sup>15 25</sup> In contrast with a community based model, New York State employed a top down approach by using state resources to fund the establishment of hub and spoke telestroke networks. To keep up with annual costs, many of these networks operate on a fee for service or subscription based practice, where local centers pay an annual fee for coverage.

A 2013 survey of state laws and regulations regarding telestroke reimbursement was notable for remarkable state to state variability.<sup>7</sup> Only half of all US states have any policies addressing reimbursement for telemedicine. Even then, the majority of these policies only apply to state funded programs, while only 15 states regulate private payer reimbursement for telestroke services. Of these states, two have outlawed private payer reimbursement for remote services, while nine others require 'payment parity', or equal reimbursement for remote or in-person assessments.<sup>7</sup> Many states lack 'coverage parity', where a covered service is reimbursed regardless of how it is provided (in-person or remotely). Regional telestroke networks will continue to be limited by uncertain laws regarding reimbursement until interstate consensus can be reached on basic tenants of reimbursement.

In addition to the uncertain legal framework for reimbursement, national regulatory policies further complicate reimbursement. For instance, Medicare will only reimburse for telemedicine services if the patient is in a designated 'rural health professional shortage area (HPSA)' or a critical access facility.<sup>26</sup> A HPSA is defined as a rural region with a shortage of

primary care physicians. Unfortunately, this definition is not responsive to the needs of patients with AIS, as it is the shortage of neurologists, not primary care physicians, that limits adequate assessment for thrombolysis. Similarly, the shortage of neurologists includes underserved hospitals in urban and suburban communities who are excluded from HPSA designation.<sup>27</sup> Even when geographic restrictions are met, reimbursement is contingent on other regulations, including the technology used. For example, a Georgia based telestroke network that pioneered telestroke in the US used one way audiovisual connectivity, and was subsequently not eligible for Medicare reimbursement because it did not use two way connectivity.<sup>28</sup>

Finally, in situations where all legal and regulatory standards are met, existing coding options continue to limit reimbursement for telestroke services. Medicare started reimbursing remote thrombolysis in 2006,<sup>29</sup> with the goal of accelerating broader adoption of telestroke. However, these codes only apply to patients who are thrombolysed and remain at the originating hospital. If the patient is subsequently transferred for subspecialty care, neither hospital is entitled to reimbursement for the thrombolysis.<sup>15</sup> Unfortunately, this provides a disincentive for referring hospitals to participate in a telestroke network, while also increasing costs for the referral center.<sup>30</sup> Recognizing this disincentive, New York State was the first state to institute a transfer code for state payers to reimburse drip and ship stroke care.<sup>31</sup> This remains an exception, with the majority of drip and ship care not reimbursed. Since most states do not have parity laws requiring private payers to reimburse remote services, private payer reimbursement remains low.<sup>7</sup> Similarly, even when services are reimbursed, the current range of billing codes does not reflect the services offered. Many payers recognize billing codes for initial evaluation and management, but do not differentiate between a consultation and ongoing remote management of critically ill patients.<sup>32</sup> Critical care billing codes specifically require that the treating physician be in close physical proximity to the patient (usually on the same physical unit of the hospital) and are silent as to their use in telemedicine encounters, and therefore inappropriate as written to support telemedicine. The lack of appropriate billing codes to reflect more time intensive services leads to reduced reimbursement rates that further disincentive the proliferation of telestroke. The overwhelming majority of surveyed telestroke networks cite reimbursement as a common obstacle to initiating or expanding a telestroke network, and over 40% of these networks do not receive reimbursement for their services.<sup>4</sup> This is incompatible with broad adoption of telestroke. The potential of telestroke to improve system wide outcomes and generate long term cost savings will remain unrealized until the financial components of telestroke are aligned.

