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# United States Medicolegal Progress and Innovation in Telemedicine in the Age of COVID-19: A Primer for Neurosurgeons

Telemedicine has received increased attention in recent years as a potential solution to expand clinical capability and patient access to care in many fields, including neurosurgery. Although patient and physician attitudes are rapidly shifting toward greater telemedicine use in light of the COVID-19 pandemic, there remains uncertainty about telemedicine's regulatory future. Despite growing evidence of telemedicine's utility, there remain a number of significant medicolegal barriers to its mass adoption and wider implementation. Herein, we examine recent progress in state and federal regulations in the United States governing telemedicine's implementation in quality of care, finance and billing, privacy and confidentiality, risk and liability, and geography and interstate licensure, with special attention to how these concern teleneurosurgical practice. We also review contemporary topics germane to the future of teleneurosurgery, including the continued expansion of reciprocity in interstate licensure, expanded coverage for homecare services for chronic conditions, expansion of Center for Medicare and Medicaid Services reimbursements, and protections of store-and-forward technologies. Additionally, we discuss recent successes in teleneurosurgery, stroke care, and rehabilitation as models for teleneurosurgical best practices. As telemedicine technology continues to mature and its expanse grows, neurosurgeons' familiarity with its benefits, limitations, and controversies will best allow for its successful adoption in our field to maximize patient care and outcomes.

**KEY WORDS:** Telemedicine, Teleneurosurgery, Medicolegal, COVID-19, Innovation

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elemedicine is defined as remote delivery of synchronous or asynchronous clinical services. Over the last 25 yr, telemedicine's development has rapidly grown in conjunction with the maturation of internet technology.<sup>1</sup> Increased broadband speeds, improved highdefinition camera quality, and growing potential in machine learning for algorithmic prediction of diseases in remote diagnoses and interventions<sup>2,3</sup> have led to increases in telemedicine

ABBREVIATIONS: CARES, Coronavirus Aid, Relief, and Economic Security; CMS, Center for Medicare and Medicaid Services; COPPA, Child Online Privacy Protection Act; EARN IT, Eliminating Abusive and Rampant Neglect of Interactive Technologies; HIPAA, Health Insurance Portability and Accountability Act; HITECH, Health Information Technology for Economic and Clinical Health Act; IMLC, Interstate Medical Licensure Compact; MSA, metropolitan statistical area development and utilization across disciplines, including telestroke,<sup>4</sup> teledermatology,<sup>5</sup> teleintensive care unit (ICU),<sup>6</sup> and teleradiology.<sup>7</sup> Telemedicine's adoption into neurosurgery has been historically limited because of the nature of neurosurgical practice, limiting applications to predominantly outpatient follow-up and postoperative care.<sup>8</sup> The COVID-19 pandemic has pushed neurosurgeons toward telemedicine adoption, limiting exposure and conserving personal protective equipment to curb viral transmission. Virtually overnight, telemedicine has become an integral part of neurosurgical practice and has the potential to significantly influence the field's future.

Recent government policies have facilitated adoption of telemedicine technologies in response to COVID-19, but there remain considerations affecting the impact of teleneurosurgery, including universal access, necessary technology and overhead,<sup>9</sup> favorable medicolegal measures and reimbursement framework, interinstitutional collaboration,<sup>9,10</sup> and buy-in from providers and patients alike.<sup>11</sup> State and federal prepandemic regulatory frameworks have led to an inconsistent and sometimes burdensome patchwork regarding licensure and training, financing and billing, malpractice and liability, and privacy and confidentiality. Understanding how to navigate these barriers and potential opportunities may help neurosurgical practices increase overall access and innovate for better patient care, especially when considering temporary policies included in the Coronavirus Aid, Relief, and Economic Security (CARES) Act with pre-existing telemedicine policies and regulations.

