


Evaluating Knowledge, Practice, and Barriers to Informed Consent Among Professional and Staff Nurses in South Africa: An Empirical Study

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Résumé de l'article

Contexte : Le consentement éclairé (CE) est une obligation éthique et juridique protégée par les droits constitutionnels à l'intégrité corporelle, au bien-être et à la vie privée en Afrique du Sud. La loi nationale sur la santé de 2003 a codifié les règlements en matière de CE, exigeant que tous les professionnels de la santé informent les patients sur le diagnostic, les risques, les avantages, les options et les droits de refus, tout en tenant compte de la langue et du niveau d'alphabétisation des patients. **Objectifs** : L'objectif principal de cette étude était de déterminer le degré de conformité des infirmières professionnelles/du personnel infirmier sud-africain avec les réglementations actuelles en matière de CI et de vérifier les obstacles socioculturels ayant un impact sur la pratique correcte de la CE. **Méthodes** : Une enquête transversale utilisant des questionnaires semi-structurés a été utilisée pour évaluer les connaissances et la pratique de la CE parmi les infirmières de la province de KwaZulu-Natal. Les données ont été analysées à l'aide de SPSS, v.21. Des statistiques descriptives, des tests de chi carré et une analyse de contenu ont été utilisés pour comparer les cadres/domaines infirmiers. **Résultats** : Trois cent cinquante-cinq (355) infirmières, 92% de femmes, ayant de 1 à 41 ans d'expérience professionnelle, ont participé à cette étude. Les informations divulguées par les infirmières aux patients comprenaient le diagnostic (77 %), les avantages du traitement (71 %), les risques (69 %), les recommandations (65 %), les risques de refus (80 %) et le droit de refus (67 %). Les infirmières (80 %) ont estimé que la divulgation des informations était adéquate, tandis que 85 % ont déclaré que les patients comprenaient les informations divulguées. **Conclusions** : Les infirmières exerçant dans les hôpitaux publics locaux avaient une connaissance modérée des règlements sur la CE. La mise en oeuvre pratique semblait déficiente. Les obstacles à la CE sont la langue, la charge de travail, les contraintes de temps, le manque d'interprètes et les normes de genre biaisées dans la profession infirmière. Pour améliorer la pratique de la CE et la qualité globale des services de santé en Afrique du Sud, les infirmières ont besoin d'une formation professionnelle continue en matière de droit et d'éthique de la santé, d'un « corps d'interprètes formés » et d'une transformation de la profession infirmière en fonction du genre.

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ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

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Sylvester C. Chima^{a,b}

Résumé

Contexte : Le consentement éclairé (CE) est une obligation éthique et juridique protégée par les droits constitutionnels à l'intégrité corporelle, au bien-être et à la vie privée en Afrique du Sud. La loi nationale sur la santé de 2003 a codifié les règlements en matière de CE, exigeant que tous les professionnels de la santé informent les patients sur le diagnostic, les risques, les avantages, les options et les droits de refus, tout en tenant compte de la langue et du niveau d'alphabétisation des patients. **Objectifs :** L'objectif principal de cette étude était de déterminer le degré de conformité des infirmières professionnelles/du personnel infirmier sud-africain avec les réglementations actuelles en matière de CI et de vérifier les obstacles socioculturels ayant un impact sur la pratique correcte de la CE. **Méthodes :** Une enquête transversale utilisant des questionnaires semi-structurés a été utilisée pour évaluer les connaissances et la pratique de la CE parmi les infirmières de la province de KwaZulu-Natal. Les données ont été analysées à l'aide de SPSS, v.21. Des statistiques descriptives, des tests de chi carré et une analyse de contenu ont été utilisés pour comparer les cadres/domaines infirmiers. **Résultats :** Trois cent cinquante-cinq (355) infirmières, 92% de femmes, ayant de 1 à 41 ans d'expérience professionnelle, ont participé à cette étude. Les informations divulguées par les infirmières aux patients comprenaient le diagnostic (77 %), les avantages du traitement (71 %), les risques (69 %), les recommandations (65 %), les risques de refus (80 %) et le droit de refus (67 %). Les infirmières (80 %) ont estimé que la divulgation des informations était adéquate, tandis que 85 % ont déclaré que les patients comprenaient les informations divulguées. **Conclusions :** Les infirmières exerçant dans les hôpitaux publics locaux avaient une connaissance modérée des règlements sur la CE. La mise en œuvre pratique semblait déficiente. Les obstacles à la CE sont la langue, la charge de travail, les contraintes de temps, le manque d'interprètes et les normes de genre biaisées dans la profession infirmière. Pour améliorer la pratique de la CE et la qualité globale des services de santé en Afrique du Sud, les infirmières ont besoin d'une formation professionnelle continue en matière de droit et d'éthique de la santé, d'un « corps d'interprètes formés » et d'une transformation de la profession infirmière en fonction du genre.

Mots-clés

Afrique du Sud, bioéthique empirique, consentement éclairé, lois, soins infirmiers, dynamique des genres, hôpitaux publics, réglementations, soins de santé, pays en développement

Abstract

Background: Informed consent (IC) is an ethical and legal obligation protected by constitutional rights to bodily integrity, well-being, and privacy in South Africa. The National Health Act 2003 codified IC regulations, requiring that all healthcare professionals inform patients about diagnosis, risks, benefits, options, and refusal rights while factoring in patients' language and literacy levels. **Objectives:** This study's primary aim was to determine the extent of South African professional/staff nurses' compliance with current IC regulations and ascertain socio-cultural impediments impacting proper IC practice. **Methods:** A cross-sectional survey using semi-structured questionnaires was used to evaluate knowledge and practice of IC among nurses in KwaZulu-Natal province. Data were analyzed using SPSS, v.21. Descriptive statistics, chi-squared tests, and content analysis were used to compare nursing domains. **Results:** Three hundred fifty-five (355) nurses, 92% females, with 1 to 41 years of professional experience, completed this study. Information disclosed by nurses to patients included diagnosis (77%), treatment benefits (71%), risks (69%), recommendations (65%), risks of refusal (80%), and right of refusal (67%). Nurses (80%) felt information disclosure was adequate, while 85% reported that patients understood disclosed information. **Conclusions:** Nurses practicing in local public hospitals had moderate knowledge of IC regulations. Practical implementation appeared deficient. Barriers to IC included language, workload, time constraints, lack of interpreters, and skewed gender norms in the nursing profession. Nurses require continuing professional education in healthcare law and ethics, a "corps of trained interpreters", and gender transformation in the nursing profession to improve IC practice and overall quality of healthcare service delivery in South Africa.

Keywords

South Africa, empirical bioethics, informed consent, laws, nursing, gender dynamics, public hospitals, regulations, healthcare, developing countries

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INTRODUCTION

The informed consent doctrine and ethical nursing practice

The International Council of Nurses (ICN) Code of Ethics for Nurses (2012) (1), revised (2021) (2), suggests that nurses have four fundamental responsibilities: “to promote health, to prevent illness, to restore health and to alleviate suffering” (1, p.1; 2, p.2). Regarding informed consent (IC), the ICN code also suggests that nurses should ensure that individuals receive “accurate, sufficient and timely information in a culturally appropriate manner on which to base consent for care and related treatment” (1, p.2), and “ensure IC for nursing and/or medical care which includes the right to choose or refuse treatments” (2, p.9).

Therefore, nurses should:

- i. Provide sufficient information to permit informed consent to nursing and/or medical care, and the right to choose or refuse treatment (1, p.6; 2, p.9).
- ii. Provide teaching/learning opportunities related to informed consent, privacy and confidentiality, beneficence and nonmaleficence.
- iii. Provide guidelines, position statements, relevant documentation and continuing education related to informed consent to nursing and medical care (1, p.6).

Consistent with the above recommendations, the South African Nursing Council (SANC) Code of Ethics for Nursing (3) states that “ethics is an integral part of the nursing profession and forms the foundation thereof” (3, p.3). The SANC code says that “ethical principles have to be upheld at all times by all nursing practitioners in whatever role they fulfil as direct or indirect patient care providers, including, amongst others, educators, administrators, researchers, policy developers and others, in any setting whatsoever” (3, p.5). The code “is binding upon all nurse practitioners and all categories of persons registered under the Act” (3, p.6). Furthermore, the SANC code states that “nurses are at all times expected to observe and apply fundamental ethical principles in their interaction with healthcare users [...] which include respect for the autonomy of eligible persons to make their own decisions and choices in matters affecting their health” (3, p.4-5). The code then reminds all nurse practitioners that “...these responsibilities will be carried out with the required respect for human rights, including cultural rights, the right to life, choice and dignity without consideration of age, colour, creed, culture, disability or illness, gender, sexual orientation, nationality, politics, race or social status” (3, p.3).

Recent studies suggest that nurses practicing in South Africa may not be well prepared for the ethical practice of nursing or knowledgeable about the basic ethical principles and legal doctrines applicable in modern healthcare (4,5), including suggested roles regarding IC (5,6). Despite implementing the ICN and SANC codes of ethics, this deficiency persists, emphasizing the importance of IC and respect for persons in the nursing code of practice (1-3). It has been suggested that overcoming these deficiencies may require better training in healthcare law, ethics, and human rights (5,6), as well as the socio-cultural and human resources issues currently facing the nursing profession and global healthcare delivery (7-10). While, there may have been some improvements in recent times, one area where there are still identifiable gaps in nurses' knowledge, especially in multicultural societies and resource-constrained settings, is with regards to knowledge and application of ethical and legal rules of IC during nursing care (4-6,8-9). Other areas where there could be knowledge gaps among South African nurses, as reported by a recent study on social accountability in nursing include, “inadequate social skills, lack of initiative, inability to apply theoretical knowledge to patient care, lack of basic nursing skills, and lack of understanding of professional practice” (11, p.5). While the latter observation was part of a social accountability study in the nursing profession in South Africa, it is trite to say that ‘ethos and professionalism’, including informed consent, are core tenets of all nursing curricula in South Africa and elsewhere as emphasized by the ICN and SANC codes of ethics (1-3); so while the SANC code states in its preamble that “ethics is an integral part of the nursing profession and forms the foundation thereof” (3, p.3), there is an important gap between professional aspirations and the on-the-ground reality of South African nurses. This knowledge gap amongst nurses regarding ethical nursing practice, including IC, may not be limited to South Africa; other studies show similar challenges for nurses trained in other parts of the world, including developed countries, e.g., Indonesia (12), Korea (13), Japan (14), Greece (15), and the Netherlands (16).

The ethical principle of respect for autonomy and informed consent

The doctrine of IC is derived from the ethical principle of respect for autonomy (17-20). It has been suggested that while there are many theories regarding the concept of autonomy, there may be ongoing debates regarding a universally accepted definition, leading to a situation where there are diverse interpretations of this concept by nurses, such as “self-governance, liberty, rights, privacy, individual choice, freedom of will, governing one's behavior, and being one's person” (16, p.420). Based on these different understandings and interpretations of the meaning of respect for autonomy, authors from one study concluded that nursing “caregivers seem to value different notions related to respect for autonomy depending on a particular circumstance” (16, p.429). The authors concluded that a multidimensional understanding of respect for autonomy might best fit the context for nursing home care (16). This apparent lack of clarity regarding the application of the principle of respect for autonomy in nursing may have led to incomplete definitions by some nursing professionals, such as, “autonomy within ethics means that individuals have the right to information and, on the basis of this, the right to agree or to refuse to participate in research”, as suggested by one author (9, p.504). Such incomplete understanding may leave essential aspects of the IC doctrine, including capacity, comprehension, and voluntariness when refusing or consenting to medical treatment or research

since valid IC should ideally occur in the absence of coercion, deception, or any undue influence (17-21). Misconceptions about respect for autonomy and the key elements of IC may also lead to the misapplication of this doctrine during clinical nursing care and practice. Therefore, the question has arisen about how to best apply the principle of respect for autonomy in other nursing domains, apart from nursing home care (22).

