

Informed consent for telemedicine in South Africa: A survey of consent practices among healthcare professionals in Durban, KwaZulu-Natal

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Background. The Health Professions Council of South Africa is drafting guidelines to regulate the practice of telemedicine. These emphasise the need for signed informed consent for all aspects of the consultation process, including data transmission and storage.

Objective. To survey current practices relating to gaining informed consent both in routine clinical practice and when using information communication technologies (ICT).

Methods. A cross-sectional descriptive study was undertaken using a self-administered questionnaire. It surveyed healthcare professionals' habits and practices of obtaining informed consent in clinical practice scenarios and when using the telephone, fax and email for communication and healthcare provision.

Results. A total of 193 doctors and 207 nurses completed the questionnaire. Fewer doctors took written consent than nurses, with a range of 2.6% when examining a patient to 8.3% when ordering a special examination. A significant difference was observed for all activities. Of the 67.4% doctors and 50.7% nurses who faxed patient information, only 35.3% of doctors and 42.9% of nurses obtained informed consent to do so and less than half of those obtained written consent. Few used email to send patient information, with specialists being most likely to do so among doctors ($p < 0.0001$). Of all healthcare professionals who used email, 40.7% obtained informed consent to do so.

Conclusions. Written informed consent is not routinely obtained from patients during clinical examination or when using ICT for the transfer of patient information. The issue of informed consent for telemedicine remains unresolved in South Africa.

S Afr JBL 2013;6(2):55-59. DOI:10.7196/SAJBL.287

Telemedicine is 'the use of medical information exchanged from one site to another via electronic communications for the health and education of the patient or healthcare provider and for the purpose of patient care'.^[1] It is a component of the broader field of eHealth, 'the use of information communication technology (ICT) for health'.^[2] Telemedicine can be live or synchronous, as in a video-conferenced consultation, which may be supplemented by the use of diagnostic devices such as electronic stethoscopes, otoscopes, dermatoscopes, etc.^[3] It can also be asynchronous, as in store-and-forward telemedicine, where for example photographs are attached to an email containing the patient's history and clinical findings, or posted to a secure website for later interpretation by another physician.^[4]

Telemedicine is seen as a cost-effective and efficient means of delivering healthcare to under-resourced areas. It would be a boon to the African region, which the World Health Organization reports has an average of 25 doctors per 100 000 people, with 25 of the 48 countries surveyed having $\leq 10:100\ 000$ people. In comparison, the global average is 139:100 000 people and Europe has 333:100 000 people.^[5] Telemedicine has the potential to help us overcome the extreme shortage of doctors, improve access to quality care in rural areas, and reduce the costs of patient transfer for specialist referral. Cross-border, international telemedicine will facilitate this.^[6]

Regulators see telemedicine as something new, unproven and therefore more risky, requiring regulation in order to protect both patients and doctors.^[7] The first teleconsultations were conducted by telegraph in Australia in 1874^[8] and the telegraph was used for

health purposes in the American Civil War.^[9] Telephonic consultation meets the definition of telemedicine, and the first published report of a consultation over the telephone was 3 years after its invention in 1879.^[10] Einthoven transmitted electrocardiograms over the telephone in 1905, and Brown developed an electronic stethoscope, with tele-auscultation performed in 1910.^[11] Radio has been widely used to provide medical services to ships at sea and to people on remote islands since 1920.^[9] Teleradiology was first achieved in 1948 and by the 1950s closed circuit television was being used for education, as well as for group therapy in the psychiatric service in Nebraska, US.^[9] Clearly telemedicine is not new – rather we have forgotten the past and fail to equate the daily use of the telephone in the health sector with telemedicine. Telemedicine regulation, if required, should address gaps in existing regulations.

Most of the 'problems' we face today are also not new. Aronsen^[11] reviewed the first 100 years of papers on the use of the telephone in medicine published in the *Lancet*. He noted that, 'The *Lancet* carried many entries dealing with the high cost of subscribing to the telephone, the poor quality of service, the absence of privacy occasioned by the unwarranted interception of phone conversations by the police, delays in installations of telephones for new customers, the tardiness in restoring a defective instrument to service and so on.' Little has changed.

