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Telemedicine: Legal Issues

A policy overview paper

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Telemedicine: Legal Issues

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1 Preface

This paper is one of two commissioned by the UK Department of Health to scope some of the policy implications of telemedicine.

Telemedicine: Legal Issues and **Telemedicine: Ways of Working** together identify key issues involved in telemedicine, or telehealth or health telematics, depending on the phrase in vogue. Importantly, these two documents were the first to focus, not on the technology itself, but on the implications of that technology.

“Legal Issues” is a tentative first statement to the government that something needed to be done. Since this report was commissioned, steps have been taken to identify a focus of expertise in legal issues and health, through the leadership shown in Wales.

500 years of technological change should have taught us that once the technological genie is out of the bottle, she can't be put back in. Our real responsibility is to understand the implications of this new technology, realising that what happens will probably always be a surprise.

A third area of enquiry, related to these two papers, focuses on the patient's response to care and the impact of clinical technology. Beneath the rhetoric, and change we find the same needs of people to receive care, be listened to and understood. The great fear is always that technology will replace the human ear and voice with a quick technological solution.

Michael Tremblay

1997

2 Overview: Telemedicine technology changes the nature and practice of healthcare in ways which create legal issues for consumers, private companies and regulators.

In telemedicine, information is turned into a digital, electronic entity, to be carried over telecommunications systems; it risks interception, can be accessed by just about anyone with the right tools who does not need to be within the UK's legal jurisdiction. Indeed, many of the tools themselves are ordinary devices used in a novel situation.

- The traditional basis of health care practice involves controlling access to information and uses “coded” diagnosis, prognosis and therapeutic language which is largely unintelligible to the public. In an electronic form, it can be re-represented to the public through intermediaries, automatically translated or visually represented, thus making it intelligible to the non-specialist. Indeed, non-specialists, or new health specialists may emerge to assist in this.
- Pharmaceutical companies have plans to become more involved in providing information to the public and have considered the implications of offering telemedicine-type services on health and well-being, as well as drug information. For the larger companies, they may seek business partnerships with telecommunications or information services providers for the telematics component.
- The “internet” already provides services for people to access alternative sources of information, and explanations, but without appropriate licensure or public protection in place – truly *caveat emptor*.
- Present legislation reflects information having a physical presence; electronic information, in contrast, can be moved about, copied, altered, often without a trace. A video-taping of a telemedicine consultation can be made by the consultant, the GP and the patient, each using it for different purposes. The consultation, in this form, is valid and represents the most complete form of the consultation. It can be shared, discussed and other opinions sought without compromising the validity of the original content.
- US experience suggests that state licensure systems are challenged by telemedicine when it comes to defining what medical practice is, and therefore when it comes to determining malpractice (q.v. Council on Competiveness Report, March 1996 **Highway to Health: Transforming US Health Care in the Information Age**). Key features include:
 - The physical presence of the patient in a telemedical consultation changes the structure of the consultation including how “confidential” professional discussions occur.

TELEMEDICINE: LEGAL ISSUES

- It may alter “when” medical or other professionally regulated practice actually takes place, and in so doing may alter the legal definition of the relevant activity.
- Existing medical device regulations (UK and EU) consider medical devices to have specific attributes. Radiation-emitting equipment is covered in its diagnostic and therapeutic connotation; however, the considerable benefits of telemedicine come from its mundane origins, not its spectacular use of sophisticated devices. The standards in ordinary use may or may not be appropriate in their clinical setting.
- Many existing UK telemedicine trials have been supported by British Telecom, providing ordinary video and picture-phone technology using ISDN telephone lines. The US FDA has established a working group to look at telemedicine technology within the medical device context. They will also be looking at the regulatory status of software to control these types of devices. (q.v. Center for Devices and Radiological Health, Report of 11 July 1996.)

Existing data protection legislation in the UK has no extraterritorial effect, having jurisdiction over electronically-held health records within the UK. Within the European Union, the initiatives in transborder networks, designed to develop a single market, also require convergence (if not harmonisation) of national data protection regulations.