In medical law and ethics, the term “respect for autonomy” can be defined as “the right to self-determination or freedom of choice” (17, 20). Faden and Beauchamp illustrated the principle of respect for autonomy as follows (23, p.275):

X is an informed consent by person P to intervention I if and only if:

- i. P receives a thorough disclosure regarding I
- ii. P comprehends the disclosure
- iii. P acts voluntarily in performing X
- iv. P is competent to perform X
- v. P consents to I

Application of the informed consent doctrine in South Africa and similar common law jurisdictions

It has been argued that IC is an established principle in South African medical jurisprudence (17,24-25). This was demonstrated in early 20th century South African court cases such as *Stoffberg v Elliot* 1923 (26), and *Esterhuizen v Administrator Transvaal* 1957 (27). In more recent South African cases such as *Minister of Safety and Security v Xaba* 2002 (28) and *Castell v De Greef* 1994 (29), local courts have defended patients' rights to bodily integrity and privacy, as enshrined in the South African constitution (17,25,30). This was aptly demonstrated in the *Xaba* case (28), where a high court judge rejected a police request to perform a surgical procedure on a patient to retrieve a bullet to be used as evidence in criminal proceedings against the accused. The court held that such permission would infringe on the accused person's constitutionally guaranteed rights to bodily integrity and privacy (17,25, 28,30). It has been suggested that the court's decision in the *Castell* case (29), appears to have adopted the principle of respect for autonomy based on a “prudent patient” and “material risks” standard into South African medico-legal jurisprudence (17,24-25,29). That is, the level of information disclosure required for IC should be based on what a reasonable patient would consider important before making any healthcare decision (17,25,29); this is consistent with the practice in North America as demonstrated in the Canadian case of *Reibl v Hughes* 1980 (31), and the landmark American court judgment in *Canterbury v Spence* 1972 (32), which highlighted the importance of disclosing “all material risks” during IC (17,32).

Hence, the current situation in most common law jurisdictions is that the “prudent patients standard” has become the accepted norm as confirmed by the more recent judgment of the UK Supreme Court (UKSC) Scotland, in the case of *Montgomery v Lanarkshire* 2015 (33), where the Court opined that: “An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken” (33, para. 87). The *Montgomery* court argued that it has become increasingly clear that the paradigm of the doctor-patient relationship has ceased to reflect the reality and complexity of the way healthcare services are provided or how the providers and recipients of such services view their relationship. The Court further opined that:

[...] one development which is particularly significant in the current era is that patients are now widely regarded as persons holding rights, rather than passive recipients of care from the medical profession. Furthermore, patients are also widely treated as consumers exercising choices: a viewpoint that has underpinned some of the developments in healthcare services. In addition, a wider range of healthcare professionals now provide treatment and advice of one kind or another to members of the public, either as individuals, or as members of a team drawn from different professional backgrounds, *with the consequence that, although this judgment is concerned particularly with doctors, it is also relevant, mutatis mutandis to other healthcare providers.* (33, para. 75, italics mine).

Current informed consent regulations in South Africa

The *National Health Act* (NHA) 2003 codified the legal requirements for IC in South Africa (17,34). Section 7 of this Act specifies that healthcare services cannot be provided to healthcare users (patients), without the patients' consent, unless “the patient is unable to provide informed consent and such consent is given by another person, mandated by the patient in writing to grant consent on his or her behalf” (34). More specifically, section 6 of this Act requires that information disclosed to patients 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 (34).

The Act further requires that healthcare providers must inform the patient “in a language that the patient understands while taking into account the patient's literacy level”, section 6(2)(d) NHA (17,25,34). Therefore, one can argue that in general terms,

the NHA appears to encompass most of the critical elements of IC as required by international and national ethical codes and guidelines (17,35-38).

Socio-cultural factors affecting informed consent practice in South Africa

South Africa is a complex multicultural society with a recent history of racial segregation and human rights violations (6,39,40). Currently, South Africa has a high unemployment rate, which rose to 34.4% in the second quarter of 2021 (41). The healthcare system is dichotomous, with privately funded healthcare services used by about 20% of the population who can afford to pay for private healthcare or insurance and public health services patronized by most disadvantaged citizens (42-43). Within this context, it has been previously suggested that “informed consent may be light years away from black South Africans” (19,p.4; 44, p.252), despite recent progress in social policy, including constitutional and legal reforms (25,30,34,37). Furthermore, South Africa has 11 official languages (45), which may affect the ability of nurses and doctors to communicate effectively with patients, sometimes influencing the quality of healthcare service delivery (19,46-48). Previous studies amongst South African doctors (19) and physiotherapists (48) practicing in local public hospitals have identified language as a significant barrier faced by healthcare professionals (19,46-48). It has been suggested that nurses practicing in this setting may sometimes become involved in the process of “cultural brokerage” (9), defined as “the act of bridging, linking or mediating between groups or persons for the purpose of reducing conflict or producing change” (49, p.497). Language difficulties may also require nurses to act as *ad hoc* interpreters – in addition to their regular nursing duties – to enhance patients’ understanding of IC during clinical practice (9,17,49), because local nurses are more likely to speak their patients’ home languages compared to doctors (17,19,46,47). Such additional roles may increase nurses’ workload, thereby negatively affecting their regular nursing duties, including obtaining IC from patients (17,46,47), potentially causing moral distress (5), and undermining nurse-patient relationships and the overall quality of healthcare delivery (5,17,46,47). This increased workload due to work outside the ‘scope of practice’ could also be associated with poor job satisfaction and job attrition reported amongst South African nurses (50-52).

Other factors that may influence the IC process in the African context include the power asymmetry that exists between healthcare professionals and patients, and the hierarchical culture and communalism (53-55), such as the culture of Ubuntu, “I am because we are” (53,56, p.55). In addition to the involvement of family members and elders in healthcare decision-making (9,53-55), the African spiritual worldview and other cultural belief systems can influence the IC process (17,53-59). Previous studies in Southern Africa and other reports have shown the impact of lack of education, literacy, poverty, religion, and belief systems as confounding factors when obtaining IC in African and other multicultural societies (8-9,12-14,17,25,42,53-59).

Other cross-cultural factors with impacts on the global nursing workforce

In the later part of the 20th century, the ICN advocated a nursing vision for the 21st century, which stated in part that the mission of nursing was “to lead our societies to better health” (60). This mission is consonant with the third United Nations sustainable development goal (UN SDG), whose focus is to “ensure healthy lives and promoting the well-being for all at all ages” (61, p.14). Generally, nurses comprise the highest number of healthcare professionals globally (62-64), especially in developing countries (7), where they provide essential healthcare services. Nurses are also more familiar with patients’ needs because they interact actively with healthcare users, and their families, and are arguably more aware of the cultural, environmental, and social context under which populations live (7,62). Therefore, it has been suggested that nurses may offer advice on specific aspects of healthcare, including the cost-effectiveness of healthcare and understanding of relationships between healthcare and social patterns of disease (7,8). They may also provide “cultural brokerage” in multicultural and resource-constrained settings (9,49).

Considering the importance of the nursing profession to global healthcare service delivery, the World Health Organization (WHO) declared 2020 as the “Year of the Nurse and Midwife” (YONM) (65,66) to highlight the critical role that approximately 28 million nurses play in the health of global communities (62-66). This has been re-emphasized by the advent of the Covid-19 pandemic (67) and recognized by global leaders such as United States President Joe Biden, who acknowledged that “nurses have given so much and saved so many lives throughout the course of this pandemic” (68). This observation is pertinent because while parts of the data in this study were collected in 2012, the detailed analysis was completed and reported in 2018 (17). Recent evidence suggests that some of the global health workforce problems have not changed significantly and may have indirect effects on national and international healthcare delivery (65,66). Such challenges include skewed gender norms in the healthcare workforce (63,64,69), and frequent healthcare worker (HCW) strikes (70,71). Other researchers have reported that masculinization and gender imbalance remain chronic problems within the nursing profession, especially in more traditional societies like South Africa (72-77) and some developed countries (78,79). Meanwhile, it has been projected that demographic changes and rising healthcare demands may lead to creation of 40 million new jobs by 2030 in global health and social care, with an estimated shortfall of 18 million HCWs, especially in lower-and middle-income countries (LMICs), which is required to achieve UN SDGs and universal health coverage (UHC) (61,63,70,80,81).

Since women account for about 70% of HCWs globally, gaps in global HCW supply will only be closed by addressing the gender dynamics within the health and social care workforce (63,64,69,80,81). This may be particularly important in South Africa, where there is documented evidence of gender disparity in the nursing profession due to historical inequities in setting up the local nursing profession (73-77), as well as barriers created by the feminization of the nursing profession and skewed masculine-feminine gender roles in traditional societies (72-77). Further, it has been observed that while there are gaps in

research data from all regions of the world, the most serious gaps occur in LMICs, which is of major concern, since rapid progress in healthcare services is most needed in LMICs to achieve UN SDGs and UHC by 2030 as envisaged (61,63,64,69,70,72,80,81). As a response, a notable recommendation from the WHO based on analysis of the current global health workforce is that:

Research must go beyond simply describing gender inequities and evaluating the impact of gender-transformative interventions, including understanding context-specific factors, such as socio-cultural dimensions. Moreover, research focused on implementation and translation into policy is needed to assess the viability and effectiveness of new policies and inform gender-transformative action (63, p.4).

It has also been argued that UN SDGs and UHC will only be achievable “if nurses are better educated in greater numbers and allowed to practice to the top of their education and training and being incorporated into healthcare policy decision-making” (66, p.912). Accordingly, the US National Academy of Medicine reports on the future of nursing (81), including among its recommendations “advancing the education of nurses, ensuring that nurses are part of teams that are redesigning healthcare, appointing nurses to decision-making bodies in healthcare, and increasing the profession’s diversity” (66, p.912; 81, p.9-15).

MATERIALS AND METHODS

Study aims and objectives

This study aimed to evaluate actual knowledge and practice of IC by professional and staff nurses practicing at public hospitals in KwaZulu-Natal (KZN) province, based on stipulations by current South African laws, regulations, and ethical guidelines (17,19,25,34,35). Here I have used a questionnaire-based survey to evaluate the extent of compliance with current rules regarding IC. Specific objectives were to:

1. Establish whether nurses provided sufficient information to patients before consent.
2. Determine whether patients involved in clinical procedures had the legal capacity to consent and comprehend the information they provided.
3. Establish whether the IC obtained from patients attending public hospitals was voluntary and genuinely valid.
4. Show whether there are any cross-cultural or socio-economic challenges or barriers impacting the proper practice of IC in this setting (17,19).