South Africa (SA) recently adopted a National eHealth Strategy which includes telemedicine.^[12] The Health Professions Council of South Africa (HPCSA) has been working on guidelines for the practice

of telemedicine in SA for over 7 years, and concedes that the task is difficult.^[7] They define telemedicine as, 'The exchange of information among healthcare professionals at a distance for the purpose of facilitating, improving and enhancing clinical, educational and scientific healthcare and research, particularly to the underserved areas in the Republic of South Africa.'^[13] This definition is problematic as it omits the term 'information communication technologies'. It is too broad and would include the exchange of letters or emails between practitioners, a written prescription taken to a pharmacy, a telephone consultation between doctors or the patient and a doctor, and distance learning.^[14]

These proposed guidelines for telemedicine also require written informed consent for a telemedicine consultation, with a copy kept by participating physicians and a copy given to the patient. How this will be achieved in a store-and-forward or telephonic consultation is not clear. In addition, the guidelines require a prior doctor-patient relationship, except in an emergency, and registration of participating doctors with the HPCSA. This would be a major impediment to telemedicine, as it is unlikely that rural patients will have had a prior doctor-patient relationship with the distant doctor being consulted.

Informed consent enshrines the right of autonomy and should be obtained for any medical encounter, be it face-to-face or at a distance. At issue is whether consent for telemedicine should be written or verbal, and if it is indeed practical in circumstances such as a patient-initiated telephone call. In traditional consultations, the general rule is that the riskier the medical intervention, the greater the requirement for written informed consent.^[15] Telemedicine is no different, with written informed consent typically being obtained for more complex procedures, such as robotic assisted ultrasonography or even robotic surgery.^[16-18] But is this required for all forms of telemedicine?

In several specialities, there is enough evidence that a virtual teleconsultation, be it synchronous (as in video conference) or asynchronous, is clinically as good as a face-to-face, in person consultation.^[19,20] As such, standard practices for gaining consent for face-to-face consultations should be followed. This is supported by the pragmatic stance of the World Medical Association (WMA's) Statement on the Guiding Principles for the Use of Telemedicine for the Provision of Health Care (2009).^[21] This statement does not require written informed consent, but does require clinicians to follow relevant protocols for verbal, written or recorded consent and, where appropriate, to note such consent in the documentation of the consultation.

Telemedicine serves the ethical principle of beneficence, in that it widens the capacity for many practitioners to share skills and knowledge in under-resourced areas.^[22, 23] For telemedicine to gain acceptance, it needs to be integrated into everyday practice and be seen as an alternate form of face-to-face consultation. The HPSCA's proposed telemedicine regulations will make this difficult. It is therefore important to know doctors' and nurses' current approach to consent in everyday practice and when using information and communication technologies.

Objective

This study aims to survey the habits and practices of health professionals working in the private and public sectors in Durban, KwaZulu-Natal, when obtaining informed consent in clinical practice and when using ICT.

Method

A quantitative, descriptive, cross-sectional survey was undertaken of doctors and nurses working in the private and public sectors in KwaZulu-Natal. A questionnaire was developed to investigate when and how doctors and nurses take informed consent in various clinical scenarios, including when using ICT. The questionnaire was used to gather demographic data such as qualification, gender and area of practice, and covered issues such as telephone, cellular phone, fax and email use. Participants were asked if they routinely sought informed consent for four activities which could be part of a clinical encounter (taking a history, examinations, ordering a special investigation such as an X-ray or blood test, and referring the patient to a colleague) and whether the consent was written or verbal. The questionnaire was initially administered to several doctors and nurses for validation and to address any possible ambiguities. It was then distributed to doctors and nurses, and self-administered. Nurses were recruited at public and private hospitals and occupational health clinics, while doctors were recruited at continuing professional development meetings. Convenience sampling was used. A sample size of 400 people was chosen following recommended guidelines.^[24] Participation was voluntary and ethical approval was obtained from the Biomedical Research Ethics Committee of the University of KwaZulu-Natal. Verbal consent was obtained from participants, as no personal identifiers or information was gathered.