# **MEDICOLEGAL BARRIERS IN TELEMEDICINE**

#### **Licensure and Training**

Historically, physicians practice within the state in which they are licensed.<sup>12</sup> Proper certification safeguards patients against fraud and abuse. Telemedicine widens the neurosurgeon's reach and catchment area by enabling provision of clinical services at a distance and the continuing growth of telemedicine has resulted in a significant number of providers serving multiple patients across state lines.<sup>12</sup> Practicing in multiple states may require the physician to pay for costly and time-consuming certification from each state's medical board. The Interstate Medical Licensure Compact (IMLC) addresses some of these issues by providing a way to bypass standard medical licensure processes with participating states issuing reciprocal licensure to physiciansin-good-standing.<sup>13</sup> Thirty-four states, including the District of Columbia, and 2 territories have either passed, implemented, or introduced legislation the IMLC. The 5 states that have introduced bills to join the IMLC are further identified on the Table.<sup>13</sup> The lack of a unifying federal policy for national licensure and reciprocity has led to uncoordinated approach by individual states at their own legislative timeline based on local resources and priorities and, as a result, the slow uptake of IMLC.

Given recent surges in telemedicine demand, many institutions needed to certify their physician workforce quickly and efficiently. Prior to a Center for Medicare and Medicaid Services (CMS) 2011 rule change,<sup>14</sup> hospitals individually verified and vetted every physician through costly and lengthy processes. Today, credentialing is streamlined through certification by proxy, in which an institution may grant telemedicine privileges to any of their providers as long as the institution meets specific requirements.<sup>15</sup> During the COVID-19 pandemic, fast-tracked credentialing processes were implemented, enabling prospective providers to be credentialed in as little as 30 min through an online course; such processes are likely to remain in place after the COVID-19 peak because of logistical expediency. One neurosurgical department was able to rapidly convert their outpatient visits to telemedicine visits within 1 wk.<sup>16</sup>

Proving malpractice in the United States can be a complicated affair, which considers the communication between patient and physician within the context of events surrounding an alleged case.<sup>17</sup> Adding another layer of complexity and distance between the 2 parties, as with telemedicine, further complicates malpractice determination. One major feature of malpractice claims is reliance upon standards of care and best medical judgment.<sup>18,19</sup> The CARES Act has enabled physicians to operate through temporary waivers of statutory penalties for the pandemic duration so long as the physician practices in good faith to deliver care.<sup>20</sup> Rapid expansion and evolution of telemedicine is likely to require new and comprehensive telecare practice guidelines and laws to clarify liability as well as the extent of billable services.

Telemedicine for medical appointments has been heralded as an efficient and effective method of practice.<sup>21</sup> However, in neurosurgery, a remote exam may prove problematic when subtle neurological changes are examined. There are well-acknowledged technical limitations to the remote physical exam, such as the inability to accurately assess for findings such as tone, detailed motor strength, or masked cranial nerve findings.<sup>21,22</sup> Additionally, physical exams may be limited among individuals with pain and immobility, introducing even more uncertainty and making accurate assessments challenging. Nonetheless, given the need to balance the risk of malpractice against the importance of socially distancing through an ongoing pandemic,<sup>23</sup> neurosurgeons and advanced practice providers have found innovative ways to test for neurological symptoms via telemedicine, such as using household items to evaluate for spine pathology.<sup>24</sup> The extent of uncertainty telemedicine has on general communication between neurosurgeons and patients when discussing complicated procedures or obtaining consent is also unclear and has the potential to increase the risk legal liability. There is limited research on the prevalence of liability associated with telemedicine.<sup>25</sup> Because of the very recent uptake and increase in telemedicine in neurosurgery, it is difficult to adequately predict the true risk of medicolegal liability of remote care as insufficient time has passed for a full evaluation. In addition, as the use of telemedicine becomes more widespread in neurosurgery, it is likely that liability related to the shortfalls of telemedicine would be recognized and litigated when appropriate.

