

Review article

Legal issues in teleradiology—distant thoughts!

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Abstract. Advancements in computer technology and telecommunications have meant that all diagnostic images can now be acquired as digital signals, however the ethicolegal concepts surrounding this innovation remain unclear. In the UK there are limited practice guidelines on legal issues relating specifically to telemedicine or teleradiology. It is not yet clear whether the current law relates to telemedicine in the same way that it does for other medical specialties, or whether telemedicine raises new legal issues that need clarification. This article attempts to outline some of the potential legal issues, but the absence of case law and legislation in this area will ensure that many questions remain unanswered. The legal implications of teleradiology/telemedicine are addressed, and literature, laws and professional guidelines from the UK, USA, Australia and New Zealand are reviewed, focusing on the American licensure laws, professional relationships with patients with regards to liability, responsibility, accountability and duty of care issues, as well as issues of missed diagnosis, misdiagnosis, security and confidentiality. Teleradiology, while being actively practised worldwide, gives rise to many unanswered medicolegal questions. It is suggested that guidelines need to be implemented to safeguard patients and professionals alike.

Advancements in computer technology and telecommunications have meant that all diagnostic images can now be acquired as digital signals and this has led to the development of PACS (picture archiving and communication systems) and filmless radiology departments [1, 2]. Telemedicine has proliferated throughout much of the industrialized world [3] but, although teleradiology is now well established, the ethicolegal concepts surrounding this innovation remain unclear [4]. Most laws governing the practice of medicine were enacted long before the recent developments in sophisticated technology materialized. Consequently, the law governing such practice is yet to be developed in its own right and the potential legal ramifications need to be addressed. In the UK, there are limited practice guidelines and legal issues relating specifically to telemedicine or teleradiology, while the USA state legislation tends to focus primarily on responsibility and accountability issues, with licensure being seen as the gold standard for competence to practise.

Consequently, there is a void waiting to be filled with respect to this topic. One is presently left to ponder whether the current law relates to telemedicine in the same way that it does for other medical specialties, or whether telemedicine raises new legal issues that require clarification. This

article attempts to outline some of the potential legal issues, but the absence of case law and legislation in this area will ensure that many questions remain unanswered. Nevertheless, it is hoped that this review of practice in several nations will act as a catalyst for debate of this interesting topic in the future.

USA and licensure

Historically, the USA has led the world in this field [5], so it seems appropriate to focus a little on the guidelines and legal principles governing teleradiology in that jurisdiction. The American College of Radiology (ACR) defines teleradiology as "...the electronic transmission of radiological images from one location to another for the purposes of interpretation and/or consultation." The ACR highlights timely interpretation, secondary consultations, improved continuing education, the ability of users in different locations to view images simultaneously, improvements in access to quality radiological interpretations, and consequently improvements in patient care, as some of the benefits of this facility [6].

As technology forges ever onward, it becomes apparent that the law needs to keep pace with change. In the USA, both state and federal legislation are currently undergoing a period of transition. For instance, in Florida, a physician who practises through the use of telecommunication

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technologies must have an active license to practice in Florida, while any physician, wherever located, who has primary authority over the care or diagnosis of a patient must hold a Florida license [7]. Similarly, the states of Montana and Oregon prohibit practice of telemedicine without a telemedicine certificate issued by the state Board of Medical Examiners. In North Dakota, out-of-state physicians require full licensure to treat patients in that state, but a license is not required if the physician is in consultation with a licensed physician physically located in North Dakota who is primarily responsible for the care of the patient. Failure to adhere to the requirements stipulated may be grounds for revocation or suspension of one's license [7]. Therefore, when physicians use telemedicine across state lines, they must be aware of the medical licensure laws in each of those states so as to safeguard themselves from unintentional illegal practise.

Some states, such as Pennsylvania, allow out-of-state physicians to obtain extraterritorial licenses to account for circumstances in which one physician regularly consults with a physician from another state. However, if a telephysician renders direct patient diagnosis and treatment, then multiple licensure may be required, regardless of the states involved [8].

The Illinois Telemedicine Licensing Act 1997 states that "Licensure by this state of practitioners outside this state engaging in medical practice within this state and the ability to discipline those practitioners is necessary for the public health, welfare and safety ... 'Telemedicine' means ... rendering written or oral opinions concerning diagnosis or treatment of a patient in Illinois by a person located outside the state of Illinois as a result of transmission of individual patient data by telephonic, electronic, or other means of communication" [9]. State legislation also exists in other states, such as Illinois [10], Nebraska [11], Montana [12] and Tennessee [13], which have all seen the need to formulate controls over the practise of telemedicine, especially due to the increasing occurrence of practise across state lines.

