

## Why is telemedicine a challenge to the regulators?

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Regulators feel that telemedicine presents challenges. In part this is because of the assumption that telemedicine is new and unproven, and must therefore be regulated in order to protect the patient. Regulation requires clear and careful definition of what is to be regulated. The Health Professions Council of South Africa's proposed definition of telemedicine has deficiencies. Telemedicine is not new, nor is it a special discipline or a new branch of medicine. It involves the use of information and communication technologies in the provision of health care over distance. This includes the telephone. Instead of proposing a one-size-fits-all approach to regulations and guidelines, a more pragmatic approach to issues such as signed, written consent, prior doctor-patient relationship and licensure is required. It is proposed that regulators should seek to find deficiencies in existing guidelines and regulations and address these if required, and that clinical, operational and ethical guidelines should be developed by the governing bodies or associations of the various clinical disciplines using information and communication technologies in the provision of health care. An enabling regulatory environment is required if we are to realise the goals of improved access, service delivery and quality of care for the rural communities of South Africa through telemedicine.

The recent paper by Kekana *et al.* considers the challenges that telemedicine presents to regulatory authorities and states the need for discussion on the subject.<sup>1</sup> Is there a need to regulate telemedicine?

Argument for regulation appears to be premised on the belief that telemedicine is something new and by inference unproven. The patient is therefore placed at risk and should be protected by regulation. We are not against regulation, where necessary, but argue that technology has long been used to provide health care over distance, without the need for regulation, and that telemedicine is not new. Information and communication technologies, the radio<sup>2</sup> and telephone<sup>3</sup> have been used in the practice of medicine over distance for over a century. Furthermore, a one-size-fits-all approach to guidelines and regulations fails to appreciate the wide spectrum of practice of telemedicine across disparate disciplines using different technologies.

The first published reference including the word telemedicine appeared in 1969.<sup>4</sup> The addition of the prefix 'tele' to the practice of a component of medicine predates the word telemedicine. 'Telecardiology' was used and reported by Einthoven in 1905,<sup>5</sup> with the words 'telognosis' appearing in 1950, 'telefluoroscopy' in 1959 and 'telediagnosis' in 1967.<sup>2</sup> Health practitioners routinely use the 'telephone' to discuss patient management, give treatment instructions, obtain test results and communicate with patients. Telemedicine is not new, a special discipline of medicine, a new branch of medicine, a technology, or a mature discipline.<sup>6</sup> It is unlikely that there is any medical practitioner in South Africa who has not practised telemedicine, albeit unwittingly.

Regulators require an understanding of the aspects of telemedicine that are not covered by existing ethical guidelines and regulations, and need to decide whether these areas require specific regulation, ethical guidelines, or discipline-specific clinical, operational and technical guidelines. Where there are deficiencies,

these should be addressed in a pragmatic and not a theoretical manner.

### The definition of telemedicine

Regulation requires a clear and careful definition of what is to be regulated. The Health Professions Council of South Africa (HPCSA)'s proposed definition of telemedicine, '*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-served areas in the Republic of South Africa*',<sup>1</sup> has deficiencies. It appears to be based solely on the etymology of telemedicine, from the Greek word *tele* (at a distance) and *medicine* (derived from the Latin word *meden*, meaning healing). This definition covers a wider range of activities than is probably intended. For example, sending a patient's paper-based outpatient file from one department to another for referral in a public hospital meets the HPCSA definition, as information on health care will have been exchanged at a distance for the purpose of facilitating health care. The same would hold for a written prescription given to a patient for presentation to a pharmacist. It is doubtful that this was the intention.

The proposed HPCSA definition lacks mention of the method by which information is transmitted over distance. Kekana *et al.* provide two examples of definitions of telemedicine, one of telehealth, and one of e-health.<sup>1</sup> Common to these four definitions is the use of telecommunications or information and communication technologies (ICT). The World Medical Association (WMA)'s most recent definitions of telehealth, 'the use of information and communications technology to deliver health and healthcare services and information over large and small distances' and telemedicine, 'the practice of medicine over a distance, in which interventions, diagnostics and treatment decisions and recommendations are based on data, including voice and images, documents and other

information transmitted through telecommunication systems', highlight this omission.<sup>7</sup>

