Telemedicine a need for ethical and legal guidelines in South Africa

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Abstract

Background: Telemedicine is viewed as a new way of offering medical services. It is seen as a means of overcoming the growing shortage of health practitioners in developing countries. The aim of this paper is to highlight the need for the formulation of guidelines for the ethical practice of telemedicine in South Africa.

Methods: Full-length, peer-reviewed journal papers were obtained for review by searching the electronic databases Pubmed, CINAHL and CAB International, using the Boolean-linked keywords ethics AND telemedicine, ethics AND telecare, ethics AND telehealth, and ethics AND ehealth. Additional searches were made of Google Scholar using the same search strategies, and of the web pages of national telemedicine associations.

Results: A total of 152 relevant papers were identified. Twenty-one telemedicine guidelines were obtained. Only four countries and one international association have developed ethical guidelines. Several medical disciplines have established national guidelines for their speciality. Common ethical issues identified include the doctor-patient relationship, informed consent, confidentiality, data security, adequacy of records, data standards and quality, clinical competence, licensure and medical responsibility. These are discussed with reference to the developing world where appropriate.

Conclusion: Resource constraints and other issues relevant to developing countries may require the formulation of guidelines that do not necessarily conform with those of the developed world. It is in the interests of patients and practitioners that ethical guidelines for the practice of telemedicine are developed for South Africa. If telemedicine is to be used to overcome shortages of health practitioners, it is important that contentious issues are resolved in a pragmatic way that is appropriate to our circumstances and in the best interests of the majority of our population.

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Introduction

Telemedicine is viewed by most people as a new way of practising and offering medical services and advice. As with anything new, there is often resistance to change. Gainsayers have been quick to cite potential ethical and legal problems associated with telemedicine.[1] However, there are few, if any, doctors who have not practised telemedicine. Most have done so unwittingly when they have sought or given medical advice over the telephone.

Telemedicine may be defined as the delivery of healthcare and information across distance, through the use of information communication technologies (ICTs). These ICTs include telephony, radio, fax, e-mail, the internet, videoconferencing and satellite-based communications, all of which are used to transfer information electronically. The types of information that may be transferred include documents, laboratory results, ECGs, digital photographs, radiographs, CT scans, MRI scans, real-time ultrasonography or video, video recordings, sound from electronic stethoscopes and physiological data such as blood pressure, haemoglobin saturation, heart rate and spirometry. In addition, telemedicine encompasses a wide range of activities, from diagnosis, treatment and prevention of disease, to home-care monitoring, continuing education of health professionals and patients, and research.[2]

In its present forms, telemedicine is broadly divided into store and forward telemedicine and synchronous telemedicine. In store and forward telemedicine, patient data and accompanying images or sound files are transmitted by e-mail to a colleague, who subsequently reviews the information and sends back a diagnosis and/or management plan. In synchronous or face-to-face telemedicine, patient consultations occur in real time, using video-conferencing for the consultation.

Much has been written about the potential of telemedicine to increase access to quality health care in rural areas by providing access to specialists, preventing unnecessary patient transfer, supporting rural practitioners, enabling research and providing ongoing professional education.[3,4] There is a shortage of doctors in developing countries. Thirty-one of 47 sub-Saharan African countries for which data are available have less than 10 doctors per 100 000 population, while countries like Australia, America and Italy have 249, 509 and 606 doctors per 100 000 population respectively. South Africa is reported as having 69 doctors per 100 000.[5] It is not surprising that the World Health Organisation (WHO) has identified the use of telemedicine as a possible solution to the problem of the growing shortage of healthcare professionals in the developing world and, in January of 2005, the executive board of the World Health Assembly recommended the adoption of a resolution affirming member nations' commitment to eHealth.[6]