## **Digital Privacy and Confidentiality**

The 1996 Health Insurance Portability and Accountability Act (HIPAA) created national standards to protect personal health information from unwanted disclosure. HIPAA is the dominant legal framework for healthcare privacy and confidentiality, together with other laws such as the Health Information Technology for Economic and Clinical Health Act (HITECH) and the Child Online Privacy Protection Act (COPPA). The slow adoption of telemedicine before the pandemic can be at least partly attributed to the necessarily steep requirements to ensure

State	IMLC partici- pation <sup>13</sup>	Commercial payer statutes <sup>36,40</sup>	Telemedicine reimbursement parity <sup>40</sup>	Qualified services reimbursed under state Medicaid <sup>36,40</sup>	
				Store-and- forward	Remote patien monitoring
Alabama	Y	N	Ν	Ν	N
Alaska	N	Y	Y	Ν	Ν
Arizona	Y	Y	Ν	Ν	Ν
Arkansas	N	Y	Ν	Y	Y
California	Ν	Y	Ν	Y	Ν
Colorado	Y	Y	Ν	Y	N
Connecticut	Ν	Y	Ν	Y	Y
Delaware	N	Y	Y	Y	Y
Florida	Ν	Y	Ν	Ν	Ν
Georgia	Y	Y	Y	Y	Y
Hawaii	N	Ŷ	Ý	Ŷ	Ŷ
daho	Y	N	N	N	N.
llinois	Y	Y	N	N	N
ndiana	N	Y	N	N	N
owa	Y	Y	N	N	N
Gwa Kansas	Y	Y	N	Y	N
Kentucky	Y	Y	Y	Y	N
ouisiana	Y	Y	N	N	N
Maine	N	Y	N	Y	Y
Maryland	Y	Y	N	N	N
Massachusetts	N	Y	Ν	N	N
Michigan	Y	Y	Ν	N	Ν
Vinnesota	Y	Y	Y	Y	N
Mississippi	Y	Y	Ν	Y	Y
Missouri	I	Y	Y	Y	N
Montana	Y	Y	N	Y	N
Nebraska	Y	Y	N	Y	Y
Nevada	Y	Y	Ν	Ν	N
New Hampshire	Y	Y	Ν	Y	Y
New Jersey	1	Y	Ν	Y	Y
New Mexico	Ν	Y	Y	Y	Y
New York	N	Y	N	N	Ν
North Carolina	Ν	Ν	Ν	Ν	Ν
North Dakota	Y	Ŷ	N	Ŷ	N
Dhio		Ý	N	Ŷ	N
Oklahoma	Y	Ý	N	N	N
Dregon	1	Y	N	N	N
Pennsylvania	Y	N	N	N	N
Rhode Island	ř N	Y	N	Y	N
		Y N		Y N	N
South Carolina	N		N		
South Dakota	Y	Y	N	N	N
Tennessee	Y	Y	N	Y	N
Texas	I	Y	N	N	N
Jtah	Y	Y	Y	N	N
/ermont	Y	Y	Ν	Y	N
/irginia	N	Y	Y	Ν	Y
Washington	Y	Y	Ν	Y	Ν
West Virginia	Y	Ν	Ν	Ν	Ν
Wisconsin	Y	Ν	Ν	Ν	Ν
Vyoming	Y	N	Ν	Ν	Ν
Washington, District of Columbia	Y	Y	Ν	Y	Y

patient privacy in the digital space.<sup>26</sup> In 2019, tens of millions of protected health information records were reportedly involved in data breaches in the United States<sup>27</sup>; the frequency and sophistication of cyberattacks continue to grow.<sup>28</sup>

Despite security challenges, the duty to protect patient confidentiality remains paramount, necessitating secure encryption in synchronous or store-forward asynchronous clinical encounters to prevent unwanted information disclosures. A provider can use several strategies to mitigate risks, such as using a secure connection and maintaining a private space to conduct patient encounters. In agreeing to a telemedicine evaluation, the patient takes responsibility for provision of privacy and security on their end of the digital encounter, an environment the health provider cannot control. This may not be practical or feasible, as physical privacy and device security may be difficult for individuals living with others or using shared devices.

