Understanding and Practice of Informed Consent by Professional Nurses in South Africa: An Empirical Study-Brief Report

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The Asian Conference on Ethics, Religion & Philosophy 2017
Official Conference Proceedings

Abstract

Background: Informed consent (IC) is a legal and ethical doctrine, constitutionally protected in South Africa by rights to bodily integrity, privacy, and self-determination. The *National Health Act* 2003 codified requirements for IC; stipulating that healthcare professionals (HCPs) must inform patients about diagnosis, treatment risks, benefits, options, and right of refusal, while taking into consideration patients language and literacy levels. However, multicultural societies are challenged by problems of poverty, education, language, and cultural ethos, which may influence IC practice.

Methods: This was a cross-sectional quantitative study using semi-structured questionnaires at randomly selected public hospitals in Durban city. Data analyzed with SPSS, used descriptive statistics and chi-squared tests to compare results between nurses, doctors, and patients. Local RECs and IC approved the study was obtained from all participants.

Results: Three hundred fifty-five (355) registered nurses completed the study. Majority female (92%), with 1-41years professional experience. Information disclosed by nurses included diagnosis (77%); treatment options (68%); benefits (71%), risks (69%), recommended treatment (65%). Inconsistencies observed between nurses and patients included non-disclosure of right of refusal, treatment options and risks (25-41%). Nurses' knowledge of basic laws like age of consent was deficient, (30%) accuracy.

Conclusions: This study showed that professional nurses in South Africa are deficient in knowledge of local regulations regarding IC, and would benefit from additional training in healthcare law and ethics. Barriers to IC include language, education, and workload. Provision of trained interpreters will minimize language barriers, reduce nurses' workload, and improve overall quality of healthcare service delivery

Keywords: Informed consent, nurses, ethics, law, medical practice, South Africa

Introduction

Informed consent (IC) is a legal and ethical doctrine derived from the principle of respect for autonomy and is constitutionally protected in South Africa through the rights to bodily integrity, privacy and self-determination. (The Constitution of South Africa, 1996). To enhance transparency of consent regulations in South Africa, the *National Health Act* (NHA) (South Africa Government Gazette, 2003) codified requirements for IC by stipulating that healthcare professionals (HCPs) must inform patients about diagnosis, risks, benefits, treatment options, and the right of treatment refusal, while taking into consideration patients' language and literacy levels. Further, a South African High Court decision in the case of (Castell v De Greeff, 1994) impacted on South African medical jurisprudence; leading to a shift from the paternalistic 'reasonable doctor' to a 'prudent patient' and 'material risks' standards regarding information disclosure. Arguably, a key domain of transparency in healthcare involves the open sharing of information and shared healthcare decision-making between HCPs and patients. It has been suggested that it is very important to understand that transparency in healthcare begins with the process of informed consent whereby a HCP and patient engage in open and transparent conversation regarding IC which should include discussion about the diagnosis, risks, benefits of treatment, alternatives to the recommended treatment if any, costs, risks of refusing treatment, and right of refusal. (Mayer, 2012). This is followed by an opportunity to ask questions prior to 'consent' i.e. acceptance or rejection of recommended treatment by the patient. It has been argued that transparency in medical practice begins with respect for autonomy and IC, although many physicians still view IC as a 'bureaucratic legalism' which may interfere with patient care (Brody, 1989). Some have suggested that IC should be understood as a fundamental aspect of good healthcare practice whereby any doctor not possessing skills to obtain valid consent, could be considered as lacking essential skills for modern medical practice. To enhance transparency of IC regulations in South Africa, the NHA (South Africa, 2003) codified requirements for IC by stipulating that HCPs must inform patients about diagnosis, risks, benefits, treatment options, and the right of treatment refusal, at a language and literacy level understandable to the patient. The NHA further requires that the information disclosed must include: (a) The range of diagnostic procedures and treatment options generally available to the user; b) The benefits, risks, and consequences generally associated with each option; and (c) The user's right to refuse health services and explain the implications, risks, and obligations of such refusal. The law further requires that every health care provider must inform a user of: "*the user's health status except in circumstances where there is substantial evidence that the disclosure of the user's health status would be contrary to the best interests of the user"*. Section 7 of the NHA provides some exceptions to IC where it stipulates that health services may not be provided to a healthcare user without the user's informed consent unless-

