

A review of guidelines and standards for telemedicine

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Summary

We conducted a review to establish the range and scope of current telemedicine guidelines and standards. Published guidelines were identified by searching the Medline and Telemedicine Information Exchange (TIE) databases, and by performing a Google search using the term 'telemedicine guidelines'. Three types of guidelines were identified, namely clinical, operational and technical. Clinical guidelines included those for teleradiology, telepsychiatry, home telenursing, minor injuries telemedicine, surgical telemedicine, teledermatology and telepathology. Operational guidelines included those for email communication, Internet access and videoconferencing. Technical guidelines included those from the American Telemedicine Association and the US Office for the Advancement of Telehealth. The main standards relevant to telemedicine include those of the International Telecommunication Union and the DICOM standard. The scarcity of guidelines and standards suggests that telemedicine is not yet near to routine use. If an international telemedicine organization were to take responsibility for defining guidelines, under the direction of clinicians with appropriate telemedicine experience, this might speed up their development.

Introduction

Telemedicine is a relatively new technique. At present it is not widely associated with any of the trappings of evidence-based medicine, such as quality assurance procedures, guidelines or standards. These can all be regarded as signs of maturity in a medical technique and their absence confirms the newness or immaturity of telemedicine. It may be the case that guidelines for telemedicine will evolve in due course.

The term 'guidelines' is used loosely in the literature, often being used interchangeably with 'standards'. However, the two terms have distinct meanings. The dictionary definitions include:

Standard

- (1) a degree or level of requirement, excellence, or attainment;
- (2) an acknowledged measure of comparison for quantitative or qualitative value; a criterion.

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Guideline

- a statement or other indication of policy or procedure by which to determine a course of action;
- (2) guidance relative to setting standards or determining a course of action;
- (3) a rule or principle that provides guidance to appropriate behaviour.

Standards therefore imply technical compliance with rigid and defined criteria; guidelines imply the following of recommended, and to some extent flexible, practices. Standards are quantitative and are largely prescriptive; guidelines are to some extent qualitative and voluntary. While it ought to be possible to distinguish between guidelines and standards, the field proved to be insufficiently developed for the distinction to be made usefully in the present review.

The purpose of guidelines

The aim of guidelines in health-care is to promote best practice and to improve the consistency and efficiency of health-care, based on scientific and clinical research¹. That is, guidelines are systematically developed statements to help practitioners and patients make

decisions about appropriate health-care for specific clinical circumstances^{2,3}. By definition, this implies that guidelines are a tool to aid decision making and have undergone extensive evaluation before implementation.

Guidelines may be employed by several different classes of user, including:

- (1) the general practitioner;
- (2) the specialist;
- (3) the health service planner.

The ultimate goal of health-care guidelines is to improve patient health outcomes and this has led to the development of databases providing evidence-based guidelines for clinical practice^{4,5}. However, there is little reference in the literature to guidelines for telemedicine.

Methods

As the interest in telemedicine techniques increases, guidelines describing best practice are likely to become essential in order to provide appropriate and effective health-care. Yet do telemedicine guidelines exist? A formal Medline search was conducted to identify articles containing the term 'telemedicine guidelines' in their title. The search was repeated using the search engine Google and the Telemedicine Information Exchange (TIE) database. The Medline search produced 10 articles while the TIE and Google searches identified 46 and 49 articles, respectively. The excess identified by the TIE and Google search engines included general articles recognizing the need for published guidelines. Similar searches were conducted for 'telemedicine standards' and 21 articles were identified. Table 1 lists the guidelines and standards identified in the present review.

The US led the field in developing guidelines for telemedicine health-care delivery. In some areas, such as Internet health access, there were guidelines in abundance while in other areas, particularly in the clinical domain, guidelines were virtually non-existent for many of the medical subspecialties. Although every attempt was made to include the major published guidelines on each topic, this review is not exhaustive because some medical societies have published guidelines that are available only to their own members. Many organizations responsible for developing guidelines had Websites with outdated links or had changed their Website address.

The guidelines which were identified were categorized as:

- clinical, that is relating to a medical subspecialty practised by telemedicine;
- (2) operational, that is relating to the way in which telemedicine techniques are used;
- (3) technical, that is relating to the equipment or telecommunication used in telemedicine.

