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LEGAL CONSIDERATIONS IN THE USE OF TELEMEDICINE FOR THE MANAGEMENT OF STROKE

Stroke remains a top killer and cause of disability in the United States and worldwide. The use of telemedicine for acute stroke evaluation and management, termed *telestroke*, was developed in an attempt to extend best practices provided by stroke specialists. More than a decade since its introduction into the medical literature, telestroke is in the mainstream of clinical practice. The legalities and legislation relevant to telestroke practice to date are either complex, outdated, or absent, representing a barrier to the use of telestroke.

Background

Stroke is a major public health problem in the United States[1] and throughout the world.[2] There has been a concerted effort to apply evidence-based practices to stroke care in order to improve primary and secondary prevention as well as poststroke outcomes. One facet of this effort includes the development and accreditation of primary and comprehensive stroke centers, which have been demonstrated to improve stroke care.[3] The prompt and guideline-based administration of an acute stroke evaluation and management are among the more heavily scrutinized aspects of a stroke center.[4] The rationale for the particular attention to expedient administration of acute stroke evaluation and therapy is sound, given the limited time window for administration of the only Food and Drug Administration-approved therapy for acute stroke, recombinant tissue plasminogen activator (rt-PA).[5]

Geography contributes to a disparity in stroke care, however, because most stroke centers are based in large, urban academic medical centers. It is estimated that more than 40 percent of the United States population resides outside the reasonable clinical reach of a primary stroke center. This previously presented a considerable barrier to the timely administration of acute stroke therapy. Furthermore, there remains a shortage of vascular neurologists, who are otherwise best-equipped to provide desired outcomes,[6] to meet the heavy demands of incident stroke.

In an attempt to combat the rural-to-urban disparity and expand the availability of best stroke practices, Levine and Gorman proposed the development of telemedical outreach for acute stroke evaluation and management, which they called telestroke.[7] Since then, the practice of telestroke has been found to have a high inter-rater agreement with a bedside examination[8] to enhance correct rt-PA decision making as compared to telephone-only consultation,[9]and to be cost-effective.[10]In light of these findings and the perception of benefit by acute stroke providers and patients, there has been growing interest in and a rapid expansion of telestroke networks both in the United States[11] and internationally.[12]

Legal Considerations of Telestroke

In spite of a robust and growing evidence base supporting the use of telemedicine in general and telestroke in particular, there are a host of legal considerations that constitute a barrier to more widespread implementation. Among them are disparate licensing and credentialing requirements among each state and nation. Furthermore, current means of coding telemedical care and arbitrary restrictions on eligibility for reimbursement serve as a financial disincentive to establish a telestroke network. In addition, informed consent and privacy concerns are other considerations with legal ramifications that require special attention as compared to in-person medical consultations.

Licensure

The essence of telemedicine is to disseminate medical expertise to patients and local providers irrespective of geographical boundaries. Currently, medical licensure and hospital credentialing processes run counter to that principle, as they are predicated almost entirely on geography. In the United States, medical licensure is under the purview of an individual state. Furthermore, in most states, a physician must be licensed in the state where a patient seeks care. Thus, a telemedicine physician must undergo the rigorous licensure process in nearly each and every state and US territory. The exceptions, which have a mechanism to grant a telemedical license for practitioners licensed in another state, include Alabama (Ala. Code § 34-24-502), Louisiana (La. Rev. Stat. Ann. §1276.1), Minnesota (Minn. Stat. § 147.032(1)), Montana (Mont. Admin. R. 24.156.802(5)), Nevada (NRS § 630.261(e)), New Mexico (NM Stat. Ann. 1978 § 61-6-6), Ohio (Oh. Rev. Code Ann. § 4731.296(C)), Oregon (Or. Rev. Stat. Ann. § 677.139), Tennessee (TCA § 63-6-209(b)), Texas (22 Tex. Admin. Code § 174.12) and Guam (10 G.C.A. § 12202). The Federation of State Medical Boards proposed the Model Act in 1995, which would afford a licensed physician in any state the privilege to practice telemedicine across state lines, limiting in-person medical care to the primary state of licensure. This act has not been formally accepted by any state to date, although the aforementioned states that grant telemedicine licensure based on a medical license in good standing elsewhere in the United States have enacted its basic tenet. A recent piece of federal legislation (42 CFR §§ 482.12 and 482.22) helped to streamline the process of being credentialed for a telemedicine site by allowing the credentialing process of the hub site to effectively "transfer," so as to better avoid onerous, duplicative administrative barriers.

Reimbursement

Reimbursement mechanisms for medicine have not kept pace with the expanded clinical use of telemedicine. The Centers for Medicare and Medicaid Services, the most prominent payer in the US health care system, requires that concurrent care by more

