Overview

What is new? Telemedicine, the provision of healthcare over a distance, has become feasible over the last two decades with the development of new information and communication technologies. Patient and doctor are able to communicate and send information to each other electronically, and medical devices and treatment delivery systems can be operated remotely or automatically. These developments raise the possibility of more personalised prevention and treatment measures, at least to some extent in all four of the senses defined in Chapter 1. Consumerisation, as discussed in Chapter 2, has not yet developed to a marked extent in the application of telemedicine in the UK, though it may well do so in the future. But the ethical issues associated with responsibilisation are of key importance for telemedicine, since some telemedicine services lead to patients (or their carers) taking, or being obliged to take, greater responsibility for their healthcare.

Which ethical values come into conflict as a result of this development? Potential conflicts could arise between the ethical value of efforts by the state to reduce harm and the ethical values of using public resources fairly and efficiently, and of individuals being able to pursue their own interests in their own way.

What is the existing pattern of interventions like? There is no overall system of interventions that cover telemedicine in all its different forms. However, many of the general governance measures relating to healthcare that rest on state-specific legal powers apply to telemedicine as they do to other means of healthcare provision, for example, those governing the conduct of medical professionals, negligence, product safety and liability, and quality and standards of health services. As for more service-specific types of intervention, the EU-wide legislation that covers medical devices is also of relevance here.

What gaps or shortfalls are there in existing interventions? It is not always clear how the system of interventions applies to telemedicine services that operate across borders. We also have concerns that the current pattern of interventions does not encourage providers of healthcare services to consider all the factors that we think are essential when deciding whether to introduce telemedicine services, including a number of considerations relating to global social solidarity.

What types of intervention might possibly fill those gaps or remedy those shortfalls? It is possible that a comprehensive and specific system of oversight could be introduced for telemedicine, but it would be difficult to define what should be included in such a system. Other options might include clarification of existing interventions and voluntary adoption of good practice by healthcare providers.

What types of intervention do we recommend, and why? We make recommendations that are aimed at promoting the benefits promised by telemedicine while trying to mitigate any potential harms. Many aspects of telemedicine are extensions of existing healthcare services and should therefore be assessed in the same way as any other such new service or technology before they can be properly introduced. Evidence for benefits and harms seems to be specific to each particular telemedicine service, meaning that overarching conclusions cannot be drawn, and we see no case for further broad-based measures applying the coercive powers of the state at this time. Rather, we advise that providers of public healthcare systems should take various factors into account when deciding whether to introduce telemedicine services, including cost-effectiveness, equity, safety, quality, the value of physical time with health professionals, and impact upon doctor-patient relationships. We also make recommendations about: (i) consent; (ii) vulnerable people; (iii) monitoring devices; (iv) cross-border issues; and (v) global social solidarity. In line with the aim set out in Chapter 4, these recommendations are based on general governance type measures where possible, although sometimes more specific measures are required.
Introduction

8.1 Most people currently access healthcare by seeing their doctor face-to-face at a surgery, visiting a healthcare centre or hospital, or purchasing medicines and health-related products in a pharmacy. But some medical care has always been provided over a distance, that is with the patient and the healthcare professional in different places (for example with advice over emergency treatment being given by radio or telephone), and in recent years various technologies have been developed and integrated that greatly extend the possibilities of remote advice, observation or treatment. Such technologies include devices that can be operated remotely or automatically, communicate with healthcare professionals to relay medically relevant information, and even deliver treatment automatically. The term ‘telemedicine’ has come to be adopted to describe these technologies and services (though its definition and proper application is disputed: see Box 8.1). Telemedicine differs from other applications in this report in that most usually, at least in the UK, the services described are provided by the healthcare system rather than initiated and funded by users themselves.

Box 8.1: Definitions of telemedicine

The word ‘telemedicine’ is often used as an umbrella term to mean any form of healthcare that involves information and communications technology and an element of distance. It thus applies to numerous forms of information transmission (voice, sound, video, pictures, text), communication technologies (telephone lines, satellites, microwave, digital wireless, internet) and user interfaces (computers, personal digital assistants, telephones, stand-alone systems). The term ‘telemedicine’ is sometimes said to be too limited, and the terms ‘telehealth’ and ‘telecare’ have been proposed to expand the concept, to include medicine and healthcare more broadly. ‘Telehealth’ is defined as the delivery of healthcare at a distance, typically embracing diagnosis (e.g. teleconsultations, teleradiology), treatment (e.g. telesurgery), health education and research. ‘Telecare’, by contrast, is used to refer to the continuous and remote monitoring of individuals and their health status to manage the risks associated with independent living, for example with a person measuring their vital signs at home and the data being transferred to a clinician.

While we recognise the different nuances in the meanings of ‘telehealth’ and ‘telecare’, we use the term ‘telemedicine’ in this report as an overarching term to include all forms of medicine and healthcare carried out at a distance.

8.2 Telemedicine raises numerous issues of responsibilisation, as discussed in Chapter 2, because some telemedicine services lead to patients (or their carers) taking, or being obliged to take, greater responsibility for their healthcare, while also sharing key personal data with remote monitors. Up to now, some aspects of consumerisation in telemedicine developments have been rather less marked in the UK, with less of the direct-to-consumer marketing and competitive online provision than applies to several of our other cases. Many of the patients most concerned (notably elderly people) are likely to find difficulties in exerting meaningful consumer choice, particularly if some form of telemedicine appears to be the only alternative to institutional care. But it may well be that the technologies concerned will in time lend themselves more to the sort of consumer developments we have seen in our other case studies.

