AMERICAN TELEMEDICINE ASSOCIATION

PRACTICE GUIDELINES FOR TELESTROKE

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TELESTROKE GUIDELINES

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PREAMBLE

Background. The American Telemedicine Association (ATA), with members from throughout the United States and the world, is the principal organization bringing together telemedicine providers, healthcare institutions, vendors and others involved in providing remote healthcare using telecommunications. ATA is a nonprofit organization that seeks to bring together diverse groups from traditional medicine and healthcare, academia, technology and telecommunications companies, e-health, allied professional and nursing associations, medical societies, government and others to overcome barriers to the advancement of telemedicine through the professional, ethical and equitable improvement in healthcare delivery. ATA has embarked on an effort to establish practice guidelines and technical requirements for telemedicine to help advance the science and to assure the uniform quality of service to patients. These guidelines, based on clinical and empirical experience, are developed by work groups that include experts from the field and other strategic stakeholders and designed to serve as both an operational reference and an educational tool to aid in providing appropriate care for patients. The practice guidelines and requirements generated by ATA undergo a thorough consensus and rigorous review, with final approval by the ATA Board of Directors. Existing products are reviewed and updated periodically as time and resources permit. Board-approved practice guidelines will be considered for affirmation, update, or sunset at least every 4 years. Practice guidelines that have been sunset may continue to have educational value but may not represent the most current knowledge and information about the subject matter.

Disclaimer. The practice of healthcare is an integration of both the science and art of preventing, diagnosing, and treating diseases. Accordingly, it should be recognized that compliance with these guidelines will not guarantee accurate diagnoses or successful outcomes with respect to the treatment of individual patients, and ATA disclaims any responsibility for such outcomes. These guidelines are provided for informational and educational purposes only and do not set a legal standard of medical or other health care. They are intended to assist providers in delivering effective and safe medical care that is founded on current information, available resources, and patient needs. The practice guidelines and technical requirements recognize that safe and effective practices require specific training, skills, and techniques, as described in each document, and are not a substitute for the independent professional judgment, training, and skill of treating or consulting providers. If circumstances warrant, a provider may responsibly pursue a course of action different from the guidelines when, in the reasonable judgment of the provider, such action is indicated by the condition of the patient, restrictions or limits on available resources, or advances in information or technology subsequent to publication of the guidelines. Likewise, the practice guidelines and technical requirements in this document do not purport to establish binding legal standards for carrying out telemedicine interactions. Rather, they are the result of the accumulated knowledge and expertise of the ATA work groups and their review of the current literature in the field and are intended to improve the technical quality and reliability of telemedicine encounters. The administrative procedures and technical aspects of specific telemedicine arrangements may vary depending on the individual circumstances, including location of the parties, resources, nature of the interaction, and in the case of children and adolescents, the adults responsible for their welfare until the age of majority.

SCOPE

The following telestroke guidelines were developed to assist practitioners in providing assessment, diagnosis, management, and/or remote consultative support to patients exhibiting symptoms and signs consistent with an acute stroke syndrome, using telemedicine communication technologies. Although telestroke practices may include a broader utilization of telemedicine across the entire continuum of stroke care, with some even consulting on all neurologic emergencies, this document focuses on the acute phase of stroke, including both pre- and in-hospital encounters for cerebrovascular neurological emergencies. These guidelines describe a network of audio-visual communication and computer systems for delivery of telestroke clinical services, and include operations, management, administration, and economic recommendations. These interactive encounters link patients with acute ischemic and hemorrhagic stroke syndromes with acute care facilities with remote and on-site healthcare practitioners providing access to expertise, enhancing clinical practice, and improving quality outcomes and metrics. These guidelines apply specifically to telestroke services, and they do not prescribe or recommend overall clinical protocols for stroke patient care. Rather, the focus is on the unique aspects of delivering collaborative bedside and remote care through the telestroke model.

The telestroke guidelines contain requirements, recommendations, or actions that are identified by text containing the key words "**shall**," "**should**," and "**may**." "**Shall**" indicates a required action whenever feasible and practical under local conditions. "**Should**" indicates an optimal recommended action that is particularly suitable, without mentioning or excluding others. "**May**" indicates additional points that may be considered to further optimize the telestroke healthcare process.

Please refer to the glossary in the Appendix for definitions utilized in this document.

INTRODUCTION

Despite advances in acute stroke treatment, stroke remains the fifth most common cause of death and the leading cause for long-term adult disability worldwide.[2] There is evidence for effective means to reduce recurrence and improving outcomes by means of early platelet inhibition,[3] intravenous alteplase,[4] Stroke Unit utilization,[5] endovascular thrombectomy,[6] and hemicraniectomy in malignant middle cerebral artery infarction.[7] However, high patient numbers, limited specialized expertise, and geographic determinants, remain major barriers that negatively impact implementation of evidence-based management.[8] These issues are especially true for remote and rural areas. In the late 1990s, the idea of telestroke took shape, in an effort to bring much needed special expertise to a larger proportion of stroke patients.

Telestroke is the use of interactive videoconferencing technologies, specifically for the treatment of patients with acute stroke.[9] The terms "telestroke," "TeleStroke," "teleStroke," and "Tele-stroke" all refer to the same care concept; a centralized or remotely based stroke care team with a stroke physician at a distant site networked with the remote stroke patient at an originating site. Telestroke programs provide services for acute stroke patients in a variety of settings including, but not limited to, Mobile Stroke Units, Emergency Departments (EDs), Intensive Care Units (ICUs), Medical Surgical Units, etc., that do not have access to onsite stroke physician services.