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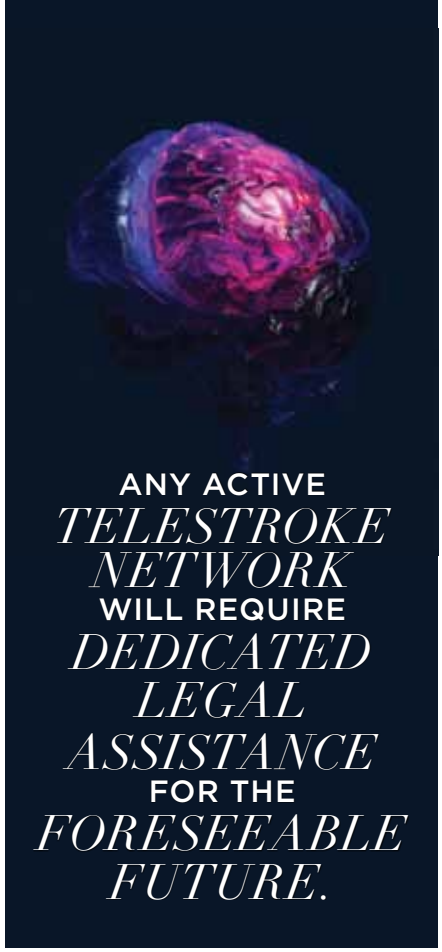
than one provider be medically necessary (42 USC § 1395y(a)) as well as that the consultation originates within arbitrary geographical constraints designated as rural for reimbursement of service. Although these stipulations are ostensibly reasonable, in practice only very few payments are provided for telemedically guided care of Medicare beneficiaries. In addition, the current federal definition of *rural* does encompass all underserved populations; thus, a provider is given a financial disincentive to practice telemedicine in other nonrural underserved areas. Nineteen states have enacted provisions that compel private insurers to cover a telemedical consultation, but the lack of a clear federal standard—Medicare payments are considered a benchmark for most medical services—leads to general ambivalence as to how telemedical services should be reimbursed, which may impede investment of resources by physicians and industry.

Informed Consent

The nature of an interaction between a medical provider and patient, in person or via telemedicine, shapes the plan of care in a fundamental way. Although experienced providers of telemedical care may argue that the warmth and empathy considered vital to a strong doctor-patient relationship is achievable to a similar degree when compared to in-person consultation, this has yet to be systematically studied and may not uniformly be the case. Among the more important elements of providing care of any sort is the informed consent process, which is heavily contingent upon the doctor-patient relationship. An interesting recent study sought to evaluate the adequacy of the informed consent process for delivery of rt-PA for acute stroke patients evaluated by telestroke.[13] The adequacy of informed consent was adjudicated by two physicians who provide stroke care with regularity, a paralegal, a bioethicist, and a layperson. There was significant variability in their responses, but overall, the group felt that the benefits, risks, and alternatives were adequately explained and understanding demonstrated in most (80%) of the 20 cases scrutinized. The authors' conclusion was that a standardized tool should be in place for time-sensitive medical emergencies being evaluated by telemedicine such that informed consent is provided in a more uniform fashion. In the era of high-quality videoconferencing for medical consultations, one can make the argument that the informed consent process should be considered no different via telestroke than in person, so long as a concerted effort is made by the telemedicine physician to establish the doctor-patient connection in spite of geographical separation.



Privacy

The right to privacy of medical records is considered fundamental and is protected by federal law (45 CFR § 160) in the form of the Health Insurance Portability and Accountability Act (HIPAA). Compliance with HIPAA is necessary whether medical information is transmitted by hand or over the Internet. Privacy and security of the telemedicine systems can be maintained by secure site license (SSL) conditional access, data encryption, intruder alerts, and access logging and reporting. The integration of security features into modern telemedical hardware and software ensures HIPAA compliance for telestroke consultations. Given the new ubiquity of smartphones and their high-quality videoconferencing capability, the desire to employ these inexpensive handheld devices for telemedicine must be matched by a HIPAA-compliant means of doing so, including the use of virtual private networks (VPN) or closed wireless networks.

Telestroke-Specific Legal Concerns

Many legal and legislative issues exist for the use of telemedicine in general, but there are some that are particularly relevant to telestroke. Some who are wary of developing a telestroke network cite the lack of legal clarity at a federal level (or even in most states) regarding shared liability between hub and spoke sites in the case of a bad outcome. For the case of acute stroke, because it seems that the majority of stroke-related lawsuits come from rt-PA *not* being administered, institution of a process that affords emergency medicine providers access to stroke specialists and that has been shown to increase rt-PA use should mitigate this concern. That said, there is still a role for establishing clear legal agreements between hub and spoke sites, be they via federal law or on an individual basis.

Overall, the practice of telestroke is alive, well, and in a growth spurt. The evidence base for its use as a boon to patients, providers, and society is strong and growing as well. Our laws have not kept pace with this growth, state-specific governance impedes standardization, and these reasons impede further expansion of telestroke use. There are clear signs of improvement, however, as numerous states are taking steps to modernize their telemedicine provisions and encourage its use through reimbursement. For many reasons, however, any active telestroke network will require dedicated legal assistance for the foreseeable future to navigate within the current climate of medicolegal and financial uncertainty. ◆

Endnotes

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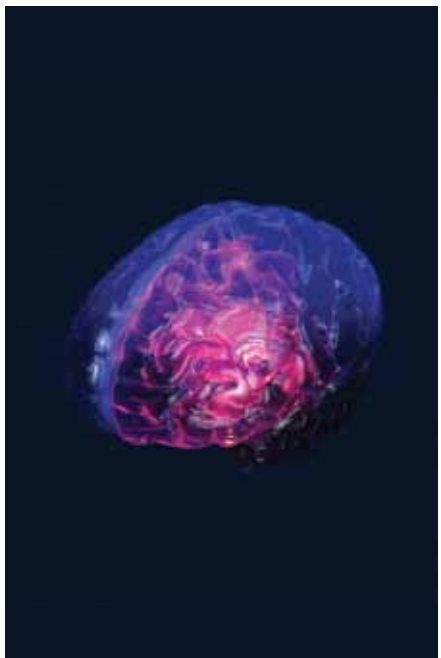

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