347 Ibid.
349 Telecare is sometimes also referred to as ‘connected health’.
Telemedicine may also lend itself to more consumerised provision in the sense of service that is more convenient in time and place for users.

8.3 Telemedicine also raises the possibility, although to a lesser extent, of more personalised prevention and treatment measures in the other senses set out in Paragraph 1.18: i.e. where it is used for more than a substitute for traditional face-to-face medical care, it can be a tool that facilitates the delivery of increasingly individualised prevention and treatment measures and it may also be conducive to ‘whole-person’ treatment. On the face of it, it may seem that telemedicine, by its very nature, is ‘de-personalised’ where it refers to healthcare provided in other ways than the more traditional face-to-face meetings between healthcare professional and patient (we return to this issue in Paragraph 8.15). But where telemedicine is used as more than a substitute for traditional face-to-face medical care, it may be a tool for greater personalisation in at least some of the senses described in Chapter 1, including more individualised preventive measures and possibly more ‘whole-person’ treatment as well. Much would seem to depend on how the technology is applied.

**Types of telemedicine**

8.4 Telemedicine encompasses numerous technologies, from basic telecommunications such as the telephone to the most sophisticated modern information and communications systems (see Box 8.2 for some examples). Each application of telemedicine has its own social and ethical implications, meaning that any new system would need to be considered on a case-by-case basis before introduction (see the recommendations later in this chapter). Examples of applications of telemedicine include the following.

- Information about a patient’s health-related biological or physiological processes is transmitted to either a healthcare professional or the patient, for monitoring purposes or as an alert when there is a potentially adverse change. This information might be used to help make decisions about treatment or for remotely activating a treatment device, such as an implanted insulin pump.

- Health-related information about individuals may be collected outside of the direct clinical healthcare context, for example remote parental monitoring of adolescent blood glucose.

- Healthcare professionals can communicate with patients, for example in ‘telepsychiatry’ via a video-conference link. The Aberdeen Royal Infirmary has trialled the HealthPresence system (supplied by Cisco) which combines video-conferencing with medical devices to facilitate a ‘virtual consultation’.\(^{350}\)

- Healthcare professionals can communicate with each other to give or seek advice or discuss any aspect of patient care. As with earlier forms of remote communication, such developments can be especially useful to assist in providing care that might be more specialist than that available locally, for example in ‘telesurgery’. A more regularly used service of this type is an established video-conferencing service that links minor injuries units in small community hospitals in the North East of Scotland with a large teaching hospital. Many minor injuries can be managed locally by nurses, and if necessary staff can request advice from specialists at Aberdeen Royal Infirmary. Using a video link allows the doctor providing advice to see the patient. In 90–95% of these requests for telemedicine advice, the result is that the patient does not need to be transferred to a larger hospital.

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\(^{350}\) The HealthPresence system includes medical equipment which enables the patient to provide information such as blood pressure, weight, pulse rate and temperature. An assistant is present with the patient to operate the medical devices. Cisco, Scottish Centre for Telehealth and NHS Scotland launched the first Cisco HealthPresence trial in Scotland in 2008. For further details, see: Scottish Centre for Telehealth (2010) Trial of a new consulting technology, available at: [http://www.sct.scot.nhs.uk/healthp.html](http://www.sct.scot.nhs.uk/healthp.html). NHS Grampian does not have any further plans to use the HealthPresence system, although other forms of telemedicine continue to be used. (Information supplied by the Scottish Centre for Telehealth.)
Developments in robotics and computer technology now enable some surgery to be carried out as ‘telesurgery’ with patients and key experts in different places. This potentially makes surgical expertise available throughout the world. An example is an operation involving the successful removal of a patient’s gallbladder, with the patient in Strasbourg and the surgeon in New York.\footnote{Marescaux J, Leroy J, Gagner M \textit{et al.} (2001) Transatlantic robot-assisted telesurgery \textit{Nature} 413: 379–80.}

Healthcare professionals can communicate with whoever is present at an emergency situation to advise them on giving care to those who need it.

Communications technologies can be used to transmit results and images such as x-rays (‘teleradiology’).

A broad definition of telemedicine can include monitoring sensors that measure a person’s activity in the home and transmit the data to relatives, carers or healthcare professionals. In this way changes in a person’s activity levels can be observed and addressed, for example by raising an alarm if there is no observable motion or if an adverse event such as a seizure is detected. We make recommendations relating to consent and the introduction of such monitoring services for vulnerable people in Paragraphs 8.37 and 8.38.