1. The user is unable to give informed consent and such consent is given by a person-

(a) Mandated by the user in writing to grant consent on his or her behalf; or
(b) Authorized to give such consent in terms of any law or court order; or where

2. The user is unable to give informed consent and no person is mandated or authorized to give such consent.

Historical Background to Informed Consent in South Africa

According to Ferdinand van Oosten, patients consent, as a requirement for all lawful medical interventions, is a well-established principle in South African common law (Van Oosten, 1989). The earliest leading cases in this area were the cases of (Stoffberg v Elliot, 1923) and (Esterhuizen v Administrator Transvaal, 1957). More recently in the case of (Castell v De Greef, 1994), the judgment of Ackerman J seems to have established the doctrine of informed consent within South African medical jurisprudence (Van Oosten, 1995). Further the South African Supreme Court of Appeal (SCA) revisited this judgement and doctrine in (Broude v McIntosh, 1998) but did not overrule this decision despite some technical reservations (Carstens & Pearmain, 2007); thereby reaffirming the doctrine of informed consent as part of South African medical law. I have previously asserted that informed consent before medical procedures is constitutionally protected right in South Africa (Chima, 2013). This was further illustrated in the case of (Minister of Safety and Security v Gaqa, 2002), where the police wanted a court order to compel an accused person to undergo a surgical procedure to obtain a bullet to be used as evidence in a prosecution. The court asserted that such and order would violate the defendant's constitutional rights to a fair trial, bodily integrity, and privacy. The consequences of the decision of the Court in (Castell v De Greef, 1994*)* on South African medical jurisprudence were that the following principles were generally adopted (Van Oosten, 1995):

1. A shift from medical paternalism to patient autonomy.
2. A shift from the 'reasonable doctor' standard to the 'reasonable patient' standard.
3. A shift in disclosure to the 'material risk' standard, where the level of disclosure required is what a reasonable patient would consider pertinent/important before making a healthcare decision
4. The Court appears to place the patients' informed consent within the framework of *volenti non fit injuria* or voluntary assumption of risk rather than delict (Van Oosten, 1995).

Standards of information disclosure

One of the more contested areas of medico-legal jurisprudence is in standard of information disclosure required for informed consent. In other words, how much information should be disclosed by the treating physician or healthcare professional to the patient for informed consent to be considered valid? On this consideration, there are two contesting schools of thought. On the one hand, there is the 'reasonable doctor standard' based on English common law as outlined by McNair J in (Bolam v Friern Health Management Committee, 1957) and generally known as the *Bolam* principle, which states that:

> A doctor is not guilty of negligence if he has acted in accordance with the practice accepted as proper by a responsible body of men skilled in that particular art… putting it the other way round, a doctor is not negligent, if he is acting with such a practice, merely because there is a body of opinion that takes a contrary view.

It has been argued that English courts have opted for a paternalistic approach by following the reasonable doctor standard which bases disclosure on the clinical judgement/ accepted practice/substantial risk/normal/usual risk principles (Van Oosten, 1991), as established in (Bolam v Friern Health Management Committee, 1957) and reaffirmed by the House of Lords in (Sidaway v Board of Governors of Royal Bethlem Hospital, 1985), where Lord Templeman said:

> At the end of the day the doctor bearing in mind the best interests of the patient and bearing in mind the patients right to information which will enable the patient to make a balanced judgement, must decide what information should be given to the patient, and what terms that information should be couched… (Sidaway, 1985)

This idea of abridged information disclosure has since been applied in several court cases such as (Chatterton v Gerson, 1981) *w*here Bristow J said that patients should be informed in 'broad terms', thereby implying that not all information is required and the nature and amount of it to be disclosed to a patient would be based on reasonable doctor-standard rather than on the requirements of the patient. Lord Scarman in *Sidaway* argued for a 'prudent patient standard' as practiced in other jurisdictions such as Canada, USA, and even Germany when he said: "It was a strange conclusion if our courts should be led to conclude that our law…should permit doctors to determine in what circumstances...a duty arose to warn." (Sidaway v Board of Governors of Royal Bethlem Hospital, 1985).

