

Executive Summary

Telemedicine is the utilization of information and telecommunications technologies to provide healthcare services when patients and providers are not in the same location. These services span a broad continuum from simple text messages and phone conversations, to the transmission of radiological images and surgeries performed through remote robotics. While telemedicine services have the potential to bring greater access to isolated patients and improve collaboration between treating physicians, the quality of care provided by these services and the cost-effectiveness are not certain. Rapid growth in the use of telemedicine has generated questions regarding the nature of the doctor-patient relationship; what was once a simple human interaction is now an ambiguous connection across state and national boundaries. Concerns regarding regulation, liability and privacy in the telemedicine context may be preventing greater adoption of telemedicine and limiting the ability to study its effects in practice.

Background

Since the late nineteenth century, doctors have been performing some version of telemedicine. From telephone consultations to diagnose diphtheria to today's remote monitoring of intensive care units, telemedicine has a long history and even greater potential for the future¹. Now defined as "*the use of electronic information and communications technologies to provide and support health care when distance separates the participants,*" telemedicine has a wide variety of applications within the US healthcare system.² Primary care and specialist consultations, transmission of diagnostic images, remote patient monitoring, health education and follow-up services, and continuing medical education are just some of the current uses of telemedicine.³

Over the past 40 years use of telemedicine services has grown substantially throughout the United States.⁴ Currently over 50% of all US hospitals have some sort of telemedicine capacity, with 200 telemedicine networks and 3,500 service sites nationwide.⁵ The Veterans Administration completed over 300,000 remote consultations in 2011, and approximately 1 million US patients have cardiac implants that are monitored remotely.⁶ In addition to domestic uses, telemedicine – teleradiology in particular – has opened the US healthcare market to foreign doctors who provide remote consultations during overnight shifts when on-site staff is limited.⁷

Supporters argue that patients benefit from greater access to high quality care at lower cost through the use of telemedicine. For patients in rural areas who may be unable or unwilling to travel for routine or specialized care, telemedicine substantially increases access to providers. Between 1996 and 2004, 85% of rural counties qualified as Health Provider Shortage Areas (1 primary care physician per 100,000 population) at least once.⁸ Telemedicine networks, such as the one developed by the Oklahoma State University of Osteopathic Medicine, connect dozens of rural community hospitals, clinics and mobile workstations with urban hospitals and research centers.⁹

On the other hand, quality outcome studies conducted in the last few years have shown mixed results for a variety of telemedicine applications. The evidence suggests that telemedicine provides better or equal quality of care for conditions such as heart disease and psychiatric illness.¹⁰ Proof of cost-effectiveness for telemedicine is also debated due to the high start up costs and wide variability between services. In one study of veterans with chronic conditions, home telehealth and coordination of care services led to a 19% reduction in hospital admissions and 25% reduction in bed days of care.¹¹ Another meta-study of telemedicine found that only teleradiology showed clear cost-effectiveness, while other services were comparable to standard practice.¹²

Given the wide variety of possible applications, telemedicine occupies a grey-area within the health policy and legal frameworks. As of February 2014, 34 states and the District of Columbia have pending legislation related to telemedicine.¹³ Laws addressing reimbursement, consent, online prescribing and licensure for telemedicine vary by state.¹⁴ In 2013, 11 state medical boards could issue a telemedicine license to practice across state lines, while 57 state boards required the physician to be licensed in the state where the patient is located.¹⁵ Medical malpractice and liability standards have not been established due to a lack of telemedicine-focused cases. With the rise in international telemedicine – in which the provider is a foreigner contracted to provide remote consultations – it is unclear who is liable in the event of an adverse outcome.¹⁶ Finally, reimbursement from both Medicaid and private insurers varies considerably throughout the country depending on the state, type of service, and where it is provided.¹⁷

Evidence

The evidence used throughout this document was collected from academic, government and industry-funded sources. For assessments on the quality of care associated with telemedicine services, conclusions from peer reviewed medical journals took precedence and were not limited to studies that took place in the United States. Information regarding the extent to which telemedicine is used in practice was garnered from both industry publications and testimony given before the FTC by trade associations. Searches of the academic literature were conducted using PubMed, LexisNexis and Google Scholar, and standard Google search for non-academic publications. Search terms included: telemedicine, telemedicine quality of care, telemedicine cost effectiveness, teleradiology, telemedicine laws/regulation.

Problem

The problems associated with telemedicine can be attributed to the challenge of fitting new technology into the conventional notion of the doctor-patient relationship, and the implications that this has on the current regulatory and legal frameworks. Redefining the doctor-patient relationship to include telemedicine requires that we clarify who is practicing medicine, when and where this practice occurs, what services are rendered, and how liability is defined. Only with a

standardized definition of the doctor-patient relationship will providers truly embrace the potential of telemedicine without fear of litigation.