Approximately 87% of acute strokes are ischemic.[10] Selective patients are generally good candidates for IV alteplase, a thrombolytic agent that helps reverse or prevent disability from this type of stroke, if administered within the guideline recommended timeline window for thrombolytic therapy. The more quickly the patient receives alteplase, the greater the chances for recovery with minimal to no deficits. Patients who receive alteplase within the first 90 minutes of symptom onset are nearly three times more likely than patients who did not receive alteplase, to have favorable outcomes three months after the stroke experience.[11] Alteplase remains the only FDA approved reperfusion drug in acute ischemic stroke.

The following guidelines are designed to aid in the development of effective, safe, and sustainable telestroke practices. The development of these guidelines has been a collaborative, systematic approach, based on the best available evidence and clinical expertise. These guidelines are intended to promote standardization of telestroke care delivery, providing guidelines for minimum requirements for delivering safe and effective care, and thus positively impacting clinical outcomes. It is advised that guidelines, position statements, and standards from other professional organizations and societies be reviewed and incorporated into practice as well.

ADMINISTRATIVE GUIDELINES

ORGANIZATIONS

Professional entities providing and receiving telestroke services **shall** follow the agreed upon standard operating and administrative policies and procedures of the relevant governing organizations.

LEADERSHIP

Executive leadership at the originating site **shall** cultivate a shared vision of the incorporation of the telestroke model of care into the innovative care delivery model. This vision **should** be clearly articulated throughout the entire organization.

Executive leadership at the originating site **shall** incorporate principles of change management and the American Association of Critical-Care Nurses (AACN) Standards for Establishing and Sustaining Healthy Work Environments,[12] to guide strategic planning and executive decision-making.

Executive leadership at both the originating and distant sites **should** recruit and develop leaders (sometimes referred to as *Stroke Champions*) to implement and sustain care models that support interprofessional partnerships with the goal of transforming clinical work by building collaborative relationships to enhance patient care.

Executive leadership at the originating and distant sites **shall** ensure that telestroke clinical leaders are appropriately positioned within the organization to participate in key decision-making forums with the authority to make necessary decisions. Policies and procedures **shall** reflect that telestroke roles are integrated into the Acute Stroke Response, as well as quality assurance processes and sentinel event reviews.

Escalation processes **should** be created and sustained to focus on patient safety and allow healthcare

professionals advocacy on behalf of patients and their families, regardless of practice setting. All healthcare professionals **should** have a mechanism to report, investigate, and resolve issues surrounding patient safety and quality. The mechanism **should** be non-punitive and sensitive to ensuring that the close collaborative relationship between telestroke consultants and receiving facility staff is not compromised. The same standards should be applied to providers participating in a distributed network through a provider organization or other cooperative arrangements. Ideally, providers may be part of a larger organization.

ROLES AND RESPONSIBILITIES

For successful operation of a telestroke system, there **should** be agreed upon key roles and responsibilities. There **should** be support and buy-in of key stakeholders, such as hospital administrators, information technology (IT), clinical personnel, human resources, legal, and finance, among others.

The Telestroke Hub/Distant Site Physician Director: The physician champion for telestroke at both the Hub/Distant and Spoke/Originating sites **shall** supervise the administrative issues that commonly arise. At the Hub/Distant site, the telestroke physician champion **may** be named medical director. This role **should** cultivate enthusiasm for telemedicine among other stroke center clinicians, develop and maintain relationships with Spoke/Originating telestroke sites, and design evidence-based care pathways. This role **may** be best served by a vascular neurologist or vascular neurosurgeon, or other stroke expert. Qualifications for this role **shall** include vascular neurology fellowship training or equivalent, attendance at courses in cerebrovascular diseases and telemedicine, and continuing medical education (CME) credits in stroke and telemedicine. A telestroke champion at the Spoke/Originating site **should** be familiar with telestroke protocols, telemedicine technology platforms, criteria for transfer to a site providing higher levels of care, referral arrangements, cerebrovascular disease, and telemedicine in general.

Telestroke Program Manager: This role, based at the Hub/Distant site, **should** interface with medical staff services, IT, legal offices at both the stroke center and at all supported Spoke/Originating sites/hospitals. This role **should** ensure contracts are in place, licensure and credentialing are current, training and education are being delivered, billing and coding are accurately performed, quality measures are in place, quality assurance processes are being followed, and overall administrative oversight is provided for the telestroke program, under the medical director's supervision.

Emergency Department Stroke Champion: ED physician roles at telestroke Spoke/Originating site facilities **should** include familiarity with telestroke alert criteria, processes and procedures for initiating a telestroke call and consultation, telemedicine technology platforms, and stroke clinical protocols. ED nurse roles **should** include interaction with Emergency Medical System (EMS) personnel, intake of an acute stroke patient, triage, recognition, rapid evaluation, and stroke treatment protocols.

Other Telestroke Roles: Qualifications for roles of other contributing telestroke providers **should** be focused on optimal acute stroke care, telemedicine technology proficiency, troubleshooting, and familiarity with working effectively within regional stroke systems of care. Other hospital provider roles **may** depend on the scope of the practice, but could include hospitalists, neurointerventionalists, intensivists, and radiologists.

Telestroke roles at Spoke/Originating sites **may** also include EMS personnel, Physician Assistants (PAs), Advanced Practice Nurses (APNs - Nurse Practitioners), laboratory and radiology personnel, IT administrators, or other personnel who are committed to training clinical providers and providing quality oversight to the program. The originating and receiving facilities shall designate an IT liaison with specialized training in the hardware, software, and clinical algorithms associated with telestroke services, as this role is critical to the seamless functioning of the technology. Many small or rural hospitals may not have the IT resources to ensure someone has specialized training. It could be the responsibility of the Distant Site and/or the telemedicine technology vendor to provide support to the Originating Site, depending on the arrangement and available personnel at the Originating Site.

The oversight **should** include a review of consecutive telestroke cases for timeliness of emergency evaluations, correctness of clinical decision-making, appropriateness of treatment delivery, and comprehensiveness of post-ED care for the patients not transferred to the stroke center.