Clinical telemedicine guidelines

Clinical guidelines are implemented with the aim of providing recommendations on appropriate healthcare delivery within individual medical subspecialties.

Teleradiology

Teleradiology is widely regarded as the most mature telemedicine application and is one of the few specialties with published guidance and recommendations for best practice. The American College of Radiology (ACR) originally published standards for teleradiology in 1994; there were revisions in 1996 and 1998. The current, comprehensive set of teleradiology standards was designed to promote the delivery of high-quality radiological care⁶. The ACR standards include information on technical standards as well as practice guidelines. The ACR has emphasized that its teleradiology standards require periodic revision in the light of clinical, scientific and technological advances, and are intended to act as a model of radiological health-care delivery.

The ACR standards outline the goals of teleradiology, such as improving access to radiological services in remote or under-served areas. The standards state that all users must be appropriately qualified and trained to use the teleradiology system. Equipment specifications recommend that all new equipment should comply with the Digital Imaging and Communication in Medicine (DICOM) standard for digital image acquisition⁷. Information on appropriate file compression ratios, data transmission, display capabilities, archiving and retrieval, security and reliability of the system are also provided as part of the standard. Users must have appropriate licences to practise and conduct themselves in a manner consistent with the rules and regulations set out by their professional body. All documentation should be recorded and a qualitycontrol programme be put in place to evaluate the performance of the teleradiology system.

Telepsychiatry

Telepsychiatry is a realtime telemedicine application that is offered routinely as a service, particularly in the

Table 1 Telemedicine guidelines and standards

Subject	Author	URL	Status
Predominantly clinical practice guidelin	nes		
Teleradiology	American College of Radiology ⁶	http://www.acr.org/	Mature (first version issued in 1994)
Realtime telepsychiatry	American Psychiatric Association (APA) ¹⁰	http://www.psych.org/pract_of_psych/ tp_paper.cfm	Approved by the APA Board of Trustees in 1998
Online psychiatry	International Society for Mental Health Online (ISMHO) ¹¹	http://www.ismho.org/suggestions.html	Officially endorsed by ISMHO in 2000
Realtime telepsychiatry	Royal Australian and New Zealand College of Psychiatrists (RANZCP) ¹²	http://www.ranzcp.org/	Position statement from 1999
Realtime telepsychiatry	Queensland Telemedicine Network (QTN) ¹³	http://www.health.qld.gov.au/qtn/pdf/ mhg4.pdf	Designed for use in Australia, but more generally applicable
Telemedicine in home care	American Telemedicine Association (ATA) ¹⁴	http://www.americantelemed.org/news/ guidelines.html	Draft
Handling of telephone enquiries relating to accident and emergency problems	British Association for Accident and Emergency Medicine (BAEM) ¹⁹	http://www.baem.org.uk/tele.htm	Published
Surgical practice of telemedicine	Society of American Gastrointestinal Endoscopic Surgeons (SAGES) ²⁰		Approved by board of governors in 1999
Teledermatology	American Academy of Dermatology (AAD) ²²	http://www.aadassociation.org/ positionState.html	Approved by board of directors in 1999. Accessible to AAD members only
How to take clinical photographs in dermatology using a digital camera for non-dermatologists	ATA ²⁴	http://www.americantelemed.org/news/ newres.htm	US army
Clinical use of email	American Medical Informatics Association ²³	http://www.amia.org/pubs/other/ email_guidelines.html	Endorsed by board of directors in 1997
Telepathology (realtime, pre-recorded and hybrid)	ATA ²⁵	http://telepathology.upmc.edu/ata/ guideline.html	Draft, 1999
Predominantly operational guidelines			
Doctor–patient communication by email	American Medical Informatics Association ²³	http://www.amia.org/pubs/other/ email_guidelines.html	Endorsed by board of directors in 1997
Protocols for ophthalmologists and general examples of disclaimer notices	Ophthalmic Mutual Insurance Company (OMIC) ²⁶	http://www.omic.com/new/digest/10_2/ surfers.cfm	Formulated by a private organization
Security issues surrounding patient information systems	British Medical Association ²⁷		Interim guidelines, 1996
Code of Conduct for medical and health Websites	Health On the Net Foundation ²⁸	http://www.hon.ch/HONcode/ Conduct.html	Published
Principles to guide the development of Website health content, online	American Medical Association (AMA) ²⁹		Published journal article
advertising and sponsorship Guidelines for online doctor–patient communication	US medical malpractice insurers and medical societies ³⁰	http://www.medem.com/erisk.html	Published
Guidelines for disclosure, patient privacy and quality-of-content issues of Websites	Internet Healthcare Coalition (IHC) ³¹	http://www.ihealthcoalition.org/ethics/ code0524.pdf	Published, 2000
Guidelines for the patient Guidelines for health-care delivery via videoconferencing	Yellowlees ³² Queensland Telemedicine Network ³³	http://www.health.qld.gov.au/qtn/ guidelines.htm	Informal guidance Designed for use in Australia, but more generally applicable
Predominantly technical standards	0.00		
Guidelines for the compatibility, inter- operability, scalability and reliability of telehealth equipment and systems for use in US federal telemedicine programmes	(OAT), the Health Resources and Services	http://telehealth.hrsa.gov/pubs/tech/ techhome.htm	Interim guidelines, 1999
H.320 standard for videoconferencing using ISDN, and the more recent H.323 standard for videoconferencing	International Telecommunication Union (ITU) ³⁷	http://www.itu.int/itudoc/itu-t/rec/h/ h320.html	Mature
using IP networks Medical image communications	Digital Imaging and Communications in Medicine (DICOM) standard ⁷	http://www.rsna.org/REG/practiceres/ dicom/index.html	Mature