**Box 8.2: Telemedicine devices and systems**

**Assistive technology** – a product or service designed to promote independence and self-management for disabled people, older people or those with chronic conditions. For example, a pilot of a ‘Whole System Demonstrator Programme’ was carried out in England in 2008–2010 to test the potential of telemedicine to support people with long-term chronic conditions (including diabetes, heart problems, chest problems and those who were elderly and frail).\footnote{The pilot was funded by the Department of Health in England and was the largest trial of telemedicine in the UK to date. See: Department of Health (2008) Government launches national debate on the future of care and support, available at: http://www.mmmnetwork.nhs.uk/med-man-new-details.php?newsid=1641; Department of Health (2008) Whole systems demonstrators: An overview of telecare and telehealth, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_100947.pdf.}

**Biosensor** – a device that detects physiological changes in the body and turns it into an electronic signal.

**Micro electro-mechanical system** (MEMS) – a small integrated device or system that combines mechanical and electrical components that can sense and control on a micro-scale.\footnote{Vittorio SA (2001) Micro electro-mechanical systems (MEMS), available at: http://www.csa.com/discoveryguides/mems/overview.php.}

These devices and systems can sometimes be combined, for example by linking biosensors with MEMS to monitor patients and transmit the information to patients themselves or healthcare professionals.

**Telemedicine in developing countries**

Although the potential range of uses of telemedicine in developing countries is not dissimilar to that in the developed world,\footnote{Vitto R (2008) Telemedicine support for the developing world \textit{Journal of Telemedicine and Telecare} 14: 109–14.} it raises some distinctive ethical and social issues. Some commentators suggest that telemedicine may have a more profound impact on developing countries than on developed ones, owing to the possibility of provision of medical care, education and support from countries with more specialised resources.\footnote{See, for example: Edworthy SM (2001) Telemedicine in developing countries \textit{British Medical Journal} 323: 524–5.} Telemedicine could enable specialist medical care to be delivered in parts of the developing world where this care would not otherwise be available. For example, the global ‘e-referral network’ operated by the
Swinfen Charitable Trust provides expert second opinions to doctors in developing countries via an internet-based messaging system. The expertise is provided free of charge by volunteer consultants mainly from developed countries. The system allows medical personnel in developing countries to send clinical photographs, x-rays, a patient’s history and any other relevant material to the Swinfen Trust. The Trust then notifies the most appropriate available specialist and forwards the case to him/her. In its first ten years of operation, the Trust provided telemedicine advice for over 2,000 patients.356

8.6 However, it has been found that telemedicine initiatives in developing countries often have not matured into sustainable programmes,357 and some argue that potential demand for these services is not being met.358 Many developing countries lack sophisticated electrical and telecommunications infrastructures, especially in remote and poor areas, making it hard to provide remote medical services to those who are likely to need them most.359 It has also been argued that “although current efforts using telemedicine have demonstrated positive effects in countries in need, they have not substantially reduced or compensated for a fundamental lack of healthcare.”360

8.7 There are concerns that, should telemedicine become widespread in developing countries, such a development could lead to a new form of medical ‘brain drain’, insofar as health professionals might begin providing remote healthcare related services to developed countries to the detriment of patients in their own countries. But that is not the only possible effect of telemedicine on development: the technology might also be seen as a way of providing healthcare professionals in developing countries with access to higher pay and better training, without necessarily leaving their home countries, having the effect of reducing rather than increasing the ‘brain drain’. The technology might also serve to increase professional links between developing and developed countries.361 Exactly how these various factors will play out is not known, but we return to this issue in our recommendations in Paragraphs 8.45–8.48.

Benefits and harms

8.8 A number of potential advantages and disadvantages of telemedicine are included in Table 3.1.

**Potential advantages**

- Being at home rather than in institutional care;
- convenience;
- more equitable access to healthcare;
- cheaper care; and
- earlier return home from hospital.

**Potential disadvantages**

- Dangers of misuse;
- reduction in the quality of the doctor-patient relationship;
- a ‘virtual brain drain’;

inappropriate early discharge from hospital; and
surveillance of lifestyle.

**Convenience and access to specialists**

8.9 Telemedicine offers some patients opportunities for accessing healthcare more conveniently and reducing the need to travel and overnight stays in or near a hospital or other healthcare facility. It has particular advantages in remote or rural areas where there are fewer specialist doctors. Some services can be provided in the privacy of the patient’s home, and at times that suit them. Telemedicine can thus be a useful ‘add-on’ to more traditional, face-to-face healthcare and can also offer additional services than might otherwise be available, such as more frequent monitoring (see Box 8.3 for an example). Doctors may also benefit from telemedicine, with the possibility of reducing travel, increasing their access to specialist opinions and offering opportunities for more efficient training.

**Box 8.3: Congestive heart failure (CHF) monitoring after a hospital stay**

CHF is a clinical syndrome that is increasingly prevalent in Western countries, with a yearly mortality rate of up to 50% of people with the condition. Regular and effective monitoring is an important element of CHF management, because the signs of deteriorating health may be “subtle and difficult to recognize”.

CHF remote monitoring programmes have been trialled in which patients complete a monitoring session each morning, weigh themselves, answer a health questionnaire or provide other health data via the internet. This information can be transmitted directly to a doctor. On the basis of this information, the patient may continue to be monitored, or further treatment may be needed if there has been a deterioration in their condition.


**Patient satisfaction and concerns about replacing face-to-face consultations**

8.10 The broad range of services available and being developed makes it difficult to give an overall summary of levels of patient satisfaction with telemedicine services. Whether or not patients consider telemedicine services to have been implemented successfully seems to be heavily contextual: it depends on the nature of the service being delivered, location and finance. For example, there has been enthusiasm for the provision of healthcare services to those in remote or rural locations because it may, to some extent, mitigate the problems of distance between doctor and patient. However, even there it is not always certain that the potential benefits are realised, due to factors such as the structural organisation and the culture of the relevant healthcare providers.

