



Original contribution

Medicolegal aspects of telepathology

Stanley T. Leung MD, JD*, Keith J. Kaplan MD

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Summary A pathologist may practice telepathology in another room from the original slide using the hospital intranet, he/she may practice it if a CD-ROM is reviewed with a “virtual histologic image” or digital slide. As pathology becomes increasingly subspecialized, and pathologists are progressively more engaged in practices situations where they may not be in a centralized laboratory location, use of telepathology technology may be increasingly common. We touch on select medicolegal and reimbursement issues in the practice of telepathology. Primary and secondary legal sources are reviewed, as well as primary medical references. Telepathology is an evolving area of telemedicine. Guidelines for primary opinion telepathology should be driven from best practices in conventional laboratory procedures and can enhance the practice of pathology. However, it should be undertaken with the understanding that the legal and regulatory environment involving such practices is evolving as well. © 2009 Published by Elsevier Inc.

In simplest terms, telepathology is the interpretation of transmitted digital histologic images while physically separated from the derivative glass slides. The key is not the distance that separates the viewer from the slide but the interpretation of histologic data visualized on a computer monitor. A pathologist may practice telepathology in another room from the original slide using the hospital intranet or if a CD-ROM is reviewed with a “virtual histologic image” as well as a digital slide. The use of the Internet has expanded the capability for whole slide images or static images to be reviewed remotely at a distance from the point of care.

The concepts discussed in this document should be generally applicable to all 3 types of telepathology: static (store and forward), dynamic (synchronous), and hybrid (static-dynamic) implementations.

We address a few of the medicolegal issues facing the practice of telepathology in the United States.

Patient safety has historically been the purview of state law through defining the practice of medicine and licensing

of its practitioners. Telemedicine presents unique issues to the states which seek to protect its residents from the distant practice of medicine. For instance, many states with large rural populations have developed complex telemedicine laws because of the utility of this technology in underserved rural areas, while many states in the densely populated East Coast do not refer to telemedicine in its statutes or regulations. Interestingly, Texas and California, states with large rural areas as well as large urban populations, have some of the most comprehensive telemedicine laws and regulations involving everything from public health and professional licensure to insurance and public utilities.

1. Definition

Telemedicine is the process by which doctors in one location can treat patients in another, aided by a fast Internet connection and specialized equipment. It can be as simple as digital transmission of an x-ray or pathology slide for interpretation by a remote expert or as complex as a surgeon

* Corresponding author.

E-mail address: sleung@qcmetro.com (S. T. Leung).

operating on a patient halfway around the world using a virtual interface with robotic instruments. Remote telemonitoring of intensive care units is another example. In simplest terms, telepathology is the practice of digitizing histological or macroscopic images for transmission along telecommunication pathways for diagnosis, consultation, or continuing medical education [1].

Each state that addresses telemedicine defines telemedicine based upon the purpose of the definition; however, generally, such statutes refer to the use of technology for the delivery of health care services when the provider of such services and the patient are not in the same physical location. Not only can these definitions vary between states; they can vary within the state depending upon the statute.

The Federal government also has varying definitions of telemedicine from the Centers for Medicare and Medicaid Services, the Food and Drug Administration, and the Rural Utilities Services. For example, statutes and regulations refer to telemedicine as “telehealth,” “interstate practice of medicine,” “remote medicine,” or “practicing medicine by electronic means.”

For the purpose of this document, telepathology will be defined as electronic, multimedia communication between pathologists for the purpose of primary diagnoses and diagnostic consultation second opinion. It may also be extended to include similar diagnostic communication between other physicians (nonpathologists) and a laboratory staff by qualified laboratory personnel—trained technicians, technologists, or a pathologist’s assistants—and a remote pathologist and when the laboratory personnel is under the supervision of a pathologist.