Study design

This study was a descriptive cross-sectional survey using semi-structured questionnaires to collect quantitative and qualitative data in contemporary clinical practice settings. The descriptive approach allowed participants to describe their actual experiences with the IC process.

Study location and setting

The study was carried out at selected public hospitals within the eThekweni metropolitan municipality, KZN, South Africa. This municipality comprises a major urban city (Durban) and semi-urban areas (townships), with an estimated population of 3.5 million people (2011 census) (17,19,82). The area comprises a diverse population of predominantly 80% Black Africans, with various socio-economic, environmental, and governance challenges (41-45). There are 18 provincial or public hospitals within this municipality, ranging from the tertiary, regional, district, and specialized hospitals for chronic diseases (e.g., tuberculosis) and psychiatry (83). Public hospitals in the eThekweni health district are relatively well-staffed. Many serve as teaching hospitals to train medical students, doctors, nurses, and allied healthcare professionals up to postgraduate levels (17,19,48,83-85). Based on an online listing by a provincial government department, there were about 40 provincial and private hospitals in the eThekweni municipality (86). However, this study included only the 18 public hospitals in the municipality, out of which six were selected using multi-stage stratified random sampling.

Target population

There are three categories of registered nurses in South Africa: professional nurses, staff nurses, and auxiliary nurses (17,84,85). A professional nurse, sometimes called a “nursing sister”, completes a minimum of a 4-year tertiary nursing education and is certified to practice comprehensive nursing and midwifery; a staff/enrolled nurse is a registered nurse with a minimum of 2-3 years tertiary nursing education; and an auxiliary nurse has one year of nursing education (17,84-85).

Inclusion and exclusion criteria

All eligible nurses in the categories of “professional” and “staff/enrolled nurse” at the selected hospitals who were available and willing to participate during the study period (March to June 2012), had an equal opportunity to participate. I recruited only professional nurses and staff/enrolled nurses for this study, because I wanted to evaluate the knowledge and practice of registered nurses who were fully trained and certified to provide comprehensive and basic nursing care to patients. Nurses in

a supportive role, such as auxiliary nurses or nursing students in training, were excluded. Any completed questionnaires submitted by these latter categories of nurses were screened out and excluded from further analysis.

Sampling procedures

I conducted statistical design and analysis for this study with the guidance and assistance of a qualified biostatistician from the College of Health Sciences, UKZN. In addition, the statistical method and parameters used for this study were evaluated and approved by the Health Research & Knowledge Management subcommittee of the KZN Department of Health, a provincial research ethics committee (REC). The preliminary sample size for this study was calculated using a web-based sample size calculator by Raosoft® (87). The formula for sample size calculations is embedded in the software program at a 95% confidence level and a 5% margin of error (17,19,87). Using these parameters, the estimated number of nurses for recruitment for this survey was 373. The study was conducted for three months, from March to June 2012. Manual distribution and retrieval of questionnaires were done with assistance from three trained research assistants who were multilingual (English/Zulu/Xhosa/Sotho). We made multiple site visits to selected hospitals during the study period after obtaining ethics approval from the various regulatory authorities and permission from gatekeepers at each chosen institution. Repeated visits enabled participant recruitment until we reached the maximum number of willing participants.

The first step in identifying hospitals for inclusion in this study involved identifying all functional hospitals in the eThekweni municipality during the study design, as listed on a government website, including categorization into public and private hospitals (86). Secondly, we differentiated public from private hospitals based on governmental classification (83,86). We identified 18 hospitals as being provincial/public hospitals. Finally, with the advice of a qualified biostatistician, the hospitals were listed alphabetically, and I included every third hospital on the list, excluding non-functional, infectious disease, and semi-private hospitals. Further, I purposively selected two tertiary hospitals involved in the training of healthcare professionals for inclusion to increase the yield of qualified nurses in the desired categories, thereby increasing the possibility of obtaining a wide range of nursing experience. It should be noted that I sought written permission from all eligible hospitals, and only those hospitals that granted permission in writing during the study period were included in the study, as previously reported (17,19). Finally, I could not extend the analysis to private hospitals due to time constraints, resources, and difficulty in obtaining permission from private healthcare facilities.

Work units and nursing domains studied

Clinical wards and outpatient clinics in each participating hospital were randomly sampled. The aim was to test 30% of the clinical wards and clinics at selected study sites (88); according to Terre-Blanche and others, 30% of any population is generally adequate when conducting a cross-sectional descriptive study (17,88). Eligible professional and staff nurses working in the wards and clinics willing to participate in the study were given an equal chance to complete the study questionnaires. The researcher and research assistants randomly selected wards or clinics on the day of the site visit. Nurses who were willing to participate were first given the IC documents to read and sign, and the study questionnaires given to willing participants for completion. Occasionally, the matron-in-charge of the ward or clinic was approached for permission in order to not disrupt the work environment. In such cases, I explained the study, and then the matron-in-charge collected and distributed the questionnaires to nurses during times when it was less problematic for the work environment. Research assistants were then informed when completed questionnaires were ready for collection; all participants who completed questionnaires were also required to read and sign the IC document.

The nursing domains evaluated included surgical, internal medicine, pediatrics, and obstetrics and gynecology wards and clinics, as shown in Figure 3. Regarding the choice of nursing domains studied and reported here, this study was not designed to target any particular nursing domain from the outset but was designed to collect data from all willing nurses from the selected hospitals and nursing frameworks. The nursing domains identified were categorized based on the data obtained from nurse respondents after data aggregation and statistical analysis. The nursing domains were not determined *ab initio* – they were the product of chance and a random selection, and were identified and categorized during data analysis.

Research instruments

Data were collected using a semi-structured questionnaire for nurses with appropriate modifications (17,19). In terms of the South African NHA 2003 (34), all healthcare providers, including nurses, must obtain valid IC from patients before treatment. The NHA does not distinguish between the scope of practice for healthcare professionals but simply specifies in section 6 of the Act that all healthcare providers obtain informed consent prior to treatment (34). Therefore, the questionnaire used for this study was designed with all healthcare providers in mind, including nurses, to evaluate their understanding of IC based on applicable ethical principles and current regulations during clinical practice. The questionnaire consisted of four parts, as previously reported (17,19,48). The first section was designed to obtain demographic data about respondents, including dependent variables, such as age, sex, job title, department in the hospital, years of professional experience, and clinical specializations. The second part contained questions about IC practices such as time spent on obtaining IC, patient workload, information disclosed to patients, language and methods used to communicate with patients, and challenges nurses face when obtaining IC. The third section asked general knowledge questions about local healthcare laws such as age of consent to medical treatment and age of consent to termination of pregnancy, including understanding information disclosure standards. The fourth section solicited knowledge from nurses about understanding and practice of implied and presumed consent. The questionnaire for nurses was first circulated for comments among a small cohort of doctors and nurses from clinical wards at

a tertiary hospital to test for face and content validity. The questionnaire was then slightly modified based on the comments from the pilot study group before distribution to all eligible participants. Participation in the study and completion of the questionnaire was entirely voluntary. A sample questionnaire is included in the supplementary material (S1).

Data analysis

Data analysis was done using the Statistical Package for Social Sciences (SPSS) version 21 (17). Primary data were collected using questionnaires. I also collected information on local statutes and regulations from information available in the public domain via a literature review. In addition, I collected current consent forms from the selected public hospitals for comparative analysis, when available (17). Respondents completed questionnaires manually, and then these were collected and stored in a locked cabinet to maintain security and confidentiality. A trained research assistant captured data from questionnaires into a single laptop computer at the end of each site visit. The raw data were later evaluated for completeness by the principal investigator (PI, author) and periodically cross-checked for completeness and accuracy by a qualified biostatistician.

Statistical methods

Quantitative analysis

I used descriptive statistics such as proportions, median, mode, and interquartile ranges in summarizing the data. Bar charts, pie charts, and graphs were used to present the results using Microsoft Excel®, 2003. I calculated the scores for comprehension of IC from participant responses. The Mann-Whitney U test was used to analyze differences in scores between different nurse categories and other applicable variables. The Kruskal-Wallis test was used to explore the relationship between 1) education level and scores, 2) clinical department and scores, and 3) professional category and scores. Pearson's chi-squared or Fisher's exact tests were used to test the association between any categorical variables and compare the informed consent aggregate scores (ICASs) between nurse categories; and Cronbach's alpha was used to evaluate the reliability of questions used in calculating the ICASs (17,89).

Qualitative analysis

Content analysis was used to evaluate qualitative data (90). In this case, we captured all open-ended responses from each participant verbatim within SPSS. These data were then aggregated and summarized using the embedded statistical procedures. Verbatim responses from participants were then printed out and visually analyzed using memos and inductive coding for word content and critical sentences. Some recurring key sentences or expressions were then extracted (Table 3). The PI, with frequent references to the captured raw data and memos, verified the accuracy of the data, and consistency in reporting was done by coding and interpreting data.

Validity and reliability of statistical methods

The validity of a research study may be defined as the "accuracy and trustworthiness of instruments, data, and findings in research" (91). It has been argued that ensuring validity helps make the researcher's evaluations more credible and provides secure data, inferences, and conclusions (92). This study confirmed validity by using several techniques such as multiple triangulation (17,91-94). In addition, there was an extensive literature review before the preparation of the study instruments. Face validity refers to subjective judgments on whether the research instrument appears to measure what it ought to measure (95). This study maintained face validity by constructing questions relevant to the study's aims and objectives as derived from an extensive review of pertinent literature and case law (17). Content validity relates to knowing whether all interview items reflect the whole range of potential meanings in a study (95). In this study, the researcher included all potentially relevant questions and items in the study instruments based on an extensive literature review before finalizing the study questionnaire (17). I evaluated the face and content validity of the research instruments by pre-testing the questionnaires with a few nurses and doctors at a tertiary hospital, soliciting their comments and suggestions, which I then incorporated into the final questionnaire before distribution to all potential respondents.

Ethical considerations and approvals

I obtained ethical approval for this study from the University of South Africa (UNISA) Research Ethics Committee (17). Ethics approval (HRKM180/11) was also issued by the Health Research & Knowledge Management sub-committee of the KZN Department of Health (a provincial REC). I obtained additional approvals from the eThekweni municipality department of health and each selected hospital after evaluating the research protocol and ethical approvals. All hospital gatekeeper and ethics approval letters are available as previously reported (17). Finally, written IC was obtained from every participant in the study. I maintained participants' confidentiality via safe storage and data anonymization and reported research results anonymously.

RESULTS

Demographic characteristics of the sample population

The response rate for this study was 95% (355/373). Most nurse respondents in this study were female (92%), with a median age of 39 years (range 22-62). The age distribution of participating nurses showed a normal distribution using the One-sample Kolmogorov-Smirnov test (mean = 39.25; SD = 9.912). Most respondents self-identified as professional nurses 85% (300/355), while 15% (54/355) identified themselves as staff or enrolled nurses (Figure 1). Nurses had 1-41 years of professional experience (median = 9 years), and all participating nurses (99.7%), except one, worked in public hospitals (99.7%); whether this particular nurse was dually employed in a public and private hospital is unknown. All data reported here were collected at the selected public hospitals during the study period; analysis of the single questionnaire from respondent working in a private hospital had no impact on the results reported here. Demographic characteristics of participating nurses are shown in Table 1. All major hospital departments were represented in this study, including internal medicine, surgery, obstetrics and gynecology, and pediatrics. The study also included nurses with specialized training practicing in trauma/casualty, theatre/perioperative, burns/critical care, and neonatal intensive care nursing units. Respondents classified by years of professional experience and hospital departments/nursing domains where this study was conducted are illustrated in Figures 2 and 3.

