Article

The practice of telemedicine and challenges to the regulatory authorities

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The practice of telemedicine is viewed as a possible solution to the human resources crisis in health care in South Africa and internationally. Reports on its successful implementation and combating of health-related problems are readily available from both developed and developing countries. Even though these reports indicate that telemedicine seems to have addressed the problem related to the shortage of health care personnel, it is still posing a challenge to regulatory authorities such as the Health Professions Council of South Africa. The regulatory authorities are there to ensure that quality health care service is delivered and that the patient will be protected from possible mismanagement by the health care practitioners involved. Misconduct can occur through improper clinical care or excessive billing.

Policies and guidelines from both developing and developed countries were reviewed to highlight how telemedicine is regulated elsewhere. The focus was on the ethical implications of telemedicine practice. Telemedicine has proved itself to be a possible solution to the human resources crisis, especially in developing countries or where there are vast rural communities. Success of telemedicine has been reported in a number of developed and developing countries as a way of alleviating the human resources crisis and providing quality health care to needy communities.

Scarcity of health care practitioners is experienced around the world. The situation seems worse in African countries, as reported by the Department of Health in South Africa. A report issued in March 2008 highlights the fact that Africa carries 24% of the world's disease burden with only 3% of the world's health workers.[1] It is because of situations like this that telemedicine is practised all over the world. Through telemedicine it is possible for health care practitioners to exchange information about patients' conditions without the patient having to travel from one area to another. Health care disciplines in which this practice is growing the fastest include radiology, pathology and dermatology. Telemedicine is also used for education and training of health care practitioners. In providing quality care for patients, the practice of telemedicine ensures that advice or service by appropriately trained and qualified practitioners is made available. Successful implementation and combating of diseases through the practice of telemedicine are reported from low-income and developing countries such as sub-Saharan Africa and India.

What poses a challenge to the regulatory authorities is how this practice should be regulated, as it has grown to the extent that it is being practised across the borders of countries and continents. The Universal Declaration on Bioethics and Human Rights was adopted on 19 October 2005, at the 33rd session of the United Nations Educational, Scientific and Cultural Organization (UNESCO)'s General Assembly.[2] The declaration affirms that *'ethical issues raised by the rapid advances in science and their technological applications should be examined with due respect to the dignity of the human person and universal respect for, and observance of, human rights and fundamental freedom'.*

The universal principles identified by UNESCO[2] are based on shared ethical values and are meant to guide scientific and technological development such as the practice of telemedicine. The principles are aimed at reconciling the demands of what is regarded as inviolate principles of human rights with the constantly evolving applications of science and technology.

This paper considers the challenges that would confront any regulatory authority with regard to telemedicine. The paper is intended to evoke discussion among all involved in and concerned about the practice of telemedicine, both within and across the borders of countries and continents.

Definitions of telemedicine

There are various terms that refer to the practice of telemedicine. Terms such as 'telehealth' or 'e-health' and 'teleconsulting' are used. According to the World Health Organization (WHO):[3]

- Telehealth is the provision of health care at a distance using information communication technology (ICT) facilities.
- E-health, on the other hand, combines the use of electronic communication and information technology in the health sector. It involves the transmission, storage and retrieval of digital data for clinical, educational and administrative purposes.

Although the WHO defined telemedicine in 2005, the World Medical Association (WMA) provided an expanded definition. Telemedicine is defined as *'the practice of medicine over a distance, in which interventions, diagnostic and treatment decisions as well as recommendations are based on data, documents and other information transmitted through telecommunication systems'*.[4] The services included according to this definition are set out in Table I.

The Telemedicine Act of 2003 of India[5] provides a more expanded definition: *'practice of medicine delivered across distances via telecommunications, including audio, visual and data communications, and interactive video technology, performed by licensed or otherwise legally authorised individuals'*.

Teleconsulting is practised either off-line or on-line. Off-line teleconsultation does not involve real-time network communication such as videos, but may involve the exchange of e-mails. On-line teleconsultation is a type of remote consultation that involves real-time network communication systems and is usually used for emergency situations.

The HPCSA[6] defines telemedicine as *'the exchange of information on health care at a distance for the purpose of facilitating, improving and enhancing clinical, educational and scientific health care and research, particularly to the under-serviced areas in the Republic of South Africa'*. This authority also recommends that patient-initiated teleconsultation is restricted to situations in which a previous health care professional-patient relationship existed for the same or a related health condition. An existing relationship will enable the health care professional to render a proper and clinically justifiable diagnosis, intervention or treatment action plan.

