



HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA

**GUIDELINES FOR GOOD PRACTICE
IN THE HEALTHCARE PROFESSIONS**

**GENERAL ETHICAL GUIDELINES FOR
GOOD PRACTICE IN TELEMEDICINE**

**DEVELOPED BY THE HUMAN RIGHTS, ETHICS AND
PROFESSIONAL PRACTICE COMMITTEE**

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THE SPIRIT OF PROFESSIONAL GUIDELINES

Practice as a health care professional is based upon a relationship of mutual trust between patients and health care practitioners. The term "profession" means "a dedication, promise or commitment publicly made".¹ To be a good health care practitioner, requires a life-long commitment to sound professional and ethical practices and an overriding dedication to the interests of one's fellow human beings and society. In essence, the practice of health care professions is a moral enterprise. In this spirit the HPCSA presents the following ethical guidelines to guide and direct the practice of health care practitioners. These guidelines form an integral part of the standards of professional conduct against which a complaint of professional misconduct will be evaluated.

[Note: The term "health care practitioner" in these guidelines refers to persons registered with the HPCSA].

¹ Pellegrino, ED. Medical professionalism: Can it, should it survive? *J Am Board Fam Pract* 2000; 13(2):147-149 (quotation on p. 148).

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1. INTRODUCTION

1.1 The objective of the South African Telemedicine System as established by the National Department of Health is to deliver healthcare services at a distance to South African communities in under-served areas. The system has been established to alleviate the human resource crisis as experienced and is geared to improve the links and communication between developed healthcare facilities and the underdeveloped rural areas. Different categories of Health Care Practitioners will be involved.

1.2 The Health Professions Council of South Africa (HPCSA) has a mandate to regulate healthcare provision by ensuring that services are provided by qualified and skilled healthcare practitioners. This regulatory mandate applies to healthcare practitioner in both state and privately-owned health care institutions. It is the mandate of the HPCSA to protect the “patient” against possible abuse by healthcare practitioner on one hand and to provide guidance for good practice to the professions.

1.3 All Telemedicine services should involve a healthcare provider where there is an actual face-to-face consultation and physical examination of the patient in a clinical setting. The consulting practitioner will communicate the information to the servicing practitioner, who will then provide the necessary assistance.

Note: These guidelines must be read as a whole and not piece-meal as the overall purpose may be lost. The guidelines must further be read in conjunction with other ethical booklets of the HPCSA which include but are not limited to:

- Booklet No 1: General ethical guidelines for healthcare professions*
- Booklet No 9: Seeking patients' informed consent*
- Booklet No 10: Confidentiality*

2. PURPOSE

The purpose of these guidelines is twofold:

(a) Firstly to provide an ethical framework that draws from the core values and standards in Booklet No 1 and pertinent laws.

(b) Secondly, to provide guidelines to Healthcare Practitioners engaged in telemedicine practices within and outside the South Africa.

3. DEFINITION OF CONCEPTS

These guidelines first provide definitions of telemedicine and other related terminology as used in the guidelines.

3.1 Telemedicine

For the purposes of these guidelines, “telemedicine” is defined as:

The practice of medicine using electronic communications, information technology or other electronic means between a healthcare practitioner in one location and a healthcare practitioner in another location for the purpose of facilitating, improving and enhancing clinical, educational and scientific healthcare and research, particularly to the under serviced areas in the Republic of South Africa.

Note:

1. Telemedicine involves secure videoconferencing or similar forms of technology which enable healthcare practitioners to replicate the interaction of traditional face-to-face consultations between healthcare practitioners and the patient.

2. Telemedicine as defined refers to where information is exchanged electronically either on or off-line, formally, informally or as a need for a second opinion.

3.2 Health establishment

“Health establishment” means the whole or part of a public or private institution, facility, building or place, whether for profit or not, that is designed to provide inpatient or outpatient treatment, and diagnostic or therapeutic interventions

3.3 Healthcare practitioner

“Healthcare practitioner” means a person providing health services, registered in terms of the Health Professions Act No 56 of 1974, to include any other appropriate disciplines as defined in the National Health Act No 61 of 2003.