8.11 There are concerns that telemedicine could be used by health services to replace face-to-face consultations between healthcare professionals and patients that both find beneficial. The World Medical Association’s *Statement on the ethics of telemedicine* notes that telemedicine

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measures should generally augment face-to-face care, rather than replace it: “telemedicine should be employed primarily in situations in which a physician cannot be physically present within a safe and acceptable time period.” Going further, the Department of Health for England’s 2005 report, Building telecare in England, stated: “As we move towards the future, there is no doubt that new technologies will play an increasing role in all parts of our lives. However, we must take care not to allow these new technologies to control or isolate us and whilst the world around us is fast changing our basic human needs remain the same. Some care services will always be, quite rightly, delivered personally. Human contact is vital to maintaining quality of life. As we embrace the new possibilities and promise that the future brings we must make sure that our values are not weakened but strengthened by using these technologies to complement traditional forms of care.” We return to the issue of patient satisfaction with telemedicine services in our recommendation in Paragraph 8.35.

8.12 There are some instances in which the use of telemedicine is said to be inappropriate, or where ‘hands-on care’ is to be preferred. Some years ago, for example, the British Medical Association argued that telemedicine should not be used for intensive care: “We believe that the introduction of telemedicine for intensive care would have a detrimental effect on outcomes, given that critical care is a ‘hands-on’ skill and requires a multidisciplinary team approach, both of which telemedicine would not be able to provide”. But this view is by no means universally held: some people believe, on the contrary, that there are circumstances in intensive care units where telemedicine has an important role to play and is increasingly becoming standard practice.

8.13 A good doctor-patient relationship involves openness, trust and good communication, to enable patient and doctor to work together to address the patient’s needs. The review of evidence carried out for this report found that communication is a key determinant of healthcare outcomes, and hence the way some telemedicine services affect health outcomes may be, in part, through changes in the way doctors and patients communicate with one another. But because telemedicine services come in so many forms, the impact on the doctor-patient relationship is likely to vary from one application of telemedicine to another.

8.14 The evidence review carried out for this report found little empirical research about the impact of telemedicine on doctor-patient relationships. There have been several relevant literature reviews, which have found methodological and conceptual weaknesses in most of the studies examined, but concluded that such research as there has been reveals high levels of patient satisfaction with telemedicine (particularly with respect to travel, waiting time, and access to comprehensive specialist care) along with “some disquiet” over provider-patient communication that falls a long way short of hard or conclusive evidence.

8.15 If consultations take place virtually via video-conferencing rather than physically, the constraints of the technology may affect the process, for example through limited scope for sensory input and non-verbal communication, and by the way it affects social and professional distancing between doctor and patient, particularly given that norms and standards for such teleconsultations are not yet fully developed.\(^{373}\) Changed behaviour caused by the 'tele' format might also limit the trust needed to facilitate patient disclosure and cooperation. On the other hand, the use of telemedicine in some circumstances might serve to promote more patient-centred interactions which recognise patients as collaborators who bring strengths and resources to the interaction.\(^{374}\) So, as we suggested in Paragraph 8.3, whether the patient receives more or less care that is 'personalised' (in the sense of being tailored to their particular needs) seems to depend less on anything inherent in the technology as on how the care is delivered and who delivers it. On the one hand, non-verbal communication, including voice quality and tone, eye contact, posture, touch, activity and other cues can all be absent or more difficult to interpret using telemedicine (the extent of the difficulty depending on the device being used). Some patients may also feel that telemedicine reduces their sense of privacy, which may hinder patient communication during some encounters. On the other hand, it is possible that the use of telemedicine may create a setting in which other patients can feel more relaxed, especially if they are in their own homes or feel they can discuss potentially embarrassing matters with greater ease. Consultations via telemedicine often require greater patient participation, for example in situations where patients are asked to use a blood pressure machine as part of the consultation.\(^{375}\)

Cost-effectiveness

8.16 The wide variety of telemedicine applications means that no general conclusions about their cost-effectiveness can be drawn. Indeed there is no easy way of measuring the cost-effectiveness of such applications. Cost-effectiveness is, of course, important when considering introducing a new service and we make a recommendation about this element in Paragraph 8.31. Proponents of telemedicine argue that it can increase the efficiency and cost-effectiveness of healthcare delivery through better management of long-term conditions, reduced hospital stays, improved accessibility to services and sharing of healthcare resources. But a recent evaluation noted that "several systematic reviews have found little evidence that telemedicine is cost saving."\(^{376}\) Problems in determining the cost-effectiveness of telemedicine services include: the difficulty of generalising results (e.g. what may be considered cost-effective in a rural setting may not be applicable to the inner city);\(^{377}\) whether or not cost-effectiveness should take into account (or be subordinate to) clinical effectiveness;\(^{378}\) and the institutional context within which the service is provided (e.g. a public healthcare provider such as the National Health Service (NHS), the military or a commercial organisation such as an oil rig).\(^{379}\) Conclusions about cost-effectiveness may also depend on the particular telecommunications equipment used.\(^{380}\)

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380 May CR (2002) Failure to compare cost
8.17 In 2008, the European Commission noted that, although some studies demonstrated benefits of telemedicine on a small scale for patients and healthcare systems, “there is limited evidence of the effectiveness and cost-effectiveness of telemedicine services on a large scale”. The Commission said that “commonly accepted methodologies for assessing effectiveness, such as those used to assess pharmaceutical products, must be further developed” and it has stated its intention to “support the development, by 2011, of guidelines for consistent assessment of the impact of telemedicine services, including effectiveness and cost-effectiveness”. Two examples of studies are given in Box 8.4.

