

# A SOUTH AFRICAN PERSPECTIVE TO MEDICAL LAW AND ETHICS IN NURSING: GETTING BASIC PRINCIPLES RIGHT

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## ABSTRACT

The legal requirements for informed consent and confidentiality of patient information are clearly specified in chapter two of the *National Health Act* (NHA). Along with informed consent, the right to privacy is enshrined not only in the *Constitution* but also obligations to recognize this right are set out in the NHA. The study aims to survey the habits and practices of healthcare providers working in the public and private sectors in Durban, KwaZulu-Natal, when obtaining informed consent in clinical practice. A quantitative descriptive questionnaire was developed to investigate how nurses take informed consent in various clinical scenarios. A total of 207 nurses completed the questionnaire and the data was analyzed using Chi-squared, T-test and Z-tests. While 84.5% took consent to examine a patient, only 56% did so when ordering a special investigation with 19.8% taking written consent. Consent to refer patients to other healthcare providers was obtained by 67.6%, and 15% was obtained in a written format. There were 14% of nurses who did not use a computer at all. Of those who did, few used emails to send patient information, 19.1%, and less than half of those obtained informed consent to do so. The key conclusions of this study are that informed consent practices among nurses fall below legal requirements, and written consent is not routinely obtained, even for those

practices that carry some element of risk, such as special investigations or transmitting health information via fax or email.

**KEYWORDS:** confidentiality, ethics, informed consent, medical law, nursing practice

## INTRODUCTION AND BACKGROUND INFORMATION

Principlism, the ethical theory as proposed by Beauchamp and Childress, is widely recognized as the foundational principles in medical ethics. These principles are respect for patient autonomy, beneficence, non-maleficence and justice, and have been incorporated in ethical guidelines and textbooks for healthcare professionals worldwide (Fassin, 2008:262). These principles are important as they benchmark the manner in which patients should be provided healthcare services. Autonomy is the capacity of the individual to make informed decisions based on relevant information given about his or her health, and this process is facilitated by obtaining informed consent (Jack, 2014:14). Informed consent can be defined as an autonomous authorization by individuals for a medical intervention (Chima, 2013:2). It is, however, much more than that; it is a continuous process of information sharing, understanding, trust, lack of coercion and willingness (Lemonidou, 2003:74).

Obtaining informed consent from users encourages the right to self-determination and autonomy, as well as freedom of choice. The sharing of adequate information also allows for rational decision making on the part of the user. The need for informed consent in the South African healthcare setting has become compounded with the introduction of the *National Health Act No. 61 of 2003 (NHA)* (South Africa, 2003). The *NHA* is the central piece of South African health legislation and regulates the provision of healthcare and service delivery from healthcare providers.

It effectively brought health legislation in line with the *Constitution*. The *Act* uses terms 'health care provider', which means a person providing health services in terms of any law, including the *Nursing Act of 2005 (NA)* and 'user', which refers to the person receiving treatment in a healthcare facility. This is in keeping with international consumer rights movements (South African Government, 2003). The shift away from using the term 'patient' is an important one, as it changes traditional perceptions of healthcare, which were generally paternalistic in nature towards an autonomous, self-determination one.

The legal requirements for informed consent and confidentiality of patient information are clearly specified in chapter two of the *NHA*. Section 6(1) states healthcare providers must inform a user of their health status, the range of treatment and diagnostic options, the benefits, risks and costs of these options and the right of the user to refuse health services (South African Government, 2003:s.2, ss.8). In general this means that all healthcare providers are obliged by law to inform users of these options in a lay person's language, disclosing all serious and known risks, but it is not necessary if the risk is a remote or highly unusual one.

Informed consent can be obtained in the following ways: by expressing consent verbally, in a written format, or in an unspoken or tacit manner by nodding of the head (Moodley, 2011:117). Written consent is generally obtained for procedures that are inherently more risky, such as surgical procedures using standard procedure specific consent forms. Determining how much information these forms should have in them is challenging given the pluralistic nature and varied literacy levels of our population. In the current era of a more litigious society, the advice from medical protection societies is to obtain written informed consent for most healthcare interactions. This serves as proof that some communicative interaction took place. It is also recommended as good practice to write in the clinical notes that expressed consent has been obtained, if there is no formal separate consent form.