### Technological barriers

When telestroke was initially conceived, audiovisual connectivity was not standard, and therefore technical considerations represented significant barriers to initial experiences with telemedicine.<sup>33</sup> Initial requirements for fixed workstations and moderate quality interfaces have since given way to a multitude of site independent platforms offering low latency, high quality connectivity in user friendly formats.<sup>34 35</sup> The proliferation of broadband internet access and advances in telecommunication have led to standard audiovisual connectivity with high bandwidth internet connections for most regions. Although technology continues to improve, it is the use of the technology, and not the technology itself, that is now the largest barrier to practice. In a retrospective review assessing factors associated with high rates of telemedicine adoption and use, usability, local

technical support, and appropriate training were three critical factors to maximize telemedicine adoption.<sup>33</sup>

While the technology underlying telestroke has become routine nationwide, broadband connectivity has not. Broadband internet access is not universally available across the USA, and the rural areas in greatest need of remote telemedicine services are also least likely to have broadband connectivity.<sup>36 37</sup> The lack of reliable broadband access in these areas restricts the spread of telemedicine.<sup>38</sup> Given the deliberate pace of broadband expansion,<sup>39</sup> there has been increasing interest in leveraging cellular data networks to circumvent the lack of hard wired connectivity. Preliminary pilot experiments using fourth generation cellular connectivity to facilitate telestroke have been encouraging,<sup>40 41</sup> suggesting that mobile connectivity in the future may be able to sustain high quality low latency audiovisual connectivity in rural areas. State lawmakers could work with cellular coverage providers to incentivize increased coverage of rural catchment areas. Similarly, cellular providers could create quality of service level guarantees that prioritize bandwidth for telemedicine to maximize the efficacy of cellular connectivity. Further studies will be required to demonstrate feasibility, cost, and safety of fourth generation networks, but this is clearly a promising strategy to extend telestroke coverage to underserved rural communities. With further natural evolution of communication technology, these technological barriers are likely to continue to decrease over time.

### Practice barriers

The importance of clinician adoption and investment in telestroke as a practice model cannot be overemphasized. Membership in a telestroke network, or consultation with a telestroke physician, is entirely dependent on the practice pattern of local facilities and physicians. Early American experiences with telestroke demonstrated the importance of engaging key stakeholders in local facilities to encourage the adoption of the platform,<sup>15</sup> emphasizing pre-existing local connections to establish a network. In a retrospective analysis of differing adoption rates in comparable telestroke networks, leadership support and standardizing telestroke into the workflow were crucial factors that led to increased telestroke assimilation in member hospitals.<sup>42</sup> Referral rates, as a surrogate for telestroke use, also reflect the correlation between familiarity and utilization of a telestroke network. In an early German telestroke network, referral rates ranged from 2% to 86%, reflecting site specific differences in telestroke adoption.<sup>43</sup> Nevertheless, as familiarity increased, so did thrombolysis rates. Similarly, a retrospective review of over 44 000 AIS patients treated in US telestroke networks demonstrated an increasing rate of remote thrombolysis throughout the 8 year study period.<sup>44</sup> Together, these data demonstrate the importance of stakeholder acceptance of telestroke to increase access to thrombolysis. Telestroke expansion will be contingent on effective strategies to engage and partner with local physicians who can both champion and use telestroke in otherwise underserved facilities (box 1).

### HORIZONS FOR TELESTROKE

Despite practical barriers to expansion detailed above, convincing evidence of efficacy has appropriately led to increasing calls for the expansion of telestroke, including endorsement by the American Heart Association,<sup>45</sup> producing increasing pressure to leverage this modality in AIS management. With the new evidence of benefit of endovascular therapy for ELVO patients, the most disabled of the stroke population, and the limited accessibility of this treatment, the importance of specialist evaluation for acute stroke presentations has never been greater.

**Box 1 Potential barriers to expansion of telestroke services***Administrative*

- ▶ State licensing
- ▶ Hospital credentialing
- ▶ Information transfer logistics

*Legal*

- ▶ Contractual negotiations
- ▶ Hospital liability
- ▶ Physician malpractice liability
- ▶ Protected patient information regulations

*Financial*

- ▶ Cost of initiation and maintenance
- ▶ Network
- ▶ Electronic medical record
- ▶ Equipment
- ▶ Education
- ▶ Administrative
- ▶ Legal
- ▶ Coding for rendered services
- ▶ Reimbursement fees for services
- ▶ Distribution of reimbursement

*Technical*

- ▶ Data transfer
- ▶ Broadband internet connectivity/distribution
- ▶ Cellular network accessibility/capacity
- ▶ Local technical support/expertise
- ▶ Local training
- ▶ Secure electronic medical record transfer
- ▶ Secure imaging transfer

*Practice patterns*

- ▶ Adoption and utilization by clinicians
- ▶ Education
- ▶ Staff availability and responsiveness
- ▶ Support from institutional leadership

Considerations refer to both the spoke and hub center.