All data were entered in an Excel spreadsheet and SPSS version 21 was used to perform statistical analysis. Descriptive statistics were used to describe the population demographics. Fisher's exact test was used to compare results between doctors and nurses and the χ^2 test for comparison between the three groups of doctors (specialists, general practitioners and medical officers). α was set at 5%.

Results

A total of 193 doctors and 207 nurses completed the questionnaire, of whom 193 (48.2%) worked in the public sector, 136 (34%) were in private practice and 71 (17.8%) worked in both sectors. There were significantly more nurses than doctors in the private sector ($p < 0.0001$) and, as expected, there was a significant difference in gender between doctors and nurses ($p < 0.0001$). Doctors were divided according to area of specialty with 54 (13.5%) general practitioners (GPs), 101 (25.3%) medical officers (MOs) and 38 (9.5%) specialists (Table 1). MOs are doctors who are registered as general practitioners and work in public hospitals.

Doctors or nurses did not regularly obtain consent for routine clinical activities. The percentage of nurses taking consent ranged from 56.0% to 84.5%, and the percentage of doctors from 28.5% to 74.6%. Significantly more nurses gained informed consent to take a history ($p < 0.0001$) or examine a patient ($p < 0.0001$) than doctors. Few took written informed consent: for nurses this ranged from 11.1% taking written consent when examining a patient, to 19.8% taking it when ordering a special investigation. Doctors uniformly took written consent less often than nurses, with a range from 2.6% taking written consent when examining a patient to 8.3% taking it when ordering a special examination. The difference was significant for all activities. Only two GPs obtained written consent, one for special investigations and the other when referring a patient. There was no difference in the rate of gaining consent or written consent between the different groups of doctors (Table 2). Written informed consent was obtained more often in the private sector than in the public sector. Consent was gained for all activities by 30.8%

of respondents, with 10.5% relying solely on implied consent (Table 3).

Doctors were significantly more likely than nurses to use a telephone in clinical practice (Table 4). Significantly more nurses (22 (10.6%)) reported that they do not use the telephone for routine clinical activities, compared with four doctors (2.1%), consisting of two GPs and two MOs ($p=0.0004$). Short message services (SMS) were used by 36.5% of respondents.

Patient information was sent or received by fax by 67.4% of doctors and 50.7% of nurses, with only 35.3% of doctors and 42.9% of nurses obtaining informed consent to do so, and less than half of these obtaining written consent. Few of the healthcare professionals in our study used email to send patient information, with specialists being most likely to do so among the doctors ($p<0.0001$). Of all those who used email, only 40.7% obtained informed

consent to do so (Table 2). Those who worked in the private sector (18.4%) and both sectors (33.8%) were more likely to email information ($p<0.0001$) to others than those in the public sector, but not more likely to obtain consent to do so. Similar results were found when using a fax (Table 3).

Discussion

Of the 72 doctors and nurses who sent patient information by email, as would occur in an email-based store-and-forward service, only 13 (18.1%) took written informed consent and 44 (61.1%) did not ask for any consent. Similarly 61.2% of practitioners who transmit patient information by fax did not seek consent, and only 9.8% of those who did took written consent. Over 50% of doctors and nurses did not take written or verbal consent for any of the clinical activities reviewed in the questionnaire. Fewer than 10% of all doctors obtained written informed consent for: taking a history; examining a patient; ordering a special investigation; or referring a patient. Written informed consent does not appear to be part of the culture of routine clinical practice in this region.

