



Informed Consent: A Complex Process in Iran's Nursing Practice

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Informed consent should not be regarded as a rigid process. Instead, it should be regarded as a flexible process that provides patient with the right amount of information required to facilitate meaningful decision-making. Informed consent is an important ethical and practical part of patient care. Understanding the moral foundation of informed consent can help to guide therapists in their communication with all patients. Nurses, as members of the multidisciplinary team, are currently key contributors in providing information to patients regarding the treatment process. But in this process, there are some challenges that make it difficult. This paper describes the underlying ethical and regulatory requirements as well as related challenges regarding informed consent in the context of a nursing practice in Iran.

Key Words: Informed consent, Ethical challenge, Moral challenge, Nursing ethic, Iran

INTRODUCTION

The importance of informed consent, prior to nursing care procedures, has been highlighted in literature as patient's understanding of clinical informed consent is often poor. The International Council of Nurses promotes a Code of Ethics, which emphasizes on the nurse's role in providing patients with information to support informed consent [1]. In order to gain patient cooperation, it is necessary to inform patients about the anticipated side effects of the treatment. Ethical imperative that obligates us to always tell the truth in all aspects of clinical practice is completely impractical. The consent statement is the primary vehicle for conveying information to patient. In every case, the patient is told what is known about the goals of treatment, the risks of treatment, and the alternatives to treatment. Patients have a right to know about their health, available diagnostic and treatment options and their risks and probable benefits, and to choose alternatives. Patients or their families have a right to decide, in consultation with their physician and other health care providers, which proposed medical interventions they will or will not accept. Meanwhile, there will be more complex judgments in which the outlines of alternative treatments should be explained to patients and they should be reassured that, the decided treatment policy will always be in

their best interests. The patients are given the opportunity to ask questions, and then sign a consent form that has been explained to them [2]. It is important that patients are given the opportunity to read the consent form fully before signing it [3,4]. For many patients and family members, personal values affect the health care decisions, and health care providers have a duty to respect the autonomy, rights, and preferences of their patients and their families. Unfortunately, this is inconsistently realized today. The care that patients receive doesn't always align with their preferences. Our theoretical point of departure is based on ethical perspectives that can be found in different declarations concerning professional ethics particularly in nursing. In this paper, the rationale behind the concept of informed consent and its related challenges in Iran's nursing practice are explained.

The International Council of Nurses (2012) promotes a Code of Ethics, which emphasizes the nurse's role in information giving to support informed consent.

MAIN SUBJECT

1. An Overview

The legal doctrine of informed consent in the Nuremburg Code is a set of guidelines drafted at the end of World War

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II to prohibit medical experimentation on humans in the name of science. Informed consent is grounded on the notion of human autonomy. Every person has a legal right to determine what is done, or not done, to his or her body [5]. Failure to ensure patient's understanding during informed consent is a potential safety issue [6]. The Agency for Healthcare Research and Quality named the confirmation of patient's understanding during informed consent one of 11 priorities of safety initiatives in 2001[7]. All would agree that, a clinician must be able to give advice according to the particular circumstances of the patient, but what if the physician is ill informed or dogmatic? Many regard traditional practices based on the theory that states; "doctor knows best". Legal frameworks have defined current standards of practice for various healthcare professions, including nursing. Nurses, as members of the multidisciplinary team, are currently key contributors in providing information to patients regarding the treatment process. But in this process, there are some challenges that make it difficult.

2. Ethical and legal aspect of informed consent

Too often, health care providers focus on informed consent as a protection from litigation or a legal formality and not as an opportunity to work with the patient to ensure the best outcome [8]. Informed consent to a therapy is a process, rather than a onetime disclosure of information, that occurs in biomedical contexts. In fact, the elements that render a patient-centered and quality-driven consent conversation, such as respect for patient autonomy and clear communication, are the same elements that render a legally sound consent conversation [9]. The law emphasizes on five legally required elements of informed consent, including a discussion of the patient's health status as it relates to the procedure, a description of the procedure itself, and a discussion on the benefits of, alternatives to, and risks of the procedure [10]. It is worth emphasizing that, there are ongoing challenges associated with providing open and honest disclosures in medical practice.

