

Legal Liability Issues in Health Care Telematics*

Caroline Laske M.A. LL.M.

Free University of Brussels (VUB)
Wezembeekstraat 4A, B-3080 Tervuren; Tel & Fax: +32/2/767.00.81

Abstract. This paper deals with questions of liability that may arise with the implementation and use of telematics and informatics in the health care sector. Traditionally liability has evolved around the responsible health care professionals. However, with the increasing reliance on informatics and telematics in health care may come a shift away from this concept of liability to the idea of shared liability between the responsible health care professionals and those who have provided this technology.

1. Introduction

It is inevitable that the introduction of new technology goes hand in hand with new and/or different types of responsibilities and liabilities. For example, data protection legislation introduces duties on the data controller (frequently the health care professional) that may not be relevant in a manual environment. While in a great many states manual files are outside the scope of data protection legislation (though the new EU Directive will harmonise this matter by the beginning of the next century), health care professionals keeping electronic records are bound by such legislation and by a number of data protection duties that are imposed on data controllers. Therefore, liability under data protection law arises for the responsible health care professional in the digital environment if these duties have not been observed or have been carried out negligently.

Furthermore, information technology may by its very nature seemingly contradict established legal duties, and its use could therefore give rise to liability for not conforming with such duties. For example, a legal duty to sign health care records may not be compatible with the electronic patient record generated in the digital environment, in particular if manual signature is specifically required. Thus it is the very form of electronic documents (ie. the digital form) which may not answer certain given legal requirements. On the other hand, if it is a matter of authenticating the record and its content, it could be argued that digital signatures fulfill this requirement, though this is not explicitly confirmed by either

* The topic of this paper is a part of the ISHTAR project co-financed by the Health Care Telematics Application Program of the Commission of the European Union (DGXIII).

legislation or case law. In other words, health care professionals working merely on electronic support may be liable for using a medium generating documents which are as such not legally recognised, though obviously they are not outlawed either.

Liability is obviously a vast subject covering various spheres and a great number of legal principles. This paper will merely deal with questions of liability where the use of information technology intervenes more directly in the process of diagnosis and treatment of patients and where there is thus a danger that liability towards patients is blurred or diluted by the fact that a third element, namely the computer, is introduced in the patient - health care professional relationship. Three scenarios will be considered:

- decision/knowledge support
- telemedicine
- teleassistance

2. Decision/Knowledge Support

Decision support and knowledge based systems as tools assisting in medical diagnosis and treatment intervene in the health care process and inevitably the question of liability is raised when something has gone wrong. There should be little doubt that health care professionals must remain liable for any damage to their patients even if diagnosis/treatment have been assisted by decision/knowledge support systems. It would be unethical to allow health care professional to discharge liability onto the computer, since the computer as such is not answerable under the rule of law. In other words, a health care decision should always remain primarily a human one and the health care professional in charge should remain answerable to his/her patients.

Nevertheless, it could be argued that with the increasing reliance on such new technology the health care professional as the user charged with malpractice may have a cause of action against those who have provided him/her with this technology. Following this line of argument the extent to which a user is liable may depend on the extent of the man-machine interaction, according to which the greater the user's share the greater his/her responsibility in the outcome. If the system in question is a simple knowledge data base to which the health care professional refer with a specific query, the decision in relation to the patient is still entirely a human one, even if influenced by the answer to the query of the knowledge support system. This is becoming progressively less so when dealing with real-time process control systems such as the surveillance of patients in emergency departments or perhaps some time in the future with medical robotic instruments undertaking operations. As the human decision factor decreases, so may the potential responsibility of the user. It is in other words a matter of the extent to which the IT application is under the control of the health care professional. If it can be considered that the technology encompasses an element of autonomous nature, there is a decrease in the human decision factor and the result may be

a shift in potential liabilities away from the user and towards those involved in the development of a given system, architecture, network, clinical protocol etc.