For those organizations that utilize telestroke services for inpatients with suspected acute stroke syndromes, the same oversight should be applied. Additional personnel including hospitalists, neuro-hospitalists, rapid response teams, and other emergency responders would be included in these reviews.

HUMAN RESOURCE MANAGEMENT

The organization **shall** create guidelines for EMS, ED, general inpatient, and ICU settings which specifically describe telestroke processes, roles and responsibilities, appropriate staffing models, hours of operation (24/7/365 unless telestroke services are backfilling specific vacant time slots), methods of communication (e.g., telephone, video, Voice Over Internet Protocol [VOIP] audio integrated with video), procedures around routine and emergency stroke care delivery, and plan for escalation processes (e.g., power, equipment, or Internet failure, or patient requiring transfer to another facility for higher level of care or endovascular treatment). These guidelines **should** match the needs of the patient population and bedside healthcare professionals. Each organization **should** support orientation, staff development, and competency of telestroke programs. An On-Call list **shall** be available so that staff know exactly who to call when an acute stroke patient presents. Ideally, a single call **should** activate the acute stroke team, which includes the telestroke consultant.

HEALTH PROFESSIONALS: REGULATORY CONSIDERATION (ACCREDITATION/CERTIFICATION)

Telestroke professionals (typically Neurologists, Neurosurgeons, and Emergency Medicine physicians) **shall** be fully licensed, registered, and credentialed with their respective regulatory, licensing, and accrediting agencies, with consideration to administrative, legislative, and regulatory requirements of the site where the patient and Spoke/Originating site healthcare professional are located. This consideration **shall** include all federal and state regulations regarding prescriptive authority, and it **shall** be updated as changes occur. Credentialing via reciprocity processes **shall** be adopted to minimize recurrent paperwork burden on both ends.

State licensure and regulation rules are undergoing increasing national and regional debate. The ATA (www.americantelemed.org), the Federation of State Medical Boards (FSMB) (www.fsmb.org), and the Robert J. Waters Center for Telehealth & e-Health Law (CTel) (http://ctel.org) provide helpful resources for locating the most current state requirements for practicing telemedicine.

Healthcare professionals **shall** be aware of their locus of accountability and all requirements (including those for liability insurance) that apply when providing telestroke services. The telestroke leadership and the organization's legal counsel **should** insure that malpractice carriers are notified when a new clinician is planning to provide clinical services via telemedicine. Likewise, when a physician is no longer providing clinical care, the carrier **should** also be notified. The use of telestroke modalities **shall** establish a healthcare professional-patient relationship, which includes all responsibilities inherent in that relationship.

Telestroke healthcare professionals **may** need to negotiate with local facilities to allow an exemption from certain obligations contained in the facilities' regulations and bylaws (e.g., TB testing requirement, non-stroke related committee meetings) while providing telestroke services. These negotiations **should not** exempt telestroke healthcare professionals from participation in local hospital committees relevant to their telestroke programs.

Healthcare professionals providing telestroke services **shall** have the necessary clinical preparation, orientation, ongoing education, and professional development to ensure they possess the necessary competencies to promote quality care and patient safety.

PRIVACY AND CONFIDENTIALITY

Telestroke healthcare professionals and healthcare organizations in the United States **shall** incorporate the requirements for privacy and confidentiality in accordance with the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information for Economics and Critical Health Act (HITECH). In the United States, additional state regulations **shall** be followed for privacy, confidentiality, and patient rights; these may apply above and beyond requirements in place for general healthcare interactions. Telestroke services provided to patients physically located in other countries **shall** operate in conformance with the privacy laws in effect for that country. Other international laws **shall** be consulted and implemented as appropriate.

Policies and procedures **shall** address the privacy and security needs of the patient from both a technological and human rights perspective. Examples include capabilities, communication restrictions, and processes that protect patient privacy during remote audio/visual assessment. Providers should consult their legal counsel regarding recording consults.

Organizations providing telestroke services **shall** have policies to maintain patient privacy/confidentiality when visitors from outside of the organization tour the telestroke center/facilities/equipment.

All identified possible acute stroke patients and their families **shall** receive information, including the role of the telestroke program in patient management, the use of the technology, and assurance of confidentiality, as time permits in the emergent setting. Information not conveyed before the therapeutic interaction ensued can be communicated after treatment has been delivered and stabilization established.

Some state regulations **may** require consent for telemedicine consultations; therefore, these telemedicine consents **shall** be included as part of the organization's general consent process. Frequently, the telemedicine consent is included as part of the general consent for treatment.

FISCAL MANAGEMENT

Organizations **shall** establish budgets that encompass the cost of implementation, which may include such items as hardware, software, data lines, licensing fees, credentialing fees, call reimbursement, marketing and communication costs, personnel, supplies, and real estate. The budget **should** also include on-going expenses related to maintenance of the program, which **may** include such items as hardware and software upgrades, equipment replacements, and staff education.

The budget **should** also identify current and projected revenue for operating the telestroke services. Revenue items **may** include payer reimbursements, private contributions, grants, and general support from the healthcare facility and/or healthcare system.

Organizations **may** consider a financial model that addresses possible expansion and/or enhancement of the telestroke services. These modifications **may** include expansion to additional Spoke/Originating sites, additional equipment, and/or using existing equipment for other services such as teleneurology. Fiscal metrics **should** be customized to reflect the goals of the individual telestroke program, and they require regular reevaluation at the executive level.