- Are telecommunications services providers responsible for ensuring the quality of the information when transmitting clinical (or life-critical) information? There is the view that telecommunications providers can be held responsible for the content of the signals (e.g. transmitting libellous or pornographic information).
- The information involved in telemedicine (comprising anything that can be reduced to digital form: health records, videos, sound recordings, tracings, radiographic images, test results, etc.) does not need to respect national or other boundaries, and can move into other legal jurisdictions, with different rules, conduct and standards.
 - Massachusetts General Hospital ran a radiological imaging service for a Saudi Arabian clinic over a telephone line.
 - Pathology results move electronically between Berlin and Madrid in a microscope workstation trial.

Health telematics makes it possible to offer a clinical service to a larger catchment area than the current geographically-based services. Such a service can be defined sufficiently to be of interest to the private sector.

- EL (94) 94 is designed to restrict exclusive relationships between the private sector and the NHS. The private sector’s interest in having a relationship lies in two areas: [1] disease management and [2] managed care. The two areas, together, provide the basis for managing specific clinical services and, by aggregating the demand across a larger geography, offer a uniform service funded through a fixed or capitated fee. In the jargon, this is a “carve-out”, and for it to work most effectively, the referral population would need to be as large as possible, and subject to a uniform service. In

such arrangements, it would not make good business sense to distinguish public and private service recipients, or service purchasers, since the essential logic rests on managed-care cost-containment strategies plus best-practice to ensure service quality.

- The Welsh experience with tele-dermatology raised the possibility of a national online dermatology service, and demonstrates a real example of how telematic technology could carve-out a clinical service.
- There are many examples of novel healthcare environments, like outer space, and off-shore oil rigs (q.v. M. Tremblay, *Telemedicine and Society*, **British Journal of Health Care Management**, 2(March 1996) 162-164) and many novel ways of practising healthcare which raise the possibility of private-sector involvement:
 - tele-radiology: remote viewing service for diagnostic tests and images,
 - tele-pathology: remote analysis and transmission of pathology data, including remote microscopy,
 - tele-psychiatry: interviewing and therapeutic sessions, e.g. prisoners in high security settings,
 - tele-ambulance service: vital signs telemetry in accident and emergency situations between paramedics, or other people, and specialist base stations,
 - tele-homecare: monitoring of ambulatory patients in their homes.
- Other areas of interest in the private sector where technology would be pivotal in structuring carve-outs, include:
 - outsourcing the electronic health record using data warehousing technology for storage, and encryption technology for transmission and data protection; EDS, Equifax/AT&T are capable of achieving this;
 - radiological imaging transmission for remote reading linked to the establishment of centralised imaging centres; GEC/Picker, GE Medical Systems, and others are capable of this.
- Through this electronic re-aggregation of service populations, telemedicine makes it more difficult to put in place controls on access to consultative advice, suggesting that telemedicine creates a greater opportunity to ensure a comprehensive range of services, regardless of “local” priority setting.
- Is any priority-setting possible under these circumstances -- if the care can easily be accessed technologically somehow and somewhere, is there at least a moral responsibility to provide it (q.v. Diana Brahams’s comments in **Telemedicine – risks and opportunities**, Royal Society of Medicine, 1996)? Certainly, if the NHS is seen as providing a comprehensive health service for a fixed fee and institutes restrictive measures through priority setting/rationing, is a bad health outcome for

a person the denial of a medically necessary benefit, or malpractice (q.v. a US case, *Fox v Health Net of California*).

2.1 Key question 1: Is telemedicine technology creating legal issues for which new laws will be needed, or is present law generally adequate?

Certainly the US experience suggests that, in a federal system, their existing legislation is proving inadequate to cope with the specificity of existing licensure systems and inter-state relations. At present, the FDA and FCC, as regulators, are both actively investigating the extent to which existing regulatory machinery is adequate. The AMA and a number of states are moving to correct deficiencies in licensure. The US health insurance reform legislation includes a charge to HCFA to develop a Medicare payment policy for telemedicine by next year.

The BMA has limited its comments to concerns about data protection, while the Royal Society of Medicine has held a round-table on the implications and risks. The NHS appears not to have considered telemedicine apart from the data transmission issues on the NHSNet.

An article is to appear in the journal **Telemedicine and Telecare** looking at the medico-legal issues of telemedicine. Kennedy and Grubb's **Medical Law** is silent, and no articles have appeared to date in the bulletin **Health Law**.

Telemedicine raises issues about who controls what information about care and whether "freelance" clinics could access consultants independently of formal "referral systems". Similarly, existing systems of licensure and regulation of professions may be inadequate to accommodate people whose role is clearly intermediary or advisory, and who may not actually "practise" any clinical profession.