2. Licensure

In practice, credentialing and information technology/network issues may be the greatest barrier to actual use. However, within some commercial organizations, licensure may be the greatest barrier to the widespread use of telepathology in place of network issues. At the very least, it can pose a burdensome, although certainly not insurmountable, barrier to the practitioner wishing to use this technology over multiple jurisdictions. This is because of the time-consuming process of applying for a license in each state [2]. It is a time-tested prerogative of the individual states to regulate the practice of medicine [3]. The effort to standardize laws is supported by federal incentive grants to state licensing boards [4].

The basic rule is that physicians are required to obtain a license to practice medicine in every state into which that physician treats or diagnoses a patient via telemedicine. The problem is that each state has different definitions of the practice of medicine. For example, Alabama’s definition includes a physician’s written or documented opinion of any patient residing within the state [5]. Some states explicitly

address telemedicine in their laws. Some indirectly address telemedicine by including the act of diagnosing or recommending treatment through any “electronic” means as the practice of medicine [6]. Other states use broad language such as “by any means or instrumentality” in order to reach out-of-state physicians utilizing telemedicine [7]. Many states do not directly or indirectly address telemedicine in their laws or regulations [8].

Even for those states that do not address telemedicine, it is generally assumed that any act of diagnosis or recommendation of treatment is the practice of medicine in the state that the patient is located. A state’s primary purpose of regulating the practice of medicine is to protect residents from unqualified or incompetent physicians; it would be against public policy considerations if the practice of medicine were considered to be in the location of the physician [9]. In contrast, European scholars have suggested that, in order to overcome this barrier amongst European nations, the law should recognize that the practice of telepathology be assigned to the site of the practitioner, not the patient [10].

The assumption of these laws and regulations that specifically address telemedicine is that the physician was physically located in the jurisdiction in which he or she has an unrestricted license and the patient is in a different jurisdiction.

Seven states have general exceptions to their state licensure laws that applied specifically to telemedicine. Alabama, Indiana, and Minnesota do not require out-of-state physicians to obtain a license to practice medicine from their home states if the physician does not practice in their state frequently. However, only Alabama provides a definition of “frequent” in its regulations:

if such practice occurs less than ten (10) times in a calendar year or involves fewer than ten (10) patients in a calendar year or comprises less than one percent (1%) of the physician’s diagnostic or therapeutic practice [11].

Illinois and Tennessee do not require a license if the physician is merely providing a second opinion. New Jersey and Washington do not require a license if the physician does not open a physical practice in the state or accept calls in the state. Thus, it would seem that in Illinois, Tennessee, New Jersey, or Washington state, the practice of telepathology, in an exclusively consultative role as a pathologist providing a second opinion to another pathologist in the state where the patient resides, would fall under such exceptions. However, all 7 states require that the out-of-state physician has an unrestricted license to practice medicine in the location of the distant physician in order to qualify for these exceptions.

The District of Columbia and most states offer some sort of consultation exception. The primary distinction is that the out-of-state physician is required to conduct the consultation through the patient’s primary physician in the state in which the patient is located, rather than receiving the medical information and interacting directly from the patient and then

communicating the consultative opinion directly to the patient. The consultation exception does not preclude the out-of-state physicians from direct communications with the patient; it only requires that it is at the request of the licensed in-state physician.

The consultation exception is perhaps most applicable to telepathology, where a pathologist wants a consultation from an expert pathologist at a remote location. But what of the intraoperative “consult”? What if a pathologist assistant or technologist prepares a slide and a pathologist at a remote location interprets it for the clinician, such as a frozen section service? This is unlikely to be considered a consult under state consultation exceptions because of the likelihood that the treating physician would act upon the distant pathologist’s interpretation. It seems that the more independent judgment a physician makes in accepting or rejecting advice from a consultant physician, the less likely the consultant will form a physician-patient relationship (PPR) [12].

Even in the states with exceptions, the out-of-state physician is expected to comply with the medical practice laws of that state, such as privacy, incident reporting, financial interest disclosures, record keeping, informed consent, infectious disease, reporting malpractice suits, advertising, and continuity of care.