Along with informed consent, the right to privacy is enshrined not only in the *Constitution* but also obligations to recognize this right are set out in the *NHA*. Section 14 of the *Constitution* states, 'Everyone has the right to privacy, which includes the right not to have the privacy of their communications infringed' (South African Government, 1996: s.2, ss.14). Section 14 of the *NHA* states all information concerning a user, relating to his or treatment or stay in a healthcare establishment is confidential. Disclosure of any of that information is allowed only with the written consent of the user, a court order or if non-disclosure poses a serious public health risk (South African Government, 2003:s.2, ss.14). The *NHA* does, however, allow for disclosure of confidential information within the normal scope and practice of the healthcare provider duty.

Medical negligence claims in South Africa are increasing rapidly in both the private and public health sectors (Pepper & Slabbert, 2011:29). Individuals are becoming more aware of what may and may not happen to them in healthcare and the mechanisms to lay complaints with professional bodies are now much easier with media campaigns and media reports creating public awareness (Colin, 2012). Nursing is not immune to this. The South African Nursing Council (SANC) is responsible for maintaining standards for the practice of nursing and midwifery in South Africa. It has a mechanism in place whereby the public may lay complaints against a nurse for acts of commission and omission. According to the SANC (n.d.), the list of acts of reportable professional misconduct include: 'Giving confidential information about a patient to unauthorized persons' and 'Forcing a patient to sign consent for a surgical procedure'.

A review of the misconduct statistics available on the SANC website (n.d.:1 of 2) does not provide a detailed breakdown of the nature of the offence that occurred but rather uses generic headings such as maternity related, medication errors, poor nursing care, fraud/forgery/theft and assault. In 2013 the National Health System of the United Kingdom published a report reviewing the complaints process within NHS hospitals. This report highlighted key areas of dissatisfaction based on 2 500 testimonials of users and relatives of the NHS system. A lack of information from

hospital staff regarding treatment, expected prognosis and user condition was one of the main reasons for dissatisfaction. This in turn led to fears that incorrect treatment was being given and therefore complaints were laid against the NHS. Another key area of dissatisfaction reported was a lack of privacy, which users and relatives thought compromised dignity and levels of care (Clywd & Hart, 2013:15).

## STATEMENT OF RESEARCH PROBLEM

The practices of informed consent and its related aspects of confidentiality in clinical practice among nurses have not been explored within the South African setting. New laws and the introduction of information communication technology (ICT) into the healthcare arena provide new challenges in informed consent and confidentiality practices.

## PURPOSE OF THE STUDY

The study aims to survey the habits and practices of healthcare providers working in the public and private sectors in Durban, KwaZulu-Natal, when obtaining informed consent in clinical practice.

## RESEARCH METHODOLOGY

A questionnaire was developed to investigate how healthcare providers take informed consent in various clinical scenarios, such as taking a history, examinations, ordering investigations and referrals to other healthcare providers and how they manage user information if transmitted electronically by fax or email. Information as to whether the consent was obtained verbally or in a written format was asked. The questionnaire was initially administered to several healthcare providers for validation purposes. Registered professional nurses were recruited at public and private healthcare facilities and occupational health clinics. Convenience sampling was used. Data was entered into an excel spreadsheet and SPSS version 21 was used to perform statistical analysis,  $\alpha$  was set at 5%. Chi-squared, T-test and Z-tests were performed to determine the statistical significance of the responses. Only registered professional nurses were recruited into the study.

## ETHICAL CONSIDERATIONS

Ethical approval to conduct the study was obtained from the University of KwaZulu-Natal Biomedical Research Ethics Committee. Verbal informed consent was obtained from study participants as no personal information or identifiers were gathered.

## ANALYSIS

A total of 207 nurses completed the questionnaire of whom 94% were female, 39.6% worked in the public sector only, 48.3% in the private sector only and 12% in both sectors. All were in the category of Registered Professional Nurse. While 84.5% took consent to examine a patient, only 56% did so when ordering a special investigation with 19.8% taking written consent (Table 1). Consent to refer patients to other healthcare providers was obtained by 67.6% and 15% obtained it in a written format. Nurses employed in the private healthcare sector were significantly more likely to obtain verbal consent for the clinical activities than those in the public health sector (Table 4). The overall threshold for obtaining written consent was low, with less than a third obtaining written consent for a clinical activity (Table 2).