There are also movements afoot in terms of federal legislation, as Senator J Jeffords has introduced a Bill into Senate of the USA to enact the Telehealth Improvement and Modernization Act of 2000 [14]. The Act will focus on revision of telehealth payments, reimbursement for medicare beneficiaries and telehealth services provided using store-and-forward technologies. Yet despite all this, there is still no generally accepted legal definition of telemedicine [15].

Licensure is there to protect the patients within individual states. However, the interstate transfer of electronic images raises one important question,

namely is it the patient that travels to the physician or *vice versa* in these circumstances. In terms of the situation in the UK, this could have important consequences in cases of civil actions brought by patients in one geographical area against medical practitioners in a remote site. It is speculated that such cases would be heard in the patient's own jurisdiction.

Professional relationships with patients

Legal issues also arise with regards to liability, responsibility, accountability and duty of care. One could argue that the doctor-patient relationship is different in cases of teleradiology than in face-to-face consultations. In civil cases, a duty of care is usually owed if a patient has been accepted by the defendant and if issues of proximity and foreseeability can be established. When a patient requests medical services and a doctor undertakes to provide these, then the law forges the legal relationship of doctor and patient [16].

The question arises as to whether telemedicine and teleradiology can be viewed similarly in this respect. In terms of telemedicine, there is a definite bond between the patient and the physician, but in teleradiology it could be argued that the physician merely acts as a consultant, and therefore has minimal contact with the patient. How the legal process would differentiate between such relationships is yet to be tested, but what is clear is that the physician-patient relationship, with regards to proximity and responsibility, will need careful consideration. It will be important to clarify who maintains overall responsibility for the patient under these circumstances and, if, for example, clinical negligence is established, how liability would be apportioned according to the roles of the concerned parties.

Previous case law in the UK has established the precedent that a doctor who gives advice to patients over the telephone is bound by the same duty of care as a doctor in a face-to-face consultation and therefore should behave reasonably thereafter [17]. Therefore, the implication is that doctors who practise telemedicine or teleradiology would have to meet the same legal standards. In terms of proximity, the claimant in a civil action would need to establish physical, circumstantial and causal proximity [18].

Case law relating to telemedicine or teleradiology would be very interesting here, particularly if one thinks of proximity in terms of geographical distance between the parties. The court would have to determine whether the doctor-patient relationship merits the closeness required to establish a duty of care and what the content of that duty would be. Circumstantial proximity would require the doctor to act reasonably in the

circumstances, and causal proximity would be established based on the outcomes or effects resulting from those actions.

Case law in the USA has already considered whether a physician who performs a medical examination of an individual at the request of a third party has a duty of care to the examinee and, if so, what is the scope of that duty [19]. The defendant in this case claimed that he owed no duty of care as he had no physician–patient relationship with the claimant. J Trieweiler held that the healthcare provider has a duty “to exercise ordinary care to assure that when he or she advises an examinee about her condition following an independent examination, the advice comports with the standard of care for that health care provider’s profession.” It has also been suggested that if the radiologist’s report becomes an official part of the patient’s record, then it would be very unlikely that the court would find that no doctor–patient relationship had been established [20]. However, this scenario has yet to be tested in English law and it is questioned whether a similar outcome would be forthcoming.

So far, responsibility has been considered in terms of an individual’s liability, but what about the role of the employer? For vicarious liability to exist, that is the establishment of liability of the employer, three conditions would need to be satisfied.

- Has the individual committed a tort, *i.e.* a civil wrongdoing?

Clinical negligence comes under the auspices of the law of tort, whereby private or personal injury to person or property may result in damages being claimed in a court of law. The civil law provides for compensation to a person injured by another’s negligence and this is the usual avenue of redress for patients taking legal action within healthcare. The patient will claim that the doctor was negligent because he breached his duty to exercise reasonable care and skill in diagnosing, advising or treating the patient.

- Is he an employee of the defendant?
- Did he commit the tort in the course of his employment? [21]

The final statement is interesting here, as a grey area may develop in terms of role development. As radiologists develop their skills and adopt new roles, it may be that the course of employment is also deemed to have changed, and the course of employment of individuals may need to be clarified in terms of an individual’s responsibilities and scope of practice. It may be difficult for individuals to assess the limitations of their work and they may overstep the bounds of what is acceptable if they are not clear about

the guidelines established. If the radiologist’s performance is so deficient that it fails to meet the high standards set by medical professionals who also perform similar clinical tasks then, legally, it may be determined that the radiologist has acted outside the course of employment. Similarly, from an ethical viewpoint, it is paramount that individuals are clear about what they are competent to do and their own scope of practice, so as to safeguard the interests of patients.