Information disclosure

Time spent on information disclosure

Most nurses (41%, 144/350) reported spending about 5-10 minutes on the IC process, while 24% (85/350) reported spending 10-20 minutes, and 16% (57/350) reported spending less than 5 minutes on IC. When asked if this amount of time was sufficient, the majority of nurses, 52% (185/353), answered yes, while 41% said it was not sufficient. Those who said time was insufficient gave various reasons for the negative response, including time constraints, large patient numbers, language barriers, and poorly educated patients who required more time for explanations. Time spent on IC by nurses is illustrated in Figure 4.

Figure 1. Nurses by occupational category

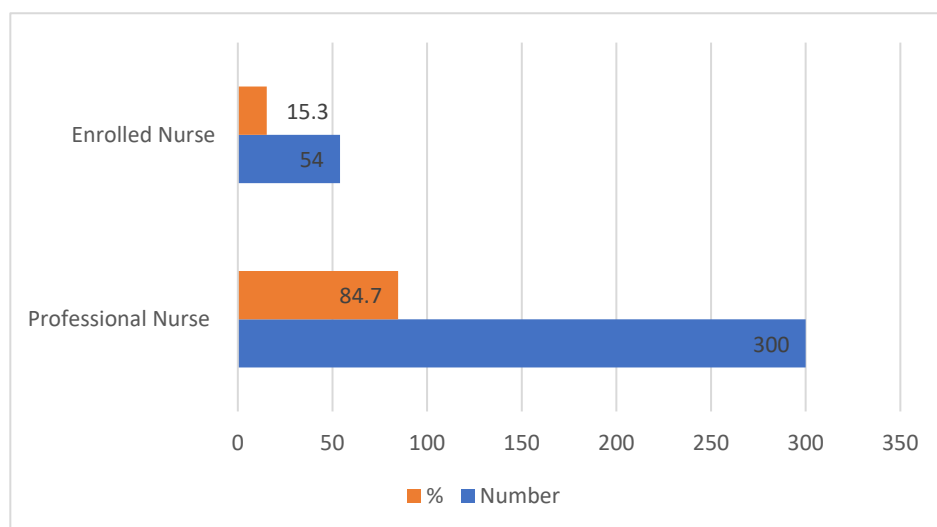


Figure 2. Nurses categorized by years of professional experience

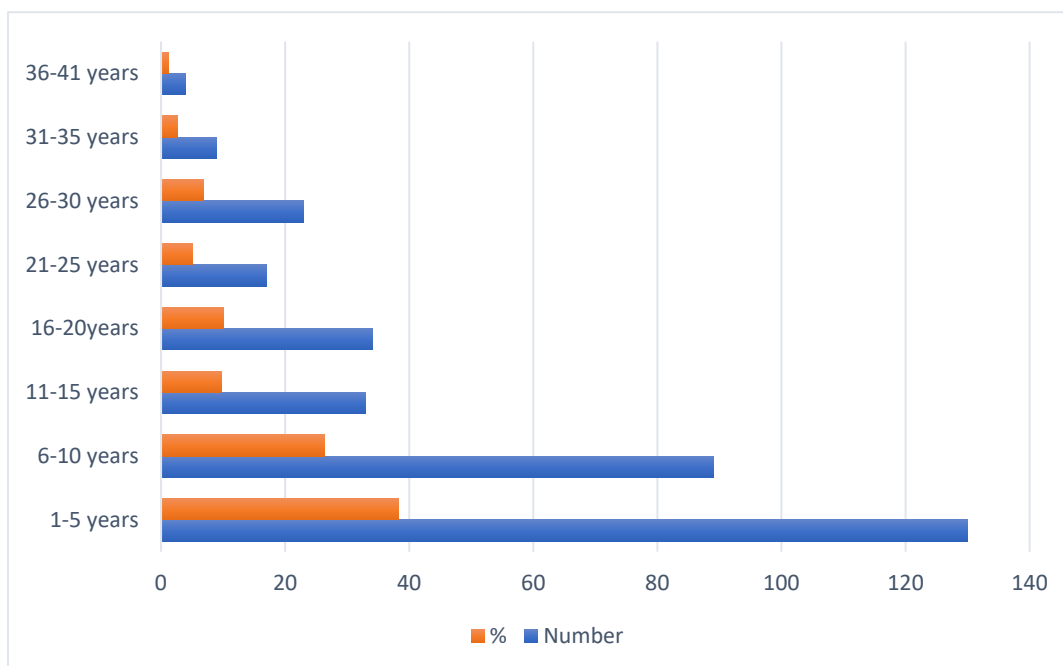


Figure 3. Nursing domains and hospital departments where the study was conducted

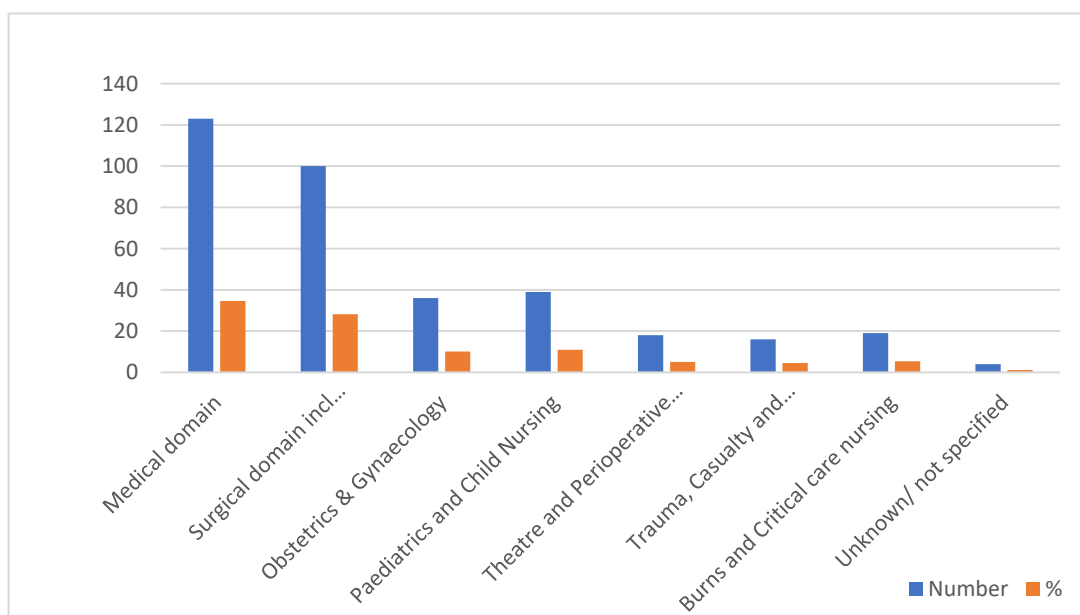


Table 1. Demographic characteristics of nurse participants

Item	Number	Percent (%)
Gender		
Male	26	8.4
Female	283	91.6
Missing data	46 [#]	
Professional category		
Professional nurse (Nursing sister) §	300	84.7
Enrolled nurse (Staff nurse)	54	15.3
Missing data	1 [#]	
Age of respondents (years)		
Minimum	22	
Maximum	62	
Mean	39.25	
Standard deviation	9.912	
Professional experience (years)		
Minimum	1	
Maximum	41	
Median	9	
Area of Practice		
Public hospital	354	99.7
Private hospital	1	0.3
Categorized by years of professional experience		
1-10	219	64.6
11-20	67	19.8
21-30	40	11.8
≥31	13	3.8

Note: §Professional nurse (minimum 4-year nursing degree or diploma); *Staff/eEnrolled nurse (minimum 2-year nursing diploma) (84-85); #Missing data: Some respondents did not respond to this question (excluded from data analysis).

Information disclosed

Information disclosed to patients by nurses during IC included diagnosis was reported by 77% (265/346) of nurses. Treatment options were disclosed by 68% (233/345), while recommended treatment was disclosed by 65% (223/346) of nurses. Risks of refusing recommended treatment were disclosed by 80% (277/346) of nurses, while 71% (246/346) disclosed treatment benefits. Patients' right to refuse recommended treatment was disclosed by 67% (232/346) of nurses. More than two-thirds of nurses, 69% (238/346), disclosed the risks of treatment, while 23% (81/346) reported that they also revealed treatment costs. Overall, 78% of nurses felt that the amount of information disclosed to patients was adequate. Details of information disclosure by nurses are shown in Figure 5, while overall satisfaction with information disclosure is illustrated in Figure 6.

Nature of risks disclosed

Most nurses in this study reported disclosing the most common and serious risks to patients, with 80% (256/320) telling the "most common risks", while 42% (134/319) of nurses disclosed "serious risks". However, only 36% (114/318) of nurses reported disclosing "all material risks" to patients.

Methods used to obtain informed consent

Most nurses reported obtaining written IC from patients (49%, 167/343), while 8% (26/343) reported obtaining verbal consent. Another 39% (135/343) of nurses reported using both methods, verbal and written, to obtain IC from patients, while 5% responded "it depends".

Mode of communicating with patients

Most nurses (59%, 206/350) reported communicating with patients verbally using the patients' local language; 39% (135/350) of nurses reported using English, while 56% (195/350) reported using both English and the local language. Other methods used to enhance patient information disclosure included diagrams and pictures as reported by 20% (69/349) nurses, while the use of interpreters was reported by 56% (197/349) of nurses.