What makes informed consent valid?

1. **Information disclosure:** provision of adequate information
2. **Competence:** capacity to understand that information
3. **Voluntariness:** decision making in the absence of coercion or deception
4. **Comprehension:** understanding of information provided
5. **Consent:** agreement to the proposed procedure/treatment or participation in a research study. Therefore, informing the patient must not be simply a ritual recitation of the contents of a written document. Rather the healthcare professional or researcher must convey the information, whether orally or in writing, in language that suits the individual's level of understanding (Tekola et al., 2009).

Socio-cultural Issues Impacting on the Practice of Informed Consent in South Africa

The socio-cultural milieu of South Africa shows that about 25%- 30% of the population is unemployed, with low labor force participation rate of 54% compared to a global average of 69% (Vollgraaff, 2011). Therefore, basic health care is unaffordable for most of the local South African population (Chima, 2015). There are also historical inequities within population groups with some authors asserting that 'informed consent is light years away from the black South Africans' (Mhlongo & Mdingi, 1997). Further, there is a dichotomy in the organization of the South African healthcare system, which is dual in nature consisting of private hospitals/medical practice which is patronized by the fewer patients (20%) who have health insurance or financial means to pay for private healthcare services, compared with the public

health services which accounts for the majority (80%) of indigent patients and citizens (KwaZulu-Natal Department of Health, 2010).

Impact of socio-cultural factors on informed consent practice in South Africa

This evident dichotomy in health services may influence the practice of informed consent in South Africa. Furthermore, most African societies being culturally complex and paternalistic in nature may require that consent or approval be obtained from community elders/extended family members, or men as heads of households before the actual patients/human subjects can provide consent (Irabor & Omonzejele, 2007). The challenge here then is to ensure that informed consent is truly voluntary and that community or surrogate consent is not substituted for individuals' consent, which ideally should be obtained voluntarily in the absence of coercion (Ijsselmuiden & Faden, 1999).

Methods

Study rationale-justifications for using empirical methods to study informed consent

Sulmasy and Sugarman (2001) have described two potential reasons for studying the actual conduct of a group with regards to compliance with moral and ethical dilemmas.

(a) To describe compliance with existing moral norms and
(b) To determine whether policies and procedures designed to operationalize certain moral norms have been successful (Chima, 2013; Sulmasy & Sugarman, 2001).

Other empirical studies have shown that people generally have problems in understanding the risks and benefits of medical treatment and decision making, and this could impact on the actual application of the existing law (Musschenga, 1999). For example, a study by means of a questionnaire on Dutch nurses charged with taking care of nursing home resident with due respect for their libertarian rights and, respect for autonomy revealed that the nurses were not complying with the existing regulations (van Theil & van Delden, 1997). Based on the above observations, it has been suggested by that to guide action; ethical guidelines must be based on reality and should be formulated in such a way that it is continuous with accepted moral norms (Birnbacher, 1999). Others have suggested that empirical ethics should be used to defend or criticize concrete moral principles or practices rather than make general claims about moral concepts (De Vries & Gordijn, 2009). Consequently, in recent times, applied ethicists have shifted towards combining empirical, especially social scientific research with normative ethical analysis. Proponents of this approach called 'empirical ethics' have argued that the study of people's actual moral beliefs, behaviour and reasoning should be the starting point of ethics. It has also been acknowledged that the methodologies of the social sciences, especially quantitative and qualitative research, using surveys, interviews and questionnaires is probably the best way to map the reality of people's actual moral norms (Borry, Schotsmans, & Dierickx, 2004). However, complex multicultural societies in Africa and elsewhere are inherently challenged by problems of poverty, poor education, language, and

unfamiliarity with libertarian rights-based autonomy, cultural issues, and the power asymmetry between doctors and patients. Some of which could impact on the practice of IC. To evaluate whether the quality of IC practiced by HCPs in South Africa is consistent with current local laws and international standards, I conducted an empirical study to evaluate the clinical practice of IC by HCPs at local hospitals. The general objective of this study was to establish whether informed consent is obtained from patients prior to involvement in clinical procedures in South Africa. Specifically, I wanted to establish whether:

1. Sufficient information is provided to patients in clinical practice before consent is sought.
2. Patients involved in clinical procedures understand the information given.
3. Consent is obtained from patients voluntarily.
4. Whether informed consent provided by patients in clinical practice in South Africa is legally and ethically valid

Research design: The study design was a descriptive cross sectional study in contemporary clinical practice settings. This is because the time between procuring informed consent and treatment is very short and patients are normally in hospital for a limited time. The descriptive approach allowed doctors, nurses, and patients to describe their experience with the informed consent process as it is, thereby bringing out the required information. Further I employed the technique of "triangulation" in this study which has been defined as "the combination of methodologies in the study of the same phenomenon" (Denzin, 1978). The original purpose of triangulation was to seek confirmation of apparent findings- consistency. More recently it has also been used for completeness purposes. In this study, I have applied the method of data triangulation which involves the use of multiple data sources in the study to get diverse views to aid in validating the conclusions, therefore in this study I applied time triangulation, space triangulation, and person triangulation.

Study location: This study was carried out at selected public hospitals within EThekwini metropolitan municipality district in KwaZulu-Natal Province of South Africa, and its environs. Ethekwini municipality comprises a major urban city (Durban) and semi-urban areas (townships) with a population of around 3.2 million people (2010 estimate) (Statistics South Africa, 2011). Based on data from KZN department of Health, there are 17 public hospitals in Ethekwini district municipality (KZN Department of Health 2011). According to Terre-Blanche (2008) 30% of the population is adequate when conducting a descriptive study (Terre-Blanche, Durkheim & Painter, 2008). Based on these criteria, 6 provincial/public hospitals were finally included in this study.

Target populations: This was a simultaneous study involving patients, medical doctors, and professional nurses at selected provincial hospitals within Ethekwini municipality KZN were targeted for the study. All medical doctors and professional nurses within the randomly selected hospitals were given an opportunity to participate in the study.

Sampling procedures: Multi-stage stratified random sampling was used to select participating hospitals. Purposeful sampling was used to include the two central tertiary hospitals within the district because they contain the largest number of

medical doctors including specialists as well as professional nurses. The rest of the public hospitals within the municipality district were randomly sampled. A total of 5 hospitals from Durban and one outlying hospital in nearby Pietermaritzburg with rotating surgical registrars from Durban were included in the study. Therefore, a total of 6 provincial/public hospitals were included in the study population.

Sample size: Preliminary sample size for each group of study participants was calculated using a web based sample size calculator by Raosoft ® (http://www.raosoft.com/samplesize.html), based on the formula for sample size and margin of error. Using this freely available software the estimated sample size for each category of participants was calculated. In this case, an estimate of 373 professional nurses were needed to complete the study at a 95% confidence level.

Inclusion & exclusion criteria for nurses: There are 3 categories of registered nurses in South Africa, professional nurses, staff nurses and nursing auxiliaries (South African Nursing Council (SANC), 2012). A professional nurse sometimes called a nursing sister is an individual who has completed a minimum 4-year degree programme at university or tertiary institution, and are certified competent to practice comprehensive nursing and midwifery. An enrolled or staff nurse is a registered nurse with a minimum of 2-years tertiary nursing education, while an auxiliary nurse has 1 year of nursing education. In this study only nurses in the categories of professional nurse and enrolled nurse were included (SANC, 2012).