There have been legal challenges to secure encryption, the most recent being the Eliminating Abusive and Rampant Neglect of Interactive Technologies (EARN IT) Act of 2020,<sup>29</sup> like similar attempted bills before it, seek to purposefully weaken secure encryption and hardwire backdoors for law enforcement in the surveillance of illegal activity. However, opponents of the law argue that backdoors can be exploited, leaving companies and entities, including practicing physicians, vulnerable, particularly in light of HIPAA and patient-provider confidentiality.<sup>30</sup>

Integrated service digital networks, advanced encryption standard 5, and virtual private networks are 3 security solutions to answer the growing threat of unwanted data breaches.<sup>31</sup> One emerging technology that may hold promise is blockchain.<sup>32,33</sup> Blockchain technology utilizes a master ledger with decentralized information designed to resist modification. The integrity of the online data mining currency Bitcoin<sup>34</sup> depends on blockchain technology's security protocols and ability to identify unique individuals and discern who has secure access to privileged information. Blockchain may serve a comparable role in telemedicine networks, authenticating proper access to patient information and further protecting physicians from potential data breach malpractice claims. However, before a robust blockchain security infrastructure can be developed within healthcare, significant roadblocks must be addressed, including steep computing requirements and protocol development.<sup>35</sup>

#### **Reimbursement and CMS Limitations**

Although licensure and privacy are certainly part of why adoption has been slow pre-pandemic, the most substantial hurdle in setting up a clear, uniform framework for telemedicine has been the often confusing and inconsistent regulatory patchwork governing billing and reimbursement. Although the deregulatory 1135 Waiver in response to the COVID-19 pandemic has temporarily eased reimbursement restrictions, before the pandemic, CMS had notable geographical limitations to where patients should be located to be eligible for reimbursement, including hospitals, physician offices, skilled nursing facilities, or within a statistically rural area.<sup>14</sup> There are a few instances in which geographical limits may not apply, such as dialysis centers, mobile stroke units, and home care for substance use disorders.<sup>36</sup> Additionally, the list of technological services and types of patient encounters eligible for reimbursement is not guaranteed.<sup>36</sup> CMS generally limits reimbursement in favor of synchronous technology, ie, a live patient encounter. Store-andforward and other asynchronous technologies that do not require the presence of the patient cannot bill for services under Medicare despite emerging evidence that such technologies may be an overall net positive in cost savings.<sup>37-39</sup>

Other policies govern CMS telemedicine reimbursement; however, additional payment structure and how telemedicine is defined and practiced is primarily the responsibility of state legislatures, which collectively lack broad reciprocal consensus on telemedicine reimbursement beyond video conferencing technology. As of 2020, asynchronous technology is billable in only 24 states, billable services at home in 19 states, and reimbursement for remote patient monitoring in 12 states (Table).<sup>36,40</sup> As of October 2019, 42 states and the District of Columbia have laws governing private insurance reimbursement for telehealth measures (Table), but only 10 offered true "payment parity" in which healthcare systems were guaranteed a similar reimbursement rate for in-person and telehealth services. States with true payment parity laws at that time included Virginia, New Mexico, Delaware, Georgia, Utah, Arkansas, Missouri, Kentucky, Hawaii, and Minnesota.<sup>40</sup>

## **COVID-19 AS OPPORTUNITY**

The COVID-19 pandemic has reshaped political appetite for telemedicine reforms in the immediate and near future. In March 2020, the United States enacted the CARES Act, providing 3 notable changes to boost the telemedicine adoption in response to the pandemic. First, the Secretary of Health and Human Services was given the right to waive statutory Medicare coverage requirements for telehealth, including that patients be outside metropolitan statistical areas (MSA) and that providers have a prior face-to-face relationship with the patient in the last 3 yr. Second, payment parity for reimbursable telemedicine services to match in-person visits was mandated for the pandemic duration. Additionally, temporary relaxation of HIPAA laws allowed for a more flexible and inclusive definition for what telemedical services may be reimbursed under Medicare and Medicaid, including audio-only technologies, remote patient monitoring, and home care services. Finally, \$27 billion USD was allocated in increased funding for telehealth to address healthcare infrastructure and access shortfalls in telemedicine, workforce development, and coronavirus testing.<sup>20</sup>