MANAGEMENT OF PATIENT RECORDS

The telestroke program **should** use processes and policies for documentation, storage, and retrieval of health records, consistent with the organization, industry, and government standards. Interoperability **should** be prioritized to ensure the seamless flow of information between patient information systems to enhance clinical support and promote provision of emergency stroke care. Direct interfaces between the telestroke program and hospital electronic health records (EHRs), laboratory, pharmacy and bedside monitoring system represent the highest standards of interoperability. Due to the emergent nature of acute stroke management, and the reality that consultants often provide services at many different facilities, this ideal, two-way shared interface of information systems may not be feasible or realistic. However, this level of interface **should** be the goal.

DOCUMENTATION AND ELECTRONIC HEALTH RECORD

Policies and procedures regarding clinical documentation that originates from the telestroke service **shall** be established in compliance with organizational legal and risk management oversight. The goal of such documentation **should** be clarity of the telestroke clinical intervention (evaluation, assessment, consents, and recommendations) and a complete clinical picture, based on the available data in the telestroke consultant's note that is integrated into the patient's permanent EHR. If the patient is transferred, the telestroke consultation note **shall** be part of the records sent with the patient to the receiving facility.

Coordination, and when possible, integration of the EHR for telestroke consult documentation **should** be done as it is important for the prevention of errors and timely access to accurate patient data.

Dedicated telemedicine software packages **may** be used to facilitate standard telestroke consult documentation across a network, where direct access to the EHR is not feasible or practical.

WORKFLOW AND COMMUNICATION

Documentation policies and procedures **shall** be developed for the successful patient care hand-off or transfer of responsibility. Direct peer-to-peer communications **shall** be encouraged to minimize possible miscommunications.

DATA RETRIEVAL

There **shall** be the ability for the telestroke physician to access and review current data specific to the consult from Picture Archiving Communication Systems (PACS – a radiology image transmission system) to facilitate communication and the decision-making process. There **shall** be access to bedside data to further facilitate communication and decision making.

TELESTROKE TRAINING

Adequate orientation and training of EMS, hospital, ED staff, radiology technologists, and physicians participating in telestroke **shall** be offered, as it is vital to the success and collaboration between the remote Hub/Remote stroke consultant/neurologist and the onsite Spoke/Originating telestroke team. Ongoing training **may** be necessary during software upgrades, during quality initiatives, and for new hospital employees and physicians. For those originating facilities that access telestroke services on a part-time basis (e.g., off hours or nights/weekends – when there may be a gap in neurology coverage), there would be two algorithms for directing the acute stroke evaluation. As such, intermittent or mock training sessions may be warranted to ensure that staff on all shifts maintain competency with the use of telestroke when included in the acute stroke algorithm.

Training **should** encourage staff acceptance of the use of telestroke services. This training **should** include efforts to build trust and develop integrated team workflows, incorporating both onsite staff and remote physicians. Special training may be required.

PATIENT RIGHTS AND RESPONSIBILITIES

Patients and families **shall** be informed and educated about the role of telestroke in the integrated care delivery model. Use of remote healthcare professionals and audio/visual technology **shall** be included as part of telestroke specific patient education.

Healthcare professionals **should** be particularly mindful with the use of audio/visual technology for the provision of patient/family privacy with sensitivity to cultural considerations. Appropriate language translation services **should** be employed for patients and families, when appropriate.

Apprehensions regarding the role of telestroke and/or components of the audio/visual technology **should** be addressed collaboratively with the patient/family, the telestroke consultant, and the bedside team. They also may be addressed through organizational policies.

QUALITY AND OUTCOMES

Telestroke services **shall** have systematic quality improvement and performance management processes in place that comply with all organizational, regulatory, and accrediting requirements. The quality

indicators **shall** include administrative, technical, and clinical components for the provision of telestroke services. Further, they **shall** be used to make technical, programmatic, and clinical changes based upon best new evolving technology, practice principles, evidence-based guidelines, clinical research, and any changing service requirements.

Telestroke staff, administrators, and local stroke coordinators/champions **should** be aligned to meet specific program outcomes and process measures. In addition to shared goals, the hospital and telestroke service **may** have unique metrics based on their unique contributions to the program. A process for the reporting and dissemination of quality metrics and outcomes **should** be developed to facilitate both administrative and operational analyses.

Telestroke value is optimized by increasing quality and access while controlling cost. Ongoing monitoring and evaluation of costs, access, and quality **should** be performed by both the hospital receiving telestroke services and the telestroke providing organizations, to identify opportunities at each site for enhanced value.

Telestroke services **shall** have a process in place to monitor quality and outcome metrics. Domains of quality measures **should** include technology parameters, and process measures. The adequacy of video and audio connections during telestroke consultations and technology failures preventing adequate patient evaluations **should** be documented and reported. CT quality and readability are also important to telestroke assessments. Telestroke networks **should** record, at a minimum, times from door to CT scan, camera connection, completion of consult, and administration of intravenous alteplase, when applicable. For patients transferred for endovascular therapy, time to decision, and time from door-in to door-out are also important measures. The training of personnel involved in telestroke networks, including physicians, nurses, and administrators, **should** be defined and documented. Relevant outcomes **should** include percent of patients treated with intravenous alteplase, stroke mimics, transfers, complications, and patient and provider satisfaction. Quality and outcome measures **should** be reviewed by telestroke leadership on a regular basis. Results **should** be used to improve processes by a continual loop of feedback and reassessment. In Hub/Distant and Spoke/Originating networks, both Hub/Distant and Spoke/Originating sites **should** contribute to a common quality and outcomes monitoring process, and they **should** share results to ensure uniformity of patient care, implementation of improvements system-wide, and identification of opportunities for enhanced value.

RESEARCH PROTOCOLS/INCORPORATING CLINICAL TRIALS INTO TELESTROKE NETWORKS

Research involving telestroke's contributions to patient care and clinical outcomes and patient recruitment into larger studies, especially trials recruiting rural populations **should** be encouraged and supported by the organization; such research opportunities **shall** be in compliance with the organizations' institutional review board (IRB) approval process.