US and Australia^{8,9}. Guidelines have been drawn up by the American Psychiatric Association (APA), the International Society for Mental Health Online (ISMHO), the Royal Australian and New Zealand College of Psychiatrists (RANZCP) and by the Queensland Telemedicine Network (QTN)^{10–13}. The guidelines proposed by the APA, the RANZCP and the QTN focus on videoconferencing techniques (realtime telepsychiatry) while the ISMHO guidelines refer to online telepsychiatry services (i.e. pre-recorded or store-and-forward telepsychiatry).

The telepsychiatry guidelines recommend gaining informed consent from the patient before participation in teleconsultations and ensuring that the patient is made aware of the limitations of the techniques for delivering care, as well as the potential benefits. The guidelines concentrate on the process of delivering mental health services remotely, rather than on technical requirements. A general rule of thumb, endorsed by the available telepsychiatry guidelines, is that procedures should be followed in the same way as in face-to-face consultations. The responsibilities and roles of the health-care staff should be carefully defined before the teleconsultations. There should be appropriate contingency plans in the event of equipment failure. The remote care of serious cases, such as suicidal or seriously demented people, is not generally recommended unless no alternative is available.

Home telenursing

The American Telemedicine Association (ATA) has approved a set of clinical guidelines for the use of telemedicine in home care, also known as home telenursing¹⁴. These proposed guidelines have been forwarded to national bodies for review and hence can be considered only as draft guidelines at present. The guidelines define patient protocols, health provider protocols and technology requirements to ensure the successful delivery of home care. The main focus of the guidelines is to ensure that home telecare is appropriate for individual patients and that proper documentation is maintained in the patient's health-care record. Clear instructions and a contingency plan are recommended in the event of a communication breakdown so that patient care is not compromised. Patient confidentiality must be protected at all times.

Minor injuries telemedicine

The need for telemedicine guidelines in minor injury units (MIUs) has been recognized¹⁵ but to date none has been formally defined by any national accident and emergency (A&E) body. Individual telemedicine proponents have drawn up protocols for use in their

local environment, but widespread standardization has not yet occurred¹⁶. A group of experts in the UK formulated a resource document outlining telemedicine protocols for MIUs. This document covered teleconsultation protocols, drug protocols, radiography protocols and management protocols¹⁷. The British Association for Accident and Emergency Medicine (BAEM) has stated that all MIUs should have close links with their nearest A&E department and that telemedicine links, including facilities for the transfer of electrocardiograms (ECGs) and X-ray images, should be encouraged¹⁸. The BAEM has also published guidelines on the handling of telephone enquiries relating to A&E problems¹⁹.

Surgical telemedicine

Guidelines for the surgical practice of telemedicine have been formulated by the Society of American Gastrointestinal Endoscopic Surgeons (SAGES)²⁰ based on its framework document for post-residency surgical education²¹. Definitions and concepts specific to surgical practice by telemedicine are explained and appropriate applications for use are outlined. From an educational perspective, the guidelines state that videoconferencing may supplement supervised handson training in the instruction of new procedures. From a clinical perspective, remote patient evaluation, consultation, triage decisions and non-operative treatment of a patient are considered acceptable applications of remote surgical practice. At present the SAGES does not advocate carrying out remote surgery as part of a routine clinical service.