3. Who should obtain inform consent from patient?

In Iranian healthcare system, an informed consent is obtained from all patients prior to the interventional procedure by staff nurses, but, it is legally the duty of patient's own physician to obtain the consent from patient. The primary duty of a physician is to do what is best for his/her patient and he/she may withhold disclosure of information regarding any unwanted consequences of a treatment where full disclosure will be detrimental to the patient's

total care and best interest. If physicians are sure about the correct general policy of management, and if they recommend the treatment according to their judgment or preference, they are excused from any ethical criticism on the grounds of freedom of clinical judgment. Therefore, what was wrong then, is right now. The physician, who truly cares for patients, ought to involve them in decision-making process because it benefits the patients. Some physicians worry that, more stringent information disclosure requirement would risk overwhelming patients with information, causing distress or leading them to make poor decisions, while doctors' time would be taken by lengthy explanations, creating a drain on healthcare resources. The physician's role is to ensure relevant information is presented to patients enabling them to use the information meaningfully [11]. The ethical and legal position is clear that, physicians must not withhold information simply because they disagree with the decision that patient is likely to make if given that information. Here emerges the important role of nursing education that sufficiently emphasizes on the importance of patient autonomy and its various aspects [12]. For healthcare professionals, helping participants to achieve realistic expectations from the procedure is an important part of the informed consent process. Unrealistic hopes or expectations can pose a challenge to understanding. It may also result from the lack of full awareness regarding the extent and impact of limited health literacy. The problem of how a patient is informed about "competing" care paths, when each path is best understood by different physician experts, is a generic problem in all of medicine nowadays [13], and there is a big question: How should we inform the patient? If it's the duty of physicians, so why the nurses are informing the patients and their families? Meanwhile, there is a debate on whether the nurses have enough information and knowledge on the procedure or the process of treatment. Nurses are not technically or even legally responsible for providing information necessary for informed consent as there is an ethical responsibility to look out for the patient's best interest. The nurse's role is both as a witness and as the patient's advocate. As patient advocate, it is the nurses' responsibility to ask questions from the patient to determine whether he or she has received sufficient information to make an informed decision, even though, the nurses often assume the responsibility to make sure client's signature is on the consent form. The nurses are not legally responsible for obtaining the informed consent. Moreover, patients are not sensitive or serious about what nurses tell them. Because Iranian people have a poor image of nursing, and they more trust the information given to them by physi-

cians rather than nurses [14]. When nurses are shown as “doctors’ helper” rather than as patient advocates, they lose credibility [15]. Thus, empowering nurses is essential for enhancing their roles, strengthening their professional image, and continuously improving the health care system.

4. Is the process of obtaining informed consent correct in Iran's healthcare system?

The informed consent is obtained from patients on admission to a hospital/clinic or before a procedure/surgery. Patient must be given basic information about the procedure before signing the consent form; ensuring that, the patient has assented or consented to the intervention. Assent refers to a patient's acceptance of a treatment, intervention, or clinical care. But in admission time, patients and their families are full of stress and that is not a right time to be asked for consent. Is this signature, despite the tensions associated with admission, still considered conscious or voluntary? In order for the patient's consent to be valid, he/she must be considered competent to make the decision and his/her consent must be voluntary. Clients should give their consent voluntarily and should not be impelled to do so. Patients should have a real understanding of the risks that would be involved in their treatment process [16].

The informed consent document must be written in patients' own language and should be easily understood by them. The language must be non-scientific and non-technical, and medical terms must be defined or explained to patient in simple terms [17]. Iranian people speak and write in Persian and there are many Accents and Dialects in Iran that make the Persian language difficult, that is why we need to explain and inform patient thoroughly. Verbal consent still contains all elements of written consent, however, the items of the consent are verbally explained to patient and they agree to undertake the procedure. The nurses use patient's own language or a translator, where available, to provide information on particular procedures to the client verbally.

5. To what extent should patient be engaged in the decision making process

Consistently, as many as 20% of patients, who participate in shared decision-making, choose less invasive surgical options and more conservative treatment than patients who do not use decision aids [18]. Studies also illustrate the potential for wider adoption of shared decision-making to reduce costs. When conducted correctly, informed consent is an example of shared decision-making

[19]. For shared decision-making to be considered a valid method to obtain informed consent, open and honest communication between the patient and multidisciplinary team is essential. Informed consent should not be considered as a onetime paper pushing transaction, but as a dialogic process that continues throughout the treatment. How nurses engage in decision ecology depends on the relationships that nurses develop with members of multidisciplinary team and patients in their care. In line with the Frank study nurses as a key member of multidisciplinary team should involve patients more in the decision-making process [20]. We believe that, more nurses' involvement in this process leads to more shared decision making.