The addition of the use of ICT or telecommunications to the definition of telemedicine limits the scope of activities but incorporates ICT-based activities that are not necessarily considered to be 'telemedicine'. The use of 'telephone' in clinical practice was reported in the *Lancet* in 1879.<sup>3</sup> Despite slow uptake and early resistance from conservative physicians, the telephone is now an integral part of medicine, for communication with colleagues and patients, at a distance, to facilitate health care. Similarly the fax is used to confirm telephonic prescriptions. The WMA's Statement on Guiding Principles for the Use of TeleHealth for the Provision of Health Care includes the use of the telephone for telemedicine.<sup>7</sup>

The telephone is set to play an even greater role in health care through mobile health (m-health) the latest addition to the e-health alphabet soup. Mobile health refers to the use of mobile electronic devices and includes personal digital assistants (PDAs), mobile phones and smart phones for the practice of medical and public health. With the ubiquity of mobile phones and their ongoing evolution as smart phones, m-health is seen as the new technology platform for e-health and telemedicine. m-Health is not a new service, but a communications technology that will assist in health care delivery and access to health care, similar to the telephone in the early 20th century. The United Nations Foundation has established an m-Health Alliance to facilitate m-health internationally, and the South African mHealth Alliance was recently launched. Increasingly, telemedicine, from patient education, data collection, treatment reminders, image and sound transmission, drug prescription and decision support systems to continuing medical education, will be conducted and facilitated using this communication platform. Ethical and legal guidelines must be cognizant of this.

Careful consideration must be given to whether the definition of telemedicine includes electronic medical records (EMRs), either intentionally or unintentionally, as the current approach to consent and the requirement for a previous doctor-patient relationship becomes problematic with an EMR. The definition of telemedicine must be skillfully crafted and may require exclusions.

## Legislation and licensure

Including the use of ICT and/or telecommunications in the definition of telemedicine raises several questions. Should the use of the telephone, fax, PDA, smart phone, videoconferencing (telephony and an image), e-mail and the Internet, by health practitioners for the provision of health care, be regulated? Is there need for health professionals to be specially licensed and accredited to use these telemedicine devices? Is special training needed to use them? Do we require legislation for their use? Do we require health professionals to obtain signed, written consent from patients when using the telephone to communicate with patients, seek a second opinion or give medical orders to nursing staff, and must copies be kept by all parties concerned?

If the use of the telephone has not previously required regulation or guidelines, why then the need for newer forms of telemedicine to be regulated?

Risk to the patient or practitioner is a determining factor for regulation. Robotic telesurgery currently carries greater risk than standard surgery and requires specific technical, clinical and op-

erational guidelines. Whether additional ethical guidelines are required is not clear. That one mode of telemedicine has associated additional risk does not mean that this applies to all its forms. Published guidelines on the use of telemedicine in different clinical specialties make the point that a telemedicine consultation or encounter should be no different to routine practice and there should therefore be no additional risk to the patient.

Specialist disciplines should, through their professional organisations and associations, develop appropriate clinical, technical and operational guidelines and if necessary ethical guidelines, relevant to telemedicine in their specialty and the South African context. Some issues will be common across disciplines. Others will have specialty-specific issues, e.g. telepsychiatry, teledermatology, and teleradiology. National guidelines for the practice of telepsychiatry are being developed and co-ordinated by the South African Telemedicine Association.

Kekana *et al.* note that the HPCSA has no requirement for accreditation of medical practitioners to practise telemedicine, then state that the regulations on the National Telemedicine Systems of South Africa have specified who may practise telemedicine in South Africa, citing the National Health Act No. 61 of 2003.<sup>1</sup> The proposed regulations were never promulgated. Currently any health professional may practise telemedicine in South Africa, which we believe is appropriate to provide greater access and quality of care to people in our rural, under-served areas. The draft regulations were based on the Malaysian Telemedicine Law of 1997.<sup>8</sup> Telemedicine and how it is practised has evolved and the Malaysian Law's restrictions are now seen as obstructive and counter-productive, particularly for developing countries that most need the benefits of international telemedicine service provision.