Telestroke networks **should** be encouraged to contribute to knowledge by offering patients the opportunity to participate in clinical trials. Using telemedicine, investigators can identify patients appropriate for clinical trials. Physicians performing telestroke consults **should** be aware of active clinical trials and the inclusion/exclusion criteria. Clinical features, details of history, and CT findings, can be reviewed remotely to select patients appropriate for specific trials. With accurate remote assessments, unnecessary transfers to assess possible trial candidates can be avoided. In some cases, the trial might be initiated at the remote site, and in other situations, a transfer may be necessary for the patient to be enrolled at a participating site. Identification and recruitment of patients from rural hospitals increases

the diversity of study populations and reaches areas not typically included in clinical trials. Recruitment through large telestroke networks also expands the pool of stroke patients contributing to higher enrollment, more rapid completion of studies, and greater opportunities for generalization. Telemedicine itself could be the subject of trials comparing telestroke and in-person evaluations. Research activities **should** always conform to study protocols and comply with good research practices, as outlined by the local or central IRBs.

PHYSICAL CONSIDERATIONS

The physical layout (including space, equipment placement, and secure examination space) and ergonomics of the ED, general admissions floor, and ICU **should** be addressed early in the telestroke planning process. This process **should** include input from clinicians, technology engineers, and physical plant engineers. Architectural design **should** consider communication essentials between and among telestroke team members and staff from the various potential care areas. These **may** include audio/visual equipment storage, wireless equipment placement, as well as dedicated bandwidth to provide stable, reliable communication, and assurance of quiet environments to allow clear, optimal interactions throughout the acute care facility. To facilitate its administration, storage of alteplase in the Emergency Department is strongly recommended.

NETWORKS

Hospitals receiving telestroke consultations will have varying services they can provide, but minimally include head CT scan imaging and administration of IV alteplase. If there is need for unavailable ICU care, additional stroke diagnostic workup or care, or endovascular intervention, transfer **should** proceed to the closest available and qualified facility by ground or air transport, as safety, time, or complexity concerns dictate. Prearranged network transfer protocols **should** help expedite and facilitate patient transfers to these destination facilities.

CLINICAL GUIDELINES

SETTING PROGRAM GOALS

Executive leadership **shall** direct both the telestroke and bedside stroke leadership in the review of program goals and the determination of priorities. Telestroke service is not designed to replace local services, but to complement or augment local stroke care through the leveraging of resources and the standardization of processes.

Operational execution **shall** be designed to attain program goals within defined standards of care. Telestroke programs frequently have similar goals including improved patient outcomes, cost savings, and the leveraging of resources, but the structure of each program may vary depending upon the organizational goals, types of available technical and human resources and types and sizes of acute care facilities receiving clinical service.

OPERATIONAL/SERVICE HOURS

Telestroke operational/service hours **should** be 24 hours per day, 7 days per week, and every day of the year. There **shall not** be down time except when the technology unexpectedly malfunctions. For all facilities, there should be a "back-up" plan in which the acute stroke team can rely on other communication modalities to confer necessary clinical information to make an informed recommendation for acute management.

TYPES OF PATIENTS SERVED

The executive, stroke, and telestroke leadership **shall** determine the scope of telestroke patient service. When the scope of the telestroke responsibility is determined, flexibility should be based on patient needs, available services, and maintenance of the standard of care, according to the goals of the telestroke program.

By definition, the telestroke service is designed to provide assessment, diagnosis, management, and disposition decision making services to patients with acute stroke. However, how an organization defines the utilization of the telestroke resource varies. The decision to provide telestroke services to all patients, regardless of classification (ischemic and hemorrhagic), severity, time since stroke onset, and treatment opportunities **should** be determined by the telestroke and stroke leadership team.

Additionally, some telestroke programs provide service to acute stroke patients located outside the traditional ED, such as in prehospital mobile stroke units, in ICUs, in medical or surgical units, and in interventional neuroradiological suites, with the use of either mobile devices or hardwired technologies. Mobile stroke units are a relatively new application in which an ambulance with a built-in CT scanner and telemedicine system are used with qualified medical personnel, to guide and support administration of IV alteplase in the field.

Some telestroke programs incorporate endovascular intervention. Patients requiring endovascular intervention may well receive IV thrombolytic bridging therapy. However, the clot burden may be too great to lyse with IV thrombolytic therapy alone. If available, these patients should be transferred rapidly to a comprehensive stroke center that has vascular interventionalists who may attempt invasive procedures to reopen an occluded vessel. For these patients, the timed emergent period is not over until the invasive procedure opens the vessel, or the procedure is determined to be contraindicated.

STAFFING MODELS

Telestroke network models generally consist of Spoke/Originating sites, where the acute stroke patients are located, and Hub/Distant sites where the telestroke provider is located. Telestroke models exist either as distributed staffing models or Hub and Spoke staffing models. In the distributed model, telestroke services are delivered to hospitals from providers at distant sites on a contractual basis. The distant providers generally have no affiliation with the hospital other than that concerning the discrete episode of care. If a patient requires a higher level of care, protocols exist to transfer the patient to a primary or comprehensive stroke center in the community. Staffing coverage for telestroke consults **may** be supplied by an independent for-profit company or by an organized group of providers. In the Hub and Spoke staffing network model, a regional stroke center generally provides telestroke services at the distant site to hospitals within the region (originating sites). The stroke staff members are generally

credentialed at the originating sites. When transfers are indicated, the regional Hub stroke center receives the patient from the Spoke hospital. Continuity of stroke care is provided, beginning by virtual care, and then (post-transfer) by direct in-person care.