**Technology**

As telecommunication technology and high speed connectivity become increasingly standard, the barriers to entry will continue to decrease. The rapid proliferation of fourth generation cellular technology, broadband internet access, and high resolution video communication suggest site independent platforms for remote consultations will become standard. This would facilitate shorter latencies to evaluation and treatment, as remote physicians would be able to do an evaluation from anywhere with an internet or cellular connection.<sup>46 47</sup>

**Regulation and billing**

Legal and regulatory barriers nonetheless persist, but advocacy efforts by local medical societies and telemedicine advocates have led to an increasingly favorable environment for telestroke in many states. Regional coordination of such efforts will help facilitate legal and regulatory changes, with the aim to leverage a patchwork of pre-existing networks into an integrated regional network. Such efforts will ultimately hinge on the ability to demonstrate financial viability of telestroke, including both cost effectiveness and reimbursement for services. In light of this pressure, telestroke advocates continue to design cost effectiveness studies to quantify the financial impact of telestroke and

thus bolster advocacy efforts to streamline reimbursement. One such example is the ongoing effort to rectify the gap in reimbursement for drip and ship services. To address concerns regarding the cost of reimbursing drip and ship, a recent study modeled both hospital specific and network wide costs as a function of transfer rates, identifying a range of transfer rates consistent with net cost savings.<sup>24</sup> Studies like these, along with advocacy efforts, have led CMS to evaluate estimated costs of instituting billing codes for drip and ship services and portend a favorable climate for telestroke expansion.

**Telestroke applications in stroke prevention**

As telestroke is poised to grow, there is increasing interest in leveraging telemedicine to optimize AIS management throughout all phases of the disease process. In the domains of primary and secondary prevention in stroke systems of care, telestroke connectivity could be used to provide neurovascular expertise for stroke prevention in otherwise underserved communities. For instance, an Australian integrated care project leveraged telestroke to optimize secondary prevention strategies in patients with recent ischemic infarcts. Remote neurologists coordinated medication management with the patient's primary care physician, significantly increasing the percentage of patients meeting secondary prevention goals.<sup>48</sup> Future applications of telestroke could lead to remote clinic visits, remote consultations, or continuing medical education with local physicians to optimize modifiable risk factors and leverage neurovascular expertise to decrease the incidence of AIS.

**Ambulance based telestroke evaluations**

In settings where prevention has failed, telestroke is now being used to increase the speed of thrombolysis via prehospital consultations and radiography. Modeled after prehospital ECG in myocardial infarction, a prospective trial in Germany equipped ambulances with a mobile CT scanner, point of care testing, and telestroke connectivity to facilitate prehospital assessments and thrombolysis.<sup>49 50</sup> Patients evaluated in the prehospital phase were six times more likely to receive thrombolysis within the 'golden hour', and twice as likely to be discharged home.<sup>51</sup> The generalizability of these findings is notably limited by the fact that in Germany a physician is routinely present in all ambulances, and emergency medicine trained neurologists were physically present in these ambulances. As a proof of principle, this initiative has led to American pilot studies using telestroke to connect a remote neurologist to CT equipped ambulances. Two separate studies in Houston, Texas and Cleveland, Ohio, USA, are exploring the safety and efficacy of prehospital telestroke to accelerate thrombolysis.<sup>52 53</sup> Further studies will be required to assess functional outcomes and cost effectiveness. Prehospital diagnosis could also identify patients who would benefit from endovascular therapy and accelerate recanalization time via prehospital activation of the endovascular team. Similarly, patients found to have an ELVO could be triaged in the field to a center capable of endovascular therapy, thereby accelerating reperfusion by eliminating transfer delays. If validated, prehospital application of telestroke has the potential to dramatically accelerate thrombolysis and mechanical recanalization, and optimize outcomes after AIS.