Cross-border telemedicine remains an international problem. The term 'glocal' describes the need for policy makers, regulators and legislators to think globally while acting locally.<sup>9</sup> The need to develop a Global eHealth Convention to cover, among other things, cross-border practice of telemedicine is being addressed. The European Union is developing a framework and legislation to facilitate cross-border telemedicine and reimbursement within the EU Community.<sup>10,11</sup>

Kekana *et al.* state that India requires specific registration for the practice of telemedicine, citing the Telemedicine Act of 2003.<sup>1</sup> Like the South African Regulations, the Bill was never enacted. But there are lessons to learn from the draft Indian documents. To develop e-health laws in India, the following solutions were offered for practice of telemedicine across borders:<sup>12</sup>

1. mutual recognition between countries to recognise the licence granted by the home country to allow the doctor to practise in the other country
2. reciprocity between countries where licensed doctors can practise in both countries
3. registration, 'where the doctor submits to the legal regime governing medical negligence and malpractice in the country where the patient resides or communicates from, but not the licensing requirements for doctors in that country'
4. limited licensure, where a doctor obtains limited licensure through a licensed referring doctor in the country where the patient resides or communicates from.

The first three options extend the limited Malaysian model, which includes only option 4.<sup>8</sup> For the developing world countries in need of international support to overcome the shortage of medical practitioners and specialists, options 1 and 2 appear to be the most sensible.

To our knowledge, the only country that regulates who may practise telemedicine or accredits practitioners for telemedicine is Malaysia.<sup>9</sup> In the USA, practitioners are bound by the rules of the states in which they are licensed to practise. Some states allow practice across state boundaries, while others do not. There is no requirement for special accreditation to practise telemedicine other than licensure. Most state telemedicine legislation in the USA relates to payment for telemedicine services. France has legislation covering telemedicine, the Health Insurance Act (13 August 2004), which does not mention specific registration or accreditation.<sup>13</sup> Another form of accreditation is peer assessment. The Swinfen Charitable Trust, an international humanitarian telemedicine service, offers free telemedicine services provided by a network of specialists who have been accredited by their peers.<sup>14</sup>

## Consent

It has been argued that telemedicine is something new with added risk to the patient, who therefore needs extra protection, which can be achieved through the implementation of written, signed consent for a telemedicine encounter.

The proposed HPCSA guidelines appear to follow this argument and for a telemedicine encounter require that consent should be written and signed by the patient, a copy being kept in the patient's records and a copy supplied to the patient. The procedure to be followed when one practitioner consults another or gives treatment instructions by telephone, fax, or e-mail is not explicitly covered and as these actions constitute the practice of telemedicine it is assumed that the intention is that written, signed informed consent be obtained.

Chouinard and Scott investigated informed consent for videoconsultation in the 14 provinces, territories and jurisdictions of Canada.<sup>15</sup> The telehealth experts' consensus was that videoconsultation has moved beyond the experimental stage; 86% felt that videoconsultation was a communication tool and not a '... service distinct to that of face to face consultation'. They therefore felt that an implied model of consent for videoconferencing was acceptable. Six of 14 jurisdictions used written consent, of which two jurisdictions wanted to change to verbal consent. Chouinard and Scott recommended that there should be a move to an implied consent model which will promote the integration of videoconsultation into routine health care.<sup>15</sup> South Africa should give due consideration to this if we are to reap the potential benefits of synchronous telemedicine.

Should signed, written informed consent be required where it has not previously existed and where there is no added risk? Radiology practices in South Africa are changing to computed radiography. For routine imaging the patient usually meets only administrative staff and the radiographer. A digital image is transferred through a direct physical connection, a network or the Internet to a radiologist, who may be at a remote venue, and/or stored in a picture archiving system for later retrieval. This is teleradiology, with information transmitted over distance, and is seen as part of the natural technical evolution within the specialty. Public-sector X-

ray images in the Eastern Cape are sent electronically to radiologists in other provinces for reporting. In several provinces in South Africa, computed tomography and magnetic resonance imaging scanners are linked to academic sites for specialist radiological interpretation and plain film X-rays have been digitised and sent for reporting.<sup>16</sup> Does teleradiology under these circumstances place the patient at greater risk?

Current practice does not require written, signed, informed consent for a routine X-ray, be it film or digitally based. It can be argued that consent is implicit if the patient presents for the X-ray investigation. Why should written, signed consent now become a requirement for routine teleradiology?