3.4 The consulting healthcare practitioner

The “consulting healthcare practitioner” refers to the practitioner who conducts a “face-to-face” interview or examination with the patient or refers patient’s information to a remote location for further advice or intervention.

3.5 The servicing healthcare practitioner

The “servicing healthcare practitioner” refers to the practitioner who offers advice or intervention or patient information from a remote location.

3.6 The requesting patient

The “requesting patient” is the patient who requests to be treated by the servicing healthcare practitioner. This applies only where there is already an existing relationship between the patient and the healthcare practitioner.

3.7 Other terms that relate to consultation

Other terms relate to consultation as used in telemedicine as described by the World Medical Association:

- 3.7.1 Asynchronous: Refers to data transmission that involves a mechanism where the patient information from the consulting healthcare practitioner's site is temporarily stored and then retransmitted to the servicing healthcare practitioner's site or vice versa. A common asynchronous transmission includes the transmission of patient information via email.

- 3.7.2 Synchronous: Refers to the continuous, uninterrupted transmission of patient information from the consulting health care practitioner's site to the consultant health care practitioner's site, or vice versa. The flow of patient information does not include any storage or intended delay in the transmission of the patient data.

4. ETHICAL GUIDELINES

Although telemedicine has become an essential tool in alleviating human resource crises and supporting primary healthcare services, particularly those of vulnerable communities in South Africa. It also raises important ethical and legal issues.

4.1 Competence, registration and authorisation

- 4.1.1 According to the Health Professions Act, No 56 of 1974, registration is a prerequisite for practising a profession in terms of which a professional board has been established, where such practice is for gain within South Africa, or for any other health profession the scope which has been defined by the Minister in terms of the Act, unless a practitioner is registered in terms of the Act in respect of such profession.

- 4.1.2 Only practitioners who have been deemed competent and are registered in their respective professions are authorised to participate in telemedicine practice in

South Africa either as consulting healthcare practitioners or servicing healthcare practitioners.

- 4.1.3 In the case of telemedicine across country borders, practitioners serving South African patients should be registered with the regulating bodies in their original states as well as with the HPCSA.
- 4.1.4 Consulting healthcare practitioners are responsible for ensuring that the servicing healthcare practitioner is competent according to South African healthcare standards.
- 4.1.5 Consulting healthcare practitioners and servicing healthcare practitioners are held to the same standards of medical practice as healthcare practitioners who conduct face-to-face consultations.

4.2 Healthcare practitioner-patient relationship

- 4.2.1 The relationship between the patient and the healthcare practitioner is established when the practitioner agrees to treat the patient and the patient agrees to be treated.
- 4.2.2 In telemedicine the practice of medicine occurs where the patient is located at the time telemedicine technologies are used.
- 4.2.3 The relationship between the patient and the healthcare practitioner must be based on mutual trust and respect, and this applies to both servicing and consulting practitioners.
- 4.2.4 Core ethical values as outlined in the HPCSA guidelines for Healthcare practitioners are also applicable in telemedicine practice and the fact that a patient's information can be moved using electronic means does not alter the ethical duties of health care practitioner.

4.2.5 The professional discretion of healthcare practitioners engaging in telemedicine regarding the diagnosis, scope of care or treatment should not be limited or influenced by non-clinical considerations of telemedicine technologies.

4.3 Assumption of primary responsibility

4.3.1 The World Medical Association (WMA) makes a distinction between telemedicine consulting and the servicing practitioners regarding where the primary responsibility lies.

4.3.2 According to the WMA:

(a) The consulting practitioner remains responsible for the treatment, decisions and other recommendations given to the patient, as well as for keeping detailed records of the patient's condition and information transmitted and received from the servicing practitioner.

(b) The servicing practitioner must keep detailed records of the advice he or she delivers as well as the information he or she receives and on which the advice is based.

(c) The servicing practitioner must further ensure that the advice or treatment suggestions given were understood by the consulting practitioner or the patient.

4.4 Evaluation and treatment of patient

4.4.1 A documented medical evaluation must be done and the relevant clinical history necessary to diagnose underlying conditions as well as any contra-indications regarding the recommended treatment must be obtained before providing treatment, including issuing prescriptions, electronically or otherwise.