Misdiagnosis or missed diagnosis

In terms of diagnosis, it is clear that conventional radiology allows the radiologist to examine the patients if necessary, but in teleradiology the radiologist may also have a duty to warn the patient that the lack of opportunity to physically examine him may increase the risk of misdiagnosis or missed diagnosis [22]. Fundamentally, there are three models in teleradiology: teleradiology, teleconsultation and telemanagement [23]. Diagnosis is made within 4–24 h of images being produced, as immediate diagnosis is not required, and images are transmitted to a remote site. Teleconsultation occurs within half an hour and is different as the patient may still be waiting at the examination site or primary care physician’s office. Perhaps a second opinion is being sought in these circumstances. Telemanagement occurs in real-time and the radiologist manages the patient as if the patient was on site for the examination, so that an immediate diagnosis is required. Therefore, one may also need to consider the individual duties that fall under the umbrella of teleradiology, so as to address fully the legal responsibility and liability of the physician. Depending on the mode of service, the turnaround time may differ [23].

The Royal Australian and New Zealand College of Radiologists (RANZCR) has seen fit to draft its “position on teleradiology” to ensure that standards are maintained and that the chances of inaccuracies in diagnosis are minimized [24]. In the absence of any other guidelines, a court of law may use these in assessing the standard of care [22].

Data acquisition and manipulation issues are key factors for consideration in terms of image quality and diagnosis. The development of digital imaging has required radiologists to adopt new skills to overcome the potential for image degradation during the process of digitization and transmission of non-digital images. However, there is a responsibility to ensure that the equipment is fit for the purpose for which it is used. In Australia in 1997, it was acceptable if the digitization system used a laser or charge-coupled

device scanner capable of scanning in 2 K spatial resolution and 8 bit contrast depth, with an even grey-scale depth up to an optical density of at least 3.0. The diagnostic workstation would have needed to incorporate an 8 bit grey-scale monitor with a spatial resolution of 1 K × 1 K or better [24]. Nowadays, one should be operating with a 12 bit contrast depth and 12 bit grey-scale monitor, and the optical density range should be from base fog level up to 3.4 or higher. So, there is an onus of responsibility to ensure that, as an operator, one keeps pace with change and that equipment does not become substandard.

To clarify this further, it may help to separate conventional projection radiography, such as plain films, fluoroscopy, computed radiography (CR) and digital radiography (DR), from sectional images such as CT, MRI, ultrasound and single photon emission tomography (SPECT) etc. The former occurs either through digitization, as previously described, or CR and DR, which comes with 2 K × 2 K × 12 bits. Sectional images require direct DICOM output, which is of 2 bytes per pixel (although data may only be 12 bits).

From a legal point of view, it would be negligent to produce and examine images of substandard quality by reason of inferior equipment or resulting from variable operator dependency, such as may arise through lack of experience in interpreting images by such methods. Consequently, any errors in diagnosis arising from such practice may be entitled to compensation. Therefore, the advantages of teleradiology are only relevant if images are of sufficient quality, and "...there should not be a significant loss of spatial or contrast resolution from image acquisition through transmission to final image display." [6].

Questions have been raised about the accuracy of diagnosis in the digital domain and how this may impact on the malpractice ramifications of teleradiology. Conflicting reports appear in the literature and comparisons of the accuracy of diagnosis via the digital and conventional radiology methods tend to proffer evidence that is generally inconclusive [20]. This is reinforced by Berger and Cepelewicz [25], who have reported that although many investigators do indicate equal accuracy between the two methods, none the less "additional studies will be required to conclusively show whether teleradiology systems permit radiology diagnoses of the same quality as do the original plain radiographs." In the 5 years since this publication, technological developments have ensured that such concerns are difficult to justify.

There have been major advancements in film digitization, and the quality of image is certainly comparable, but it may be open to question in

a court of law whether there has been any degradation of image during transmission and whether this has impacted on the accuracy of diagnosis. There may be further concern that the operators of the digital process may also lack the experience to achieve the optimal viewing conditions and, in this case, the defendants would have to establish their competence to use these methods. After all, it has been consistently held in case law that inexperience is no defence for clinical negligence or malpractice [26, 27]. As a matter of public policy the law must set a standard for the benefit of all below which anyone engaging in risk-creating behaviour may not fall [16].

