Medicolegal and regulatory aspects of whole slide imaging-based telepathology

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Abstract

Telepathology is lauded for its potential to overcome geographic barriers and bring expert diagnostic opinions to underserved regions. However, the legal and regulatory aspects governing its use in the United States and abroad are disparate and incomplete. In addition, there is essentially no case law that specifically addressed telepathology. Important issues to consider for the implementation and practice of telepathology, including state and regional licensure requirements, credentialing and privileging, liability and medical malpractice coverage, privacy and security, medical device regulation, and reimbursement for services are reviewed here for several regions, including the United States, Canada, the European Union, and China.

Keywords digital pathology; international law; medical devices; medicolegal; regulations; telemedicine; telepathology; whole slide imaging

Introduction

A commonly held maxim is that law lags behind technology, and telepathology is no exception. Telepathology has its roots in "television microscopy", a technology first demonstrated in the 1950's, yet telepathology itself — literally, the practice of pathology at a distance — has remained a niche application. The earliest forms of practical telepathology emerged in the 1980's and relied primarily on robotic microscopy platforms or direct point-to-point video. Whole slide imaging (WSI), where digital representations of glass slides are created and presented in a store-and-forward manner, has now largely replaced earlier technologies as the preferred platform for telepathology.[1] While WSI and traditional video based microscopic telepathology (manual or robotic) are divergent approaches to providing telepathology services, they share a common legal and regulatory environment. WSI, under the guise of the marketing-friendly term "digital pathology", differs enough from traditional microscopy that it has received additional scrutiny as an emerging medical device.[2]

Interest in telepathology has accelerated as digital pathology has matured, and the rush to adopt it has had both altruistic and financial motivations. Like music, movies, and popular media before it, the conversion of an old medium (glass slides) to digital bits brings with it industry-changing disruptive potential. With the availability of sufficient bandwidth and computing power, reviewing a digital slide across national or international borders is equivalent to reviewing it down the hall. Erasing geographic barriers through networking and telecommunications has the potential to extend general pathology services to underserved populations, as well as allow accessibility to real time, on-demand subspecialty expertise. This article will review the legal and regulatory aspects governing the use of telepathology today, both in the United States and internationally.

Terminology and scope of this discussion

For the purpose of this review, the term "primary diagnosis" refers to the rendering of a definitive diagnosis by the pathologist of record. A "secondary diagnosis" refers to either: 1) a formal consultation between the pathologist of record and a consulting pathologist or 2) a second opinion diagnosis sought by a clinician or patient after a primary diagnosis has been rendered. In both cases, this discussion assumes that final diagnoses are rendered entirely using WSI and without the use of the original glass slides. Intraoperative diagnosis (e.g. frozen section diagnoses), when applicable, is discussed separately.

When discussing telepathology, the "transmitting site" is where an image is acquired (presumably near where the patient received their care) and the "receiving site" is where the interpretation is performed.

Lastly, the content of this article constitutes the opinion of the authors and should not be misconstrued as legal advice. Prior to initiating any telepathology-based diagnostic services, one should review any local, state/provincial, and federal applicable regulations, statutes, laws and treaties. One should also consult with one's medical liability insurance provider to ensure that the proposed telepathology services are covered. Finally, the ethics of performing telemedicine in general (not covered in this article) should be reviewed prior to implementing any telepathology services.[3]

Issues to consider

There are a number of distinct issues that must be considered when discussing the practice and implementation of telepathology, including licensure requirements, credentialing, liability and medical malpractice coverage, medical device regulation, reimbursement for services, and privacy and security.

Licensure

Licensure requirements for telepathology depend greatly on the nature of the services provided (primary versus secondary diagnosis) and the locales of the transmitting and receiving sites. It is a safe and recommended practice to have a valid medical license for both the transmitting and receiving sites when providing a primary diagnosis via telepathology. However, because locales differ in how they define the "site at which medicine is being

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practiced", exceptions to this rule do exist. In general, secondary diagnosis requires only a license at the receiving site. Again, exceptions exist, and in many cases, secondary diagnosis telepathology is not specifically addressed by local regulations. Intraoperative diagnosis is addressed even less frequently, but all groups that have reported on their frozen section telepathology practice have elected to be licensed at both the receiving and transmitting sites. We recommend that formal intraoperative diagnosis be treated as a primary diagnosis in this respect.