3. Malpractice and liability

There is little case law that addresses the unique liability issues that could arise in telemedicine. Indeed, the state regulation of torts and medical malpractice usually leads to administrative remedies prior to adjudication by the courts. Thus, it is unlikely that a case would rise to the level of an appellate court in order to establish such case law.

The traditional tort or malpractice analysis should be performed in evaluating telemedicine liability:

- Duty
 - (Is there a PPR? Foreseeable plaintiff?)
- Breach of the duty
 - (Has *standard of care* been met?)
- Damage caused by Breach
 - (Is there a remedy at law or equity?)
- Proximate Cause
 - (1. Actual “but for...”, substantial factor? 2. Foreseeable injury?)

This framework can be translated into the questions one should ask in telepathology:

- Duty:
 - What state is the patient located?
 - What state is the pathologist located?
 - To which state medical boards has the pathologist subjected himself in rendering the diagnosis?

- Breach
 - Is the pathologist properly trained to use the telemedicine equipment?
 - Did the pathologist use the equipment properly?
 - Does either state have stricter telemedicine requirements?
- Proximate cause:
 - Did the pathologist fail to use telemedicine technology that could have prevented injury to the patient?
 - What traditional pathology situations are similar to the telepathology act?

Finally, pathologists should make sure their insurance covers malpractice claims arising from telepathology diagnoses. Certainly, for private insurers, it would be easier to avoid lawsuits in unanticipated jurisdictions if telepathology was not covered under their policies.

As a general rule in medical malpractice, a physician does not owe a duty to the patient unless a PPR exists. In traditional medical encounters, this exists through simple contract principles. Consent by the physician to treat/evaluate the particular person and consent by the patient to be treated are linchpins upon which the relationship exists. While the case law for telemedicine is sparse, the boundaries of the PPR created by other indirect forms of patient and physician contact are well established and are analogous. For example, telephones have been used for diagnosis and advice, and in these encounters, some courts have held that direct contact is not required to establish a PPR [13]. These courts have used the following types of guidelines for determining if such a relationship existed:

- PPR may exist where others have contracted with the physician on the patient’s behalf
- A PPR exists if the relationship was contracted for or with the express or implied consent of the patient or for the patient’s benefit
- A PPR exists when health care services are rendered on behalf of the patient and are done for the patient’s benefit [14].

In the same line of reasoning, a pathologist is held to a PPR even when the patient is not aware of the pathologist’s existence [15].

Multiple physicians can be involved in forming the PPR. An interesting question could arise as to who actually has control over the care of the patient and liability for negligence in such care. For example, a physician operating the telemedicine equipment on one end can be held jointly and severably liable for the tortious acts of the physician on the other end.

Assuming a relationship is established, the next question is what the standard of care is and whether that was met. In pathology, the analogous situation would be utilizing a courier to send slides to another pathologist for review. Pathologists have been sending each other cases for diagnostic second opinion for many years. This collaboration

has traditionally involved sending stained slides, unstained slides, tissue blocks, wet tissue, pathology reports and cover letters via courier or through conventional mail. The system has worked well and is the “gold standard” by which distant consults are made and diagnoses are compared between institutions. In defining guidelines for second opinion telepathology, pathologists should borrow, whenever possible, from the workflows and responsibilities set up in the courier-based system.

In telepathology, the reviewing pathologist must determine the adequacy of the specimen upon which a diagnosis must be rendered and liable for the diagnosis itself. A remote pathologist would be liable for the resolution of the images upon which he makes a diagnosis, just as he is liable for attempting to make a diagnosis on a suboptimal specimen or poor sampling in a traditional encounter. So the appropriate use of the technology for an immediate consult between pathologists in lieu of the “gold standard” courier system may raise the question of whether the standard of care was met. Conversely, if a pathologist working in isolation made an erroneous frozen section diagnosis and the telepathology technology was available to him for further consultation, then failing to use it could be considered to breach of the standard of care as well.