The South African National Department of Health (DOH) had already perceived the potential benefits afforded by telemedicine. In 1998 it established a series of pilot projects as phase one of the South African Telemedicine System. These were subsequently transferred to the Provincial Departments of Health. This national project was said to be the first of its kind in a developing country.[7] The South African Medical Research Council (MRC) then established the National Telemedicine Lead Programme. Despite the backing of the DOH and the MRC, the uptake of telemedicine has been limited. This has largely been due to technical and organisational challenges, failure to provide adequate and ongoing training, resistance to change, failure of the Provincial Departments of Health to incorporate telemedicine in their planning and concerns over ethical and legal issues. As a result, the DOH's pilot projects have not expanded into the national programme as envisaged. The success of subsequent projects in KwaZulu-Natal and the Eastern Cape has led to a resurgence of interest in telemedicine, with projects running or planned in KwaZulu-Natal, the Eastern Cape, Limpopo, Mpumalanga and the Western Cape.

While telemedicine provides an attractive solution to the shortage of healthcare practitioners, the way in which it should be practised has not been resolved. The WHO resolution of 2005 alludes to ethical matters by acknowledging the need to respect the principle of equality and differences in culture, education, language, physical and mental ability and geographic location.[6] It does not, however, address specific ethical questions related to telemedicine, such as the lack of direct patient-practitioner contact, informed consent, confidentiality, safety, data security and the legal implications of the cross-border, international practice of telemedicine. Nor does it address the question of vulnerability of people in disadvantaged countries, an issue that has been the focus of recent debate on ethical issues relating to standard of care and research.[3,4,8]

A question that arises is whether there is a possible need for different ethical and clinical guidelines and standards for telemedicine in developing countries? One argument revolves around the concept of an appropriate standard of care. Should a patient in a developing country be deprived of a telemedicine consultation with a specialist because the equipment and techniques used may not meet the stringent standards set in the developed world, where the standards are influenced by fear of litigation? Put another way: Is some service better than no service and could a service that does not meet the standards of the developed world constitute an appropriate standard of care in the developing world?

For example, there are internationally accepted norms and standards for the transmission and compression of digitised X-ray films (DICOM – digital imaging and communication in medicine).[9] These standards are currently not achievable with commercially available digital cameras designed for domestic use. If a doctor in a rural hospital in a developing country, with no access to a specialist radiology service, were to take a photograph of an X-ray plate with a digital camera and send the image by e-mail to a radiologist for interpretation, would this be accepted as an appropriate standard of care within available resources? Further questions arise: Can the referring doctor act on the radiologist's report? If, instead of an X-ray, the rural practitioner had sent a photograph of a dermatological condition to a dermatologist for advice on the diagnosis and management of the condition, who would take responsibility for the outcome of that management plan? What are the responsibilities of both parties for keeping records of the electronic consultation? Are the responsibilities different when the patient is seen "face to face" in a video-conference consultation?[10,11,12,13]

As part of the South African DOH's Telemedicine System, a working group was established to "Coordinate establishment of appropriate regulatory and ethical framework procedures". The resulting document, entitled "Telemedicine Code of Ethics and Professional Conduct", lists twelve, single-statement moral imperatives. The ensuing guidelines provide a one-paragraph amplification of six of the moral imperatives. Unfortunately, the code and guidelines appear to have been adapted from a code of conduct for commercial telemedicine product providers

and not healthcare professionals, as they refer to "participating members must always attempt to ensure that their products will be used in socially and environmentally responsible ways", "telemedicine designers and users must attempt to minimise malfunctions in the system by following generally accepted standards for system design and development" and "will prohibit the member from making false claims and should encourage full disclosure of all pertinent system problems or limitation."[14] There are, as such, no functional ethical guidelines for the practice of telemedicine in South Africa.

The aim of this paper is to highlight the need for guidelines for the ethical practice of telemedicine in South Africa by reviewing the current literature on ethical guidelines for the practice of telemedicine. The common ethical issues identified will be discussed and their relevance to developing countries will be examined.