Table I. Services included in telemedicine as defined by the WMA

- Transmission of patient data such as reports of symptoms and X-rays via the Internet as well as monitoring of physiological functioning
- E-mail exchange of consultation requests and responses such as communication between physician and patient
- Remote real-time examination of a patient in one location by a physician in another
- Remote real-time assistance in medical or surgical treatment of a patient, when the treatment is being performed by a lesser-skilled practitioner with the advice of the physician in another location
- Remote robotic surgery

Current regulatory framework

Core ethical values as outlined in the HPCSA[6] guidelines for health care professionals are also applicable to telemedicine practitioners. According to the Ontario Association of Radiologists (OAR),[7] the relationship between the practitioner and the patient must be based on mutual trust and respect. This is applicable to both face-to-face and teleconsulting services. The policy of the WMA[8] makes a distinction between the consulting practitioner and the servicing practitioner as far as assumption of primary responsibilities for the patient is concerned. Consulting practitioners are responsible for the treatment decisions and other recommendations given to the patient. The consulting practitioner is expected to keep accurate patient records, including the information from the servicing practitioner. The servicing practitioner, on the other hand, is expected to keep accurate records of the advice he or she delivers, as well as the information which was received.

Telemedicine practitioners also have duties acquired by being deemed qualified and registered in their respective professions. The duties as outlined in the HPCSA's general ethical guidelines for health care professionals[2] include but are not limited to the following:

- Duty to act in the best interests or well-being of the patient
- Duty to establish good working relations with other professionals when making referrals or providing advice or treatment recommendations
- Duty to patients and the need to report human rights violations or seek redress in circumstances where the practitioner believes that the patient's rights are being violated
- Duty to inform the patient about who will access their information, for what purpose and what the implications are.

It can be seen that there are differences in the way the regulatory authorities define telemedicine as well as guide how telemedicine is to be practised. But who makes the policies and guidelines? Mars and Scott[9] indicate that with a few exceptions, policy decisions that relate to telemedicine are made by individual professional organisations, health institutions, regions/provinces or states. What further complicates the matter is that although it is accepted that telemedicine can be and is being practised across the borders of countries and continents, when it comes to policy making and regulations there seems to be less consultation (if any). What impact will these differences or lack of communication have on the rights of patients to access quality health care?

Challenges to the regulatory authorities

The practice of telemedicine and related terms as defined earlier presents a number of challenges to the regulatory authorities. The possible elimination of the face-to-face consultation poses a challenge to the traditional principles that govern the patient-health care practitioner relationship. The WMA[8] states that regulatory authorities should develop ethical guidelines to address health care practitioners' responsibilities towards the patient. The guidelines provided by the WMA emphasise the need for the regulatory

authorities to provide ethical guidelines on informed consent and confidentiality. The other challenges faced by regulatory authorities are licensure, liability, quality of care, access to care and reimbursement. Fleming *et al*.,[10] on the other hand, state that ethical implications for telehealth go beyond issues of privacy and confidentiality. They recommend that providers and systems should consider the impact of telehealth on the practitioner's relationship with patients, capacity of equitable treatment and costs, as well as quality of life.

Consent

According to HPCSA[6] guidelines, informed consent for telemedicine purposes is the duty and responsibility of the consulting practitioner. The consent form should be provided in writing and include the following information: patient's details, location or site where consultation is to take place, consulting practitioner's details and location, servicing practitioner's details and location, brief explanation of telemedicine, expected risks and possible benefits. After a full explanation is given, the patient must sign the consent form. Where the patient is unable to sign, a guardian or relative should sign on behalf of the patient. A copy of the signed consent form should be kept with the patient's records and another one given to the patient. In exceptional cases patients might call on the practitioner, and this should be limited to situations where previous face-to-face consultation took place and telemedicine is used to monitor progress or provide further treatment. The practitioner can ask the patient to reaffirm the consent, faxing or e-mailing the signed copy for the record.