3. Telemedicine

Telemedicine in this paper is to be understood as a means for health care professionals to communicate with each other in the establishment of a diagnosis. The danger that liability issues may get blurred in this sort of set-up is a real one, and the increased implementation and use of such technologies should be accompanied with an ascertainable definition of the potential liabilities incurred by the various parties involved. It has been suggested [1] that this matter may be dealt with by means of concluding a contract between the parties involved in telemedicine services setting out the liabilities incurred by each party. In the absence of established rules and regulations on the matter this is certainly a handy solution which provides at least in the short run more clarity in an area that is riddled with uncertainties. Nevertheless, there are some major potential pitfalls in particular from the patient rights point of view. Such contracts embody the interests of the health care professionals or of their employers (eg. hospitals, health care authorities etc.) between whom the contract is concluded. The patient is a third party and is, under certain jurisdictions, not in a position to enforce the terms of the contract (eg. common law systems such as in the UK). The patient's interests are therefore not fully taken into account. Furthermore, unless there is a law imposing a duty on those engaged in telemedicine to conclude such a contract, a great many may not do so, in particular in small practices and in the private sector. This lack of uniformity is unacceptable in the long run, not only from the patient's point of view but also from that of society at large.

Liability may also be incurred by those providing the telemedicine services, who are not only bound by contractual liabilities, but also owe a duty of care to both the patient and the user/health care professional. Technical failure or weaknesses could give further rise to product liability under the EU Directive on Liability of Defective Products [2] if due to defective tangible and technical 'movables' of a system. However, telemedicine as a service does not raise the product liability issue.

Furthermore, there are the liabilities of the information carriers and network providers. For example, if in telediagnosis the diagnosing health care professional receives data which is erroneous due to a problem during transmission, the resulting diagnosis may be incorrect with possible injury or damage to the patient. Stringent security measures are obviously essential; these are incidentally also indispensable to satisfy the legal requirements for patient privacy and data protection.

4. Teleassistance

Teleassistance is defined in this paper as a service provided to the patient who is geographically removed from direct health care and medical support. Questions of liability are similar to those described in the previous section on telemedicine. Teleassistance is different to the extent that the patient may also intervene in its process, which raises the issue of contributory negligence on his/her part. The notion of contributory negligence hinges on the fact that the patient may be given certain responsibilities in a telemedicine set-up. Obviously the patient must have been provided with ample information and perhaps some training. Failure to do so will put liability firmly back into the camp of those who should have given the patient such instructions, usually the health care professional or provider. In any case the possibility of contributory negligence on the part of the patient must be reduced to a minimum by the adoption of measures appropriate to the specific teleassistance application.

Product liability may be more of an matter in teleassistance than in the other scenarios described above, in particular if it involves the manipulation of equipment. The patient as a layperson may not be aware of any defects.

5. Conclusion

The lack of regulation and case law in the liability issues as discussed in this paper raises considerable uncertainties as to its use. Existing legislation tends to deal merely with certification (usually a safety issue) or product liability. For the health care telematics industry this uncertainty introduces an element of risk to business decisions. The user on the other hand may find the lack of clarity too risky to make full use of such technology. There have as yet been no major cases disputed in the courts. This should however not be interpreted as meaning that there is no problem. On the contrary, if the liability issues can be addressed at an early stage of the development of these technologies, they can be formulated alongside technological advance. This strategy will avoid a more rigorous legal backlash when the first difficulties arise.

References

- [1] Allaert F. and Dusserre L. *Legal Requirements for Tele-Assistance and Tele-Medecine*, in MEDINFO 95 Proceedings, R.A. Greenes et al. (eds.) p.1593.
- [2] Council Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member states concerning liability for defective products, Official Journal of the European Communities L210/29 of 07.08.85

Selected Bibliography

- Laske C. *Legal Issues in Medical Informatics: A Bird's Eye View*, in Towards Security in Medical Informatics: Legal and Technical Aspects, (ed.) Barber et al., IOS Press 1996
- De Schutter B. and Laske C. *Legal Issues in Cognition, Knowledge Processing and Decision Making Techniques in the Health Care Sector*, in Knowledge and Decisions in Health Telematics, (ed.) Barahona et al., IOS Press 1994