Method

Full-length, peer-reviewed journal papers were obtained for review by searching the electronic databases Pubmed, CINAHL and CAB International. Searches were made on the following Boolean-linked keywords: ethics AND telemedicine, ethics AND telecare, ethics AND telehealth, and ethics AND ehealth. The results of all the searches were combined and duplicates were excluded. An additional search of the World Wide Web was made on Google Scholar® using the same search strategies. As guidelines may not have been published in medical journals, the Telemedicine Information Exchange (TIE) website was searched by country and under the heading "ethics". Where appropriate, references cited in papers were obtained and studied. Abstracts of papers presented at conferences were not included.

The papers were reviewed by both authors and the issues raised in the papers were categorised.

Table I: Telemedicine guidelines

Guideline	Society
Doctor-patient communication by e-mail (1997)	American Medical Informatics Association[13]
Security issues surrounding patient information (1996)	British Medical Association[12]
Code of conduct for medical and health websites (2000)	Health on the Net Foundation[22]
Guidelines for disclosure, patient privacy and quality content issues (2000)	Internet Health Coalition[23]
Guidelines for online doctor-patient communication (2001)	US medical malpractice insurers and medical societies[24]
Patient guidelines	Queensland Telemedicine Network
Guidelines for teleradiology (2005)	American College of Radiology[9]
Guidelines for telepsychiatry (1998)	American Psychiatric Association[25]
Online psychiatry (2000)	International Society for Mental Health[27]
Realtime telepsychiatry (1999)	Royal Australian and New Zealand College of Psychiatrists[17]
Telemedicine in homecare (2002)	American Telemedicine Association[31]
Telepathology (1999)	American Telemedicine Association[29]
Tele-ophthalmology (2004)	American Telemedicine Association[30]
Surgical practice of telemedicine (1999)	SAGES[49]
Teledermatology (1999)	American Academy of Dermatology[15]
How to take clinical photographs using a digital camera	American Telemedicine Association[16]
Ethical guidelines in telemedicine (1997)	Finnish Medical Association[18]
WMA statement on accountability, responsibilities and ethical practice of telemedicine (1999)	World Medical Association[19]
National Initiative for Telehealth Framework of Guidelines (2003)	Canadian National Initiative for Telehealth (NIFTE) [26]
Recommended Guidelines and Standards for the Practice of Telemedicine in India (2003)	Department of Information Technology, Govt of India[20]

Results

The PubMed search produced 139 references. A further 13 relevant papers were identified. Twenty-one guidelines were obtained (see Table I).

Most of the guidelines have been developed by the USA, United Kingdom, India and Australia. They focus, to different extents, on clinical, operational or technical aspects of various types of telemedicine and tend to be specific to a sub-specialty within the medical field.[9,15,16,17] Only three countries and one association have published ethical guidelines.[18,19,20]

Clinical guidelines have been developed by the General Assembly of the World Medical Association (1999) and Finland (1997).[18,19] An internet eHealth Code of Ethics was drafted in 2000 to ensure that people wishing to use the internet to manage health can do so with knowledge of the risks and benefits.[21]

Eight guidelines dealt specifically with ethical issues, such as codes of conduct for health websites,[22,23] doctor-patient relationships,[13,24] consent and communication,[9,23,24,25] security[9,12,25] and confidentiality.[1,8,19,23,26] Four of the published guidelines were devoted to the practice of telepsychiatry.[17,25,27,28] Specific guidelines exist for radiology,[9] dermatology,[15] telepathology,[29] ophthalmology,[30] and the use of e-mail in consultations.[13] The American Telemedicine Association also published guidelines on homecare in 2002.[31]

No guidelines were found addressing issues specific to telemedicine in developing countries, although the subject has been raised. A subsearch on Google Scholar using the words telemedicine, ethics and developing countries yielded over 1 100 results, with most emphasising geographical and technological difficulties and the need for ethics and guidelines.