Figure 4. Time spent on informed consent by nurses

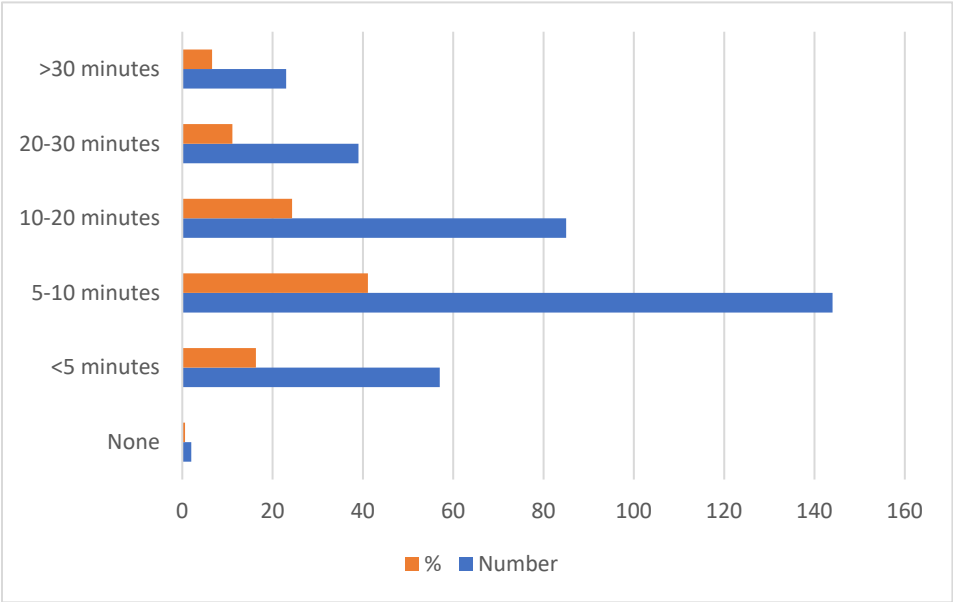
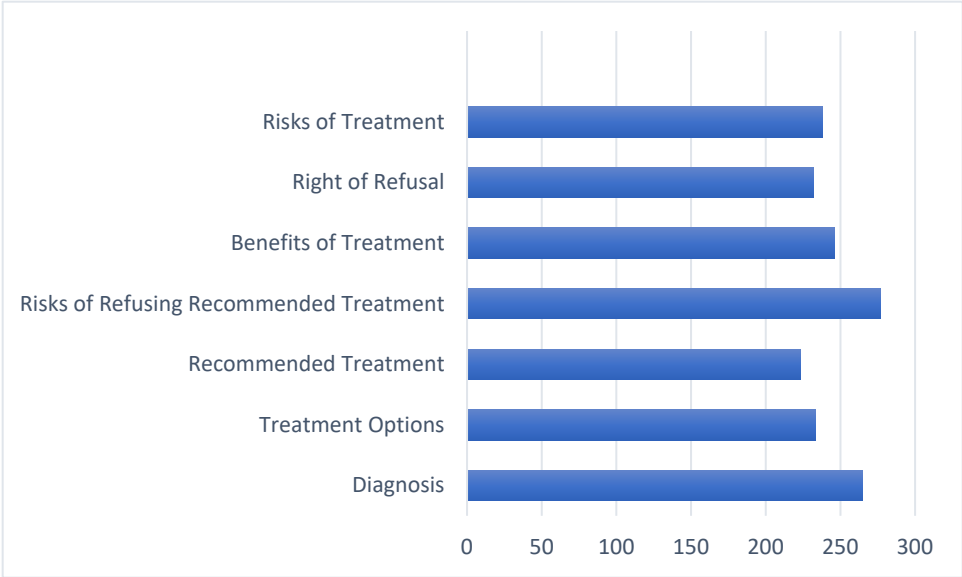
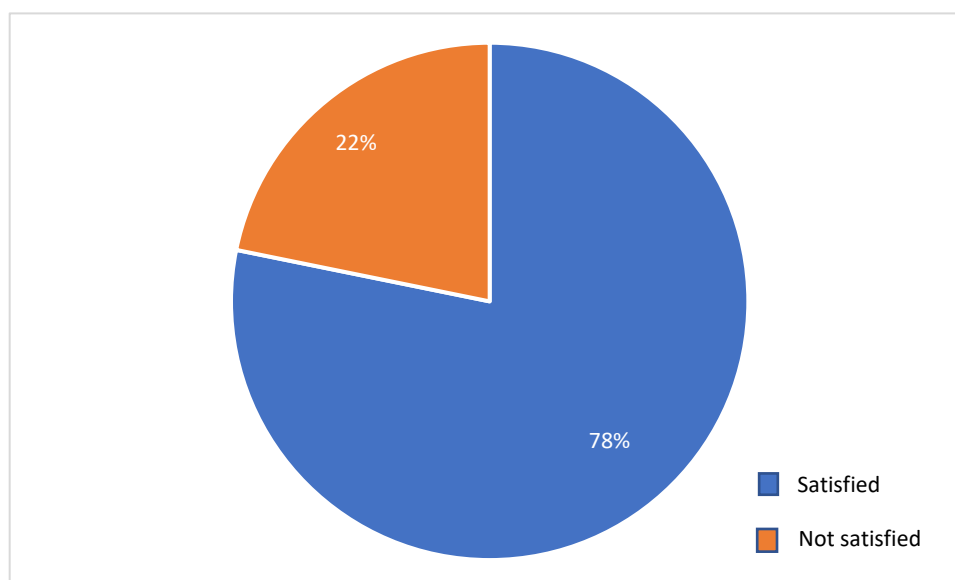


Figure 5. Information disclosed by nurses to patients or healthcare users



Note: Treatment in South African public hospitals is generally free of charge.

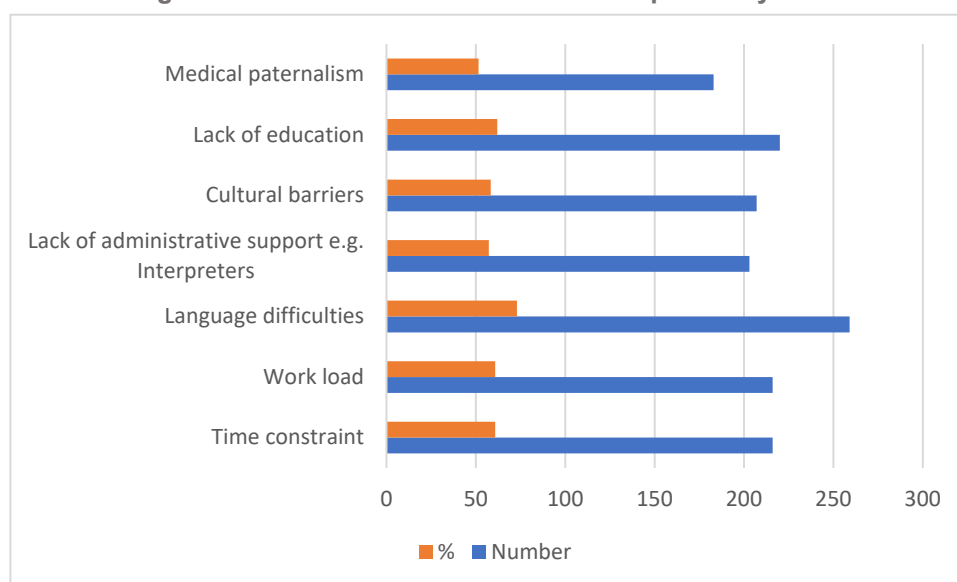
Figure 6. Nurses overall satisfaction with information disclosure

Assessing patients' decision-making capacity before consent

With regards to assessing patients' capacity before obtaining IC, 54.8% (183/334) of nurses reported that they would generally presume that patients could consent to treatment, 35.6% (119/334) responded "no" to this question, while 9.6% (32/334) were unsure. Most nurses, 76% (257/337), reported that they routinely assessed patients' capacity to consent to treatment, while 19% (64/337) said they did not. Nurses were asked to rank a series of five variables: age, sex, education, appearance, and level of consciousness, in terms of importance in assessing patients' capacity. Most nurses correctly ranked level of consciousness first, followed by age, and educational level in that order. Patients' sex and appearance were ranked as least important when determining capacity. Respondents were also asked to rank five criteria – mental status examination, psychiatric consultation, ethics consultation, court adjudication, use of surrogates, and none of the above – by the level of importance for assessing capacity in difficult cases. Most nurses ranked mental status examination first, psychiatric and ethics consultation second, court adjudication third, and use of surrogates as least important when assessing capacity in challenging cases. When asked to specify which methods they would use to determine capacity in complex cases, most nurses listed the Glasgow Coma Scale, mental status exam, orientation in time, place, person, and level of consciousness.

Barriers to informed consent identified by nurses

Nurses were asked to rank a series of potential barriers to IC on a 7-point scale, where 1 was considered the most challenging and 7 the least difficult. Most nurses ranked language difficulties as their number one challenge, followed by workload as number two. Time constraints, lack of education, and lack of administrative support, and cultural barriers, were equally ranked third. The least difficult challenge experienced by nurses was due to medical paternalism. Barriers to IC identified by nurses in this study are shown in Figure 7 and Table 2. Other cultural barriers to IC identified by nurses based on qualitative content analysis are summarized in Table 3.

Figure 7. Barriers to informed consent reported by nurses**Table 2. Barriers to obtaining informed consent reported by different categories of nurses**

Occupational rank		Time constraint	Workload	Language difficulties	Lack of administrative support (e.g., interpreters)	Cultural barriers	Lack of education	Medical paternalism
Professional nurse	N	194	190	228	181	186	197	163
	Median	3.00	2.00	1.00	3.00	3.00	3.00	6.00
	Minimum	1	1	1	1	1	1	1
	Maximum	7	7	7	7	7	7	7
Enrolled nurse	N	22	26	31	22	21	23	20
	Median	4.00	1.50	1.00	2.00	3.00	2.00	4.50
	Minimum	1	1	1	1	1	1	1
	Maximum	7	7	7	7	6	7	7
Total	N	216	216	259	203	207	220	183
	Median	3.00	2.00	1.00	3.00	3.00	3.00	6.00
	Minimum	1	1	1	1	1	1	1
	Maximum	7	7	7	7	7	7	7

Note: There was no statistically significant difference between barriers identified by professional or enrolled/staff nurses using the Mann-Whitney U test.

Nurses' general knowledge regarding the IC doctrine

When nurses were asked who should ideally obtain IC from patients during clinical procedures, 79% of nurses (270/342) reported that the nurse performing a medical procedure should obtain consent from the patient. When asked what standard should be used for information disclosure, 56% (165/295) chose the reasonable doctor standard, while 47% (138/291) chose the prudent patients' standard. When asked whose responsibility it was to ensure that adequate information was disclosed during IC, the majority of nurses, 60% (196/325), felt that it was the nurse's responsibility; 37% (121/325) felt that both nurses and patients were jointly responsible. By comparison, 12% (40/326) of nurses indicated that it was the patients' responsibility. When asked whether the amount of time spent on information disclosure was adequate, 52% (185/353) of nurses responded in the affirmative. Further, when asked if the current consent form used in KZN public hospitals was adequate, 81% (281/345) of nurses felt it was satisfactory. Some of the nurses who believed that the current consent form was inadequate gave the following open-ended responses as their reasons (not all respondents answered the open-ended questions):

"The forms need to be written if possible, in patients' language."

"Theatre/surgery consent forms should be maybe be also written in example Zulu language and to allow the patient also to read themselves with explanation of course- to increase their knowledge regarding surgery and providing consent."

"The patient should be asked to repeat back to the doctor all that he understands of what was told /explained to him in order to ascertain his level of understanding of what the procedure entails and what the risks are."

Other nurses expressed concern that current consent forms had no binding space to indicate that they disclosed information or alternatives to patients: *“Think more aspects to be added to consent form”* and *“We need a column for patients to sign for blood transfusion.”*

Voluntariness

When asked if they would allow patients to choose a specific procedure or treatment, 40% of nurses (137/337) answered affirmatively, while the majority 50% (170/337) did not. Nurses' responses to general questions regarding IC knowledge and practice are summarized in Table 4.