4.4.2 Treatment, including issuing a prescription based solely on an online questionnaire does not constitute an acceptable standard of care.

4.4.3 When prescribing care using telemedicine consulting practitioners should ensure that informed consent is taken in accordance with the standards practice used in face-to-face issuing of prescriptions.

4.5 Professional duties

4.5.1 Healthcare practitioners engaging in telemedicine must observe the professional duties imposed in the HPCSA's General Ethical Guidelines for Good Practice.

4.5.2 Duties to patients include, but are not limited to, always acting in the best interest or well-being of the patient, respecting patients' privacy and dignity, giving patients the information they need about their conditions, and maintaining confidentiality at all times as required by the National Health Act No 61 of 2003 and the SA National Patients' Rights Charter.

4.5.3 Healthcare practitioners should not give medical advice or provide treatment using telemedicine without obtaining proper informed consent from the patient for both the treatment to be given and the use of telemedicine technology.

4.5.4 The consulting and servicing healthcare practitioners they should verify:

- (a) The location of the consulting or servicing healthcare practitioner;
- (b) The identity and qualifications of the consulting or servicing healthcare practitioner; and
- (c) The identity of the patient.

4.6 Duty to inform and informed consent

4.6.1 This section must be read in conjunction with HPCSA guidelines regarding informed consent in Booklet 9 and the provisions of the National Health Act.

4.6.2 Informed consent for the use of telemedicine technologies must be obtained in writing.

4.6.3 Informed consent documentation for telemedicine practice should include the following:

- (a) The identities of the patient and the servicing healthcare practitioner.
- (b) The servicing healthcare practitioner's practice number.
- (c) The types of transmissions consented to using telemedicine technologies (e.g. prescriptions, refills, appointment scheduling, patient education etc.).
- (d) Agreement by the patient that the servicing practitioner will decide whether or not the condition being diagnosed or treated is appropriate for a telemedicine consultation.
- (e) Details of the security measures taken with the use of telemedicine technologies, such as encrypting data, password protected screen savers and data files, or the use of other reliable authentication techniques.
- (f) Any material risks to confidentiality arising from the use of telemedicine technologies that may influence the patient's decision to consent.
- (g) The patient's express consent to the transmission of the patient's personal medical information to a consulting healthcare practitioner or other appropriate third parties.

4.6.3 When telemedicine is used the patient should be informed regarding who will access their information, the purpose of the telemedicine service, the cost of the service and what the implications of the use of such information will be.

4.6.4 It is the duty and responsibility of the consulting practitioner to obtain informed consent for telemedicine purposes.

4.6.5 The documentation regarding informed consent for telemedicine practice should include the following:

- (a) The patient's name and address and the location or site of consultation;
- (b) The consulting practitioner's name, practice address and number, and location;
- (c) The servicing practitioner's or practitioner's names, practice addresses and numbers, and location;
- (d) A brief explanation of telemedicine;
- (e) The types of transmissions consented to using telemedicine technologies (e.g. prescriptions, refills, appointment scheduling, patient education etc.).
- (f) Details of the security measures taken with the use of telemedicine technologies, such as encrypting data, password protected screen savers and data files, or the use of other reliable authentication techniques.
- (g) Any material risks to confidentiality arising from the use of telemedicine technologies that may influence the patient's decision to consent.
- (h) The expected risks, possible benefits of and alternatives to telemedicine;
- (i) Agreement by the patient that the servicing practitioner will decide whether or not the condition being diagnosed or treated is appropriate for a telemedicine consultation.
- (j) The patient's agreement, after a full explanation was given, including the patient's express consent to the transmission of the patient's personal medical information to a consulting healthcare practitioner or other appropriate third parties.
- (k) The signature of patient, the patient's parent, the patient's guardian or the patient's caregiver - the relationship to the patient should be specified;
- (l) The signature of the witness.

- 4.6.6 A copy of the consent form should be kept with patient's records and a duplicate given to the patient.
- 4.6.7 In the case of videoconference consultations, the patient must be aware of the presence of other people on the other side, and that the patient's identity may be revealed to such people, and must consent to this.