The challenge comes when the hospital has contracted an outside company, as happens with teleradiology in developed countries. A hypothetical report by Gaffney and Rozousky[11] gives an example of the possible ethical and legal implications. Here the patient had no idea of who was going to provide a radiology report and was not asked to give consent. The report provided by the radiologist from the contracted company nearly cost the patient her life. Should a misdiagnosis or inappropriate recommendations be made, who should be held liable? What kind of information will the patient give consent to? Should it be for privacy and confidentiality, or include possibility of system capacity or failure?

Confidentiality

With regard to remote real-time examination of a patient in one location by a physician in another, for example, the practitioner is expected to respect the patient's autonomy and treat all information as confidential. Confidentiality of patient information during telemedicine consultation involves safe and secure transmission and storage of data. The Electronic Communications and Transactions Act (No. 25 of 2002)[12] of South Africa provides principles for electronically collecting personal information as well as for ensuring safe storage and retrieval. To protect the identity of the patient, the transmitted information should only be accessed by the intended recipient. Jack and Mars[13] ask whether an 'email encryption available from commercial communication software like Microsoft Outlook … can be considered to be sufficient security'. The HPCSA guidelines state that all personal computers of telemedicine practitioners should only be accessed by authorised personnel with the use of login/a password.[6] The HPCSA further states that access to information by other health care practitioners, patients or third parties should be authorised by the health care practitioner in charge of the patient. Access should further be in accordance with the rules and regulations as outlined in the Promotion of Access to Information Act, No. 2 of 2000.

The challenge posed by the technical and electronic communication media is complicated by involvement of non-health care practitioners such as information technology (IT) specialists, who manage the equipment and are responsible for producing patients' records. These IT operators are not registered with the regulatory authorities. In cases such as these, the registered health care practitioner takes responsibility for ensuring privacy and safety of all patient information.[8] Mars and Scott[9] go on to ask who should ensure confidentiality for digital telephone transfers or video-conferenced teleconsultations.

Quality of care

Regulatory authorities such as the HPCSA have as their mandate protection of patients from possible mismanagement by health care practitioners. Monitoring of practitioners and their electronic systems determines whether the quality of the information transmitted from one site to the other is optimal and will therefore not compromise the diagnostic, interventional or even therapeutic decisions made. The HPCSA guidelines[6] state that for situations where face-to-face consultation between the patient and the practitioner is not possible, telemedicine must only be conducted when there has been a previous relationship and face-to-face consultations have taken place. The HPCSA further states that all first-time teleconsultations are restricted to situations where a primary health care practitioner is involved in a face-to-face consultation and physical examination of the patient is performed. This is to ensure that the practitioner is familiar with the patient's condition. The patient's right to be referred for a second opinion should not be overlooked by the practitioner. In the case of an emergency, referral for telemedical treatment should be used only for stabilising the patient, after which the patient must be advised to seek alternative treatment, which will involve a physical examination.

Access to care

Telemedicine is intended to improve access of patients to health care of an appropriate level and quality. Guidelines should highlight this aspect while regulating the practice to ensure equity of access. Jack and Mars[13] highlighted the fact that improved access should also maintain quality when information is transmitted from one location to the other. Practitioners have an 'obligation to ensure that technology used for telemedicine is reliable, of sufficient quality, correctly calibrated and that it will not fail or compromise the patient'. The challenge to regulatory authorities, according to Fleming *et al*.,[10] is that telemedicine tends to focus only on the identified problem and not on the whole being. The HPCSA[6] guideline that telemedicine be permitted only where there was previous face-to-face consultation is to ensure that the patient is treated as a whole being. Access to health care is further complicated by registration and licensure requirements.

Registration and licensing

The provision of telemedicine services across the borders of countries and continents poses a challenge to regulatory authorities. An

investigation into regulations passed by countries outside South Africa showed that in some countries practitioners are expected to be accredited to provide telemedicine services, while others only require practitioners to be on a general register of their respective council. There is currently no specific registration or accreditation for telemedicine practitioners with the HPCSA.[6] This differs from the situation in India and Malaysia. In a preliminary report on health information and telemedicine of Malaysia[14] it is stated that only doctors licensed by the Malaysian Medical Council or those who practise through a doctor licensed in Malaysia are allowed to practise telemedicine.