While studies have shown that telepathology can be used with efficacy in intraoperative consultations where the disease entity has high intraobserver agreement [16,17], certain kinds of diagnoses wrought with high interobserver variability may have inherent obstacles. For instance, Odze et al. [18] have shown that, although there is no significant difference in the degree of interobserver variability in telepathology diagnosis of dysplasia in ulcerative colitis using fluid images over glass slides, when participants were given the glass slides to review, most of the expert gastrointestinal pathologists (51%) changed their diagnosis, and a majority of these cases (61%) downgraded the degree of dysplasia from the original telepathology diagnosis. The high interobserver variability is well documented in issues of gastrointestinal dysplasia. This discordance has been described in inflammatory skin diseases and telepathology as well [19]. However, if there is an established high discordance rate between the telepathology image diagnosis and the glass slide, it raises standard of care issues for these types of specimens. Furthermore, the type of telepathology technology used can show differences that should be considered when requesting or providing consultation. An earlier study by Odze et al. utilizing static images instead of fluid ones, again looking at dysplasia in ulcerative colitis, showed the participants changing the grade of dysplasia upon examination of the glass slide (38%) with a majority downgrading the degree of dysplasia [20].

A pathologist may be liable for the improper use and lack of training to use telemedicine equipment properly, just as a physician would be expected to use any piece of medical equipment with requisite training and care. Moreover, as technology is bound to fail, distortion or deletion of

information can occur; it is recommended, in order to avoid liability, when this is recognized by a physician, that a diagnosis not be rendered since it would be difficult to judge the extent of distortion [21]. When the information is distorted without the knowledge of the pathologist, the equipment manufacturer may be held liable for faulty equipment.

And just as in traditional pathologist encounters, a pathologist could be held liable for a late diagnosis. Interestingly, in an attempt to avoid liability, radiologists and referring physicians sometimes enter into a contract that expressly states that the radiologist is serving as a consultant for then physician and does not have a relationship with the patient. This arrangement may seem attractive for those who engage in telepathology. However, even if this does indeed protect the pathologist from the duty requirement of liability, it has been noted that such a dubious arrangement could increase the liability of the referring physician, through the theory of *respondeat superior*, where the pathologist is merely an agent of the surgeon; it is the surgeon that had the “right, ability or duty to control” the activities of the pathologist. It would certainly be an untenable situation for any clinician to assume responsibility for a histopathologic diagnosis, if such contracts are feasible at all [22].

4. Federal antikickback law

Under the antikickback statute, it is a criminal offense to knowingly and willfully offer, pay, solicit or receive any remuneration to induce referrals of items or services reimbursable by any federal health care program [23]. If an arrangement that would otherwise implicate the statute meets the requirements of all safe harbors, then the arrangement would not violate the statute.

Although Medicare provides limited reimbursement for telemedicine services, this does not reduce the antikickback risks for telemedicine arrangements because such an arrangement could implicate the statute by inducing any other referrals beyond the telemedicine services involved. For example, if the necessary intent were present, the antikickback statute would implicate an arrangement where a hospital provided free telemedicine equipment to a pathology group while the group’s outpatient biopsies are processed at the hospital, assuming that the hospital collected a technical fee for each specimen and the pathology group could reassign the processing of the tissue to another facility.

The Office of the Inspector General (OIG) is responsible for enforcing the antikickback statute. The OIG has published two advisory opinions and one special fraud alert addressing telemedicine-related fraud issues.

In 1994, the OIG issued a special fraud alert concerning clinical laboratories which stated that the provision of free computers or fax machines to physician offices by these labs could constitute illegal remuneration under the antikickback statute unless the physician:

- used such equipment exclusively for coordinating laboratory services, and
- the equipment was integral to the physician's use of the laboratory's services [24].