The WMA guideline offers a pragmatic approach, 'The physician providing telehealth services should follow all relevant protocols and procedures related to: informed consent (verbal, written, and recorded) ...', 'Relevant legislation and regulations that relate to patient decision-making and consent should be applied', and 'Consent for telehealth should follow similar principles and processes as those used for other health services.'<sup>17</sup>

Careful consideration is required of the different spheres of consent that may be required for different aspects of telemedicine. A one-size-fits-all approach is not appropriate.

## Concern about the validity of informed consent for telemedicine

Valid consent must be based on substantial knowledge of the act consented to by the patient, who has the right to withhold consent.<sup>17</sup> Obtaining informed consent that explains how electronic data are to be transmitted and/or stored in a secure manner when using a telephone, fax, videoconference unit, e-mail or the World Wide Web is difficult for the technology-literate doctor, even more so when the patient is technology naive and consent is gained through an interpreter. The extent of this problem is probably greater than expected. Mobile phone or Internet penetration is a surrogate marker of technology awareness. Mobile phone penetration in South Africa is now in the region of 100%, but Internet penetration is still low, at 11%,<sup>18</sup> and 49% of South Africans do not know what the Internet is.<sup>19</sup> There is also an invalid assumption that the lexicons of the 11 official languages have words for the technology and data security measures that can be employed in various forms of telemedicine encounters.<sup>20</sup>

## Quality of care

The proposed HPCSA guidelines state that a telemedicine consultation '... must only be conducted when there has been a previous relationship and face-to-face consultations have taken place'. The South African government sees telemedicine as a means of providing access to scarce human resources, especially specialists, and improving quality of care for rural patients. This requirement would, by and large, limit most telemedicine in the public sector to follow-up consultations.

Teleradiology in the public sector would become impractical, as the patient would have to travel to see the radiologist to establish a face-face relationship before the radiologist can report on the X-ray film. If at some later date the patient requires another X-ray and a different radiologist is on duty, the patient would once again

have to travel to the radiologist. Where X-ray films are transported to a centre with a radiologist for delayed reporting, this practice would also have to stop.

Similarly, several successful store-and-forward teledermatology<sup>21</sup> and tele-ophthalmology<sup>22</sup> services in the public sector, which have reduced unnecessary patient transfer by up to 80%, would be curtailed. Proposed diabetic retinopathy screening services using digital retinal cameras and Internet-based transmission of images would not be possible, nor would use of international telemedicine for second opinion or diagnostic services.

Again, a one-size-fits-all approach to telemedicine guidelines is impractical.

## Existing ethical guidelines for telemedicine

The National Department of Health's 1998 Ethical Guidelines were adapted from a code of conduct for commercial telemedicine product providers and have little to do with the clinical practice of telemedicine. They include guidelines such as 'When developing or implementing telemedicine systems, participating members must always attempt to ensure that their products will be used in socially and environmentally responsible ways.'<sup>23</sup>

## Reimbursement

Insurers pay for telemedicine services provided by radiologists and pathologists in the private sector, without necessarily appreciating that these are telemedicine services. In the public sector, practitioners are salaried and are not reimbursed for their telemedicine activities.

Telemedicine across provinces is occurring, and payment for these activities is a matter for the relevant departments of health and not an issue of national regulation. Similarly, provinces can contract with private practitioners to offer a teleradiology service, a matter between the provincial Department of Health and the contractor.

## Recommendations

It is well documented that successful telemedicine implementation requires an enabling regulatory and legislative environment. To achieve this, the following recommendations are made:

- Care needs to be taken in defining telemedicine.
- Telemedicine is not new, and regulation premised on this assumption is inappropriate.
- Clinical, technical and operational guidelines for telemedicine should be developed and approved by the specific discipline's clinical governing body or association.
- Where aspects of clinical telemedicine differ from normal, current clinical practice and are not covered by existing ethical guidelines, these should be addressed.
- Where regulations are required, they need to take into account the full spectrum of telemedicine activities that already exist and that have not been previously regulated.
- The one-size-fits-all approach to telemedicine regulation is not appropriate.