Box 8.4: Two examples of studies assessing the cost-effectiveness of telemedicine services

Cardiac telemedicine in Cumbria and Lancashire

In 2005 the then Cumbria and Lancashire Strategic Health Authority implemented a cardiac telemedicine trial to evaluate the use of an electrocardiogram (ECG) interpretation service within a primary care setting. The ECG interpretation service aimed to provide assistance to general practitioners (GPs), who often experience difficulty in interpreting ECGs, thus aiding diagnosis and patient treatment. Patients were able to receive a full ECG at their GP surgery within minutes, rather than having to attend an accident and emergency department. The six-month pilot trial indicated that the potential for the service was to prevent up to 90,000 accident and emergency visits and 45,000 hospital admissions per year across England. It was estimated that the potential financial savings could be upwards of £45 million per year for England as a whole if the programme were implemented across the country.

Teledermatology in Northern Ireland

A study of ‘teledermatology’ in Northern Ireland ten years ago examined the various factors that could affect both the clinical outcomes and cost-effectiveness of telemedicine. The study involved a randomised control trial of teledermatology services in four health centres and two regional hospitals. It concluded that, while the service in question offered “no major differences in clinical outcome” in comparison with face-to-face care, it was not cost-effective. This conclusion was based on several factors, particularly the cost of purchasing and using the telecommunications equipment and the distance patients had to travel. Had the distances been longer and the equipment less costly (for example if it was bought at 2000, rather than 1995, prices) the service would have been regarded as cost-effective.
Surveillance technologies

8.18 Remote monitoring of patients can reveal treatable medical problems and enable changes in lifestyle targeted at each individual’s circumstances. The use of technologies such as biosensors for clinical monitoring may improve quality of life and promote independent living. However, the use of surveillance devices has met with considerable opposition by those who think surveillance is an intrusion of privacy and contrary to principles of dignity and freedom. The European Convention on Human Rights, implemented in the UK by the Human Rights Act 1998, places a duty on the state to protect the freedom and liberty of individuals. The relevant parts are Article 3, which prohibits degrading or inhuman treatment; Article 5 which provides a right to liberty and security; and Article 8, which enshrines a right to respect for private and family life. Privacy and liberty are always breached to some degree when a patient is under surveillance, and such a breach in our second ethical value needs to be balanced against the benefits of using the technology (e.g. maintaining freedom and allowing independence).

8.19 The implementation of surveillance technologies that some telemedicine applications entail requires careful consideration to ensure ethical use among those who are most vulnerable, including elderly people and those with learning difficulties. For instance, in a paper on the use of electronic surveillance measures in elderly patients with dementia and people with learning difficulties, Welsh et al. (2003) declare: “What is heralded as an opportunity for increased liberty must not degenerate into the denial of basic human rights and dignity”. The ethical issues raised by the technologies led those authors to call for the introduction of clear guidelines and protocols to ensure consistent and ethical practice, and we return to this issue in our recommendation in Paragraph 8.37.

Extent of use

8.20 Since the 1990s, there has been a rapid increase in research related to telemedicine as a result of developments in information and communications technologies. The wide range of applications that come under the heading of ‘telemedicine’ and the different definitions of the field that we noted earlier make it difficult to assess the extent of these applications. For example, some people consider any application involving the use of telephones or the internet as ‘telemedicine’ whereas others would apply a more restrictive definition. In 2005, the Department of Health for England stated an intention to increase the numbers of older people who benefited from telecare by at least 160,000 nationally over two years, but the outcome of that measure was not clear at the time of writing, and within the UK or its component countries there are no centrally held records available as to the number of people aged 65 and over in the UK using telemedicine equipment in their homes or a residential context, perhaps because such services are a local government responsibility.

8.21 While integrated, comprehensive systems seem to be rare, it is generally considered that the use of certain forms of telemedicine is fairly common, has been occurring for some years and is increasing. Teleradiology and telepsychiatry are sometimes cited as examples of

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390 Liam Byrne, Parliamentary Under-Secretary, Department of Health, Hansard HC Deb, 25 April 2006, c1083W; Phil Hope, Minister of State (the East Midlands), Regional Affairs, Hansard HC Deb, 20 July 2009, c998W.
telemedicine that are fairly widespread and successful, but many telemedicine pilots that have been carried out have ceased to operate once their initial funding has run out.

Current system of interventions

8.22 There is no overall system of interventions that cover telemedicine in all its various forms. However, many of the general governance measures relating to healthcare that rest on the state-specific legal powers apply to telemedicine as they do to any other means of providing healthcare, for example those governing the conduct of medical professionals, negligence, product safety and liability, and quality and standards of health services (see Box 4.1). The EU-wide legislation that covers medical devices also covers telemedicine, and we consider these forms of intervention further below.