Table 3. Some cultural barriers to informed consent identified by nurses

1. Refusal of blood transfusion due to religious beliefs or customs: *“Jehovah’s witnesses”*
2. Cultural belief systems: *“Like Xhosa not allowed to do medical circumcision(hospital)”* or *“At times certain cultures have reluctancies [sic] to theatre or hospital interventions. View hospital as a place where people pass away”* or *“Adult patient requesting to pass out to fulfil a certain ritual before surgery [sic] is done.”*
3. Request for family consultation or involvement before consent: *“Sometimes patient will want to report at home to get consent from relatives”* e.g., *“Africans where head of family plays an important role.”*
4. Language barriers: *“Now that there are other people from Africa. Sometimes language is a barrier”*; *“Language (both verbal & sign)”*
5. Preference for traditional remedies, *“Black patients usually prefer traditional remedies”*
6. Religious beliefs: *“Patient are sometimes unwilling to get sterilized due to cultural/religious reasons”* or *“Where married women don’t want to consent for gynecological treatment without husbands consent”* or *“Patients that are fasting and cannot give consent”* or *“exposure for Moslem women”*.

Table 4. Nurse general knowledge and practices regarding IC

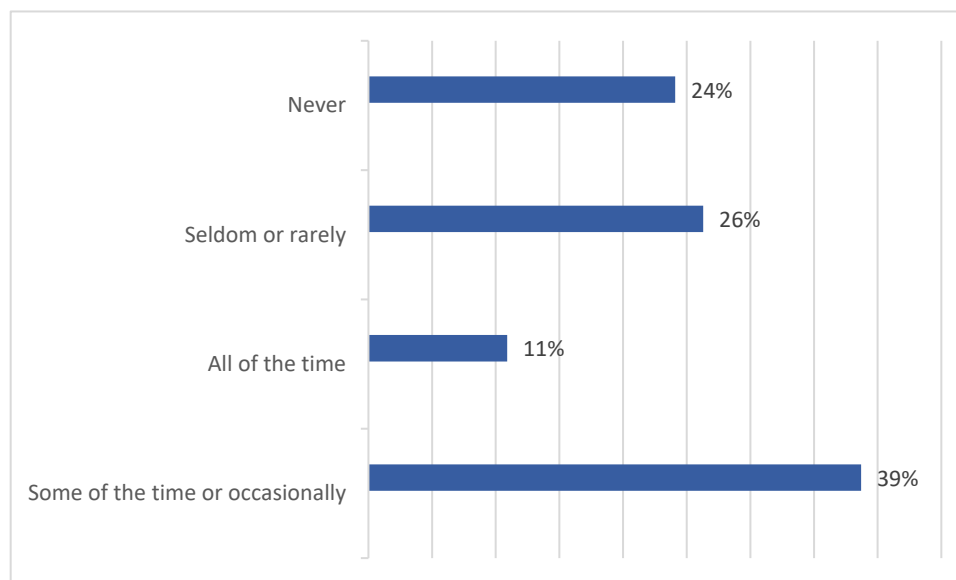
Relevant questions	Nurses (Yes) No. (%)	Nurses (No) No. (%)
Language of communication?		
English	135/350 (39)	213/350 (61)
Patients' local language	206/350 (59)	140/350 (40)
Both English & local	195/350 (56)	150/350 (43)
Methods of obtaining consent?		
Verbal	26/343 (8)	
Written	167/343 (49)	
Both verbal and written	135/343 (39)	
Who normally obtains consent?		
Nurses	50/342 (15)	292/342 (85)
Junior doctors	71/342 (21)	271/342 (79)
HCP performing procedure/treatment	270/342 (79)	72/342 (21)
Any available HCP	25/342 (7)	317/342 (93)
Standard to be used for information disclosure		
Reasonable doctor standard	165/295 (56)	82/295 (28)
Prudent patient standard	138/291 (47)	107/291 (37)
Responsibility for adequate information disclosure		
Nurse responsibility	196/325 (60)	129/325 (40)
Patients' responsibility	40/326 (12)	286/326 (87)
Nurse & patient jointly responsible	121/325 (37)	204/325 (63)
Time spent on information disclosure		
Sufficient or adequate	185/353 (52)	145/353 (41)
Current hospital consent form		
Satisfactory or adequate	281/345 (81)	42/345 (12)

Understanding and use of implied or presumed consent

When asked if they ever used implied or presumed consent during clinical practice, 41% (112/273) of nurses answered yes, while 59% (161/273) said no. When asked about specific instances when they used implied or presumed consent in practice, 26% (73/280) of nurses said they used it when patients presented at the clinic. Another 31% (87/281) said they used it when patients were admitted to the ward, and 41% (117/284) reportedly used implied/presumed consent in emergencies. However, when nurses were asked to explain what they understood by implied or presumed consent, the majority did not appear to fully comprehend its meaning. Many nurses responded that when patients showed up at a clinical facility to seek help or treatment, this automatically implied consent to treatment. Verbatim responses from nurses included statements such as: *“By routine of the patient coming to the healthcare facility, he is consenting to treatment”* or *“By virtue of the fact that you have sought my help”* and *“patient presents themselves requesting treatment.”*

In terms of overall use of implied/presumed consent in practice, 20% (44/218) of nurses reported using it some of the time or occasionally, 23% (51/218) said they used it seldom or rarely, 16% (35/218) reported using it all of the time, while 40% (88/218) said they never use implied/presumed consent in practice. The reported use of implied/presumed consent by nurses is illustrated in Figure 8. Another 57% (142/248) of nurses reported that they obtain specific permission for some clinical procedures. Examples of procedures listed by nurses where specific consent was required included blood transfusions, lumbar punctures, surgical operations (e.g., tubal ligation), and bone marrow aspiration. Other situations included HIV testing, CT scans, and anything invasive.

Figure 8. Use of implied and presumed consent by nurses



Knowledge of local healthcare laws by nurses

To evaluate the general knowledge of nurses regarding current local laws about IC, I included two specific questions on the questionnaire. On the first question relating to age of consent to medical treatment in South Africa, 30% (99/331) of nurses correctly chose 12 years as the answer, 10% chose 15 years, 55% (183/331) selected 18 years, 3.6% chose 21 years, and 1.2% of nurses were unsure. However, based on the South African Children's Act 2005, the current age of consent to routine treatment in South Africa is 12 years of age (96). On the question about age of consent for termination of pregnancy in South Africa, the majority of nurses, 58% (190/327), indicated 12 years as the correct answer, while only 8% (25/327) of nurses correctly identified any age as the response as stipulated by the *Choice on Termination of Pregnancy Act 1996* (97,98).

DISCUSSION

The study reported here was part of a triangular cross-sectional survey designed to evaluate knowledge and practice of informed consent (IC) amongst doctors, nurses, and patients at selected public hospitals in South Africa (17). According to Creswell (93), survey design provides a quantitative or numeric description of trends, opinions, or attitudes of a particular population by studying a sample of that population. Based on this, a researcher can then draw conclusions, generalize, or make claims on that specific population. Further, cross-sectional studies are commonly used in social science research to measure a particular phenomenon at one point in time in that specific population, sometimes described as one-shot studies (99). Kumar (100) further characterized a cross-sectional study as a study that defines a phenomenon by taking a section of it at any one time.

In this study, I used cross-sectional survey methodology to evaluate the practice of IC (the phenomenon) among professional and staff nurses working in public hospitals in the eThekweni metropolitan municipality, South Africa (the population under study). The rationale for this study was to establish whether South African nurses (professional and enrolled/staff) are knowledgeable regarding the ethical and legal requirements of IC; and whether they are practicing within the current regulatory framework for IC as codified in the NHA (17,34), and other relevant South African ethical guidelines and regulations (3,17,25,35,96-98). Findings from this study suggest that professional and staff nurses practicing at KZN public hospitals are only partially knowledgeable regarding current IC regulations, and implementation in practice may be deficient. For example, most nurses in the study were quite familiar with methods to evaluate patients' capacity using routine mental status exams such as level of consciousness, yet many did not know the current age of consent to routine medical treatment or the age of consent for termination of pregnancy.

Understanding and practice of IC by South African nurses

Based on this study, South African nurses' observed deficiency in knowledge regarding IC regulations was not different between professional and staff/enrolled nurses. Comparison of ICASs (17,19,48) between professional nurses and enrolled/staff nurses showed that professional nurses scored nine on average while staff nurses scored seven. However, this difference between professional and staff nurses was not statistically significant $p = 0.090$. The inadequacies in knowledge regarding IC did not differ based on the years of professional experience. Further, there was a statistically significant difference between doctors' levels of knowledge regarding IC compared to nurses (17,19). However, nurses' knowledge levels were similar to those of physiotherapists and assistants in the KZN province, based on comparisons using ICASs as previously reported (48).

An in-depth analysis of nurse responses from this study showed that nurses were more likely to disclose risks of refusing recommended treatment (80%) and benefits of treatment (71%) rather than overall risks of treatment (69%) and right of refusal (67%). This pattern of information disclosure is similar to those observed among physiotherapists and their assistants practicing in the same public hospitals in the eThekweni municipality, KZN (48). These observed similarities and differences are notable because the NHA (34) does not differentiate between IC practices among different healthcare providers (17,19,34,48). The observations from this study may also reflect similar observations from studies of newly graduated nurses from another South African nursing college, which found that nurses' competence to practice at graduation appeared inadequate (101). While one may argue that because nurses are not routinely required to obtain IC from patients, they may not need to bother about specific details of IC. Nevertheless, the current law, as specified by the NHA (34), requires that every healthcare provider obtain IC from healthcare users before medical treatment (17,25,34), which ultimately includes all registered nurse practitioners (3). This requirement also indicates that knowledge of IC regulations by nurses is not expected to be any less than those of other healthcare professionals, including doctors. This is consistent with the opinion of the UKSC in *Montgomery v Lanarkshire* (33), which argued that:

[...] since a wider range of healthcare professionals now provide treatment and advice of one kind or another to members of the public, either as individuals or as members of a team drawn from different professional backgrounds, with the consequence that, although this judgment is concerned particularly with doctors, it is also relevant, *mutatis mutandis*, to other healthcare providers (33).

On the other hand, one could argue that such criticism of nurses' factual knowledge regarding IC should not be limited to South African nurses alone because studies from other LMICS like Indonesia (12) and Nigeria (102) indicate similar deficiencies in the implementation of IC by practicing nurses, either due to inadequate knowledge or other cross-cultural factors (8,9,12,102). Furthermore, studies regarding nurse performance in developed countries such as Greece, the Netherlands, Korea, and Japan (13-16,21,22), suggest that nurses may not diligently implement all the elements of IC during nursing practice, either due to confusion about nurses' roles in the IC process, or incomplete appreciation of the ethical principle of respect for autonomy and the doctrine of IC in nursing care practice (8,13-16,103-105). It has also been suggested that nurses' roles in the IC process may be multidimensional because of the current emphasis on respect for autonomy over professional beneficence, coupled with greater awareness of patients' rights, dignity, and human rights in healthcare (1-6,39,103,105,106).

Barriers and challenges to informed consent

In this study, respondents' primary barrier to IC was language, as reported by 73% of nurses. Other barriers identified by nurses included lack of education and lack of administrative support in the form of interpreters. These three barriers point to the importance of language in the understanding and practice of IC in multicultural countries like South Africa. It has been reported that language barriers may have deleterious effects on healthcare practice, leading to unfavourable outcomes, such as misdiagnosis, failure of preventive advice, or non-compliance with prescribed medications that could ultimately lead to allegations of medical malpractice against healthcare professionals (17,46-47). In addition, language barriers during IC and clinical practice are not limited to South Africa or LMICs alone, since language barriers in healthcare have also been reported from multicultural developed countries like the USA and Germany (47,107-109). According to a study by Schenker and colleagues (108): "Language barriers are known to complicate many aspects of patient care, including receipt of medical services, patient satisfaction, interpersonal processes of care, comprehension, adherence to prescribed medication regimens, and length of hospital stay" (108, p.294). The study by Schenker et al. also reported that even where interpreter services were readily available, this did not prevent failures to document IC in patients' clinical notes among patients with low English proficiency (108). In another international comparative study between the USA and South Africa within a prehospital ambulatory-care setting. Emergency medical services telecommunicators identified telephonic interpreter services as the single most effective strategy for overcoming language barriers (109). Therefore, the impact of language barriers on the IC process and its potential impact on the overall quality of healthcare service delivery cannot be overemphasized.