The Royal College of Radiologists (RCR) Breast Group in Europe[15] stipulates certain requirements for patients who are screened outside their countries of residence or have their images interpreted outside their countries of residence. These patients are entitled to the same quality of care, standards and safeguards as if they were being treated by health care practitioners working in their countries of residence. To ensure that patients are not subjected to inferior service, the executive director of the American College of Radiology (ACR), Harvey Neiman, insists that radiologists who report on medical images from outside the USA meet the same educational and professional standards as those in the USA.[16]

The regulations on the National Telemedicine Systems in South Africa (NTSSA)[17] have specified the persons who may practise telemedicine. These are restricted to: (*i*) a fully registered medical practitioner; (*ii*) a medical practitioner who is registered outside South Africa and holds a certificate to practise telemedicine issued by the HPCSA; or (*iii*) a health care practitioner or a fully registered medical practitioner who holds a valid registration certificate to practise outside South Africa. These regulations, however, exclude other health care practitioners (such as primary health care nurses, radiographers and medical technologists) who may be engaged in physical examination of the patients or provision of medical images and laboratory results. A similar exclusion is found in the Malaysian Telemedicine Act. Mars and Scott[9] explain how the Malaysian act restricts the practice of telemedicine by stipulating that primary health care nurses must operate under the supervision of the registered medical practitioner. With the shortage of medical practitioners, especially in the underserved rural communities of most developing countries, will this licensure restriction not deny patients the right to access health care?

Reimbursement

Although the WMA guidelines did not include tariffs and commissions that practitioners may accrue for services rendered, it is essential that guidelines also address fees and commission. Such regulations should protect patients from possible fraudulent claims by health care practitioners and should ensure appropriate payment to providers.

Reimbursement for telemedicine poses a challenge in the private sector, where the patient is expected to cover the costs of the services rendered (in South African state health care institutions patients are not expected to cover the costs of teleradiology). The proposal by the National Department of Health[18] for the establishment of the telemedicine system in South Africa provides guidelines on the quality of the medical images to be sent from one practitioner to the other. The proposal further stipulates the requirements to be met by practitioners who want to practise telemedicine, as well as the ethical guidelines to be followed. However, the guidelines do not provide for reimbursement to one province by another. What would happen if a province (in South Africa) or a country cannot carry the financial burden? What would happen to health care provision in countries such as Rwanda,[19] where there is a lot of financial assistance pouring in? What if the sources do not provide any more?

Most countries' medical aid or health insurance companies do not have regulations in place to guide and control the practice of telemedicine. For companies that have contracts with health care institutions, such as Epic Radiology as cited in Orenstein,[20] a bill is sent to the hospital that requests the service, and not directly to the patient. The challenge is the reimbursement of an individual practitioner who is providing telemedicine service. How ready are the medical aid schemes to reimburse individual health care practitioners? How are the regulatory authorities monitoring the services provided through telemedicine, especially in countries where a telemedicine licence is required? How is the public protected from possible fraudulent claims from telemedicine practice?

Conclusion

The paper has highlighted challenges facing the regulatory authorities in the practice of telemedicine from both developing and developed countries. Information from sources consulted support the need for telemedicine in providing quality health care, especially in rural areas. A research report by Mbarika[21] on Mozambique indicates how two central hospitals use low-cost teleradiology to transmit and exchange images and radiographs and thus provide improved medical care. This is but one of the success stories of telemedicine.

There are, however, still some challenges to the regulatory authorities, which need to be discussed by all concerned with the practice of telemedicine. There is a possibility that patients' rights to access health care through telemedicine may be compromised through restrictive policies and guidelines. Restrictions include having primary health care nurses work under the supervision of a medical practitioner. Another restriction is having medical practitioners licensed in countries for which they may be asked to give an advice or recommendation based on their expertise. Some countries demand their practitioners to have additional qualifications and be accredited before they can practise telemedicine, while others do not.

There is a need for consultation among policy makers and their respective regulatory authorities as well as a review of how the patient may be impacted on by some policies and guidelines. The involvement of non-health care practitioners such as IT personnel in the monitoring and treatment chain also raises some ethical questions. Who is liable if the patient claims that his right to privacy and safety of information has been violated? In the case of a failure in technology, such as when information cannot be transmitted or transmitted information does not meet the required quality and standards, who should be held responsible for the possible delay in health care service delivery? Does the consent given by the patient also include possibility of technological failure or breakdowns?

Finally, the issue of fees payable cannot be ignored. Some countries have regulations on fees payable to the telemedicine practitioners, while others are still lagging behind. With such uncer-

tainties, regulatory authorities still have some work to do to ensure that patients are protected during the practice of telemedicine.

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