6. How much Patient autonomy is respected in the process of informed consent?

Patient autonomy is one of the key principles of ethical practice in nursing care. An important goal of informed consent is to respect patient autonomy [21]. The professional duty of healthcare providers is to ensure patient autonomy is respected. Health care professionals may fulfil their legal duty while failing in their ethical duty to protect and promote the autonomy of patient. However, there is no agreement as to how autonomy is defined and these varying definitions are well documented in the literature. It is clear that, many nursing procedures have the potential to threaten the autonomy of patients and may be morally significant to them [12]. Procedures which might pose a threat to patient autonomy, if carried out without consent, may not be easily identifiable. It is often assumed that, consent is required only prior to major clinical interventions or an intervention that presents significant risk to individuals [22]. In Iranian health service some hospitals are private and the rest of them are educational. In educational hospitals, patients are required to sign a consent form that states: “I allow my medical information to be used to promote medical education” This is a moral challenge: Has patient's autonomy been respected? Has patient signed the consent form voluntarily or has he/she been compelled to sign the form?

7. Paternalistic challenges

Paternalism is largely the unquestioned bedrock of the healthcare practice. Paternalism is defined as “the interference of a state or an individual with the affairs of another person, against his/her will, and is considered or motivated by the claim that, the person interfered with will be better off or protected from harm”. It is defended on the

grounds that, physicians are the gatekeepers of medical knowledge, as well as the best judges of how to use that knowledge to serve the interests of patients [23]. Paternalism has been one of the traditional characteristics of the therapeutic relationship in medicine. In paternalism, staff should only use their knowledge and skills for the benefit of patient, and never do harm and always act in the patient's best interest [24]. Are we allowed to decide on behalf of the patients? If they do not accept the treatment, are we offering them alternative treatments? Are we aware of patients' interests when we make decision on their behalf? Strong arguments are required in this filed to justify paternalistic action in any professional healthcare context [25]. Healthcare professionals require further trainings on paternalism in order to preserve patient autonomy and right.

8. How much information should be given to patient in the informed consent process?

The process of ensuring that, a patient is adequately informed prior to consenting to a procedure, has become an increasingly difficult task for the nurses. Each possible action needs to be explained fully and understood and consented to by the patient during the consent conversation [26]. Certain aspects of interventional procedures are particularly difficult for some patients to understand. There is a need for balance between too much data, and not enough information to be given to patients. Consent practices may overwhelm patients with potentially irrelevant information. In a study, it was reported that, the average length of time patients were given to express their concerns was only 23.1 seconds [27]. Patients also reported they have received less information than they needed to make an informed decision about their health [3,28]. As a client advocate, the nurses assure that, adequate time is given to client to consider the choice of treatment. Therefore, in everyday clinical practice, patient education prior to an intervention is a frequent task. Additional techniques to enhance patient understanding/comprehension that may be used by a clinician include anatomical models, information pamphlets and videos. The extent of the patient's comprehension and recall with these different methods is varied [29]. We must assess which methods of ongoing education are acceptable for all healthcare providers and efficient in the current healthcare setting.

9. Personal characteristics and informed consent

It may be time to recognize that, ill people process information differently than healthy people. Age, education

level, cultural diversity and illness are all identified as potential characteristics that may make the subject less able to comprehend information given to them during the informed consent process [30]. Level of education, apart from age, also has been found to be a significant factor in the ability of a potential subject to comprehend and recall information provided during the informed consent process [31]. An understanding of cultural differences is also very important for providing quality of care. Nurses must be aware of the need to engage in culturally sensitive practice, to enhance the quality of informed consent process [30,32].