Research instruments and data analysis: Data was collected using self-administered questionnaires for healthcare professionals and face-to-face interviews for patients. Two separate open and close-ended questionnaires were applied to patients and healthcare professionals respectively. Doctors and nurses were evaluated using the same questionnaire in English language. The data from questionnaires was captured and subsequently analysed using the Statistical Package for Social Sciences (SPSS v.21 IBM, 2012). Distribution and collection of questionnaires were conducted with the assistance 3 trained research assistants. Preliminary data from the questionnaire was captured into SPSS by a trained research assistant and this was further validated by the principal investigator and a qualified biostatistician. Descriptive statistics such as proportions, median, mode and interquartile range were be used to summarize the data. The scores for information disclosure, capacity comprehension, and volition of informed consent were worked out from the responses

Ethical considerations: Ethical approval was obtained from a University of South Africa (UNISA) Research Ethics Committee and the KZN Department of Health Research Ethics committee. Additional approval was obtained from the management of each selected hospital prior to distribution of the questionnaire. Finally, all participants were given a full information disclosure prior to providing signed informed consent.

Conclusions

Main Findings

Demographics: A total of 355 nurses completed this study. Majority of participating nurses were female (92%) with a median age of 39 years, range (22-62). Nurses had

between 1 to 41years of professional experience (median = 9). Majority were professional nurses (85%), remainder were enrolled/staff nurses (15%) Figure 1. Professional nurses, a.k.a nursing sisters had a minimum of 4-years University education or degrees in Nursing, while enrolled nurses' a.k.a staff nurses had a minimum of 2 years Diploma. Auxiliary nurses, nursing students, and enrolled nursing assistants (ENAs) were excluded from the study (SANC, 2012). Nurses from all major hospital clinical departments as shown in Figure 2.