Since an individual that practices medicine without appropriate licensure may be subject to both criminal charges and civil damages, it is vitally important to confirm licensure requirements before initiating telepathology services.

Credentialing and privileging

Credentialing is the process of regularly confirming the validity of a physician's credentials to practice medicine, whereas privileging is the process of authorizing physicians to provide specific services within a healthcare organization. In the case of using telepathology to render a primary diagnosis where the transmitting site is part of a healthcare organization (such as a hospital), the transmitting site may require both credentialing and privileging of the pathologist at the receiving site prior to rendering primary diagnoses within the transmitting organization. Further, because of how regulatory agencies, such as the Centers for Medicare and Medicaid Services (CMS), define a facility, this may be true even in cases where the transmitting and receiving sites are facilities within the same umbrella organization (e.g. in a large multi-hospital network).

Jurisdiction and choice of law

Jurisdiction refers to the court system with legal authority to bring a case to trial. Choice of law is a subsequent stage in the legal process that determines which law applies when the laws of two involved legal jurisdictions are in conflict. Choice of law can be agreed to in advance in contracts, but when it is not, the applicable law (the "proper" law) must be determined after a dispute arises. In telepathology, numerous factors, including the nature of the relationship between parties, laws in the transmitting and receiving sites, and the residences and nationalities of the parties, may influence the choice of law.

Liability, malpractice and malpractice insurance

Proving a malpractice claim requires several criteria to be met: 1) a physician–patient relationship must have existed, 2) the physician must have been negligent in that relationship, 3) the negligence must have led to injury, and 4) the injury must have resulted in damage. Of these criteria, the first is the most debated in the pathology, especially in the realm of secondary diagnosis.[4] If a formal report is issued and a fee charged, a relationship appears to be established. Contrast this to informal teleconsultations, intradepartment teleconsultation, or purely probono international work, and the nature of the relationship becomes less clear.

The issue of negligence is also complicated by telepathology. Negligence is established as a deviation from the local standard of care, but if the transmitting and receiving sites are in substantially different locations, questions arise as to which is the "local" site and therefore which standard of care should be applied. Standard of care in medicine is generally defined as what a reasonable and prudent physician would do in similar circumstances.[5] This also raises the question — does telepathology have a different standard of care than traditionally-rendered diagnostic services?

Although telepathology has great potential to improve patient care, it also adds new risks to the practice of medicine. Problems with hardware, software, and communications could introduce delays or inadvertently cause harm to patients. If it's determined that telepathology has a different risk profile than traditional pathology, one's professional liability (malpractice) insurance could possibly not cover telemedicine activities at all. Malpractice insurance may also be limited to certain jurisdictions, leaving the pathologist at the receiving sites essentially uninsured against claims in suits arising at transmitting sites. These issues must be clarified with insurance providers prior to offering telepathology services.

Medical device regulation

WSI systems are hardware and software elements that comprise a medical device. According to the U.S. Food and Drug Administration (FDA), a medical device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is … intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals …". The FDA has declared (at the time of this writing) that WSI systems are Class III devices and require premarket approval. Interestingly, the FDA has indicated that premarket approval will only be required for primary diagnosis. Secondary diagnosis and intraoperative diagnosis appear to be outside the scope of the FDA's opinion. Although device manufacturers have reportedly begun clinical studies of WSI for primary diagnosis, there have been few recent updates on this topic, and WSI systems remain "Research Use Only" devices in the United States.

The regulatory bodies in Canada and Europe have been more readily accepting of WSI systems as medical devices. Since 2013, several WSI systems have received their Class II Medical Device License from Health Canada.[6] The story is similar in Europe, where several WSI systems now hold a European Union CE Mark for In Vitro Diagnostic Devices.

Reimbursement

Reimbursement is a consistent concern in telemedicine. In many cases, services requiring face-to-face or physical contact with patients are not reimbursable when performed remotely unless special billing rules or codes exist. Since there are essentially no differences between telepathology and traditional glass slide services, the assumption has been that no new mechanism of payment is required for telepathology. Some have even suggested an added premium to incentivize the increased access to services that telepathology enables. International telepathology presents its own issues — principally, how to get paid by international clients for services rendered abroad.

Privacy and security

The issues of patient privacy, informed consent, and security of patient data do not differ significantly between telepathology and