Legal liability of healthcare professionals

8.23 Telemedicine can involve the transmission of health information across national borders, as well as the making of decisions about diagnosis, treatment and patient care. So how does legal liability over issues such as negligence or malpractice operate when the healthcare professional is located in a different country from the patient? If medical consultations and treatment are provided by healthcare professionals in one country to patients in another country, this raises issues of legal jurisdiction and governance of data, as well as issues of responsibility and professional liability. The legal principles upon which jurisdiction in cross-border practice is established were introduced long before the development of telemedicine. Jurisdiction is often determined by which country the practice is most closely associated with, or which is most fair and convenient for all the parties involved. A contract may state the applicable law and jurisdiction that has been agreed on.

8.24 Countries within the EU operate a restrictive policy which stipulates that healthcare professionals require full registration to practise within the country the patient is residing in. Effectively, it is as if healthcare professionals are travelling to the patient when they deliver a telemedicine service. Within the EU, healthcare professionals who have gained professional qualifications in one Member State are entitled to have their qualifications recognised in all other Member States, but they can be suspended or struck off the medical register after fitness to practice proceedings in one state while still being permitted to practise in another.

8.25 The likely future volume of cross-border telemedicine is debated, and some argue that there are substantial barriers to cross-border telemedicine, not just those constituted by legal and regulatory disparities but also “cultural differences, socio-political conditions (public vs. private health provision), lack of human resources, and technologic and infrastructural limitations”. We return to cross-border telemedicine in our recommendation in Paragraph 8.44.


Ibid. (See also: the Rome Convention 1980 and the Brussels Regime.)

Ibid.


Ibid.
Medical devices

8.26 In the UK, laws on product liability apply equally whether a device or part of a system is based many miles from the patient or in another room of the same hospital. Medical devices are regulated separately from medicines (we describe the latter regime in Chapter 7). There are three main European Medical Devices Directives transposed into UK law, all intended to proportion the stringency of regulation to the level of risk involved:

- Active Implantable Medical Devices (90/385/EEC) (Powered implants);
- Medical Devices (93/42/EEC) (Most other devices); and
- In Vitro Diagnostics (98/79/EC) (In Vitro Diagnostic medical devices).

8.27 These Directives require ‘Notified Bodies’ to check that manufacturers and devices meet the requirements. Notified Bodies are firms that apply for this status and there are about 80 of them across Europe and seven in the UK. Council Directive 93/42/EEC specifies ‘essential requirements’ for medical devices, placing controls on safety, performance, design, specification, manufacture, labelling and packaging. Products are classified as ‘low risk’, ‘medium risk’ and ‘high risk’ according to specifications in the Directive. Manufacturers must themselves classify their devices into these categories, and review and comply with the relevant requirements. In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA), which has already been described, carries out pre-market registration and post-market monitoring and enforcement. It awards the CE mark to products under the Medical Devices Directive if a manufacturer meets its responsibilities. The MHRA has no remit over the regulations applied outside the EU, but the Agency stated to us: “[W]e do expect that tests/products used in conjunction with a service being offered in the UK for healthcare services are safe, effective and fit for purpose... It would be the responsibility of the service provider to ensure that the laboratory chosen was suitable for the tasks that they are being requested to undertake.” (See also Paragraph 9.30 where similar issues are discussed.)

Softening the ethical dilemmas

8.28 Many of the developments in telemedicine that we have outlined offer potential benefits to patients, in terms of convenience, access and privacy in some cases, and they can also improve patient outcomes. Many of the developments do not raise new ethical issues because they are simply an extension of previous communications technologies, though due consideration needs to be given to the satisfaction of patients and healthcare professionals when introducing new applications of telemedicine (an issue we deal with in recommendations later). Beyond that, however, there are potential ethical dilemmas posed by applications of

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400 In determining what constitutes a ‘Medical Device’, and hence falls within the scope of these Directives, the MHRA states that “If a product has a medical purpose, i.e. it is specifically intended to provide or assist with the diagnosis, monitoring, prevention or treatment of a medical condition, it is likely to be a Medical Device under the Medical Devices Directive (93/42/EEC)... Software systems that are only intended for archiving/retrieving patient records/images are thus not regarded as Medical Devices... However, if [computers etc.] are put on the market by a manufacturer... and CE-marked as a complete system including software that gives the system a medical purpose, then the whole system will require CE-marking under the MDD. If the software carries out further calculations, enhancements or interpretations of captured data... we consider that it will be a Medical Device... Products intended specifically for remote diagnostic purposes are also considered medical devices.” Information provided for fact-finding meeting, held on 23 September 2009.

401 But the derivation of risk from these specifications sometimes seems to involve tricky questions of interpretation.

402 A CE mark is “a declaration by the manufacturer that the product meets all the appropriate provisions of the relevant legislation implementing certain European Directives... The initials ‘CE’ do not stand for any specific words but are a declaration by the manufacturer that his product meets the requirements of the applicable European Directive(s)”. See: Department for Business, Innovation and Skills (2010) What does CE marking mean? What do the initials CE stand for?, available at: http://www.berr.gov.uk/policies/business-sectors/environmental-and-technical-regulations/technical-regulations/ce-marking-faqs.