The reimbursement waiver to help enforce payment parity temporarily resolves the issue of financing, but there is a need for a more flexible national standard regarding reimbursable remote services. Part of this may entail revising some HIPAA provisions

to incorporate lessons learned during the pandemic, such as the possibility of allowing patients to proactively provide information to physicians on an as-needed basis (ie, store-and-forward).<sup>41</sup> By clarifying flexible standards of care that leave room for future growth and taking guidance from leading physician organizations, greater parity, and agreement may emerge at the state level. Retooling guidelines and laws to allow reimbursement for storeand-forward,<sup>42,43</sup> remote patient monitoring,<sup>44,45</sup> and expanded homecare<sup>46,47</sup> coverage for chronic conditions could significantly improve the clinical capacity of neurosurgeons while decreasing overhead and time on administrative tasks.<sup>48-50</sup> For example, patients with chronic spinal cord injuries may benefit from a more integrated, home-based care model in which telemedicine, through innovative transitional rehabilitation models, helps to bridge the gap between patients' limitations and need for care.<sup>47</sup> Indeed, there is emerging evidence that other areas of neurosurgery-related telerehabilitation such as poststroke care may provide similar benefits of increased access and integration with other established protocols such as robotic assistance, virtual reality, and speech therapy.<sup>51</sup> With greater standardization of telecare, the passage of national or state-by-state mandates for private insurance payment for telemedicine services will be easier to justify, in turn easing provider anxieties around financing the telemedicine capabilities of their practice.

A careful consideration of which policies should be continued postpandemic will be critical to help patients realize the full benefits of increased access to care through telemedicine. Abolishing prepandemic rationale for limiting telemedicine coverage to non-MSA locations opens the door to greater equity of access for underserved communities in urban and rural areas. Although access disparities within urban centers exist outside the COVID-19 pandemic,<sup>52</sup> disparity of COVID-19 outcomes further highlights the uneven access to care and greater negative impact upon communities of color.<sup>53</sup> Access to adequate care in underserved communities may improve by removing the physical distance and economic opportunity costs associated with inperson visits. Additionally, eliminating required prior face-to-face contact may facilitate improved access to subspecialists such as neurosurgeons by increasing availability and reducing financial barriers.

# **EMERGING APPLICATIONS IN TELEMEDICINE**

Increasing data have been published on telemedicine use in neurosurgery as the pandemic has progressed. One study has shown that patients highly value the use of telemedicine in postoperative appointments, decreases travel time, is safe, and does not compromise patient outcomes.<sup>54</sup> A study in India evaluating telemedicine in postoperative care for patients who had undergone neurosurgical procedures showed similar results, with significant cost-effectiveness in an environment with limited resources.<sup>55</sup> In the study, over 3000 telemedicine visits were carried out over a 6-yr period for postoperative patients from

a 1500-km catchment area, resulting in a 85% reduction in associated cost of visit with a saving of over US\$250 000 over the 6-yr period. Importantly, no obvious adverse events have been associated with the use of telemedicine. A separate study evaluating cost-effectiveness in teleneurosurgery follow-ups supports these results.<sup>49</sup> The advent of telemedicine, reducing time and costs associated with routine perioperative care traditionally managed in person, allowing more time for new patient consultation, additional operative time and other pursuits, may prove to be a paradigm shift in neurosurgery.<sup>56</sup> Furthermore, the use of telemedicine in neurosurgical practice may be of particular value in resource-scarce periods or settings.<sup>57</sup> The COVID-19 pandemic has significantly reduced the in-person patient volume of neurosurgical services as seen by the decreased number in neurosurgical operations, clinical visits, and inpatient consultations with an inverse increase in the use of telemedicine for remote neurological assessments.<sup>58</sup> This trend highlights the importance of making the most of telemedicine for the benefit of patients requiring neurosurgical assessment and management.