TELESTROKE WORKFLOWS

Implementation of a time-sensitive and efficient workflow for telestroke services is the basis for a successful clinical operation for evaluating and managing suspected acute stroke patients using remote expertise. The workflow at the Spoke/Originating site **should** include a step-wise set of processes that outlines the practice for establishing a time window for identifying a suspected acute stroke patient, activating an acute stroke team for the rapid evaluation, and incorporating the actions for initiating a telestroke consultation into that process. Depending on the service model (hub and spoke vs distributed), the contracted services **may** have specific requirements for activating a consult, such as a time-to-call, turnaround-time response, and initial available patient-related information. The actual video-conferencing consultation component **should** mimic the bedside consultation in that the work-up **should** follow recommended guidelines for the evaluation and management of acute stroke. Consideration also needs to be given to the final disposition of the patient, depending on the recommendations for treatment and management. The workflow **should** include several options for post-telestroke care, such as "remains at the Spoke/Originating site" or "transfers to a higher level of care."

Required resources (i.e., personnel and equipment) needed for telestroke services **should** be clearly outlined in both the business plan and the workflow algorithm. This documentation applies not only to Emergency Departments, but also to facilities that have inpatient services that may require an acute stroke response team. For some facilities, telestroke services **may** have already been built in as an original component of their acute stroke services. For facilities that had established stroke code processes and are subsequently implementing telestroke services as a new option in their stroke code algorithm, the workflow **should** be modified to accommodate the additional resources. Regardless of the model, successful telestroke workflows **should** have built-in processes that can accommodate variations that inevitably arise during the hyperacute stroke phase by relating the interaction with other workflow processes, as well as considering factors such as volumes, workload, staff schedules, and technology interference. The orientation and training of personnel who interface with telestroke services encompass the multiple services involved with the acute stroke process, including the EMS teams, ED personnel, ancillary support services (radiology and diagnostic services), communications offices, and IT support. Training **shall** be organized and directed by the stroke program leadership, and it **should** be integrated into the general orientation to the stroke program.

The orientation of Telestroke Services **shall** consider the following:

Who needs to know?

- Pre-hospital EMS personnel
- Providers that will utilize the services
- Bedside practitioners (including ED and critical care staff)
- Radiology
- IT support
- Rapid response teams
- The community
- All new hires that may be involved

*What **should** be included?*

- The actual process
- What to do in case there is an IT failure
- Benchmark times

Content / Training / Competency

- Knowledge of specific roles in the process
- Mock codes
- Quizzes
- Providing and reviewing documentation
- Stroke team leadership
- Benchmark times
- Determining accuracy of the evaluation
- Ensuring a high-quality neurological exam in collaboration with the telestroke MDs
- Processes and procedures after the decision is made – no treatment, treatment, or transfer

Patient and Family Education

- Bedside providers and telestroke practitioners **shall** be responsible
- Pre- and post-encounter teaching
- Explanation of the service as part of the process
- Brief description – pictures encouraged
- Identification of community resources

INTEGRATION STRATEGIES

Stroke systems of care integrate regional stroke facilities, including acute stroke-ready hospitals that often have telemedicine and teleradiology capability, primary and comprehensive stroke centers, EMS, and public and governmental agencies and resources. The goals of creating stroke systems of care include stroke prevention, community stroke education, optimal use of EMS, effective acute and subacute stroke care, rehabilitation, and performance review of stroke care delivery. Essential to effective stroke systems of care are hospitals with the capacity and commitment to deliver acute stroke care, both in the ED and on the stroke unit.[13]

The telestroke team **should** consist of a broad range of clinical, administrative, and research members at both the Hub/Distant and Spoke/Originating sites to fulfill all aspects of the telestroke dynamic. Neurologists, ED physicians, nurses, and radiologists **should** collaborate on the provision of remote care for patients with acute stroke.[14]

To gain the endorsement of Spoke hospitals, a successful collaboration between neurology, neurosurgery/neurointerventionalists, and emergency medicine practitioners is essential. Collaboration between emergency medicine and neurology practitioners is likely the most important element of a successful telestroke program.[14]

Potentially efficient models of telestroke systems **may** use vascular neurology specialty-trained nurse practitioners, physician assistants, or neurology residents and fellows to perform preliminary triage, screening, and neurologic assessments. This preliminary work **should** then be followed by a reassessment or review by a supervising vascular neurologist, depending on applicable state laws. Having emergency medicine physician stroke leaders participate at Hub/Distant-and-

Spoke/Originating centers is a model that appears to be associated with program success.[14]

TECHNICAL GUIDELINES

EQUIPMENT

Organizations **should** refer to the ATA's Core Guidelines for Telemedicine Operations documentation for minimum technical requirements. Additional technical requirements or specifications unique to telestroke applications are described below. For the purposes of this section, we will distinguish between acute stroke evaluation in the ED or hospital setting (acute care) versus follow-up care rendered in the hospital, post-acute care, and the community (subacute) care.

Organizations **shall** provide technology that optimizes audio and visual clarity for enhancement of clinical assessment (i.e., real time, two-way audio visual solutions with minimal latency). Acute care interactions ideally require high quality video conferencing cameras, enabled with pan-tilt-zoom capability, whereas subacute care **may** be able to be rendered with simpler technology and fixed lens cameras, such as in laptops tablets or mobile devices. It is particularly important to ensure that any equipment used during the encounter **shall** meet the minimum technology and performance standards necessary, and they **shall** comply with all appropriate privacy requirements. If specific applications call for the use of peripheral devices or digitally capable medical equipment, such as stethoscopes, otoscopes, ultrasound devices, etc., these devices also **shall** adhere to recognized medical standards and be inter-operable with the telehealth encounter platform. Connectivity can be achieved through wireless or hardwired interfaces, but there **should** be redundant capability to ensure reliable performance. Organizations **should** provide adequate telecommunications bandwidth to connect near and far end equipment to support the program goals and ensure quality patient care services. The minimum bandwidth used **should** be determined in consultation with the clinical, information technology, and biomedical staff of all facilities for sufficient clinical diagnosis and data transfer. Because different technologies provide different video quality results at the same bandwidth, each end point **should** use bandwidth sufficient to achieve dependable and reliable quality service during normal operation. The adequacy of bandwidth **should** be tested during the expected hours of operation, to ensure that adequate bandwidth exists when consultations are likely to occur.