Teledermatology

The American Academy of Dermatology (AAD) has issued a position statement on telemedicine, but it is accessible by AAD members only²². The statement focuses on the issues facing those who practise teledermatology and relates more to realtime teledermatology than to pre-recorded techniques. Readers interested in pre-recorded teledermatology should examine the guidelines for the clinical use of email formulated by the American Medical Informatics Association²³. The AAD position statement emphasizes the importance of maintaining accurate documentation of the consultation, ensuring patient confidentiality and having appropriately qualified personnel practising teledermatology. The minimum equipment requirements for teleconsulting are stated as well as the preferred physical attributes of the patient examination

Basic guidelines on how to take clinical photographs in dermatology using a digital camera for

non-dermatologists have been formulated by the US army and are available on the ATA Website²⁴.

Telepathology

The ATA has also formulated draft guidelines for the practice of telepathology²⁵. These guidelines concentrate on the responsibilities of the pathologist practising telepathology and apply to realtime and pre-recorded techniques, and also to a hybrid method combining both realtime and pre-recorded techniques. The guidelines state that telepathology should mirror the best practices of conventional laboratory procedures. It is the responsibility of those seeking the expert advice to ensure that all appropriate clinical information is conveyed to the remote pathologist. This does not differ significantly from conventional practice when a courier service, for example, may be used to deliver specimens from a hospital with no specialist pathology service available locally. Users should receive appropriate training and measures should be in place to assess quality control of the system.

Operational telemedicine guidelines

There are two distinct classes of telemedicine interaction—those that are pre-recorded (sometimes referred to as store-and-forward or asynchronous telemedicine) and those that occur in realtime (i.e. interactive or synchronous telemedicine). Pre-recorded telemedicine often depends on the use of email or Internet access to online care. Realtime techniques often employ videoconferencing, although more basic telephone consulting may be employed where appropriate. Both techniques have their own operational guidelines.

Email communication

The American Medical Informatics Association has issued guidelines for the use of doctor–patient email communication²³. These guidelines apply to situations where the health-care provider has assumed responsibility for patient care—that is, a contractual agreement exists between the two parties. The aim of the guidelines is to enhance the interaction between the doctor and patient. The guidelines cover privacy issues, purpose of the consultation, acceptable response time and maintenance of appropriate documentation records. Medical emergencies and sensitive health issues are not deemed suitable for email correspondence. The guidelines recommend the use of computer password-protected screen savers and encryption methods to ensure patient privacy.

Many of the guidelines on the use of email advocate a 'prevention is better than cure' philosophy since establishing clear procedures and policies before any online communication will reduce the risks involved. The US Ophthalmic Mutual Insurance Company (OMIC) has developed such protocols for ophthalmologists as well as providing general examples of disclaimer notices²⁶. The British Medical Association has also published guidelines on the security issues relating to patient information systems²⁷. These are not restricted solely to computerized systems but also include telephone enquiries in which personal health information may be disclosed inadvertently.

Internet access

The Health On the Net Foundation (HON) has issued a Code of Conduct for medical and health Websites²⁸. Any health or medical advice must be provided by appropriately qualified health professionals unless otherwise stated. Website information should support and enhance the existing relationship between the health-care provider and patient, rather than replace it. Owners of a Website must provide contact information for those seeking further information and must also respect patient confidentiality. A good example of a patient Website that meets these criteria is http://med4u.co.uk.

The American Medical Association (AMA) has also developed principles to guide the development of Website health content, govern online advertising and sponsorship, and ensure patients' and consumers' rights to privacy and confidentiality²⁹.

In the US, leading medical malpractice insurers and medical societies have developed a comprehensive set of guidelines for online doctor–patient communication³⁰. These guidelines recommend that health-care providers establish staff policies and procedures regarding online patient interaction and that patient consent be obtained. Privacy and confidentiality issues are addressed as well as the problems of using third-party Websites. Disclosure, patient privacy and quality-of-content issues have also been defined in guidelines formulated by the Internet Healthcare Coalition (IHC)³¹.