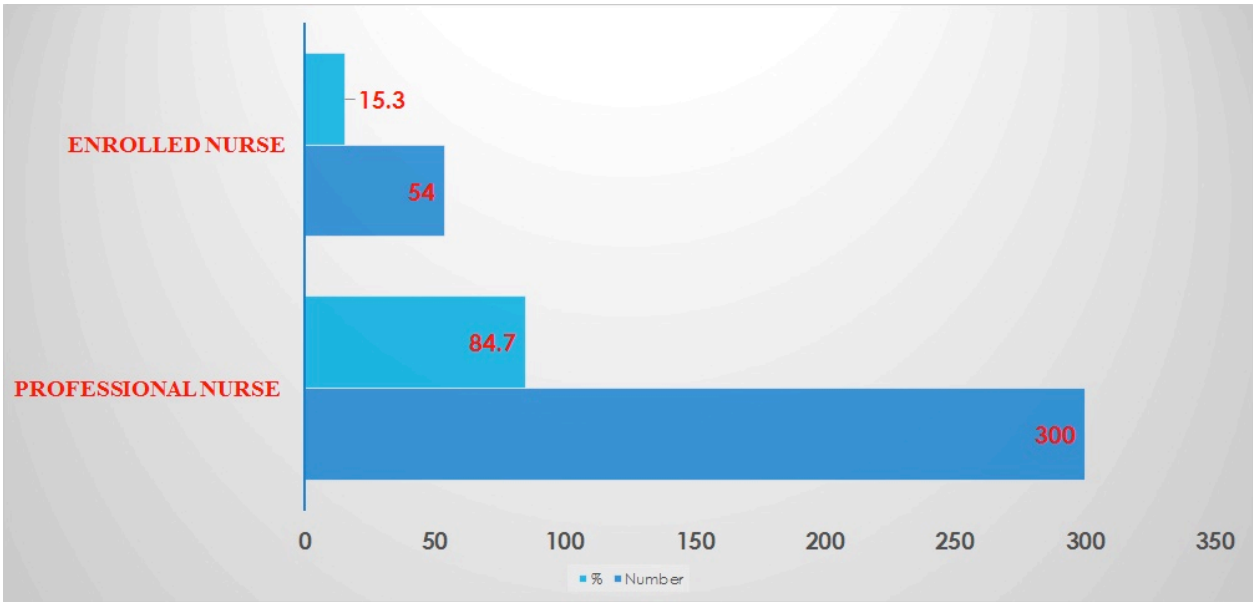

Figure 1: Nurses by professional category

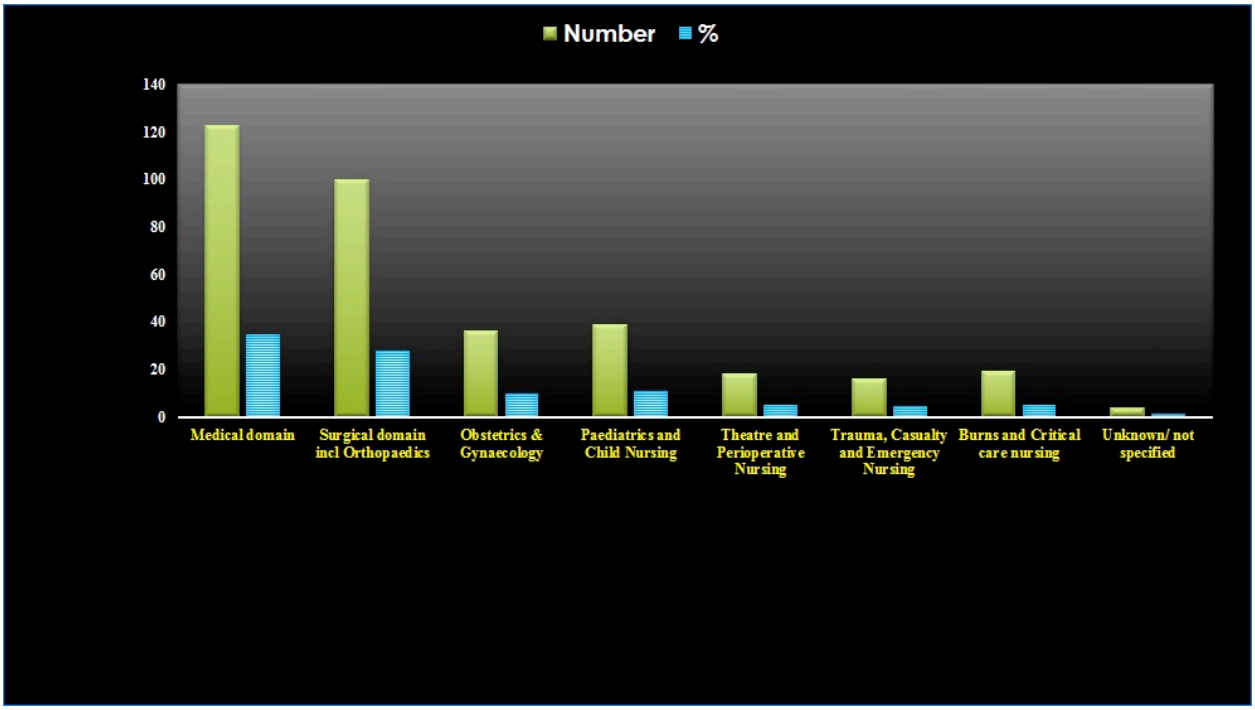

Figure 2: Clinical domains and departments of participating nurses

Information disclosed by nurses to patients: Information reportedly disclosed by nurses included diagnosis (77%); treatment options (68%); recommended treatment (65%); risks of refusing recommended treatment (69%); treatment benefits (71%); and right of refusal (67%). Triangulation of data revealed some inconsistencies between claimed disclosures between nurses and patients as previously reported (Chima, 2015). For example, patients reported that they were informed about diagnosis (81%), risks (57%), and benefits of treatment (61%). However, fewer were informed about treatment options (41%), recommended treatment (28%), and right of refusal (25%). Similarly, patients claimed that informed consent was IC was obtained verbally in 73% of cases while nurses only 8% of nurses reported obtaining consent verbally. Another interesting inconsistent observation involving nurses was the fact previously reported by doctors that interpreters were used in communicating with patients in 72% of cases when obtaining IC (Chima, 2013). On the other hand, patients reported that interpreters were involved in only 3.5% of clinical encounters (Chima, 2015). This inconsistency cannot be readily explained; however, it could be due to the practice of 'cultural brokerage', whereby nurses maybe used to 'translate, mediate and negotiate on behalf of patients' (Jezewski, 1990). In this situation, the patient may not readily recognize or relate this to the use of interpreter while a doctor or nurse may report otherwise.