Ensuring adequate bandwidth for all times and equipment is especially important if providers or patients will be using personal devices to conduct these encounters. Adequate technical support **should** be provided to ensure compliance of these devices, proper functioning, and software compatibility. Periodic testing is necessary to meet these program goals. If using a personal computer or mobile device, the healthcare professional **should** conform with the IT policies of the enterprise. Devices **shall** have up-to-date security software that is HIPAA compliant. Healthcare professionals **should** ensure their personal computer or mobile device has the latest security patches and updates applied to the operating system and third party applications that may be utilized for this purpose.[15]

Healthcare professionals and organizations **should** utilize mobile device management software to provide consistent oversight of applications, devices, data configuration, and security of the mobile devices used within the organization.[15] When the healthcare professional uses a mobile device, special attention **shall** be placed on the relative privacy of information being communicated over such technology, and access to any patient contact information stored on the mobile device must be

adequately restricted.[15] This protection includes provider awareness of the physical environment in which they will perform the consultation, and the security of any mobile networks that might be accessed. Privacy screens and earphones **should** be considered for laptops or tablets that will be used or accessed in public spaces. All devices or applications **shall** require a passphrase, biometric identification, or equivalent security feature before the device can be accessed. If multi-factor authentication is available, it **should** be used.[15] All devices **should** be configured to utilize an inactivity timeout function that requires a passphrase or re-authentification to access the device after the timeout threshold has been exceeded. This timeout **should not** exceed 15 minutes.[15] If video clips are used, appropriate processes for disposition of those clips **shall** be in place.

Mobile devices **should** be kept in the possession of the healthcare professional when traveling or in an uncontrolled environment. Unauthorized persons **shall not** be allowed access to sensitive information stored on the device, or use the device to access sensitive applications or network resources.[15] Healthcare and institutional IT professionals **should** have the capability to remotely disable or remove data from any mobile device containing personal health information (PHI) or sensitive institutional data, should the device be lost or stolen.[15] Given the need for access to multiple services and systems by modern healthcare providers, policies **should** require unique user names and passwords for all providers to prevent sharing of access keys, and providers **should not** use the same username and passwords across multiple platforms unless the organization supports single sign on or federated authentication. Providers who must use multiple different username and password combinations **should** be encouraged to use password management software to generate and maintain strong passwords.

Telestroke applications **should** support at minimum point-to-point, and ideally, multiparty connectivity. Providers **should** be able to access the system from within or outside of the healthcare facility, using the same interface and user experience. Organizations **should** consider technology interoperability when selecting systems for integration of other telemedicine services or documentation systems. Interoperability will be increasingly important as telestroke applications enter mobile stroke units, post-acute care facilities, and other avenues of care delivery. Increasingly, organizations leverage telemedicine equipment to serve the needs of multiple clinical programs. Whenever possible, equipment used for telestroke **should** be adaptable to serve the needs of other clinical programs.

Systems **shall** comply with all current and applicable State and Federal laws and regulations, governing the use of medical devices and medical information, i.e., Food and Drug Administration (FDA), HIPAA, HITECH, Waste Electrical and Electronic Equipment (WEEE). All efforts **shall** be taken to make audio and video transmission secure by using point-to-point encryption that meets recognized and accepted standards. Systems **shall** comply with the Federal Information Processing Standard, the U.S. Government security standard used to accredit encryption standards of software, and lists encryption such as Advanced Encryption Standard (AES). Healthcare professionals **should** familiarize themselves with the technologies available regarding computer and mobile device security, and they **should** help educate patients.[15] If organizations intend to provide services to patients located in other countries, they **should** be aware of relevant technical restrictions placed on information systems technology exports to certain countries.

Organizations **shall** ensure proper testing and maintenance for all functionalities for each newly installed infrastructure or endpoint. Organizations **shall** implement planned and unplanned downtime procedures that ensure continued service and **may** include the use of appropriate backup technologies and clinical protocols. Examples may include: N+1 redundancy, device component redundancy, geographic dispersed infrastructure, fast failover, failure notifications/alerts, and/or documented on-call

procedures during planned or unplanned system downtime. Policies and procedures **should** proactively address ongoing equipment maintenance, anticipated equipment and software upgrades, performance of periodic remote tests for operation and functional verification, evaluation of resource allocation, and 24/7 technical support.

INFECTION CONTROL

Organizations **shall** have infection control policies and procedures in place for the use of telestroke equipment and patient peripherals that comply with organizational, legal, and regulatory requirements.

DATA POLICY AND PROCEDURE

Organizations **shall** implement policies that address adequate data storage and retrieval, device security, time zone management, and follow long term storage standards, such as Storage Management Initiative Specification (SMI-S). Recordings of audio or video footage **should** be performed with appropriate oversight and patient/provider consent, when appropriate. Maintenance and secure storage of all sensitive information **should** be governed appropriately with written policies and procedures. Access to this material **should** be restricted to those with legitimate needs. Organizations that document medical information in third party or electronic health record systems, other than the standard health record system of the requesting site or consulting site, **should** ensure these records are stored in a manner compliant with relevant privacy and security regulations. There **should** be a written policy for how this information is stored and communicated to the referring site or consulting site, as appropriate. If multiple providers contribute to the documentation of the clinical encounter, then all providers involved **should** be indicated in the documentation, as would be expected in a traditional face-to-face encounter. The organization **should** have written policies regarding the sharing of information about the quality of consultations or benchmark performance criteria that allow for continuous quality improvement within the telestroke network.