Informal guidelines for the patient have been suggested by Yellowlees³². These include:

- (1) establishing the qualifications, credentials and experience of online health-care practitioners;
- (2) finding out what clinical and administrative guidelines they follow;
- (3) confirming the procedures for consent and confidentiality.

Videoconferencing

Comprehensive guidelines for health-care delivery via videoconferencing were set out by the Queensland Telemedicine Network³³. Although designed for an Australian audience, the protocols address issues that are pertinent to any user, regardless of country of origin. These range from questioning the need for videoconferencing to the planning and implementation stages. Minimum equipment specifications, videoconferencing etiquette and the ideal room set-up are defined. Operational issues such as installation of digital lines, bookings, appropriate documentation and the training needs of users are also addressed.

Technical telemedicine guidelines

The key to successful telemedicine is not the technology but the delivery of care³⁴. The technology itself is simply a means to an end. Indeed, most of the equipment and telecommunication infrastructure employed in telemedicine are used in other areas, such as business and education, and are not unique to health-care delivery. Equipment such as personal computers and videoconferencing units have their own technical standards, which are not altered by the fact that they are used in health-care. Peripheral equipment in telemedicine, such as an electronic stethoscope or a device for monitoring blood pressure remotely, should already comply with standards defined for use in conventional health-care delivery. The ATA Technology Special Interest Group recommends the development of a standard list of specifications and a standard format for reporting the information in sales literature³⁵.

The key issue concerning technical telemedicine guidelines is that the technology does not operate in isolation, but as part of a system; hence guidelines are essential for the entire system rather than for component parts only. A summary of technical guidelines has been formulated in the US by the Office for the Advancement of Telehealth (OAT), the Health Resources and Services Administration (HRSA) and the Department of Defense. The guidelines are intended to ensure the compatibility, interoperability, scalability and reliability of telehealth equipment and systems for use in US federal telemedicine programmes³⁶.

ITU standards

The main technical standards applicable to telemedicine are those defined by the International Telecommunication Union (ITU) for videoconferencing. The most well known are the H.320 standard for videoconferencing

using ISDN³⁷ and the more recent H.323 standard for videoconferencing using IP networks. The Australian Health Minister's Advisory Council recommends that guidelines are needed for definite categories of technology, such as videoconferencing, telephone advisory services, store-and-forward data and image transmission, rather than for specific products or vendors³⁸.

DICOM standard

The Digital Imaging and Communications in Medicine (DICOM) standard is widely recognized for medical imaging communication. It was originally developed to facilitate the transmission and storage of X-ray images, but was subsequently generalized to deal with a wide variety of medical image types. It defines a standard network interface and data model for imaging devices, which can facilitate information systems integration. Essentially the DICOM standard enables image acquisition, display of images for reporting and diagnosis, image transmission, an archive medium for long-term storage and compatibility. The key advantage of the DICOM standard is that it allows interoperability between equipment from different manufacturers. It can be used to link a wide variety of diagnostic imaging equipment, such as that for X-ray, computerized tomography, photon-emission tomography, magnetic resonance, nuclear medicine, ultrasound, computerized radiography digitized film, video-capture images and digital cardiology images^{7,36}.

How good are existing telemedicine guidelines?

Clinical practice guidelines attempt to distil a large body of medical knowledge into a convenient, ready-to-use format. They go beyond an overview and make explicit recommendations. Hayward *et al.*³⁹ have given some guidance about assessing existing guidelines (guidelines on guidelines, perhaps?). This includes:

- (1) Are the recommendations valid?
- (2) Were all important options and outcomes considered?
- (3) Was an explicit and sensible process used to identify, select and combine the evidence?
- (4) Was an explicit and sensible process used to consider the relative value of different outcomes?
- (5) Are the guidelines likely to account for important recent developments?
- (6) Have the guidelines been subjected to peer review and testing?

Also, see Cluzeau *et al*.⁴⁰ Note that most telemedicine guidelines would fail one or more of these criteria, particularly the last.

Benefits of implementing telemedicine guidelines

If guidelines in telemedicine are implemented, then a number of benefits can be expected.