CONCLUSION

By synthesizing and contextualizing the results of a comprehensive literature review, this paper describes the underlying ethical and regulatory requirements as well as related challenges for obtaining informed consent in the context of a nursing practice in Iran. As described earlier, a range of approaches could be found in dealing with these issues. It is hoped that, this document could provide a basis to stimulate debate around consent options in Iranian culture and contribute to promotion of nursing practice in this regard. We will need successful methods of communication training throughout the healthcare providers' careers. Informed consent should not be regarded as a rigid process. Instead, it should be regarded as a flexible process that provides patient with the right amount of information required to facilitate meaningful decision-making. An ethical learning healthcare system must have core commitments to engagement, transparency, and accountability in ways that are keenly sensitive to the rights and interests of patients. Nurses must act as advocates for those in their care and support people's rights to be fully involved in their own healthcare decision-making. Clients also have a right to be fully informed about the efficacy and effectiveness of specific techniques in the therapy. Health care providers should respect the wishes of patients who withhold or temporarily refuse a care in order to gain a better understanding of their situation or to come to terms with fears or other concerns regarding the proposed care. Patients deserve to be fully informed if they are to make autonomous decision regarding treatment modalities.

REFERENCES

1. International Council of Nurses. The ICN code of ethics for nurses [Internet]. 2012. [cited May 25, 2013].
2. Bollschweiler E, Apitzsch J, Obliers R, Koerfer A, Monig S, Metzger R. Improving informed consent of surgical patients using a multi-

- media-based program? Results of a prospective randomized multicenter study of patients before cholecystectomy. *Annals of Surgery*. 2008;248(2):205-211.
<https://doi.org/10.1097/SLA.0b013e318180a3a7>
3. Akkad A, Jackson C, Kenyon S, Dixon-Woods M, Taub N, Habiba M. Informed consent for elective and emergency surgery: questionnaire study. *BJOG*. 2004;111(10):1133-1138.
<https://doi.org/10.1111/j.1471-0528.2005.00669.x>
 4. McNutt L-A, Waltermaurer E, Bednarczyk RA, Carlson BE, Kotval J, McCauley J, et al. Are we misjudging how well informed consent forms are read? *Journal of Empirical Research on Human Research Ethics*. 2008;3(1):89-97.
<https://doi.org/10.1525/jer.2008.3.1.89>
 5. Bal BS, Lawrence H, Brenner JD. Medicolegal sidebar: Informed consent in the information age. *Clinical Orthopaedics and Related Research*. 2015;473(9):2757-2761.
<https://doi.org/10.1007/s11999-015-4440-5>
 6. Shekelle PG, Wachter RM, Pronovost PJ, Schoelles K, McDonald KM, Dy SM, et al. Making health care safer II: an updated critical analysis of the evidence for patient safety practices. *Evidence Report/Technology Assessment*. 2013(211):1-945.
 7. Shojania KG, Duncan BW, McDonald KM, Wachter RM, Markowitz AJ. Making health care safer: a critical analysis of patient safety practices. *Evidence Report/Technology Assessment*. Number 43. Rockville, MD: Agency for Healthcare Research and Quality; 2004.
 8. Schenker Y, Meisel A. Informed consent in clinical care: practical considerations in the effort to achieve ethical goals. *JAMA*. 2011;305:1130-1131. <https://doi.org/10.1001/jama.2011.333>
 9. Bernat J, Peterson L. Patient-centered informed consent in surgical practice. *Archives of Surgery*. 2006;141(1):86-92.
<https://doi.org/10.1001/archsurg.141.1.86>
 10. Tenenbaum EM. Revitalizing informed consent and protecting patient autonomy: An appeal to abandon objective causation. *Oklahoma Law Review*. 2012;64:697-758.
 11. Chan SW, Tulloch E, Sarah E, Smith A, Norman JE. Montgomery and informed consent: Where are we now? *BMJ (Clinical Research Ed.)*. 2017;357:1-3.
<https://doi.org/10.1136/bmj.j2224>
 12. Koller SE, Moore RF, Goldberg MB, Zhang J, Yu D, Conklin CB, et al. An informed consent program enhances surgery resident education. *Journal of Surgical Education*. 2017.
<https://doi.org/10.1016/j.jsurg.2017.02.002>