One could further suggest that the problem of lack of trained interpreters in South African public hospitals not only detracts from clinical practice but also increases the workload of nurses who may be called upon to act as interpreters on ad hoc basis as part of "cultural brokerage" (9,49). Such additional expectations from nurses, which lie outside their normal job profiles, could be partly responsible for the increased patient workload reported by nurses in this study, leading to the high turnover of nurses due to job pressures, lack of job satisfaction, and moral distress (50-52,84). Other factors identified from this study that may affect IC practice include high unemployment rates and dichotomous healthcare service in South Africa. As previously reported, most healthcare users accessing public healthcare services in South Africa are unemployed or disadvantaged

(17,25,42-43), leading to overutilization of public health services and increased workload for nurses (17,19,42). This may impact the time available for obtaining proper IC and contribute to reported poor job satisfaction, attrition, and moral distress among South African nurses (50-52,84).

Gender norms in South African nursing

Another interesting finding from this study was the comparatively low ratio of male to female nurses who participated, with 26 male nurses (8.41%) and 283 female nurses (91.6%) completing the survey. Comparison of these figures to the number of registered nurses in the KZN province, South Africa, showed that there were 48,079 nurses registered in the categories of professional and enrolled/staff nurse in 2012, of which 4145 were males, representing 8.6% registered male nurses when compared to females, as reported by statistics from the SANC (85). Furthermore, the total number of registered nurses in the male categories in 2019 showed only a marginal increase in the number of registered male nurses (6133) or 10.6%, representing a 2% increase in numbers from 2012 to 2019, based on the SANC registration figures (85), as corroborated by other sources (76-77).

First, the reported participation of male nurses in this study is consistent with the ratio of male to female registered nurses in South Africa (85). In addition, this study highlighted the gender disparity and feminization of the nursing profession in South Africa, as reported elsewhere (73-76). This skewed gender role in nursing, while a global phenomenon (63-66,72,78-81), was reinforced in South Africa by the racial and gender disparities arising during the apartheid regime (6,39,40,73-76), whereby other commentators have suggested that: "Professionalization of nursing in South Africa was part of a broader colonial project of introducing western forms of medicine to the natives [...] consequently, during the colonial period many nursing schools, operating under Nightingale's nursing model (which only admitted white female students), were created throughout the country" (73, p.648). Such practices eventually led to the virtual exclusion of men from the nursing profession, contributing to its depiction as a feminine occupation. Due to the masculine gender identity norms in South African culture, men are not traditionally encouraged to become nurses.

Those who decide to become nurses may sometimes suffer from gender identity crises (73-76), often justifying their choice of the nursing profession as accidental (73). This feminization of the nursing profession is not only prevalent in South Africa, but found globally with women representing over 70% of the HCWs in nursing and social care as reported by the WHO and others (63-64,72,78-81). Notably, in more traditional societies and LMICs worldwide, the nursing profession has become associated with a reserved job for women (63-66,72,78-81). With particular reference to midwifery, colloquially construed as "*sage-femme*," *accoucheuse*" or "woman who assists women in childbirth" (78-79), leading some authorities to conclude that "gender inequality is a pressing human rights and socio-economic issue-and it is also bad for our health" (69, p.1).

From an extensive review of relevant literature (17), one can appreciate that not many empirical studies have critically evaluated the knowledge and practice of IC by nurses in South Africa. In contrast, few other studies evaluated IC knowledge by nurses practicing in Sub-Saharan Africa (SSA) (17,102). The limited number of studies on nurses and IC from SSA have focused mainly on the knowledge and performance of nurses in the context of biomedical research (9,110,111). On IC practice by nurses, fewer empirical studies have been conducted, and are usually in conjunction with doctors (112-116), where nurses appear to play a secondary role, both in their knowledge and application of IC during clinical practice (102,112-116). Recent studies on the knowledge of ethical issues confronting nurses practicing in South Africa appeared to focus on appreciation of issues related to the nurses' pledge (4,5,101), with some reported deficiencies in nursing professionalism (11), which may reflect a superficial understanding of the importance of healthcare laws and ethics by nurses. Some identified ethical dilemmas within the nursing profession in South Africa include deterioration of the nurse-patient relationship, poor job satisfaction, moral distress, and the unprofessional attitudes of some nurse caregivers (4-6,84,101). These observations suggest that the general knowledge of ethics and healthcare laws amongst many nurses in South Africa may be inadequate, with nurses in the auxiliary and junior categories sometimes expressing concern that ethical nursing care practice is emphasized mainly among professional and enrolled nurses (5,6,101). Such observed deficiencies in nurses' knowledge of ethical issues (nursing ethos) and nursing professionalism have been highlighted by recent recommendations for nurse training in South Africa (84), and previously outlined in a report by the Democratic Nurses of South Africa (DENOSA) to the Truth and Reconciliation Commission (TRC) of South Africa 1996 (39), which stated in part:

Ethics content has always been included in nursing curricula. However, it seems that educators have largely not succeeded in teaching this subject so that it had everyday application. While provision is made for the teaching of ethics in the curriculum, nurses do not seem to identify it as significant to their professional role. In one study, it was found that 87% of the research sample indicated that they did not regard the subject Ethos as necessary to their work as registered nurses. It also appeared from interviews that, in teaching the subject, more attention was given to the history of nursing and etiquette than to ethics and professional conduct, and that students perceived the subject as a list of "dos and don'ts" (39, p.110).

Implications for nurse-training in South Africa

Although this study was limited to professional and enrolled/staff nurses in the eThekweni municipality, KZN, South Africa, the study revealed that while many nurses are partially knowledgeable about certain aspects of IC, most were deficient in specific knowledge regarding pertinent legal requirements of IC as stipulated by current South African laws. For example, with regards to the age of consent to routine medical treatment in South Africa, only about 30% of nurses correctly identified the current

age of consent for minors as 12 years (96). The amended *Children's Act* was designed to consider many child-headed households in South Africa in the background of the HIV/AIDS pandemic (17,40,96,117,118). The amended Act provides that minors aged 12 years and above may consent to routine medical treatment, thereby allowing vulnerable children access to therapy and voluntary counselling and testing for HIV/AIDs, in the absence of a parent or guardian (17,96,118). However, refusal of treatment in such cases may still be overruled, based on the magnitude of treatment required. For example, rejection of life-saving organ transplantation would be against a child's best interests and may be overridden by the courts (119).

Similarly, regarding the age of consent for termination of pregnancy (97,98), only 8% of nurses identified the correct response of any age (97). This was surprising, considering that over 92% of participating nurses in this study were females (Table 1). In the context of Africa, nurses are expected to be at the vanguard of providing accurate health advice and information to their local communities, especially women, including reproductive and maternal health advice, consistent with the goals of UN SDGs 3 and 5 (61,63). In addition, nurses represent a majority of healthcare workers globally, including those in LMICs like South Africa (7,62-66). Furthermore, information giving could also be considered an important aspect of the nurses' roles during IC as part of cultural brokerage in resource-constrained settings (9,12,49). Therefore, reports from this and other studies suggest that healthcare law and ethics training may need to be enhanced amongst all categories of nurses in South Africa (4-6,17,39,84,101).

Studies amongst nurses in other LMICs similar to South Africa, like Indonesia, have suggested that nurses have up to four different roles during the IC process. According to a study by Susilo and colleagues (12), nurses' roles in the IC process may include:

- (a) *Manager*: In this role, nurses ensure that the IC is appropriately conducted, including taking responsibility for preparing consent forms, ensuring that both doctors and patients accurately sign the documents, and ensuring that the completed forms are placed in patients' records.
- (b) *Witness*: This role requires nurses to attend meetings between patients, doctors, and family members or surrogates, witness the IC conversation between doctors and patients, and sign the IC document as a witness.
- (c) *Patient advocate*: In this role, nurses can mediate between different parties in the IC process, encouraging patients to ask questions or express any wishes to doctors and other healthcare providers, thereby enhancing the IC process and patient understanding. Similar to the "cultural brokerage" role aforementioned (9,49).
- (d) *Information giver*: In this role, nurses could elaborate on the brief information provided by doctors to assist with patient understanding and compliance with instructions for clinical procedures, e.g., fasting before anesthesia or the proper way to take medications (12, p.417-418).

Furthermore, in developed countries such as the USA and Canada, state laws and nursing councils have given clear guidelines on the role of nurses in the IC process (120-124). For example, the position statement from the New York State Board of Nursing (122) recommends that:

- I. The registered professional nurse's role in informed consent includes that of patient advocate: providing health teaching, health counseling, and support for patients in seeking clarification by the provider of any information that is not clear.
- II. The registered professional nurse must ensure that patient rights are upheld regarding access and the appropriate use of translation services as per state regulations [...]
- III. The registered professional nurse respects the patient's decision, regardless of whether the nurse agrees with that decision. A nurse may choose not to participate in cases in which the patient's decision could harm others, would require the nurse to participate in giving care that is inconsistent with the standards of nursing practice or violates the nurse's conscience. If this occurs, the nurse must then delegate nursing responsibilities to ensure continuity of patient care.
- IV. The registered professional nurse should not participate in any test or treatment in which informed consent of the patient or the patient's health care proxy agent has not been properly obtained as per facility/agency policy.
- V. The registered professional nurse should initiate appropriate action if the established tenets of informed consent are not duly processed and implemented. This action includes, but is not limited to:
 - i. consulting with the responsible healthcare practitioner to seek resolution.
 - ii. utilizing facility/agency's policies, procedures, and channels to assure patient protection and
 - iii. reporting unresolved informed consent issues to the appropriate professional and regulatory bodies.

From the current study, one can also confirm observations of persistent gender disparity in the South African nursing profession, which suggests a need to correct the gender imbalance by encouraging males to join the profession to reduce the shortage of nurses, both locally and globally (7,62-66,69,72-81). Secondly, anecdotal evidence from other studies, suggests that gender may indirectly impact the practice of IC, in the sense that traditional gender roles may encourage males to prefer disclosing information to male nurses, who are considered more masculine and authoritative than female nurses due to socio-cultural norms (72-75). Conversely, female patients in traditional societies like South Africa and Afghanistan (72), for example,

may feel more comfortable discussing healthcare needs with female nurses, especially in nursing domains like midwifery, which could indirectly affect information disclosure and IC practice in Africa, and other traditional societies (69,72-79).