Another interesting area of law could be applicable here, and that is "lost chance of recovery", whereby harm results as a consequence of delayed diagnosis. It has previously been shown that if the patient were to establish, on a balance of probabilities, that the defendant's failure to treat him promptly would have accentuated the harm suffered and was a breach of duty, then the patient would be entitled to compensation for the harm incurred [28]. It would not be too unrealistic to argue that digital radiology should speed up the reporting process in cases where the images need to be sent to a radiologist or specialist at a distant site. The Royal College of Radiologists has actually stated that the major benefits of PACS include the optimization of clinical workflow by providing "the right image at the right place at the right time" and "the facilitation of enterprise-wide clinical efficiency/effectiveness, hence improving the timeliness and delivery of patient care" [29]. Therefore, time factors relating to prompt diagnosis between digital and conventional radiology may need to be considered by the courts.

Security and confidentiality

The management of medical records, including radiographic film and other hardcopy images, is problematic in its own right, but the advent of teleradiology and computerized patient records adds to the dilemma [30]. Security issues relating to increased risk of improper disclosure of records, breach of confidentiality, access to records, alteration or elimination of records from a remote site, vulnerability of computer-stored data to accidental erasure, and methods of ensuring verification of the above are some of the problems that need to be addressed. It has previously been concluded that there are three issues relating to data security: privacy, *i.e.* who can access the data; authenticity, *i.e.* who sends the data; and integrity, *i.e.* has the data been altered during its transmission through public networks [31]. It is

suggested that the first two issues are the responsibility of the data centre or the Information Technology Services of both the sender and receiver. Privacy and authenticity can be resolved by using various levels of password, based on a balance between convenience and cost. However, integrity is the responsibility of the site where the image is generated and this may not be so easy to protect [31]. Encryption of data is one method to protect the data, but this is in need of further research as this may not be wholly reliable.

There is understandable concern about the security of data held on a computer and transmitted between sites. To protect individuals it is essential to remove personal identifiers or to encrypt transmitted information. If teleradiology images are received from overseas and a report is required, it is vital to ensure that all parties are protected. In the UK, the radiologists concerned should be covered by their defence organization and/or by Trust indemnity [29] and, as previously stated, American radiologists may need to be licensed in both their own state and the state from which the images are dispatched. Concerns about improper access of records have in part led to the implementation of guidance on this issue, so as to protect all the concerned parties [32, 33]. If radiologists do not heed such guidance then they are opening themselves up to claims of negligence.

There is also the issue of acceptance of requests via a computer electronic mail system, wherein the written request is not signed by the medical practitioner. American case law has addressed this issue [34]. The Walgreen company created and tested a computer system for the electronic transmission of prescriptions. The Board of Pharmacy determined that the system violated Wisconsin law that required physician signatures or written prescriptions. The trial court reversed the Board ruling and the Court of Appeal affirmed, holding that the electronic transmissions were more analogous to oral or telephonic transmissions and that no signature was required. The digital signature is now commonly accepted within the USA, but it is yet to be determined whether this practice will be generally accepted in the UK.

What becomes clear is that the law has not been able to keep pace with such change and is inadequate [8], and teleradiology looks like becoming the testing ground for many legal and practical issues. Nevertheless, some states in the USA have formulated laws governing these issues, for example California, where licensed providers of healthcare services that use electronic systems must comply with certain regulations, including off-site back-up data storage systems, safeguards for confidentiality and unauthorized access, authentication by electronic signature keys, and

guidelines for system maintenance [35]. It is clearly time for the medical professions in the UK and elsewhere to establish clear guidelines that can help to protect their members and patients.

Conclusion

This paper has highlighted just some of the legal issues relating to teleradiology, but has not even begun to offer answers. It is clear that teleradiology is actively practised worldwide and that its potential for the future is enormous. It also becomes apparent that it opens up numerous medicolegal questions that are only now beginning to be considered. It is vital that the interests of healthcare professionals and patients alike are safeguarded and it is suggested that this may be accomplished through the implementation of guidelines relating to the relevant issues. This paper is based on a review of multinational data and thus it must be emphasized that legal issues may be judged differently between the various jurisdictions, but there is a common goal and that is to ensure that all parties are safeguarded against the legal pitfalls so that this new technology can be used to the benefit of all.