**Decision support**

In the acute inpatient phase, the telestroke interface itself can aid clinical decision making with decision support tools. Next generation telestroke, or 'Telestroke 2.0',<sup>54</sup> will likely be designed to integrate real time clinical data to populate evidence

based algorithms that prompt further decision making. For instance, there is increasing interest in differentiating stroke mimics from true ischemic disease, particularly in the setting of telestroke.<sup>55</sup> Novel decision support tools are now being validated to aid in the differentiation of mimicry from ischemic disease in telestroke settings.<sup>56</sup> Similar decision support tools, ranging from the appropriateness of thrombolysis to triage to endovascular therapy, could similarly be developed to systematize standards of care within a telestroke network.

### Telestroke applications in rehabilitation

In the post-stroke rehabilitation phase, telestroke is currently being explored as a model for chronic rehabilitation. Telemedicine is increasingly used in rehabilitation to deliver speech therapy, occupational therapy, physical therapy, and specialist psychiatry consults to patients in underserved communities.<sup>57–58</sup> Beyond delivering access to otherwise underserved patients, telerehabilitation has the distinct advantage of working with patients in their natural, home environment, which is associated with improved functional outcomes.<sup>58–59</sup> This is especially important for stroke patients, as limited mobility may be an independent barrier to accessing rehabilitative therapy. Given the increasing ease of high quality audiovisual connectivity, tele-rehabilitation has the potential to become an increasingly common mechanism to conduct home based rehabilitation with patients recovering from a stroke. A newly funded multicenter clinical trial will compare telemedicine enabled rehabilitation and conventional rehabilitation in the NIH StrokeNet network (NCT02360488).

### Telestroke and research

Finally, the application of telestroke can similarly be leveraged to not only aid in the management of AIS, but also further clinical research to inform future therapy. The majority of AISs present in the community, while the overwhelming majority of clinical trials happen at academic medical centers. Even when patients are identified for inclusion in a trial, transfer time may lead to exclusions of otherwise eligible patients.<sup>60</sup> By linking academic medical resources to a network of community hospitals, telestroke provides access to a larger pool of patients who can be immediately enrolled in ongoing clinical trials. This would both dramatically accelerate recruitment of patients into AIS trials as well as lead to more generalizable clinical trials that reflect community practice environments. Furthermore, telestroke has the distinct advantage of being able to record entire clinical encounters, creating a repository of clinical data that can be independently assessed and mined by multiple investigators. Currently, the use of telestroke as a research tool is limited by protocols that require in-person, paper based consent.<sup>60</sup> To realize the potential of telestroke in clinical research, both consent and randomization processes will need to be streamlined in order to leverage this novel healthcare delivery model. In addition, clarity over the governing body for human research protection review is needed to determine who should review and approve the clinical trial protocol, the originating site or the expert center to which the patient will be transferred.

### CONCLUSION

AIS is a major public health issue, and remains undertreated in the developed world. Despite the advent of effective pharmacologic and mechanical treatments, healthcare delivery is limited by the current allocation of resources. Telestroke was developed as a response to geographic disparities, leveraging modern telecommunication technology to extend existing resources into

underserved communities. Now, with more than a decade of experience, telestroke has demonstrated safety, efficacy, and improved long term outcomes, providing a basis for broad based expansion. With the recent evidentiary support for endovascular treatment of stroke, telestroke further enables a remote triage of patients who may benefit from endovascular intervention, a now critical facet of a telemedicine service at a comprehensive stroke center. Further efforts will be required to navigate existing legal, regulatory, and financial obstacles to expansion. Nevertheless, telestroke will be part of the revolution of both current and future practice by efficiently delivering the standard of care to patients suffering from AIS, regardless of locale, and by identifying and facilitating transfer for patients that require services beyond what is available at the referring facility.

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