Reduced risk of litigation

In general, the purpose of any medical guideline is to improve the effectiveness and efficiency of clinical practice, provide better clinical outcomes and enhance the reliability of medical services. The introduction of telemedicine techniques does not alter these objectives. From a legal standpoint, adhering to telemedicine guidelines offers a form of immunity to health-care professionals provided that they have acted in accordance with a practice accepted as proper by a responsible body of professionals and that reasonable skill and care have been followed⁴¹. Professional bodies have begun to issue telemedicine guidelines as a result of increasing demands from members. For instance, the College of Physicians and Surgeons of Nova Scotia issued a directive stating that physicians who provide telemedicine services must have the same standards of practice as a physician who sees patients in person⁴².

Standardization of current work practices

Telemedicine affects work practices^{43,44}. The use of guidelines in telemedicine encourages standardization of work practices as well as providing evidence of quality assurance. Quality assurance is an area of telemedicine which has been almost entirely neglected to date, and the literature contains few relevant reports⁴⁵. As telemedicine enters routine health-care delivery, quality assurance will become essential.

The provision of a minimum acceptable level of care serves to maximize patient outcomes⁴¹. As with any new clinical intervention, telemedicine interventions should undergo rigorous evaluation before being integrated into mainstream care. Most clinical telemedicine guidelines emphasize the need for periodical review of the existing standards, which ultimately acts as a process for refining the procedures and protocols for health-care delivery. Clinical trials and evaluations are needed to assess the most appropriate method of delivering health-care remotely and hence provide evidence of best practice and standardization, which is essential for clinicians.

Guideline implementation

The fact that there are relatively few telemedicine guidelines suggests that certain barriers to their development exist.

Overemphasis on technology

At present there is probably too much emphasis on technology in telemedicine rather than on health-care itself. The rapid evolution of technology renders much equipment obsolete in the space of a few years. Efforts should therefore focus on the principles underlying telemedicine rather than on specific items of equipment. It has been argued that overemphasis on technology and data standards or formal and restrictive evaluation approaches could be counterproductive in the long run and hamper long-term development⁴⁶.

Who should formulate telemedicine guidelines?

At present there is no consensus as to who should take the responsibility of formulating telemedicine guidelines. It is accepted that health-care professionals should be responsible for clinical standards and generally the professional bodies, such as the appropriate Colleges, are responsible for formulating medical standards for each specialty. However, the development of telemedicine guidelines does not readily lend itself to this model, as telemedicine tends to be multidisciplinary and to involve many areas of expertise. The alternative therefore may be to encourage specific telemedicine organizations, such as the ATA or the UK's Telemedicine and eHealth Forum of the Royal Society of Medicine, to assume responsibility for defining telemedicine guidelines. Indeed, the World Medical Association (WMA) recommended that national medical associations should develop and implement telemedicine practice guidelines in conjunction with appropriate specialized organizations, such as national departments of health⁴⁷.

When should guidelines be updated?

Assuming that telemedicine guidelines have been drawn up, there is a requirement to keep them up to date. As Shekelle *et al.*⁴⁸ have pointed out, there are a variety of reasons why a set of guidelines will become outdated. These include:

(1) changes in evidence on the existing benefits and potential for harm of interventions;

M Loane and R Wootton Guidelines and standards for telemedicine

- (2) changes in outcomes considered important;
- (3) changes in available interventions;
- (4) changes in evidence that current practice is optimal;
- (5) changes in values placed on outcomes;
- (6) changes in resources available for health-care.

The most practicable way of assessing whether telemedicine guidelines need updating is to establish a review committee—probably an international expert committee—to review the guidelines regularly, perhaps every year.

Conclusion

Many telemedicine reports cite the need to develop telemedicine guidelines, but few actually exist in practice, particularly at an international level. This recognized need and the gradual evolution of telemedicine guidelines reflect the first signs of maturity in telemedicine. However, the formulation of telemedicine guidelines does not necessarily guarantee improved patient outcomes, and continual monitoring of the effect of guidelines will be required.

If widespread adoption of telemedicine guidelines is ever to occur, a consensus on guidelines must be reached. Perhaps the difficulty to date rests with the fact that individual medical organizations do not always have the technical expertise to formulate guidelines specific to telemedicine applications. It may be the case that telemedicine guidelines need to be developed by telemedicine specialists under the direction of clinicians with telemedicine experience from each medical subspecialty. Arguably this should be done by a coordinated, international approach.

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M Loane and R Wootton Guidelines and standards for telemedicine

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