403 Information supplied by the Medicines and Healthcare products Regulatory Agency.
telemedicine where the value of individuals being able to pursue their own interests in their own way runs up against the value of state efforts to reduce harm and of using public resources fairly and efficiently.

8.29 As noted above, it is not always clear how the existing regime of interventions applies to telemedicine services that operate across borders. Additionally, we think that the current arrangements do not encourage providers of healthcare services to consider all the factors that we think are desirable when deciding whether to introduce telemedicine services, including considerations of common good or solidarity at the global level. We have found no systematic evidence of harm caused by telemedicine at the present time (and indeed any such evidence would need to be collected on a case-by-case basis for each type of application) and therefore cannot justify any measures based on the application of state-specific legal powers, for the reasons given in Chapter 4. Rather, our recommendations focus on what factors providers of public healthcare systems should consider when deciding whether to introduce telemedicine services, including cost-effectiveness, equity, safety, quality, and the value of physical time with health professionals and impact upon doctor-patient relationships. We also make recommendations about: (i) consent; (ii) vulnerable people; (iii) monitoring devices; (iv) cross-border issues; and (v) global social solidarity. In line with our aim set out in Chapter 4, these recommendations are based on general governance type measures where possible, although sometimes more specific measures are required.

Using public resources fairly and efficiently

8.30 While telemedicine systems offer the possibility of reducing harm, there are obviously costs associated with introducing them into a public healthcare system, but those investments may result in overall cost savings once they are in use. While some studies indicate that some applications can be cost-effective, the evidence we have reviewed suggests that it is not yet possible to make general claims about cost-effectiveness of telemedicine (see Paragraph 8.16), and as we have already noted conclusions about cost-effectiveness depend on the framework used for evaluation.\(^{404}\) We therefore limit ourselves to recommending some factors that should be considered when deciding whether to introduce new telemedicine systems.

8.31 To ensure that public resources are used fairly and efficiently, we recommend to providers of public healthcare systems that telemedicine services should be subjected to the same criteria of cost-effectiveness, equity, safety and quality to which other health technologies are subjected. This recommendation may require careful monitoring of changes in the quality and standards of care for patients arising from their introduction, for example if people were at risk of being discharged inappropriately early from hospital due to the provision of a telemedicine service for aftercare and follow-up. (See also our recommendation about patient satisfaction below, Paragraph 8.35.)

Inequities in access to healthcare

8.32 Ease of access to healthcare services varies from one population group to another, and geography – where people live and how far they are from healthcare facilities – is an important factor shaping ease of access. Public healthcare systems including the NHS place a high value on equity in healthcare and we set out in Chapter 3 the value of social solidarity, by which we mean sharing risks and protecting the vulnerable. Telemedicine offers important opportunities to promote this value by assisting people living in remote areas, or areas without specialist services, to access healthcare in ways that do not disadvantage them in comparison with those living in other areas.

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8.33 Public healthcare systems should offer telemedicine services in circumstances where they can assist in a feasible and cost-effective manner to reducing inequities in access to healthcare, taking into account our recommendation below on patient satisfaction (Paragraph 8.35). As when introducing any new health service, consideration should be given to ensuring that inequities of access to care are wherever possible not exacerbated for some groups while they are reduced for others.

**Patient satisfaction**

8.34 Our biggest concern about the introduction of telemedicine systems that link patients to remote healthcare professionals or remote systems is that it may serve to replace time spent in the physical presence of health professionals, an aspect of healthcare valued by many people. We may therefore have to balance the value of using public resources fairly and efficiently against the value of state activity to reduce harm in this case.

8.35 We recommend that for telemedicine, the value of time spent in the physical presence of healthcare professionals should be included in any cost-effectiveness analyses (see Paragraph 8.31). We also recommend that when people would prefer not to receive their healthcare via telemedicine, a more conventional alternative service of comparable quality should also be made available whenever it is cost-effective.

**Patients without capacity and surveillance technologies**

8.36 Careful consideration should be given to the fact that certain groups for whom telemedicine applications could be considered – for example, people with dementia and people with learning difficulties – may have special healthcare needs and may have impaired capacity for informed consent. The values of individuals being able to pursue their own interests and efforts by the state to reduce harm to individuals therefore shape our recommendations on this issue.

8.37 We recommend that providers of telemedicine services observe the following conclusion made in relation to assistive technologies by the Nuffield Council on Bioethics in its 2009 report on Dementia:

Where a person with dementia lacks the capacity to decide for themselves whether to make use of a particular technology, the relative strength of a number of factors should be considered on a case-by-case basis, including:

- the person’s own views and concerns, past and present, for example about privacy;
- the actual benefit which is likely to be achieved through using the device;
- the extent to which carers’ interests may be affected, for example where they would otherwise have to search for the person with dementia in the streets at night; and
- the dangers of loss of human contact.

8.38 There may be similar problems in deciding whether or not a person with learning difficulties has appropriately agreed to use telemedicine. We recommend that providers of telemedicine services take into account the following issues when making these decisions:

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405 Provisions of the Mental Capacity Act 2005 covering England and Wales, and similar legislation in Scotland and planned for Northern Ireland, would apply to those who lack capacity to make a particular decision.