Telemedicine can range from a simple telephone call between healthcare providers to more complex applications involving remote-controlled surgery or pathology.^[25,26] All but 26 (0.7%) respondents use a telephone in their everyday practice to give instructions, advice or discuss patient problems, but fewer than 40% obtained consent to do so. In general, the medico-legal position of doctors involved in a telemedicine consultation is similar to the position when using telephone, fax, email or letter, all of which are used to provide advice from a distance and constitute telemedicine. Currently, written informed consent is not required for their use. However, the proposed HPCSA guidelines for telemedicine will require written informed consent, with copies given to

Table 1. Demographics of respondents

	Doctors: N=193, n (%)	Nurses: N=207, n (%)
Male gender	113 (58.5)	13 (6.2)
Specialty		
General practitioner	54 (13.5)	
Medical officer	101 (25.3)	
Specialist	38 (9.5)	
Work sector		
Public	111 (57.5)	82 (39.6)
Private	36 (18.6)	100 (48.3)
Both	46 (23.8)	25 (12.0)

Table 2. Doctors and nurses who take consent for different clinical and telemedicine activities, the type of consent taken

	Doctors (N=193), %			Nurses (N=207), %		
	Yes	Written	Verbal	Yes	Written	Verbal
Take consent to:						
Take patient history	28.5	4.7	23.8	67.1 [†]	15.9*	51.2 [†]
Examine patient	67.9	2.6	65.3	84.5 [†]	11.1*	73.4
Order special investigation	65.3	8.3	57.0	56.0	19.8*	36.2 [†]
Refer patient	74.6	3.6	71.0	67.6 [†]	15.0 [†]	52.7*
Fax patient information	67.4	9.8	30.0	50.7*	15.2	27.6
Email patient information	20.9	18.1	23.7	19.1	20.6	20.6

* $p<0.001$.
[†] $p<0.0001$.

Table 3. Doctors and nurses who do or do not take consent for clinical activities

	No consent, %	Consent for all activities, %	Consent for all activities bar history, %	Written consent for at least one activity, %
Nurses	9.2	37.7	7.2	33.8
All doctors	11.9	23.3*	24.4 [†]	9.8 [†]
General practitioner	14.8	14.8	37.0	3.7
Medical officer	12.9	28.7	29.2	11.9
Specialist	5.3	21.1	30.0	13.2

* $p<0.001$.
[†] $p<0.0001$.

Table 4. Consent practices when using a telephone

	Do you use a telephone to: (%)			
	Give medical instructions?	Seek a second opinion?	Prescribe medication?	Discuss patients' problems?
Nurses	59.9	82.1	35.3	35.3
All doctors	86.0 [†]	93.8 [†]	57.0*	45.1 [†]
General practitioner	88.9	90.7	66.7	50.0
Medical officer	80.2	93.1	45.5	43.7
Specialist	97.4	100.0	73.7	50.0

* $p < 0.001$.
[†] $p < 0.0001$.

the patient and kept by the participating healthcare professional. As shown in this study, written informed consent is not part of the routine practice of doctors and nurses in this region. Its imposition for telemedicine will either be ignored or will impede the uptake and use of telemedicine.

Should use of the telephone, fax and email be excluded from the requirement for written informed consent? The State of California's Telemedicine Development Act (TDA) of 1996^[27] specifically excludes telephone, fax and email from the definition of telemedicine, and therefore from the requirement for written consent that applies to all other aspects of telemedicine, such as video conferencing. While the differences between specialties can affect the specific nature of a given telemedicine consultation, it is suggested that the legal and ethical principles that govern conventional face-to-face consultations are equally valid when medicine is practised at a distance, irrespective of the complexities of the interventions.^[28-30]

In Canada and Australia, certain forms of telemedicine are becoming integrated into routine healthcare. There has been no agreement on whether written informed consent is required for video-conferenced consultations.^[31,32] Some centres favoured express verbal consent with a note made in the patient's file, while others preferred the formal written informed consent process. As video-conferenced consultation becomes part of routine healthcare delivery, the trend is to move away from written to verbal consent.