 13. Hudak JL, McLeod DG, Brassell SA, Gant DA, Shaar S, Hudak RP, et al. The design and implementations of a multidisciplinary prostate cancer clinic. *Urologic Nursing*. 2007;27(6):491-498.
 14. Hajbaghery MA, Salsali M. A model for empowerment of nursing in Iran. *BMC Health Services Research*. 2005;5:24.
<https://doi.org/10.1186/1472-6963-5-24>
 15. Gonzalez L. Nursing and the media: A mission for the center for nursing advocacy. *Nevada Rnformation*. 2005;14(4):21.
 16. Koonrungsesomboon N, Teekachunhatean S, Hanprasertpong N, Laothavorn J, Na-Bangchang K, Karbwang J. Improved participants' understanding in a healthy volunteer study using the SIDCER informed consent form: a randomized-controlled study. *European Journal of Clinical Pharmacology*. 2016;72:413-421. <https://doi.org/10.1007/s00228-015-2000-2>
 17. Joolae S, Faghanipou S, Hajibabae F. The quality of obtaining surgical informed consent Case study in Iran. *Nursing Ethics*. 2017;24(2):167-176.
<https://doi.org/10.1177/0969733015584398>
 18. Stacey D, Bennett CL, Barry MJ, Col NF, Eden KB, Holmes-Rovner M, et al. Decision aids for people facing health treatment or screening decisions. *The Cochrane Database of Systematic Reviews*. 2011;10.
<https://doi.org/10.1002/14651858.CD001431.pub3>
 19. Ripley BA, Tiffany D, Lehmann LS, Silverman SG. Improving the informed consent conversation: A standardized checklist that is patient centered, quality driven, and legally sound. *Journal of Vascular and Interventional Radiology: JVIR*. 2015; 26(11):1639-1646. <https://doi.org/10.1016/j.jvir.2015.06.007>
 20. Frank RK. Shared decision-making and its role in end of life care. *British Journal of Nursing*. 2009;18(10):612-618.
 21. Barry M, Edgman-Levitan S. Shared decision making-pinnacle of patient-centered care. *New England Journal of Medicine*. 2012 366:780-781.
 22. Shahriari M, Mohammadi E, Fooladi MM, Abbaszadeh A, Bahrami M. Proposing codes of ethics for Iranian nurses a mixed methods study. *Journal of Mixed Methods Research*. 2016;10(4):52-366. <https://doi.org/10.1177/1558689815570375>
 23. Bleas1 CR, Lilienfeld SO, Kelley JM. Evidence-Based Practice and Psychological Treatments: The Imperatives of Informed Consent. *Frontiers in Psychology*. 2016;7:1170.
<https://doi.org/10.3389/fpsyg.2016.01170>
 24. Pelto-Piri V, Engström K, Engström I. Paternalism, autonomy and reciprocity: Ethical perspectives in encounters with patients in psychiatric in-patient care. *BMC Medical Ethics*. 2013; 4:49. <https://doi.org/10.1186/1472-6939-14-49>
 25. Rodriguez-Osorio CA, Dominguez-Cherit G. Medical decision making: Paternalism versus patient-centered autonomous care. *Current Opinion in Critical Care*. 2008;14(6):708-713.
<https://doi.org/10.1097/MCC.0b013e328315a611>
 26. Olufowote JO. A dialectical perspective on informed consent to treatment: An examination of radiologists' dilemmas and negotiations. *Qualitative Health Research*. 2011;21(6):839-852.
<https://doi.org/10.1177/1049732311402097>
 27. Marvel M, Epstein R, Flowers K, Beckman H. Soliciting the patient's agenda: Have we improved? *JAMA*. 1999;281(3):283-287.
<https://doi.org/10.1001/jama.281.3.283>

28. Ford S, Schofield T, Hope T. Are patients' decision-making preferences being met? *Health Expectations*. 2003;6:72-80. <https://doi.org/10.1046/j.1369-6513.2003.00211.x>
29. Bowers N, Eisenberg E, Montbriand J, Jaskolka J, Roche-Nagle G. Using a multimedia presentation to improve patient understanding and satisfaction with informed consent for minimally invasive vascular procedures. *The Surgeon*. 2015;15(1):7-11. <https://doi.org/10.1016/j.surge.2015.09.001>
30. Halkoaho A, Pietilä A-M, Ebbesen M. Cultural aspects related to informed consent in health research A systematic review. *Nursing Ethics*. 2016;23(6):698-712. <https://doi.org/10.1177/0969733015579312>
31. Murgic L, Hébert PC, Sovic S, Pavlekovic G. Paternalism and autonomy: Views of patients and providers in a transitional (post-communist) country. *BMC Medical Ethics*. 2015;16:65. <https://doi.org/10.1186/s12910-015-0059-z>
32. Marrone SR. Informed consent examined within the context of culturally congruent care: An interprofessional perspective. *Journal of Transcultural Nursing*. 2016;27(4):342-348. <https://doi.org/10.1177/1043659615569537>