There were 14% of nurses who did not use a computer at all. Of those who did, few used email to send patient information (19.1%), and less than half of those obtained informed consent to do so. Only one nurse responded yes when asked about encryption of patient emails for security and confidentiality purposes. Patient information was received or sent by fax by 50.7% of the respondents, with 15.2% obtaining written consent to do so. Missing data was not included in the percentage and *p*-value calculations.

**Table 1:** Shows the number and associated percentages of nurses who take written informed consent during various activities

	Public sector	Private sector	Both sectors	P
Take consent to:				
Take patient history	55/83(66)	69/99 (69.7)	15/25(60)	N/S
Is the consent written?	8/55 (15)	20/69(29)	5/15(33.3)	0.02
Examine a patient	69/83 (83)	84/99(84.8)	22/25(88)	N/S
Is the consent written?	8/69 (12)	14/83(16.9)	1/22(4.5)	N/S
Order a special investigation?	38/85 (45)	65/99(65.7)	13/25(52)	0.003
Is the consent written?	8/38 (21)	29/65(44.6)	4/13(30.8)	0.007
Refer a patient to a colleague?	52/83 (62)	76/99(67.7)	21/25(84)	N/S
Is the consent written?	10/83 (12)	15/67(22.4)	6/21(28.6)	0.03

*p*, significant at <0.05

**Table 2:** Table 2: Shows the total percentage of nurses who do or do not take IC for clinical activities irrespective of where they work

	No consent %	Consent for all activities%	Written consent for at least one activity %
All	9.2%	37.7%	33.8%

**Table 3:** Shows the comparison of obtaining any informed consent between public and private health care nurses

Question	P-value	(Z test)	significant
Take patient History	0.62414	0.4949	No
Examine a Patient	0.37448	0.315	No
Order a special investigation	0.003	2.6942	Yes
Refer a patient to a colleague	0.23885	0.7009	No

*p, significant at <0.05*

**Table 4:** Shows the comparison of obtaining verbal informed consent in public and private practitioner health care nurses

Question	P-value	(Z test)	significant
Take patient History	0.02	1.9106	Yes
Examine a Patient	0.18673	0.8898	No
Order a special investigation	0.007	2.405	Yes
Refer a patient to a colleague	0.03	2.154	Yes

*p, significant at <0.05*

## DISCUSSION OF RESEARCH RESULTS

The key findings in this study are that informed consent practices among nurses fall below legal requirements, and written consent is not routinely obtained, even for those practices that carry some element of risk, such as special investigations or transmitting health information via fax or email. Overall the threshold for obtaining written consent for any of the clinical activities was low, with 33.8% obtaining written consent for at least one of the clinical activities and 7.2% obtaining at least verbal consent. Informed consent and confidentiality are the central aspects of the healthcare provider user relationship, any breach in these aspects lead to a breakdown of trust and communication. This is the point where the relationship may deteriorate to the point of litigation. Failure to obtain a proper consent may also lead to liability in terms of breach of contract, civil or criminal assault or a violation of privacy (McQuoid-Mason, 2001). An average of almost 70% of nurses

did not take any type of informed consent in spite of performing tasks that required informed consent. The p-values  $< 0.0001$  in tables 3 and 4 show that in general there is a statistically significant number of nurses who do not take any type of informed consent. Furthermore, of all the nurses who did take informed consent, only 23% obtained written consent for taking a user's history, examining a user, ordering a special investigation, or referring a user.

Regulation of healthcare practice in South Africa has undergone enormous change since the advent of the *Constitution* in 1997, which is regarded as the supreme law of the land. Sections 12 and 14 of the *Constitution* stipulate that everyone has the right to make their own decisions regarding what may and may not happen to their bodies, and everyone is entitled to privacy of their communications .