CONCLUSION

These telestroke guidelines were developed to assist practitioners in providing assessment, diagnosis, management, and/or remote consultative support to patients exhibiting symptoms and signs consistent with an acute stroke syndrome, using telemedicine technologies. These guidelines:

- Define commonly used telestroke terminology
- Introduce the need for telestroke
- Propose administrative and leadership structure, roles, and responsibilities
- Outline regulatory considerations for health professionals
- Review privacy and confidentiality considerations
- Establish fiscal management strategies
- Set out management principles for documentation and electronic health records
- Propose workflow and communication
- Highlight requisite training and qualifications for providers
- Establish patient rights and responsibilities
- Feature quality and outcomes
- Incorporate opportunities for research protocols

- Define physical and network considerations
- Present program and operational goals and expectations
- Display various staffing models and systems of care integration strategies
- Present technical specifications

Telestroke interactive encounters link patients with acute ischemic and hemorrhagic stroke and acute care facilities with remote and on-site healthcare practitioners to provide access to expertise, enhance clinical practice, and improve quality outcomes and metrics. When a clinical domain in telemedicine accrues a body of evidence supporting reliability and validity of the virtual examination, accuracy of the remote diagnosis and treatment management decision making, safety and efficacy of the telemedicine assessment, and clinical and cost effectiveness of the paradigm, it is sufficiently primed for implementation of guidelines designed for the telemedicine practitioner, administrator, and technician alike. Such is the state of telestroke today.

APPENDIX

DEFINITIONS

Terms and definitions that are commonly used in telemedicine/telestroke are available on the American Telemedicine Association (ATA) website. For this document there are several terms that need to be defined specifically:

"**Distant Site**" - Telestroke provider location; sometimes used interchangeably with "Hub Site" when referencing a Hub and Spoke Network.

"**Distributed Network**" - A model in which telestroke services are provided to multiple originating sites through arrangements with an independent corporation or an affiliated network of telestroke providers. In this setting, transfer agreements for endovascular therapy or subsequent stroke care should be defined in advance to facilitate all aspects of acute stroke care.

"**Endovascular Intervention**" - Intra-arterial thrombolysis or mechanical thrombectomy for selected patients with large vessel occlusions identified during the acute telestroke interaction.

"**Health Professionals**" - Individuals engaged in the provision of healthcare and health-related services.

"**Hub**" - Typically a comprehensive tertiary care center where vascular neurologists and other acute stroke specialists comprise a call panel delivering telestroke services to network affiliate/partner sites - "spokes." If a patient requires transfer to a higher level of care, a hub is usually the destination. Some networks may have multiple hubs.

"**Hub and Spoke**" - Networks of primary, secondary, and tertiary care settings that provide care to specific patient populations. Networks may vary in sophistication, with many working as loose

coalitions of segregated services. Typically, specialty care is provided to patients at remote settings (often rural emergency departments) by specialists affiliated with larger, more comprehensive tertiary care centers. Models are changing with an emphasis on keeping patients in their local community when possible, depending on the available level of care.

"**Organization**" - Groups, institutions, and business entities.

"**Originating Site**" - Patient location; sometimes used interchangeably with "Spoke Site" when referencing a Hub and Spoke network model.

"**Shall, Should, and May**" - This document contains requirements, recommendations, or actions that are identified by text containing the keywords "shall," "should," or "may." **"Shall"** indicates a required action, whenever feasible and practical under local conditions. These indications are found in bold throughout the document. **"Should"** indicates an optimal recommended action that is particularly suitable, without mentioning or excluding others. **"May"** indicates additional points that can be considered to further optimize the healthcare process. **"Shall not"** indicates that this action is strongly advised against.

"**Spoke**" - The affiliate or partner site in a telestroke network, underserviced or under supported by neurologists, where patient services are delivered.

"**Telemedicine**" - Telemedicine is the use of medical information exchanged from one site to another using electronic communications in an effort to improve consumer health status. Videoconferencing, video clips, transmission of still images, e-Health including patient portals, remote monitoring of vital signs, continuing medical education, and nursing call centers are all considered part of telemedicine. Telemedicine is not a discrete medical specialty. Products and services related to telemedicine frequently are incorporated as part of a larger investment by healthcare institutions in either information technology or delivery of clinical care, or both. Even in the reimbursement fee structure, there is commonly no distinction made between services provided on site and those provided through telemedicine. Separate coding for billing of remote services **may** be required. Telemedicine encompasses a broad range of patient programs and services, requiring different providers and consumers.[1]

"**Teleneurology**" - Broad application of telemedicine to the field of neurology, both acute and ambulatory care.

"**Telestroke**" - A network of audio-visual communication and computer systems which provide the foundation for a collaborative, inter-professional care model focusing on acute stroke patients. Telestroke service is designed to augment local services that are not immediately available by leveraging remote expertise and resources and the standardization of processes. It is a subdivision of teleneurology, involving telemedicine consultation for the treatment of neurovascular patients. The most common application of telestroke is for acute stroke patients (pre-hospital and hospital), but telemedicine services may extend well in advance and well beyond that time frame, and they may offer a wide variety of additional services from wellness, remote monitoring, disease prevention, subacute, rehabilitative, and re-integration into the community phases. While the primary role of telestroke is the facilitation of acute stroke patients' care, common stroke mimics will be identified and treatment recommendations may be offered.

"**Telestroke Network**" - A group of primary, secondary, and tertiary care settings that provide acute stroke care to their patient population. Telestroke networks consist of originating sites where the patients are located, and distant sites where the telestroke provider is situated. Telestroke systems exist either as a distributed or a hub and spoke model.

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