4.7 Patient confidentiality

- 4.7.1 The patient must at all times be assured that their confidentiality is protected.
- 4.7.2 Patient confidentiality should be ensured at both the consulting and servicing practitioners' sites and should follow the provisions of the Constitution, the National Health Act No 61 of 2003, the Promotion of Access to Information Act No 2 of 2000, the Protection of Personal Information Act No 4 of 2013, the Common law and the HPCSA's ethical guidelines on patient confidentiality in Booklet 10 which generally state that it is every practitioner's duty to make sure that information is effectively protected against improper disclosure at all times.
- 4.7.3 HPCSA's booklet on Confidentiality further provides guidelines on how patient information may be disclosed for example, in the case of research, education, clinical audit, financial audit or even for the publication of case histories and photographs].
- 4.7.4 Policies and procedures for documentation, maintenance and transmission of records regarding telemedicine consultations should be maintained at the same standard of care as face-to-face consultations.
- 4.7.5 Policies and procedures for telemedicine should deal with: (a) Confidentiality; (b) Healthcare personnel apart from the healthcare practitioners who will process the electronic information; (c) Hours of operation; (d) Types of transactions that are permitted electronically; (e) Required patient information to be included in electronic communications (e.g. name, identification number and type of transaction); (f) Archival and retrieval oversight mechanisms; and (g) Quality oversight mechanisms.

- 4.7.6 Electronic transmissions, (e.g. email, prescriptions and laboratory results) must be secure within existing technology (e.g. password protected, encrypted electronic prescriptions or other reliable authentication techniques). It is the responsibility of the healthcare practitioners to ensure that these non-healthcare personnel do not violate patient confidentiality.
- 4.7.7 All patient-practitioner electronic communications must be stored and filed in the patient's medical record file in line with traditional record-keeping policies and procedures.

4.8 Routine, specialists and emergency consultations

There is a need to provide guidelines on routine, emergency or specialist consultations using telemedicine technologies.

4.8.1 Routine telemedicine

- (a) Patient-initiated or second opinion telemedicine should be restricted to situations in which a previously existing healthcare-patient relationship enables the healthcare practitioner to gather sufficient knowledge of the patient's clinical condition to be able to render a proper and clinically justifiable diagnosis, treatment or recommendation.
- (b) This recommendation is in line with the WMA's regulations that telemedicine is only used as an adjunct to normal medical practice, and only replaces face-to-face services where the quality and safety of patient care is not compromised and the best available resources are used in securing and transmitting patient information.

4.8.2 Specialist telemedicine

- (a) Specialist telemedicine consultations form the bulk of telemedicine practice in South Africa because of human resource capacity challenges – particularly in rural areas.
- (b) These challenges do not however mean that patients should be over- or under-served.
- (c) The ethical guidelines for good practice as well as the ethical rules of conduct for practitioners registered with the HPCSA should be taken into consideration at all times.

4.8.3 Emergency telemedicine

- (a) Emergency telemedicine involves judgements by the healthcare practitioner often based on sub-optimal patient information.
- (b) In emergencies, the health and wellbeing of the patient are the determining factors with regard to stabilising the patient and having the patient referred for thorough medical care.
- (c) The practitioner must provide the patient with emergency instructions when the care provided by telemedicine indicates that a referral to an acute care or emergency facility is necessary for the immediate treatment of the patient.
- (d) The emergency instructions should be in writing and appropriate to the services being rendered via telemedicine.

4.9 Quality, security and safety of patient information and records

Rules on confidentiality and security of patient information applies to telemedicine as well, especially with regard to transmission and storage.

- 4.9.1 Every registered healthcare practitioner engaging in telemedicine practices takes responsibility for the quality of service delivered as well as confidentiality, security and safety of patients' information.

4.9.2 Patient information and records should consist of copies of all patient-related electronic communications, including:

- (a) Patient-practitioners communications;
- (b) Prescriptions;
- (c) Laboratory and test results;
- (d) Evaluations and consultations;
- (e) Records of past care;
- (f) Instructions obtained or produced in connection telemedicine technologies;
and
- (g) Signed informed consents to treatment and use of telemedicine.