The Malaysian Telemedicine Act of 1997 requires written informed consent prior to any telemedicine encounter.^[33] This Act was passed in an earlier era of telemedicine and some aspects are no longer appropriate. Notably, the Association of South-East Asian Nations (ASEAN) is introducing reciprocal licensure in the region, which will overcome some of its shortcomings. The French medical council goes further by recommending that patients sign an information letter prior to use of telemedicine, to ensure that they are strictly informed as to what they are consenting to before giving written consent.^[34]

Email use is not yet common. Only 72 (18%) of health professionals in our survey emailed patient information, of whom 18% sought written consent to do so. The Canadian Medical Protection Society recommends obtaining written informed consent when using email to communicate with patients.^[35] In contrast, the United Kingdom Medical Protection Society recommends making the patient aware of the risks involved when sending information by email and noting this in the patient file, but does not mention obtaining written consent.^[36]

Studies show that patients' main concerns when their medical information is transmitted electronically centre on safety and security.^[19,37,38] Technology failure can occur in video-conferenced

consultations and this eventuality should be covered in the standard operating procedures and guidelines of the relevant discipline. Data security is a concern, but is more relevant when dealing with data storage and access to electronic medical records and hospital information systems. Emails can be made secure by encryption and patient information, including emails stored on health professionals' computers, should be encrypted and password protected. Modern video-conferencing equipment encodes the data being transmitted, limiting the risk of unauthorised access to confidential information. Concerns have been raised about information security when using some voice over internet protocol (VOIP) software like Skype.^[39] It is not clear whether this concern is significant enough to require written informed consent to safeguard patients' rights.

There are few papers from the developing world on patients' concerns about privacy, confidentiality and data security in telemedicine. In a recent study from Botswana on possible use of mobile phones to photograph and transmit images of skin lesions to a store-and-forward teledermatology service, patients were not concerned about privacy. However, about half were concerned about photographs being taken of their face or genitals.^[4] A recent South African study has shown that it may not be feasible to take truly informed consent when indigenous languages do not have words for the technology used and even the concept of confidentiality is poorly understood.^[40]

Obtaining patients' informed consent prior to a telemedicine encounter is prudent, ethically correct and provides proof that the informed consent process has taken place. Whether consent should be written or verbal depends on the clinical specialty and the clinical risk involved. Section 6 of the National Health Act of South Africa states that the user of the health system should be informed of the range of diagnostic procedures and treatment options available, and their associated benefits, risks, costs and consequences.^[41] South African law regards informed consent as falling under the defence of *volenti non fit injuria*, which requires that the patient has some knowledge of the extent of harm or risk. By using this approach our courts favour the autonomy and self-determination of the patient.

Based on the low use of written informed consent found in this study, it is unlikely that healthcare professionals will take written consent for telemedicine, except in some specialties. As telemedicine uses different types of technology and covers different disciplines – each with its own specific issues, clinical protocols and needs – each discipline requires its own guidelines tailored to the local environment and needs. For example, the recently published practice guidelines for videoconference-based telepsychiatry in SA

require signed informed consent from the patient, family member or guardian as these patients are from a vulnerable group.^[42] In general, clinical telemedicine guidelines should follow the same approach to informed consent as in a routine face-to-face consultation.^[43]

Conclusions

Written informed consent is not routinely obtained from patients during clinical examination or when using ICT for the transfer of patient information. The issue of informed consent for telemedicine remains unresolved in SA, as there are no guidelines or regulations other than those for mental health. The situation is the same in most developing countries. It is recommended that the pragmatic approach taken in the WMA's Statement on the Guiding Principles for the Use of Telemedicine for the Provision of Health Care of the World^[21] should be followed at present and used as a basis for developing guidelines. Regulations should only be required where there are gaps that need to be filled.

Author contributions. CJ conducted, designed the study, performed the primary analysis, collected the data and drafted the manuscript. MM conceptualised the study, interpreted the data, assisted in statistical analysis and revised the manuscript.

Acknowledgements. We thank Dr Y Singh for his guidance and comments when reviewing drafts of this manuscript, as well as the doctors and nurses who generously gave their time to complete the questionnaires.

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