## References

1. Kekana M, Noe P, Mkhize B. The practice of telemedicine and challenges to the regulatory authorities. *South African Journal of Bioethics and Law* 2010;3:33-37.
2. Bashshur RL, Shannon GW. *History of Telemedicine: Evolution Context and Transformation*. New Rochelle, NY: Mary Ann Liebert Inc., 2009.
3. Aronson SH. The Lancet on the telephone. *Med History* 1977;21:69-87.
4. Murphy R, Bird K. Tele-medicine and occupational health services. *Proceedings of the XVI International Congress on Occupational Health, Tokyo, 22-27 September 1969*: 385-387.
5. Einthoven W. Het telecardiogram [The tele-cardiogram]. *Ned T Geneesk* 1906;50:1517-1547.
6. Craig J, Patterson V. Introduction to the practice of telemedicine. *J Telemed Telecare* 2005;11:3-9.
7. World Medical Association General Assembly. WMA statement on guiding principles for the use of telehealth for the provision of health care. 2009. <http://www.wma.net/en/30publications/10policies/t5/index.html> (accessed 5 October, 2010).
8. Laws of Malaysia, Telemedicine Act 1997. 1997, Act 564. [http://www.agc.gov.my/index.php?option=com\\_content&view=article&id=650&Itemid=204&lang=bm](http://www.agc.gov.my/index.php?option=com_content&view=article&id=650&Itemid=204&lang=bm) (accessed 5 October 2010).
9. Mars M, Scott RE. Global e-health policy: a work in progress. *Health Affairs* 2010;29:1-8.
10. European Commission. Proposal for a directive of the European Parliament and of the Council on the application of patient's rights in cross-border healthcare. 2008;CDM(2008)414. [http://ec.europa.eu/health-eu/doc/com2008414\\_en.pdf](http://ec.europa.eu/health-eu/doc/com2008414_en.pdf) (accessed 5 October 2010).
11. European Parliament. Resolution on the proposal for a directive on the application of patients' rights in cross border healthcare. Amendments to the text proposed by the Commission, 2009.
12. Health information and telemedicine: legal framework. A preliminary report. 2003; 1-26. <http://www.mit.gov.in/telemedicine/>
13. European Commission Directorate General Information Society. Study on the Legal Framework of Interoperable eHealth in Europe: National Profile France. Brussels, European Commission. SMART, 2008: 1-51.
14. Swinfen Charitable Trust. Swinfen Charitable Trust 2010. [http://www.swinfencharitabletrust.org/index.php?option=com\\_content&view=article&id=46&Itemid=55](http://www.swinfencharitabletrust.org/index.php?option=com_content&view=article&id=46&Itemid=55) (accessed 5 October 2010).
15. Chouinard I, Scott RE. Informed consent for videoconsultations in Canada. *J Telemed Telecare* 2009;15:171-174.
16. Corr P. Teleradiology in KwaZulu-Natal. *S Afr Med J* 1998;88:48-49.
17. Stanberry B. The legal and ethical aspects of telemedicine. 3: Telemedicine and malpractice. *J Telemed Telecare* 1998;4:72-79.
18. International Telecommunications Union. Information society statistical profiles 2009. Africa, 2009. [http://www.itu.int/dms\\_pub/itu-d/opb/ind/D-IND-RPM.AF-2009-PDF-E.pdf](http://www.itu.int/dms_pub/itu-d/opb/ind/D-IND-RPM.AF-2009-PDF-E.pdf) (accessed 5 October 2010).
19. Gillward A. ICT policy and regulatory frameworks: the status and challenges of SADC countries. 2009. <http://www.sadcpf.org/Gillward%20SADC%20Status%202009.ppt> (accessed 5 October 2010).
20. Jack C, Mars M. Language, cultural brokerage and informed consent: will technological terms impede telemedicine use? In: Cunningham P, Cunningham M, eds. *IST Africa 2010*. Dublin: International Information Management Corporation, 2010.
21. Mars M, Dlova N. Teledermatology by videoconference. *South African Journal of Family Medicine* 2007;50:68-68d.
22. Mars M. Telemedicine in KwaZulu-Natal, South Africa: from failure to cautious optimism. *J Telemed Telecare* 2007;13:57-59.
23. Technical Working Document 2000. TeleMedicine Technical Working Group 2000. [www.doh.gov.za/programmes/tele/telefinal.html](http://www.doh.gov.za/programmes/tele/telefinal.html) (accessed 5 October 2010).