More generally, is our legal understanding of the following issues adequate to take account of telemedicine?

- Data Protection Act, telecommunications (deregulation in the UK, and Europe) and transborder networks in the EU
- the public and private regulatory environment
- malpractice and professional licensure
 - European law relating to right of establishment of professionals
 - new professions and changing professional boundaries
- fraud, libel, theft, privacy
- Medical Devices, life-critical software, product liability.

It would appear that little is documented in the UK of the implications of telemedicine even though activity is underway within NHS trusts, for instance. The continuing move

to deregulation and opening up the public health system suggests that we are entering new territory, both as the technology advances, and as regulation retreats.

2.2 Key question 2: Does telemedicine increase the likelihood of litigation?

The US view is that “two heads are better than one”, but there is emerging experience that wider clinical consultation is leading to increasing patient expectations, and some evidence of rising litigation where technology is involved (M. Grady, *Better medicine causes more lawsuits, and new administrative courts will not solve the problem*, **Northwestern Law Review** 1068(Summer 1992)).

It is still uncertain the extent to which there will be an increase in health litigation which may in its own way set new directions in UK law. Quite separately, there are likely to be “surprises” from the European Court of Justice if it continues to be judicially active.

Standards of clinical practice apply regardless of whether the technology is used or not; therefore, the intervention of the technology does not reduce the obligation to meet standards, and the failure of the technology does not mitigate the failure to meet the standard. Is the public adequately protected by existing legislation with respect to unlicensed professionals and malpractice, when the care provider may be accessed through remote technology, or may not be a member of a licensed profession?

Who takes control of the proceedings of a telemedicine consultation – the referring GP, the consultant? Can the proceedings be edited to focus just on what the consult was about, but what of material left out, or altered, and when does the record actually begin and end? If there is a failure somewhere, who is the responsible party?

Telemedicine links are often “life-critical” and depend on reliable and certain transmission of information. Is the telecommunications carrier part of the care delivery system for telemedicine purposes?

2.3 Key question 3: Do changes in the delivery of health care (NHS internal market, EL (94) 94, outsourcing and contracting with the private sector) require an improved regulatory framework relevant to health care industries?

The current review of EL (94) 94 on disease management, and the recent consultation exercise, would not necessarily have considered how telemedicine technology can be exploited to create “carve-outs” of specific clinical procedures. The relative ease with which advanced telematic technology can be used within the existing and developing telecommunications infrastructure and the increased commercialisation of business opportunities in the public health system may require improved regulatory machinery, to protect the public adequately, and to properly regulate new healthcare businesses.

2.4 Key question 4: Can patients choose the jurisdiction within which to launch a malpractice claim when care crosses national or jurisdictional borders?

So-called “forum shopping” raises issues if the legal systems are not adequate to take account of the differing legal requirements. The Fair Trials Abroad Trust already identifies problems for EU citizens in accessing common legal services throughout the

Union; are the existing rules adequate to accommodate malpractice and negligence cases that involve health professionals in more than one Member State linked telematically?

3 Implications

- Within the European Union, efforts to create transborder networks, including efficient telecommunications systems, may not have the same objectives as UK interests. Data protection laws in the UK may be unable to protect patients' interests if clinical services are accessed outside the country without appropriate guarantees, since violations of patient confidentiality in this respect will provide no legal remedies within the UK.
- Health telematics involves various technology from other areas in clinical settings. Life-critical systems may be created out of more mundane technology, such as telephones and video cameras augmented by special computer software, but may lack appropriate regulation as medical devices.
- Changes in the structure of the NHS is creating business opportunities for the private sector to offer clinical services through the use of advanced technology. Whole carve-outs of clinical services, encompassing both public and private patients, are possible. It is not inconceivable that private companies could offer national breast-screening services, diabetic services, dermatology, imaging, pathology results reporting, health records management, etc.
- Telemedicine law is generally not well understood and may require that the UK establish a facility similar to the Center for Telemedicine Law in the US; the existing Centre for Telemedicine and Telecare at Queen's University, Belfast, does not include a legal brief, but they are not unaware of the legal dimensions. The research agenda seems to encompass both the adequacy of existing regulations and potential patient litigation and public and product liability.