Discussion

The WHO has identified the need for additional medical resources in the developing world and has proposed telemedicine as a possible solution.[6] The potential use of telemedicine to address the disparity of healthcare delivery in developing countries and, more specifically, to their rural populations, has been questioned.[32,33] Some suggest that, although telemedicine may provide healthcare services to rural areas, such service will perpetuate inequality in the provision of health care, as they believe that telemedicine cannot replace a face-to-face physical consultation.[3,4,8] Others argue that money spent on telemedicine programmes would be better spent on resources such as housing and water.[3] A counterargument posits that telemedicine diagnosis will become integrated into normal practice in the developed world and will be "part of the responsibility and obligations of the physicians". As such, it would then constitute the normal, acceptable standard of care and failure to use it when it is available might be construed as unacceptable practice.[18]

Healthcare workers in developing countries and, more specifically, in rural areas, regularly face ethical dilemmas in their everyday practice. These are caused by poor basic community services like sanitation, the provision of potable water, electricity and transport. In addition to the shortage of doctors, medical facilities in developing countries are often poorly resourced and doctors may be isolated and lack peer support, all of which affect patient management.[34] Will telemedicine add to their ethical burden?

The use of telemedicine challenges the traditional perception of the patient-physician relationship.[1] Not only is the patient no longer involved in a face-to-face consultation in the same room as the physician, but the management of his or her problem may be directed by someone with whom no communication ever takes place. This raises issues of informed consent, confidentiality, data security and medical responsibility.

Should a patient be required to provide informed consent to participate in a telemedicine consultation? The Canadian National Initiative for Telehealth Framework of Guidelines identifies differing opinions relating to expressed and implied consent for video consultation. Some say that informed consent is not required, as there is implied or tacit consent to participate in a consultation. They argue that there is no distinction between a face-to-face consultation, for which informed consent is not required, and a videoconferenced telemedicine consultation, in which videoconferencing is merely "a tool for health care delivery".[26] Others submit that implied consent should not be extended to telemedicine and contend that written informed consent should be a prerequisite, as telemedicine is not yet a routine service.[26,35]

The recommendation of the American and French Medical Associations on the responsibilities and ethics arising from the practice of telemedicine, presented to the World Medical Association in 1997, was that "Any physician requesting an expert opinion of a colleague from a distance should inform the patient of such a step and if possible, obtain consent."[19] The submission of the Finnish Medical Association to the same meeting proposed that "patient data and other information may only be transmitted to a doctor or other health professional on the request or with the informed consent (permission) of the patient and to the extent approved by him/her".[18] This was the recommendation that was incorporated into the World Medical Association Statement on Accountability, Responsibilities and Ethical Guidelines in the Practice of Telemedicine adopted in 1999.[19]

While obtaining informed consent for a telemedicine consultation appears to be a very reasonable expectation, the question arises as to what constitutes truly informed consent? For consent to be valid, it has to be based on substantial knowledge of the act consented to by the patient, with the patient having the right to withhold consent.[35] In the telemedicine context, the patient has to consent to physical examination and, if necessary, the use of electronic medical equipment during the consultation and sharing of the clinical information with other clinicians. In the case of videoconference consultations, this may extend to technical staff who may be required to be present to facilitate the consultation. Consent should also acknowledge an understanding that confidentiality will be maintained through secure transmission and storage of the information.

Obtaining informed consent becomes more difficult when the patient has had limited exposure to and knowledge of ICT. There is an obligation to explain that the consultation will not be with a physician in the same room, but rather that sophisticated ICTs will be used. There is also a requirement to explain how the patient's data will remain secure and how confidentiality will be maintained. This is a difficult task, even for the computer- and technology-literate doctor dealing with the computer-literate patient. Good patient-physician communication is required to achieve this. In South Africa, with 11 official languages and diverse cultures, patient-physician communication may be more difficult and already presents ethical challenges in some circumstances.[36]