References

1. Hawnaur J. Recent advances: diagnostic radiology. *BMJ* 1999;319:168–71.
2. Hynes DM, Stevenson G, Nahmias C. Towards filmless and distance radiology. *Lancet* 1997;350: 657–60.
3. Grigsby J, Sanders JH. Telemedicine: where it is and where it's going. *Ann Intern Med* 1998;129: 123–7.
4. Ashcroft RE, Goddard PR. Ethical issues in teleradiology. *Br J Radiol* 2000;73:578–82.
5. Wright R, Loughrey C. Teleradiology. *BMJ* 1995;310:1392–3.
6. American College of Radiology. ACR Standard for teleradiology. http://med.mc.ntu.edu.tw/~somed/teletea/document/teleradiology_standard.html
7. State Telemedicine Legislation 1999. http://www.arentfox.com/quickGuide/businessLines/telemed/e-health_telemed/e-health_lawsRegs/tmstateleg/state1999.html
8. Klein SR, Manning WL. The Health Law Resource. Telemedicine and the law. <http://www.netreach.net/~wmanning/telmedar.htm>
9. Telemedicine Licensing Act. Illinois Senate Bill 314 (July 11, 1997).
10. Chapter 225. Professions and Occupations Health Medical Practice Act of 1987. 225 ILCS 60/49.5.
11. Chapter 71. Public Health and Welfare. Article 85. Nebraska Telehealth Act. R.R.S. Neb. 71-8501 to 71-8508.
12. Title 37. Professions and Occupations. Chapter 3 Medicine. Part 3 Licensing and Utilization Plans. Montana Code 37-3-343.

13. Title 63. Professions of the Healing Arts. Chapter 6. Medicine and Surgery. Part 2. General Provisions. Tennessee Code 63-6-209.
14. 106th Congress 2d session. S.2505. A Bill to amend title XVIII of the Social Security Act to provide increased access to health care for medicare beneficiaries through telemedicine. The Telehealth Improvement and Modernization Act 2000.
15. Kamp GH. Medico-legal issues in teleradiology: a commentary. *AJR* 1996;166:511-2.
16. Kennedy I, Grubb A. Medical law. London: Butterworths, 2000:278.
17. Barnett v Chelsea and Kensington Hospital management Committee [1969] 1 QB 428, [1968] 1 All ER 1068 (QBD).
18. Lowns v Woods (1996) Aust Torts Reports 81-376 (NSWCA).
19. Diana L. Webb v T.D. & C.H.A. No. 97-255 Supreme Court of Montana. 951 P.2d 1008; 1997 Mont.
20. Berlin L. Malpractice issues in radiology — teleradiology. *AJR* 1998;170:1417-22.
21. Keenan D. *Smith & Keenan's English law*, (11th edn). London: Pitman Publishing, 1995:366.
22. Pickett SM, van der Heide GW. Medicolegal risk in telemedicine: risk control in teleradiology. *Med J Aust* 1999;171:563-5.
23. Huang HK. Teleradiology technologies and some service models. *J Comp Med Imag Graphics* 1996; 20:59-68.
24. Royal Australian & New Zealand College of Radiologists. Position on teleradiology. Sydney: RANZCR, 1997. http://www.racr.edu.au/open/pol_teleradiology.htm
25. Berger SB, Cepelewicz BB. Medical-legal issues in teleradiology. *AJR* 1996;166:505-10.
26. Nettleship v Weston [1971] 2 QB 691 (CA).
27. Wisner v Essex AHA [1987] QB 730, [1986] 3 All ER 801 (CA).
28. Hotson v East Berkshire AHA [1987] AC 750, [1987] 2 All ER 909 (HL).
29. Board of the Faculty of Clinical Radiology. The Royal College of Radiologists. Guide to information technology in radiology, teleradiology and PACS (2nd edn). London: Royal College of Radiologists, 2000.
30. Brenner RJ, Westernberg L. Film management and custody: current and future medicolegal issues. *AJR* 1996;167:1371-5.
31. Zhou XQ, Huang HK, Lou SL. Authenticity and integrity of digital mammography images. *IEEE Trans Med Imaging* 2001;20:784-91.
32. Department of Health. The NHS IM&T security manual. National Health Service HSG(96)15. London: HMSO, 1996.
33. National Health Service. Using electronic patient records in hospitals: legal requirements and good practice. London: National Health Service, 1998.
34. Walgreen Co. v Wisconsin Pharmacy Examining Board and Wisconsin Department of Regulation and Licensing, 217 Wis. 2d 290; 577 N.W. 2d 387; 1998 Wisc. App. LEXIS 201 (1998).
35. California Health and Safety Code. 122149 (1995). In: Brenner RJ, Westernberg L. Film management and custody: current and future medicolegal issues. *AJR* 1996;167:1371-5.