The doctor-patient relationship

8.39 The interactions between healthcare professionals and patients can change as a result of telemedicine services, and have the potential to result in both benefits and disadvantages for patients and healthcare professionals. But as we indicated earlier, those changes seem to depend heavily on context, technology and perhaps individual characteristics as well (see Paragraph 8.15), and there has been little empirical research conducted to date that investigates the impact of telemedicine on doctor-patient relationships. Such research is important to assess likely effects if telemedicine comes to be applied on a larger scale than it is at present.

8.40 In the light of our value of efforts by the state to reduce harm, we recommend that public healthcare providers should carry out an evaluation of any impact upon the doctor-patient relationship for every telemedicine service that is implemented.

Responsibilisation

8.41 Applications of telemedicine involving monitoring and feedback functions may mean that some people are given immediate warnings that their conduct – whether it be by behaviour, diet, or non-adherence to treatment – is potentially harmful to their health. (For example, a glucose or alcohol monitor can be linked to appropriate warnings.) Such applications make it possible for willing individuals to become more involved in their health and healthcare and may give them information they need to make responsible decisions about their health. However, people may also find themselves held more responsible by healthcare professionals for poor health outcomes that might be ascribed to their own actions in the light of such information and alerts. Responsibilisation can thus cut several ways, as we have noted in earlier chapters.

8.42 We consider that healthcare professionals should not rely on monitoring and feedback devices as the basis on which to make decisions about denying treatments to patients. Instead, healthcare professionals should use the information gained (as they do for other sources of information) to help them in working with the patient to provide him/her with the most suitable care available in that healthcare system.

Cross-border responsibility

8.43 As noted in Paragraphs 8.23–8.25, there are some ambiguities about where legal responsibility for the conduct of healthcare lies, and which jurisdiction applies in terms of liability when the healthcare professionals and patients are located in different countries. There is potential for serious harms to be caused here.


407 Noting that Paragraph 7 of the UK General Medical Council’s Good Medical Practice states “You must not refuse or delay treatment because you believe that a patient's actions have contributed to their condition.”
8.44 In order to try to reduce harm to individuals, we recommend that countries ensure that the services people receive from overseas-based health professionals meet the same requirements as those provided by health professionals based within their own country. In the UK, this responsibility will fall to the Government Health Departments based in England, Scotland, Wales and Northern Ireland.

Telemedicine and developing countries

8.45 We discussed in Paragraph 8.5 how the knowledge and clinical experience of healthcare professionals based elsewhere can improve patient care and efficiency of resources in developing countries, especially in remote areas. Telemedicine may also be used to contribute to medical education in both developing and developed countries. For example, consultants may gain knowledge from the experience of being involved in treating a wider range of cases, including the more severe or rare ones. More broadly, telemedicine may serve as an instrument that counters or compensates for the medical brain drain from developing to developed countries, which is often held to be a mechanism that exacerbates global inequity in healthcare, and which for some might be considered a harm sufficiently serious to justify the use of state-specific powers to reduce that harm.409

8.46 In the light of our value of social solidarity, in this case involving transnational issues of massive health inequities, we recommend that the possibilities for telemedicine to improve patient care and clinician education in developing countries should be explored by those countries and international organisations. The World Health Organization and other international agencies should encourage the development of low-cost, within-country telemedicine networks (supported from out of the country where appropriate) that demonstrably benefit health outcomes, and that can be shown to be cost-effective and sustainable.

8.47 Telemedicine may open possibilities for healthcare professionals in developing countries to provide services for developed countries remotely. There have been some examples of this, but it is not clear how much further it will go. Such a change might possibly reduce the medical brain drain from developing to developed countries that was referred to earlier, enabling more trained medical professionals to stay in developing countries and perhaps also provide healthcare there. But any such change might also mean the tying up of healthcare professionals in developing countries who as a consequence provide fewer services to local people (see Paragraph 8.7).

8.48 Again taking seriously the value of global social solidarity, we recommend that healthcare systems in developed countries should monitor any impacts of outsourcing their healthcare services to developing countries via telemedicine. In the UK, this monitoring should be carried out by the UK Government Departments of Health. We consider such monitoring to be especially important in the light of the UK’s Code of practice for the international recruitment of healthcare professionals, which precludes the active recruitment of healthcare professionals from developing countries, unless there has been a reciprocal government-to-government agreement that healthcare professionals from that country may be targeted for employment.410

409 For example in the form of taxes on organisations in developed countries that employ medical professionals trained in developing countries (suggested to us in private communications).
**Future impact**

8.49 Telemedicine could be of particular significance when considering the impact that an ageing population will have on health and social care.\(^{411}\) As noted in earlier chapters, older people use healthcare more than other demographic groups, and therefore healthcare providers will need to assess ways in which telemedicine can be used to improve cost-effectiveness.\(^{412}\) Some forms of telecare could be particularly suited to the provision of health services to older people, in so far as telemedicine can help promote independence and detect early changes in health status. It has also been argued that telemedicine is important as a way of better supporting vulnerable adults, those with long-term chronic conditions and those with dementia.\(^{413}\)

8.50 Hence it is likely that, at least in the UK and other developed countries, we will see increased use of telemedicine in many different forms in the future. Indeed, a recent report by Deutsche Bank Research suggested that telemedicine turnover in Europe might be expected to grow by an average of 10% each year across Europe until 2020.\(^{414}\) The prospects for future growth make it important for the ethical issues discussed here to be carefully considered.

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