The medical licensing system that allows each state to certify and regulate healthcare workers has led to nationwide inconsistency in defining who is licensed to practice telemedicine. Advocates of the state-based system emphasize the value of state's rights while opponents accuse medical boards of anti-competitive and rent-seeking behavior. In addition, inconsistent definitions of where medical treatment or diagnosis takes place – in the location of the patient or the provider – cause confusion for licensing, reimbursement, and liability. Some states require that doctors be licensed where the patient is, while others do not, or that the physician-patient relationship does not begin without a face-to-face meeting.¹⁸ Medicaid requires that patients, but not providers, be located at designated facilities. Reimbursement by private insurance varies by state, with various services mandated for coverage.¹⁹

The growth of specialist practices and international contractors further complicates the doctor-patient relationship in terms of liability. In the event of an adverse outcome, some courts have taken the position that hospitals should be held accountable while other courts have ruled that the independent contractor is to blame.²⁰ With patients often unaware whether their x-ray is being read down the hall or in India, there is sufficient asymmetry of information to cause concern. Finally, the transmission of sensitive patient information across long distances increases the need for secure information systems and privacy protection.

Policy Options

Develop a Nationally Recognized License to Practice Telemedicine

Under the current legislation, each state has the authority to license and regulate health professionals operating within that state. It is possible for individual physicians to receive a waiver to practice in a different state from where they were licensed, but this requires significant time, administrative effort and payment of annual fees.²¹ One-time allowances are occasionally made for providers to consult with out-of-state specialists in special circumstances so that patients can access their “talents and expertise...without having to travel” but requirements for these exceptions are not uniform.²² Some states and the American Medical Association have attempted to bar out-of-state physicians from consulting via telemedicine, which supporters of telemedicine claim is rooted in a desire to protect financial interests.²³

The development of a nationally recognized medical license – or a more limited telemedicine-only license – could resolve the issue of state-by-state licensing, which is anti-competitive in nature. This national license would allow patients greater access to specialists without the added physical hardship and financial burden of travel. Such a program is not unheard of, as demonstrated by the success of the Veteran's Administration licensing program, which accepts providers who have a valid license from any state regardless of where they practice.²⁴ The

adoption of a national licensing program for telemedicine consultations would allow states to ensure provider competence while giving patients greater access to care.

Recommend Clarification of Malpractice Standards

Malpractice, tort and civil procedure laws related to conventional medical practice already vary considerably between states. Many of these statutes will cover future telemedicine cases, but due to the “novel jurisdictional issues presented by telemedicine encounters,” the existing legal framework is not sufficient to protect either patients or physicians. Where the physician-patient relationship was previously defined under “simple contract procedure,”²⁵ in which both parties had equal information regarding the transaction, courts have accepted new definitions of this relationship, including third party contracting, implied consent, care that is rendered for the patient’s benefit, and in situations where no direct contact occurs.²⁶

The FTC could recommend that state legislatures clarify malpractice and tort law in relation to telemedicine, as well as evaluate existing malpractice insurance coverage. States would not be required to adopt any new malpractice legislation, but would be made aware of the loopholes that currently exist in relation to liability in telemedicine. Since few courts have handed down rulings regarding telemedicine cases, this would give states the chance to establish clear guidelines for future cases, particularly those that involve inter-state consultations.

Establish Guidelines for Data Transfer to Ensure Protection of Patient Privacy

Inherent to telemedicine is the need to share sensitive patient information across great distances, sometimes via telephone conversations but often through the transfer of medical records or images. Transmission of patient’s personal identification information – such as one’s address, insurance status, or social security number – in addition to their personal health information requires that security standards be in place to meet all HIPAA requirements. While large hospitals are likely to be equipped with secure data management systems for electronic patient records, it is possible that smaller clinics or private practices are not as well protected from cyber attacks. In order to protect patient privacy, the FTC could mandate that all systems used for the transmission of patient records for telemedicine services meet a nationally uniform standard. This would be especially pertinent to store-and-forward services, in which patient information is collected and transmitted through secure email, and for direct communication between patients and providers via non-secure email. Setting standards for what sort of information can be transmitted, by whom, and with what level of consent is vital for the protection of patient privacy.

Recommendation: Develop a National Telemedicine License

The greatest barrier to expansion of telemedicine services within the United States is the limit placed on providers by state licensing requirements. These

restrictions limit competition by preventing inter-state medical practice and harm consumers by limiting access to providers, specialists in particular. The FTC is in the position to develop a nationally recognized telemedicine license based on the Veteran's Administration model. This model will ensure that all practitioners of telemedicine are both competent in their medical knowledge and educated on the unique aspects of telemedicine (i.e. privacy and liability considerations). Loosening the restrictions on telemedicine will also encourage the expansion of the telemedicine industry, which will result in greater competition to develop high quality systems. This expansion will provide the data necessary to make more accurate cost-benefit calculations and will allow providers to make more informed choices as to what telemedicine services they wish to offer.