This could be applicable beyond computer and fax machines for laboratory services and extended to more sophisticated telemedicine-related equipment. For example, physician access to hospital telemedicine equipment for remote consults could implicate the statute unless the hospital takes necessary precautions to make sure the equipment and services are only used for the benefit of hospital patients or any additional use is charged to the physician in accordance with the fair market value of access to the equipment.

In 1998, the OIG issued an advisory opinion regarding an arrangement between an ophthalmologist and an optometrist for telemedicine consultations provided by the ophthalmologist for optometrist's patients [25]. The physician leased equipment to the optometrist that was necessary to facilitate the telemedicine consults. The optometrist could also use the equipment to provide other services to her patients independent of the consults by the physician. The telemedicine consults were offered to the patients for free. The OIG determined that the arrangement did not implicate the antikickback statute because:

- the lease agreement for the equipment complied with the equipment lease safe harbor requirements;
- patients referred to the ophthalmologist through the free telemedicine consult were allowed an opportunity to choose any ophthalmologist to provide those services; and
- the ophthalmologist's free telemedicine consults only resulted in minimal and incidental business benefits for the optometrist.

A safe harbor is remuneration-specific and does not protect the entire arrangement. As in the previous example, the safe harbor only protected the remuneration directly related to the lease of the equipment, not necessarily the increased value of the entire practice.

In 1999, the OIG issued another opinion related to the fraud exposure upon the expiration of a federal grant supporting a rural telemedicine network [26]. The OIG found that the health system's financial support of telemedicine equipment provided to rural health care providers would not violate the antikickback statute because of the clear Congressional intent that network support was expected to continue beyond the grant to establish needed telemedicine infrastructure in rural areas in the United States. Even with Congressional intent, however, the OIG was clear that any health care provider that stood to profit from the telemedicine network should share the appropriate costs born by the health system to maintain the infrastructure in order to avoid violating the antikickback statute. Thus, volume-based

discounts and arrangements where an entity is reimbursed on the number of Medicare referrals that are generated raise antikickback concerns.

In order to be convicted of Medicare fraud, an individual must "knowingly and willfully" solicit or receive, or offer or pay, remuneration in order to induce business reimbursed under any federal health care program. The federal courts define "knowingly and willfully" with wide variance, so a physician could be accused of fraud as long as he or she knowingly got paid or received a benefit in exchange for Medicare referrals [27]. Although this is a controversial area of the law, commentators have noted the stringency with which this can restrict certain provider arrangements [28]. It may not be necessary that the beneficiary knew that the act was illegal, just that there was knowledge of the receipt of such benefits in exchange for the referral [29]. For example, fraud could occur if a pathology practice owns a telemedicine network and provides it to a surgicenter or small medical center; the pathology group may be in violation of the antikickback statute if it charges less than the fair market value for the services it provides to the clinical practice or hospital on the theory that such savings are remuneration to induce referrals of specimens, in particular, if such telepathology equipment is used by the clinical center for other purposes. The pathologists do not need to be aware that this is illegal or even below fair market value, only that they received some sort of benefit from the arrangement [30].

There are, however, two relatively new antikickback safe harbors concerning telemedicine. The new exceptions at 42 CFR §1001.952(x) and (y) apply to situations in which a physician receives free electronic prescribing technology or training or free electronic health records software, information technology or training.

Telepathology is an evolving area of telemedicine. Guidelines for primary opinion telepathology should be driven from best practices in conventional laboratory procedures. More than ever before, pathologists often work in central offices geographically separated from the clinics, where cytology and surgical samples are obtained, and the histology laboratories, where cytology preparations and tissue are processed and slides are made. As pathology becomes increasingly subspecialized and pathologists are progressively more engaged in practices situations where they may not be in a centralized laboratory location, use of burgeoning telepathology technology can enhance the practice of pathology. However, it should be undertaken with the understanding that the legal and regulatory environment involving such practices is evolving as well.

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