Consent has always been intrinsically linked with the issue of confidentiality. The risk of unauthorised access to electronically transmitted and stored data is a major concern to the patient and phy sician.[1,37,38,39,40,41] The right to privacy is enshrined in the South African Constitution of 1996, Section 14, (d), which states that "Everyone has the right to privacy, which includes the right not to have the privacy of their communications infringed."[42] This implies that the onus is on the practitioners or the health authorities concerned to ensure that patients' data are transmitted and stored in a secure manner. This is in keeping with the recommendation of the World Medical Association: "Because of the risks of information leakage inherent to some types of electronic communication, the physician has an active obligation to ensure that all established standards of security measures have been followed to protect the patient's confidentiality."[19]

Is this a reasonable expectation in a rural setting in a developing country, where all that may be available for a doctor to perform a telemedicine consultation with a specialist is a telephone and modem, with an e-mail link, using a commercial service provider? When does the patient's right to health supersede his or her right to privacy? In this less than ideal situation, can the e-mail encryption available in commercial communication software like Microsoft Outlook®, which requires the recipient of the e-mail to "unlock" the e-mail with an encryption key, be considered to be sufficient security? What level of security is required on the hard drives of computers of doctors who participate in store and forward e-mail-based telemedicine? Guidelines are required in this area if telemedicine is to advance.

Allied to this is the responsibility of maintaining adequate records. There is a degree of consensus that both the referring health practitioner and the person consulted should keep adequate records of all aspects of the case and the findings and recommendations of a telemedicine consultation.[43,44] The matter of responsibility for the prescription of drugs requires further consideration, as does the issue of electronic signature.

Questions have arisen as to whether telemedicine allows for the same standard of care that exists in a traditional consultation.[45,46] The test for the standard of care expected of medical practitioners is: How would a reasonably competent practitioner in that branch of medicine have acted in a similar situation?[42] Telemedicine may enhance that standard of care by providing access to specialised care in the resource-poor setting. The assumption is made that the data transmitted for a telemedicine consultation are of an appropriate quality, quantity and relevance for a medical opinion or decision to be made. This raises the question of image standards and quality. There are technical guidelines and standards for radiology, dermatology and psychiatry, which may be unachievable in resource-constrained situations.[9,15,25] What is needed are guidelines for the developing world that set, for example, minimum image standards for the practice of different fields of medicine and that acknowledge the shortcomings associated with reduced image resolution. It is interesting to note that expediency may drive change,

for the United States armed forces in Iraq now make regular use digital photography for management in the field.

Another area that requires investigation is the obligation to ensure that the technology used for telemedicine is reliable, of sufficient quality, correctly calibrated and that it will not fail and or compromise the patient.[47] Vagaries in power supply and telephone communication links in rural areas make reliability and equipment failure issues that need specific consideration when producing guidelines for developing countries.

There is also the expectation that the practitioner offering a telemedicine opinion is competent in the field and will be available for additional follow-up consultation if required.[11,44,48] Is there an ethical expectation that health practitioners should have additional training and be accredited to practice by telemedicine? Presently it is not an identified prerequisite and, in most existing services, practitioners have learned the necessary skills through trial and error. Ideally, users of telemedicine should undergo some familiarisation with and training in the use of the ICT that they will be using. A requirement for licensure to practice telemedicine would probably defeat the purpose of improving service to under-resourced areas. One approach might be to include a basic telemedicine familiarisation programme in the medical undergraduate curriculum. This would also enable young healthcare practitioners to utilise telemedicine during their community service and formative years.

It is in the interests of patients and practitioners that obstacles to the practice of telemedicine in South Africa be resolved in a pragmatic way that is appropriate to our circumstances and in the best interests of the majority of our population. The DOH, through the South African Telemedicine Service (Phase 1), began the process of investigating ethical and legal issues relating to the practice of telemedicine in South Africa.[14] This work needs to be revisited and developed further, in consultation with practitioners with first-hand experience gained in the practice of telemedicine in South Africa and other developing countries. The formulation of ethical guidelines will provide the foundation for the development of clinical guidelines for the ethical practice of telemedicine in different disciplines.

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