STRENGTHS AND LIMITATIONS

By definition, cross-sectional studies are designed to capture a picture of a segment of the study population at a single point in time, sometimes referred to as one-shot studies (99). Based on such results, a researcher can make generalizable claims or draw pertinent conclusions about that population under investigation (93,99,100). Here, I used survey data from professional and staff nurses at public hospitals in KZN to draw inferences about IC practice in the nursing profession and healthcare services delivery in South African public hospitals. However, this study was conducted over a limited time period (2012) at selected public hospitals in the KZN province. There is ample evidence that this study's findings present broad cross-cultural factors affecting healthcare service delivery and the practice of IC in South Africa, especially from a nursing perspective. These include problems of poorly educated and disadvantaged patients, language barriers in a multilingual society, and skewed gender dynamics in the nursing profession in South Africa. A decade later, these problems have not been completely resolved despite some progress in recent years (17,84). Therefore, the results of this study are still relevant to the nursing profession since they provide a baseline to assist in tackling some of the problems facing healthcare service delivery in South Africa.

Potential limitations of this study may include the fact this study was conducted at selected public hospitals in the eThekweni metropolitan municipality, an urban setting/municipality. A similar survey in more rural or other urban settings in South Africa may yield different results based on the various socio-cultural factors prevalent in different settings. Furthermore, one could forecast that similar studies, if conducted in private, for-profit hospitals in South Africa may yield different results because they are patronized by more knowledgeable, better educated, or well-off patients, who have the means to procure personal healthcare services. Reports from IC studies in more developed countries – such as Greece, which may have similar private healthcare users as South Africa – have shown that doctors and nurses may be more compliant with IC disclosures in private healthcare settings (104). However, another study from Western Cape province in South Africa regarding ethical issues in nursing practice, conducted in private healthcare settings, suggested similar deficiencies in knowledge regarding IC among nurses in private hospitals (5). Therefore, nurses practicing in private hospitals in South Africa are unlikely to be more knowledgeable than those practicing in public hospitals because nurses are generally trained using similar curricula at South African nursing colleges (4-6,84,101,125). However, there could be stricter compliance by nurses working in private hospital settings with current regulations due to the added fear of medical negligence litigation, lower patient workloads, better remuneration of nurses, and more educated and knowledgeable patients.

The data analyzed and presented here were based on professional and staff nurses' self-reporting of IC practices. One can assume that the nurse respondents provided an accurate report of their knowledge and current practice of IC; however, it is possible that the data reported in the questionnaires are not an accurate reflection of IC in practice. Nonetheless, since this survey comprised effects from a large sample size of 355 nurses from randomly selected public hospitals with variable experiences in different nursing domains, it is unlikely that this limitation would have contributed significantly to any bias due to the triangulation of data (17), which have all contributed towards minimizing bias and improving overall study reliability.

Finally, while the current study was designed as a general survey of nurses' knowledge and practice of IC at South African public hospitals, future studies could be directed at the comparison of IC practice in public and private healthcare, or different nursing domains, such as pediatric nursing, midwifery, or theatre nursing, to identify the specific factors influencing IC practice in different nursing specializations in South Africa. A systematic study designed to evaluate knowledge and practice of IC among nurses working in other nursing domains could provide a better understanding of IC practice within different nursing domains in Africa. In addition, future studies could also evaluate the impact of gender dynamics on the nursing profession or IC practice, especially in traditional societies like South Africa.

CONCLUSIONS

This study reveals that overall knowledge of IC regulations was somewhat inadequate amongst all categories of participating nurses. There was no statistically significant difference in knowledge and practice of IC between professional nurses with a minimum of four years of tertiary nursing education compared to staff nurses with a minimum of 2-3 years nursing college education. The findings concerning knowledge of IC regulations by professional and enrolled nurses in South Africa suggest the need to re-emphasize training of all categories of nurses in healthcare law, ethics, and human rights, with a particular focus on the legal and ethical requirements of IC in clinical practice, and knowledge of basic local laws. Despite specific South African regulations requiring all healthcare providers to disclose particular elements of IC to patients before medical treatment, this study suggests that many registered nurses are not fully conversant with basic laws concerning IC. The study also revealed a gender disparity in registered nurse categories, which requires gender transformative initiatives in nurse recruitment and training. Further, the process of IC requires local nurses who often have multiple demands on their time to act as ad hoc/informal interpreters, leading to excessive workload for nurses in public hospitals. Therefore, it may be a prudent public health policy for the government to develop a corps of trained interpreters to assist nurses in their work, which could ultimately result in better job satisfaction, less job attrition among nurses, and improve the overall quality of healthcare service delivery in South African hospitals.

Furthermore, training at all nursing colleges and universities in South Africa may require modification of the nursing curricula to better reflect the roles of nurses, which may include the need for nurses to be proficient in the four roles outlined for nurses, including nurse as manager, patient advocate, witness, and information giver during IC practice. It is also important that all registered nurses understand that they are legally obliged to obtain valid IC from patients when necessary, notwithstanding time constraints, increased workload, or language barriers. Valid IC among vulnerable population groups is critical to ensuring patient safety, and respect for patients' autonomy, dignity, and human rights, compatible with patient-centred healthcare as suggested by the TRC in 1998:

Training in human rights must be a fundamental and integral aspect of curricula for healthcare professionals. This training should address human rights practice factors, such as knowledge, skills, attitudes, and ethical research practices. Knowledge of and competence and proficiency in the standards (both national and international) to which [health professionals] will be held accountable should be a requirement for qualification and registration (39; 6, p.11-12).

Finally, to achieve the global objectives of nursing, which include leading our societies to better health by achieving the UN SDGs and UHC (60-61), it has been suggested by some nurse leaders (66) that the profession ensure that it trains nurses who resemble the populations and communities they serve. Also, it is important to speak out clearly about global health inequities and help developed nations shift from investing most of their healthcare funds in acute care to building healthier communities and encouraging gender transformation in nursing education, especially in developing LMICs.

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None to declare

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S1: QUESTIONNAIRE FOR HEALTHCARE PROFESSIONALS (DOCTORS AND PROFESSIONAL NURSES)

SECTION A: DEMOGRAPHICS

1. Age of the Respondent:

2. Gender

() Male () Female

3. Are you a doctor or a professional nurse? _____

4. Years of professional experience or rank _____

5. Area of specialization, please state _____

6. Department in the hospital _____

7. Public () or Private Practice () _____

SECTION B

8. How many patients do you see on average in a day? _____

9. How much time do you spend giving information about a treatment or procedure in to a patient during a professional encounter?

() < 5 minutes () 5-10 mins
() 10-20 mins () 20-30 mins
() > 30 mins () None

10. Do you think this amount of time is sufficient?

() Yes () No () Don't know

11. If No, Please explain why? _____

12. Do you think the information you provide is sufficient to procure valid informed consent?

() Yes () No () Don't know

13. Do you think the consent form currently used in your hospital is adequate to obtain valid informed consent from patients?

() Yes () No () Don't know

If No, please explain why _____

14. What information do you routinely provide to your patients? Please tick or circle all that apply

() Diagnosis Y or N () Risks Y or N
() Treatment Options Y or N () Benefits Y or N
() Recommended Treatment Y or N () Right of refusal Y or N
() Risks of refusing recommended treatment Y or N
() Costs of medical treatment or each option Y or N

Any additional information? (Please specify) _____

15. Do you allow your patients to choose a procedure or particular treatment?

() Yes () No () Don't know

16. Do you explain the benefits of the procedure to the patient?

() Yes () No () Don't know

17. Do you explain the risks of the procedure to the patient?

() Yes () No () Don't know

18. If yes, what types of risks do you routinely explain to the patient?

A. Most common risks () Yes () No () Don't Know
B. Most serious risks () Yes () No () Don't Know
C. All material risks () Yes () No () Don't Know

19. What language do you use to explain/obtain informed consent from your patients?

- A. English () Yes () No () Don't know
 B. The patients local language () Yes () No () Don't know
 C. Both English and local language () Yes () No () Don't know

20. Which of the following methods do you use to explain/obtain consent from patients? Please tick all that apply.

- () Words () Diagrams
 () Pictures () Interpreter
 () None

21. Do you think your patients understand the explanations given to them?

- () Yes () No () Don't know () Don't think so

22. Do you routinely obtain consent in emergency cases?

- () Yes () No () Don't know () It depends

If you choose it depends, please explain _____

23. How do the patients normally provide consent?

- () Verbally () Written () Both () It depends

If you choose it depends, please explain _____

24. Who obtains informed consent from patients in your practice or clinic?

- A. Nurses
 B. Junior doctors
 C. The doctor performing the procedure/treating the patient
 D. Any available healthcare professional
 E. Don't know

25. What are the challenges you face in the process of obtaining informed consent from a patients in clinical practice?

Please rank in order of importance (where 1 is most important and 7 is least important):

- A. Time constraints ()
 B. Work load ()
 C. Language difficulties ()
 D. Lack of administrative support e. g. interpreters ()
 E. Cultural barriers (). Please specify _____
 F. Lack of education ()
 G. Medical paternalism (Doctor knows best) ()

26. Do you routinely assess the competence of your patients to consent to treatment?

- () Yes () No () Don't know

27. If Yes please rank the following criteria in terms of importance in assessing patient capacity or competence to consent to treatment (where 1 is most important and 5 is least important):

- A. Age ()
 B. Sex ()
 C. Appearance ()
 D. Educational level ()
 E. Level of consciousness ()

28. Do you generally presume that your patients have the capacity to consent to medical treatment?

- () Yes () No () Don't Know

29. In difficult cases, which of the following methods do you/ would you use determine if a patient has the capacity to consent to treatment (Please rank in order of importance where 1 is most important and 6 is least important)

- A. Mental Status Exam () Please specify which one _____
 B. Psychiatric consultation ()
 C. Ethics consultation ()
 D. Court adjudication ()
 E. Surrogates () Please specify _____
 F. None of the above ()

SECTION C. Generic questions on informed consent

30. Do you have any suggestions or recommendations regarding informed consent?

31. At what age can a minor consent to routine medical treatment in South Africa? (Please choose one)

12 years () 15 years () 18 years () 21 years () Don't know ()

32. At what age can a woman request for termination of pregnancy in South Africa? (Please choose one)

12 years () 15 years () 18 years () Any age () Don't know ()

33. In your opinion, which standard do you think should be used for information disclosure before obtaining consent from patients?

- A. Based on a reasonable doctor standard () Yes () No () Don't know
 B. Based a reasonable/prudent patient standard () Yes () No () Don't know

34. Whose responsibility is it to ensure adequate information disclosure before informed consent?

- A. () Doctor or healthcare professionals responsibility
 B. () The patients responsibility
 C. () The patient and healthcare professional are jointly responsible

Section D

35. Do you ever use implied or presumed consent when treating patients? () Yes or () No

If yes, when do you usually use implied or presumed consent?

- A. When the patient present themselves at the Clinic () Yes () No () I don't know
 B. When the patient is admitted to the Ward () Yes () No () I don't know
 C. In an emergency () Yes () No () I don't know

36. What do understand by the term implied or presumed consent?

Implied consent: _____

Presumed consent: _____

37. How often do you use implied or presumed consent when treating patients?

- A. Some of the time or Occasionally ()
 B. All of the time ()
 C. Seldom or Rarely ()
 D. Never ()

38. Do obtain any additional or specific consent for certain procedures? () Yes () No

If yes, please list all or any procedures for which you would obtain specific consent from the patient:

Thank you for your assistance