In South Africa the requirements for a legally valid and informed consent have been set out in court in the case of *Castell v De Greeff*, stating that the consenting party 'must have had knowledge and been aware of the nature and extent of harm or risk', 'must have appreciated and understood the nature and extent of the harm or risk' and 'must have consented to the harm or assumed risk' (*Castell v De Greeff* 1994 (4) SA 408 (C) at 425). Consent 'must be comprehensive, which extends to the entire transaction, inclusive of its consequences'. The harm or assumed risk refers to any procedure that a reasonable individual if warned about that risk would attach some significance to it. This may include ordering of special investigations such as blood tests and X-rays. Understanding and appreciation of risk satisfies the requirements of capacity to consent. The NHA states that if a user cannot give informed consent and if another is not mandated to give consent on that user's behalf, a spouse, partner, adult child or brother or sister of the user may give consent (South African Government, 2003:s.2, ss.7). Children of 12 years and older may now consent to their medical treatment and surgical interventions, as long as the child is of sufficient maturity and has the mental capacity to understand the benefits, risks and social implications of the treatment (Jamieson & Lake, 2013). A nurse will need to be aware of whether the child consenting has this mental capacity and if not who, under the *Children's Act*, may consent for them on their behalf.

According to The International Council of Nurses (ICN) code of ethics (n.d.), guidelines state that 'The nurse ensures that the individual receives accurate and sufficient and timely information in a culturally appropriate manner on which to base consent to care and treatment' and 'The nurse hold in confidence personal information and uses judgment in sharing'. The practice of nursing in South Africa is no different. At the end of 2013, the SANC published a *Code of Ethics for Nursing Practitioners* (n.d.:1 of 3). This document incorporates the four ethical principles as well as the principle of fidelity pertaining to confidentiality of information and truth telling.

Where South African healthcare users felt their rights to informed consent and privacy have been violated they have taken the matter up in court. The following case highlight how our courts view HCP misconduct when there is failure to obtain

a proper informed consent and a failure to maintain confidentiality (*C v Minister of Correctional Services (REF:1996 (4)SA292 (T))*).

The facts were that C, the plaintiff, was standing in a queue in a hospital passage when he had been informed by the nurse, employed by the department, that a blood sample was taken from him to test for HIV and other sexually transmitted diseases. He was verbally informed of his right to refuse such testing. The department of correctional services had adopted a policy, and informed consent was a prerequisite prior to HIV testing. The nurse was apparently unaware of this policy, which had been in place for three years. C subsequently tested positive for HIV and instituted a claim against the Minister of Correctional Services for invasion of privacy. The Court found in the plaintiff's, C's, favour, and remarked that the testing process was done in full view of other prisoners, which invaded his privacy and that proper informed consent was not obtained. He was awarded damages. From this case it is clear that policy was not followed and that the court found obtaining verbal consent was not a legally valid consent and confidentiality was breached. In this case it is apparent that the nurse, while qualified, did not have the training to obtain consent for HIV testing in a legal and ethical manner according to correctional services policy. The reasons for this are not clear. The prisoner C felt strongly enough about this to complain at the highest level and found compensation for the violation of his rights.

The p-values of table three show that a statistically significant proportion of both private and public practice nurses do not take informed consent. This holds true for all the practices studied, except when ordering special investigations. It has been shown in this study that more private practice nurses obtain informed consent for special investigations than their public practice counterparts. Those working in the private sector are significantly more likely to obtain written consent for investigations, history and referrals (table four). Whether this is due to individual hospital policy using standard consent forms available in the private sector was not investigated. The Health Professional Council of South Africa (HPCSA), the statutory body for healthcare providers registered under the *Health Professions Act*, such as doctors, have ethical guidelines on obtaining informed consent (HPCSA 2008). These state that while the primary responsibility to obtain consent lies with the doctor concerned, this task may be delegated to other members of the healthcare team such as a nurse, provided they have sufficient knowledge and training. Ethical guidelines form an integral part of standards of professional conduct and may be used to evaluate a complaint of professional misconduct against a healthcare provider.

Respect for privacy is recognized in South African law. Privacy defined as 'the freedom from unauthorized intrusion' refers to the right that belongs to the user, confidentiality refers to the duty that is an obligation of the healthcare provider to keep information in a manner that is intended to be private or secret (Murray, 2011:747). In 2007 our then incumbent Minister of Health brought an urgent application to the High Court for the return of her hospital medical records, which had been sold to a national newspaper.



Her confidential medical information and facts regarding her hospital stay for surgery were widely published in the press (Bateman, 2007:333). A South African nurse who had subsequently immigrated to New Zealand was implicated in the theft of these records. An extradition order was due to be served against her to answer the charges. The records were stolen from a secure archive in the hospital. Information regarding an individual's health status is extremely sensitive and an inability to keep that information private can lead to harm to that individual, either professionally or personally. Section 14(1) of the *NHA* outlines that all information concerning a user, including information relating to his or her health status and treatment or stay in a health establishment is confidential. Section 17(1) places the responsibility of protection of health records on the person in charge of the establishment (South African Government, 2003:s.2, ss.17).