Barriers to informed consent reported by nurses: Major challenges to obtaining IC reported by doctors and nurses included language barriers, time constraints, lack of administrative support e.g. interpreters, and patients' educational level. Tests of significance using Mann-Whitney U test showed that the 'lack *of administrative support e.g. interpreters'* was statistically significant across different clinical specialities ($p \leq 0.013$). The barriers to informed consent was previously reported for doctors (Chima, 2013). A comparison of doctors and nurses is shown in Table 1.

Challenges	**Doctors** **No. respondents**	**Nurses**	**Median score** **Doctors/Nurses**	**P-value (Mann-Whitney U Test)**
Time Constraints	146	216	2.00/3.00	0.120
Work Load	143	216	3.00/2.00	0.171
Language difficulties	147	259	2.00/1.00	0.002
Lack of administrative support, (E.g. Interpreters)	138	203	4.00/3.00	0.022
Cultural barriers	134	207	5.00/3.00	0.000
	142	220	4.00/3.00	0.002
Lack of education	131	183	7.00/6.00	0.000
Medical paternalism (Doctor knows best)				

Note: p-values calculated using Independent samples Mann-Whitney U test; significance level = 0.05

Table 1: Challenges to informed consent (Doctors vs. Nurses)

Time Spent on Informed Consent: Majority of nurses (41%) reported spending about 5-10 minutes on the IC process, consistent 53% of doctors as previously reported (Chima, 2013). This Another 24% of nurses spent 10-20 minutes, while 16% spent less than 5 minutes on IC as shown in Figure 3. When asked if this amount of time was sufficient, majority of nurses 52% answered affirmatively, while 41% responded negatively.