4.9.3 The patient's records established during the use of telemedicine must be accessible and documented for both the healthcare practitioners involved and their patients.

4.9.4 It is the registered healthcare practitioner's responsibility to ensure that non-registered personnel who may be offering auxiliary or technical services, are aware of the need for such quality, security and safety and that they adhere to the stipulated guidelines.

4.9.5 Quality assurance

- (a) Healthcare practitioners, both from the consulting and servicing sites, should not practice telemedicine without ensuring that the equipment and accessories used are optimally operational.
- (b) Periodical quality control tests and servicing of equipment should be carried out and records kept for verification.
- (c) The quality and quantity of patient information received should be sufficient and relevant for the patient's clinical condition in order to ensure that accurate medical decisions and recommendations are made for the benefit of the patient.
- (d) Good communication contributes to quality patient information being transmitted from one practitioner to the other.

- (e) Quality should further be ascertained in the manner of documenting patient information.
- (f) A standardised manner of documentation is recommended to ensure that all healthcare practitioners adhere to the same protocol in terms of history taking, reporting on findings, creation of reserves and hard copies where necessary.
- (g) Where images are transmitted from one location to the other, it is the responsibility of both the consulting and servicing practitioner to ensure that there is no critical loss of image resolution from acquisition to final display.

4.9.6 Security

- (a) Patient information should only be transmitted from one site to the other and stored, with the full knowledge and approval of the patient, in line with the informed consent guidelines.
- (b) Only the information that is relevant to the clinical history of the patient should be transmitted electronically.
- (c) To protect the identity of the patient when information is transmitted between sites, it is essential that personal identification should be removed and the transmitted information is encrypted.
- (d) All personal computers of the telemedicine service should be accessed by authorised personnel only through the use of a login password.
- (e) There are three factors central to the security of patient information, namely:
 - i) Privacy: Who can access it?
 - ii) Authenticity: Who sends the information?
 - iii) Integrity: Has the information been altered during its transmission through the public networks?
- (f) Access to information by other healthcare practitioner, patients or third party should be authorised by the healthcare provider in charge of the patient and be carried out according to the rules and regulations as outlined in the Promotion of Access to Information Act, of 2000.

4.9.7 Safety

Health care practitioners using telemedicine should:

- (a) Avoid accidental damage and loss of patient information;
- (b) Provide safe procedures to avoid any alteration or elimination of patient data;
- (c) Ensure that patient information obtained electronically is kept in line with the HPCSA's guidelines on the keeping of patients' records in Booklet 15;
- (d) Comply with the legal requirements for data messages in the Electronic Communications and Transactions Act No 25 of 2002 regarding the protection of information and the principles regarding the electronic collection of personal information.

5. SOURCES CONSULTED

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Ethical guidelines for good practice in the health care professions

The following Booklets are separately available:

- Booklet 1:** *General ethical guidelines for health care professions*
- Booklet 2:** *Ethical and professional rules of the health professions council of South Africa as promulgated in government gazette R717/2006*
- Booklet 3:** *National Patients' Rights Charter*
- Booklet 4:** *Seeking patients' informed consent: The ethical considerations*
- Booklet 5:** *Confidentiality: Protecting and providing information*
- Booklet 6:** *Guidelines for the management of patients with HIV infection or AIDS*
- Booklet 7:** *Guidelines withholding and withdrawing treatment*
- Booklet 8:** *Guidelines on Reproductive Health management*
- Booklet 9:** *Guidelines on Patient Records*
- Booklet 10:** *Guidelines for the practice of Telemedicine*
- Booklet 11:** *Guidelines on over servicing, perverse incentives and related matters*
- Booklet 12:** *Guidelines for the management of health care waste*
- Booklet 13:** *General ethical guidelines for health researchers*
- Booklet 14:** *Ethical Guidelines for Biotechnology Research in South Africa*
- Booklet 15:** *Research, development and the use of the chemical, biological and nuclear weapons*
- Booklet 16:** *Professional self-development*