Using information communication technology (ICT) to transmit health information is inevitable and in keeping with international trends (Police, 2010: 245). Keeping that information private, in this era of technology, dominates ethical concerns from healthcare providers, legislators and users alike (Beran, 2010:129). Studies have shown that difficulty in encryption of emails leads to a significant risk of unauthorized persons accessing those emails (Caffery & Smith, 2010:20). The implications of this are significant and may lead to loss of reputation, employment, social standing. Medical Professional Organizations (n.d) suggest obtaining written informed consent if healthcare providers and users are going to communicate via email, detailing the potential risks involved as a protective defensive measure.

In this study only 10% of nurses received emails from users and of those 41% obtained written consent prior to doing so. Of those 8% knew about encryption of data and 27% knew about the importance of backing up user data. The use of electronic means to transmit user information will have a profound effect on how HCPs manage health information. The *Protection of Personal Information Act (POPI)* has recently been signed into law by the State President (South African Government, 2013). This Act sets out the obligations of healthcare providers and healthcare establishments when processing any health information from users. Any personal information held must be protected from loss, damage or unauthorized destruction, and unlawful access (South African Government, 2013:s.3). The healthcare provider will be expected by law to implement reasonable technical and organizational measures to ensure this protection. Written consent will be a requirement from the user to process his or her information. Failure to comply with *POPI* may incur a fine of 10 million rand and/or a term of imprisonment.

It is yet unknown what the full impact of *POPI* and the *Child Care Act* may have on the practice of healthcare in SA as they have yet to be tested in a court of law. What is certain is that they will present challenges and will require significant change management in healthcare and education of HCPs in order to ensure compliance and avoid punishment.

Does this impact on nursing practice? The answer is most definitely. Stellenberg and Dorse looked at ethical issues confronting nurses in private hospitals in the Western Cape. Included in the variables they used were autonomy and confidentiality. They found some of their study participants did not assure privacy or maintain confidentiality and 12% of the participants did not acknowledge autonomy of their patients (Stellenberg & Dorse, 2014:38).

Occupational health, primary health and community health nurses fundamentally work in an independent capacity. The SANC defines a Clinical Nurse Specialist (CNS) as ‘a person having a qualification in the area of specializing, in-depth knowledge and expertise that enables her/him to focus on facility care and work closely with medical officers on a consultative basis’ and an Advanced Nurse Practitioner (ANP) is defined ‘as a person who focuses on primary care, health assessment, diagnosis and treatment. This category can work with medical officers on a referral basis.’ Nurses, like all healthcare providers in South Africa, are bound by the obligations set out in the *NHA*, not just those of the *Nursing Act*, therefore the responsibility to uphold these obligations, including the promotion and protection of user autonomy, is theirs as well. Upholding the responsibility to obtain informed consent within the hospital setting can be problematic, with doctors blaming nurses and nurses blaming doctors when there has been a failure to do so. Once there is blame and a complaint reported, harm has already been done, which is then difficult to undo.

## CONCLUSION

According to the *National Strategic Plan for Nurse Education (2012/13-2016/17 (NDOH) 2012-2017. S4.3)*, there is an urgent need to revitalise the nursing profession within a revitalised healthcare system of South Africa. Major challenges identified were professional ethos and ethics as well as governance, leadership, legislation and policy. A point of intervention is to incorporate ethics into all streams of nurse education. This study on how Registered Professional Nurses in KwaZulu-Natal obtain informed consent in clinical practice and maintain confidentiality of health information in an electronic format has revealed areas of concern and falls short of legislative requirements and ethical guidelines, and a knowledge of relevant medical law and health rights would assist in addressing this. New laws directly affecting healthcare practice will be challenging to comply with in an already challenging under-resourced healthcare environment. It is humbly submitted, that when basic ethic principles are adhered to, it will foster a relationship of trust and dignity between HCP and user. Once these are in place the rest should follow.

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## COMPETING INTERESTS

The authors state that they have no financial or personal relationship(s) which may have inappropriately influenced them in writing this article.

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