Neurosurgery devices that can be monitored and programmed remotely offer a unique opportunity in telemedicine. Patients with implanted deep brain stimulation devices, for example, may be restricted in their ability to visit specialized centers because of geography, financial consideration, and limited support systems.<sup>59</sup> Next-generation devices in epilepsy and hydrocephalus that can be accessed and programmed remotely lend themselves to telemedicine.<sup>59,60</sup> Such devices can potentially monitor patients in real time with strategies to alert the provider and patients before a problem becomes clinically apparent.

The successful implementation and integration of telestroke the use of telemedicine in the hospital for patients undergoing evaluation and management for cerebrovascular insult—has shown remarkable success both domestically and internationally.<sup>9,61</sup> Telemedicine has facilitated communication with community and rural hospitals to appropriately manage patients, including transferring care to a comprehensive stroke center during complicated scenarios as required. Analyses have repeatedly shown that clinical outcomes using telestroke are equal to in-person care and further reduce hospital and societal costs.<sup>62-65</sup>

Telesurgery, or the use of robotics to perform hospital rounds and surgical procedures, is another emerging telemedicine component.<sup>66,67</sup> Currently, nearly 50% of the US population is more than an hour away from tertiary medical centers capable of providing adequate neurosurgical care, rehabilitation, and/or stroke management.<sup>66,68</sup> The deployment of robotic platforms may help reduce geographical disparities in neurosurgical care and extend the range of high-volume centers of excellence. This may be critical in a field such as stroke care, in which high-volume centers have demonstrated significantly better outcomes than low-volume centers.<sup>69</sup> In addition to elective surgeries, management of teletrauma appears to show positive results in emergency surgeries.<sup>70</sup> Another area that shows great promise for neurosurgery is telementoring and collaborative

teleconsultation for complex surgical cases. Telementoring allows surgical knowledge to be disseminated into otherwise underserved and rural areas and expand local neurosurgical capability, which may limit unnecessary, costly hospital transfers while flattening the geographic burden of neurosurgical care.<sup>71-73</sup>

Despite early successes, more research is required to understand which aspects of the surgical encounter, including pre-, peri-, and postoperative care, can be performed remotely. There is skepticism on whether routine surgical care can effectively be telemonitored given that some cases necessitate close postoperative follow-up and quick action to prevent catastrophic complications.<sup>74</sup> Also, current robotic platforms may be prohibitively expensive in the short term, despite potential long-term economic benefit,<sup>66</sup> meriting caution until these technical issues are addressed. Aside from technical and feasibility challenges, several legal and ethical concerns are worth noting. The first is the need for FDA approval, as the efficacy and safety of these proposed remote interventions will need to be examined with greater scrutiny. Second, updated legal frameworks for telepresence in surgery will need development and clarification to provide a framework regarding a standard of remote surgical care.<sup>66</sup> Lastly, how remote practice affects the provider-patient relationship will need examination. A positive physician-patient relationship has a number of effects, one of which, in terms of medicolegal issues, is the reduced rate of malpractice claims.<sup>75</sup> It is unclear how these dynamics may change if consultations and routine follow-up visits are conducted remotely.

## CONCLUSION

Telemedicine has experienced a dramatic growth amidst the COVID-19 pandemic but remains limited in neurosurgery.<sup>76</sup> Significant barriers in actualizing telemedicine's potential in neurosurgery remain, ranging from medicolegal issues around reimbursement and tort reform to patient confidentiality, access to technology, and patient-provider comfort. However, telemedicine has also served to facilitate the neurological assessment of many patients unable to be seen in person, holding much promise to its continued use in neurosurgery.<sup>76</sup> As telemedicine technology and policies involving its use continue to evolve, neurosurgeons remaining engaged and well informed in the nuances and challenges surrounding its successful implementation may be better equipped to provide quality neurosurgical care to patients otherwise unable to receive it in both the pandemic and postpandemic era.

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