The first step toward the development of such a national license will require coordination with state medical boards, which will likely be hesitant to relinquish their control over license revenues. Compromise with these bodies – through the sharing of administrative costs or equal division of licensing fees – will be necessary to gain their support. Coordination with the American Medical Association would be ideal, as they share an interest in protecting provider interests. Finally, regulatory changes are likely to spur new legislation that will address the issues of liability and privacy.

¹ Bennett Thomas, "Telemedicine in the 1990s: Issues and Opportunities," *New Telecom Quarterly* 4 (1998): 29.

² Marilyn J. Field, Ed., *Telemedicine: A Guide to Assessing Telecommunications for Health Care*. (Washington DC: The National Academy of Science, 1996).

³ "What Is Telemedicine?" American Telemedicine Association, Web. 24 Apr. 2014.

⁴ Calvin Bruce. "Telemedicine: Growth and Impact." *Healthcare Review*. September 1, 2010. <http://www.healthcarereview.com/2010/09/telemedicine-growth-and-impact/>

⁵ "What Is Telemedicine?" American Telemedicine Association, Web. 24 Apr. 2014.

⁶ Ibid.

⁷ Thomas R. McLean and Edward P. Richards Teleradiology: A Case Study Of The Economic And Legal Considerations In International Trade In Telemedicine *Health Affairs*, 25, no.5 (2006):1378-1385. doi: 10.1377/hlthaff.25.5.1378

⁸ Mark P. Doescher et al. "Persistent Primary Care Health Professional Shortage Areas (HPSAs) and Health Care Access in Rural America." *Rural Health Research Center: Policy Brief*. September 2009.

⁹ Janice Francis-Smith. "Demonstrating the amazing potential of telemedicine." *The Journal Record*. Oklahoma City, Ok. March 16, 2004.

¹⁰ "Examples of Research Outcomes: Telemedicine's Impact on Healthcare Cost and Quality." American Telemedicine Association. April 2013.

¹¹ Ibid.

¹² Risto Roine, Arto Ohinmaa, David Hailey. "Assessing telemedicine: a systematic review of the literature." *Canadian Medical Association Journal*. 165 (6) 2001: 765-71.

¹³ "State Telehealth Laws and Reimbursement Policies: A Comprehensive Scan of the 50 States and the District of Columbia." Center for Connected Health Policy: The National Telehealth Policy Resource Center. February 2014.

¹⁴ Ibid.

¹⁵ "Telemedicine Overview: Board-by-Board Approach." Federation of State Medical Boards. June 2013.

¹⁶ Thomas R. McLean and Edward P. Richards "Teleradiology: A Case Study Of The Economic And Legal Considerations In International Trade In Telemedicine" *Health Affairs*, 25, no.5 (2006):1378-1385

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- ¹⁷ "What Are the Reimbursement Issues for Telehealth?" *Health Information Technology and Quality Improvement*. US Department of Health and Human Services, Web. 24 Apr. 2014.
<http://www.hrsa.gov/healthit/toolbox/RuralHealthITtoolbox/Telehealth/whatarethereimbursement.html>
- ¹⁸ Tara Kepler, Charlene L. McGinty. "Telemedicine: How to assess your risks and develop a program that works." *American Health Lawyers Association*.
http://www.healthlawyers.org/Events/Programs/Materials/Documents/HHS09/kepler_mcginty.pdf
- ¹⁹ "What Are the Reimbursement Issues for Telehealth?" *Health Information Technology and Quality Improvement*. US Department of Health and Human Services, Web. 24 Apr. 2014.
- ²⁰ Thomas R. McLean and Edward P. Richards "Teleradiology: A Case Study Of The Economic And Legal Considerations In International Trade In Telemedicine" *Health Affairs*, 25, no.5 (2006):1378-1385
- ²¹ "Comments by the American Telemedicine Association before the Federal Trade Commission Examining Health Care Competition." March 10, 2014.
- ²² Marilyn J. Field, Ed., *Telemedicine: A Guide to Assessing Telecommunications for Health Care*. (Washington DC: The National Academy of Science, 1996).
- ²³ David Pittman. "FTC Set to Join Telemedicine Debate." *MedPage Today*. March 1, 2014.
<http://www.medpagetoday.com/MeetingCoverage/HIMSS/44551>
- ²⁴ "Potential Costs of Changes in Licensing Requirements Outweigh Benefit." *United States General Accounting Office*. May 1999.
- ²⁵ Tara Kepler, Charlene L. McGinty. "Telemedicine: How to assess your risks and develop a program that works." *American Health Lawyers Association*.
- ²⁶ *Ibid.*