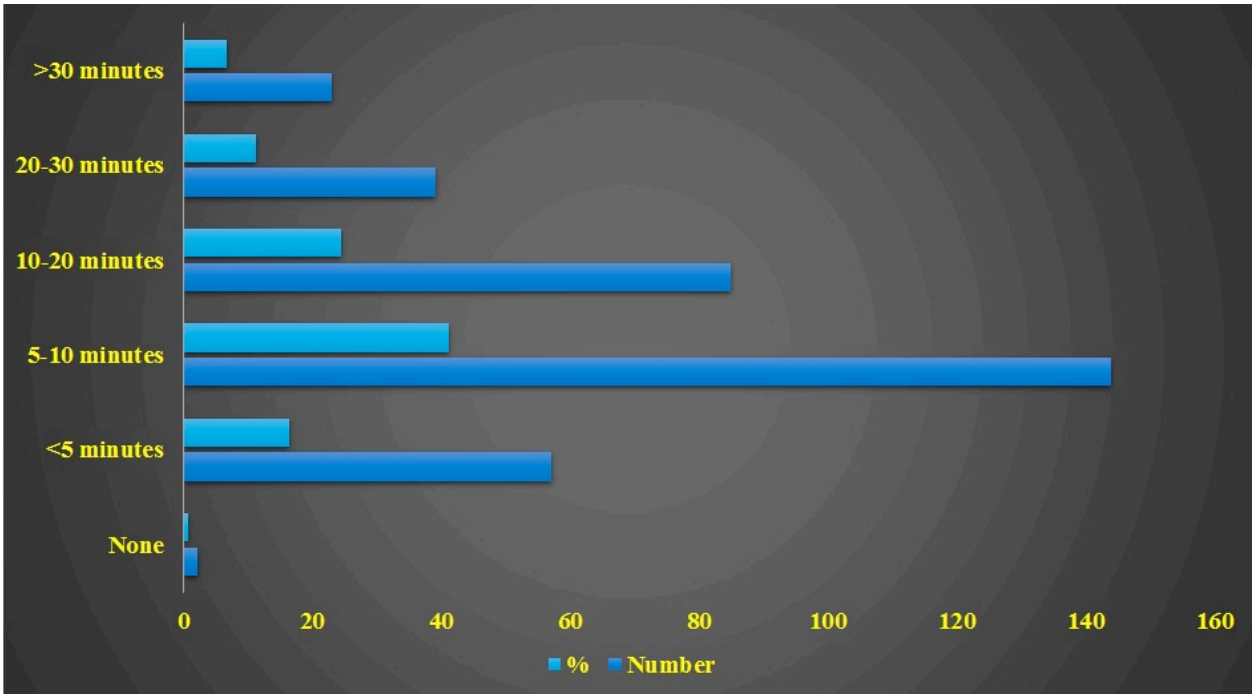

Figure 3: Time spent on informed consent by nurses

General knowledge of IC by healthcare professionals: Questions pertaining to general knowledge of IC regulations in South Africa such as 'age of consent to treatment' and 'legal age of eligibility for termination of pregnancy' in terms of (Choice on termination of pregnancy Act, 1996) were inserted into the questionnaires for to gauge the level of general knowledge of HCPs regarding local laws. Results showed that only 71% of doctors and 30% of nurses could correctly identify the age of consent for routine medical treatment. Similarly, only 30% of doctors and 8% of nurses knew age of consent for termination of pregnancy. Further, to compare IC knowledge across occupational ranks of doctors and nurses using quantitative means, I developed an Informed Consent Aggregate Score (ICAS) (Chima, 2013). Comparison of ICAS scores between doctors and nurses ICAS showed that nurses scored lower than doctors with a median score of 8 versus 10. This difference was statistically significant ($p \leq 0.001$). However, there was no significant difference in knowledge level between professional nurses with 4 years' degree or more, and enrolled nurses with a minimum of 2 years nursing diploma.

Implications of these findings

This study shows that nurses practicing in South Africa are generally aware of the importance of informed consent in clinical practice, although not all adhered to the key elements as specified in the (NHA, 2003), or are familiar with the requirements based on international standards. Generally South African nurses understand the basic

elements of informed consent such as comprehension, capacity, information disclosure and volition. However large percentages of professional nurses are still unaware of general changes in South African law, such as the age of consent to treatment or the age at which a woman can request for termination of pregnancy. This study also confirmed that majority of patients utilizing South African public hospitals are vulnerable because of their indigence and lack of alternative means of obtaining healthcare. However, the study also indicated that despite their evident vulnerability, most patients in Africa are generally aware of their right to information disclosure, human rights and dignity in healthcare as previously reported (Chima, 2015).

Limitations of the study

Potential limitations to this study include the fact that it was carried out in and urban metropolitan municipality in South Africa (Durban), with an arguably better educated and more knowledgeable population group by South African standards. It is possible that a similar study in a rural location in South Africa may yield a different result. It is also unclear whether a study in a more cosmopolitan South African city such as Cape Town or Johannesburg with different population demographics may or may not produce a different result. Finally, it is also possible that similar studies on patients utilizing private healthcare services may produce a different result because it has been suggested that doctors in private healthcare setting in Greece are more likely to provide detailed information to patients (Falagas et al. 2009).

Conclusion and recommendations

This study identified the major cultural factors militating against IC practice in this setting as language barriers, poverty, and poor communication skills by HCWs, consistent with findings from studies from other multicultural and multilingual settings South Africa (Schlemmer & Mash 2006) and USA (Flores, 2006). One can conclude that there is need to further educate patients and HCWs on patients' rights and the legal requirements of IC. There is a need for further training of nurses on improved communication skills and ethics and healthcare law. This will enhance the healthcare professional-patient relationship, patient's rights, and human dignity. Future research should focus on informed and shared healthcare decision-making to improve preventive healthcare services in Africa. Finally, more continuing education programmes should be initiated to further educate South African healthcare workers on the key elements of informed consent to meet required international standards and local laws. There is also a need for an interpreter 'corps to aid local language translation and improve patient understanding, improve informed consent practices amongst local populations, reduce the burden on nurses who have to play the dual role of interpreters and caregivers. This will help to minimize nurses' workload and reduce HCP attrition and improve the overall quality of healthcare service delivery.

Acknowledgements

This paper is derived in part from a research project entitled "An investigation of IC in clinical practice in South Africa," which is being completed as a thesis for the award of the LLD (Doctor of Laws) degree at the University of South Africa (UNISA).

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