ACCEPTED 15 NOV 18

https://doi.org/10.18295/sQUMJ.2019.19.01.003 SOUNDING BOARD

Female Patients and Informed Consent

Oman's cultural background

Amal A. Al Balushi

المرضى الإناث والموافقة المستنيرة الخلفية الثقافية لعمان

أمل أحمد البلوشية

ABSTRACT: Female patients in Oman face a certain amount of pressure from their families when making high-stakes decisions regarding personal healthcare. In fact, some women waive their right to make decisions, typically giving that responsibility to their husbands or fathers. This article highlights the need to empower females in decision-making when it comes to their own well-being. Moreover, informed consent should not be signed by anyone but the patient herself if the patient is deemed competent by a medical professional.

Keywords: Informed Consent; Female; Decision Making; Clinical Competence; Medical Ethics; Patient Rights; Oman.

الملخص: تواجه المريضات في عُمان قدرًا معينًا من الضغط من أسرهن عند اتخاذ قرارات عالية المخاطر فيما يتعلق بالرعاية الصحية الشخصية. وفي الواقع تتنازل بعض النساء عن حقوقهن في اتخاذ القرارات، ويمنحن عادة تلك المسؤولية لأزواجهن أو لآبائهن. يبرز هذا المقال الحاجة الى تمكين الإناث من صنع القرار عندما يتعلّق الأمر بصحتهن. إضافة على ذلك، لا ينبغي أن يوقع أي شخص غير المريض على الموافقة المستنيرة إذا أعتبر المريض مؤهلاً للتوقيع من قبل مهنى طبى.

الكلمات المفتاحية، الموافقة المستنيرة؛ أنثى؛ اتخاذ القرار؛ الكفاءة السريرية؛ الأخلاقيات الطبية؛ حقوق المريض؛ عمان.

PATIENT WHO SIGNED AN INFORMED CONSENT form cannot be considered informed without comprehending the medical procedure as well as its associated risks and benefits. Patients often turn to their families for opinions and, in some cases, for decision-making. It was observed by the author, during specialised tertiary clinical care, that female patients in Oman typically make medical decisions with their family's approval and only sign an informed consent form after such a discussion. However, male patients, in general, inform their family of their decision and only seek advice or an opinion when the decision affects the family dynamics. As research addressing female consent in Oman is scarce, this article discusses the process of informed consent and addresses female empowerment in informed consent.

"Informed" and Medical Information

Due to the growing accessibility of the internet, a vast amount of medical information is widely available. Patients can easily find information related to their conditions as well as proposed procedures; however, they also risk receiving conflicting or even false information.² This

information overload can hinder a patient's ability to make a decision. Therefore, the role of healthcare providers is extremely important in guiding the patient. Some studies have shown that written information provided to patients before obtaining consent increases understanding.^{3–5} While written forms and informative hand-outs are helpful, they cannot replace discussion or direct communication. A well-informed consent process starts with a good doctorpatient relationship. Communication is vital in this process to ascertain the patient's worries, expectations and social ramifications that may affect the decisionmaking process and the delivery of medical care in general.

Although legal guidelines are important to regulate this process, maintaining good standards of care, preserving patients' rights and actively discussing procedures are essential to the process of obtaining informed consent. Providing a satisfactory explanation for com plete patient understanding should depend on a communicative doctor-patient relationship rather than obligation by the law.⁶ An informed consent document alone may not be sufficient to achieve an adequate level of understanding of the information related to or implications of a medical procedure. Many factors affect a patient's ability to understand the contents of an informed consent document, including their health literacy, culture and level of

Muscat Directorate of General Health Services, Ministry of Health, Muscat, Oman E-mail: amel.albulushi@gmail.com

education. Active discussion is also important in revealing a patient's values and priorities for the healthcare provider to deliver the intervention in a way that suits the patient best. Moreover, a conversation between healthcare provider and female patients may reveal any inconsistencies between the consent and the wishes of the patient, implying that the decision was not autonomous.

The availability of resources via the internet have improved medical literacy.7 Some female patients, however, remain dependant on others for healthcare-related decisions. Therefore, this dependency is due to a lack of female self-ownership rather than information availability. Self-ownership should be empowered by refusing consent from any other parties if the female patient is deemed competent.

Currently, there are no available data in Oman regarding female patients who request others to sign their informed consent on their behalf. It is recommended that this issue be studied and followed up by amendments to policy and procedural documents of informed consent in Oman.8

Decision-Making and Female Patients in Oman

For the purpose of this article, competence and decisionmaking abilities will be considered synonymous. A patient must be competent and autonomous in order to provide informed consent.9 In addition, this process should be voluntary and free of coercion. 10 To establish a person's ability to make a decision, five conditions must be present according to The Stanford Encyclopedia of Philosophy: (1) the person must understand the proposed treatment or management procedure; (2) they must appreciate the significance of the presented facts and the implications of a decision; (3) they should be able to reasonably weigh the risks and benefits of the procedure and its alternatives; (4) they should be able to communicate a decision or choice; and (5) in order to establish capacity, a person needs to have some values against which they can weigh the risks, benefits and have a construct of what is best.¹¹ Furthermore, the capacity for decisionmaking is not a permanent status.12 A patient can lose or acquire this capacity over time depending on the status at the time of decision-making. If a patient is deemed incompetent or lacks decision-making capacity on one occasion, it is necessary to re-assess the patient if there is a suspicion that the decision-making ability has changed. Only the patient has the freedom to decide or to involve others in their decision-making process.

Laws, regulations and policies maintaining women's rights are available in Oman; however, such laws and policies require periodical assessment and modification, if necessary.¹³ Physicians need to start encouraging the independency of women from their families, especially male members.

Oman has a collectivistic and family-oriented culture, which creates a strong social support system for patients, where family members support each other in difficult times. However, collectivism may limit the rights of the individual. Patients in Oman, as in other places, depend on their family for high-stakes decisions such as in cases of cancer or surgery.⁶ Dependent women in Oman tend to rely on their husbands, fathers or brothers, while elderly patients rely on their sons.

Many cultures have a patriarchal society.¹⁴ A study from China, also a country with a collectivistic culture, revealed that the majority (77.3%) of adult female patients preferred their family to make decisions on their behalf.¹⁵ In Saudi Arabia, patients preferred the involvement of their families when dealing with a diagnosis of a terminal or chronic illness.16

It was previously suggested that the dependence of female patients on their families may be attributed to their psychosocial development and that females develop a sense of autonomy at a slower rate than males due to societal influences.¹⁷ This development is probably much slower in patriarchal societies that encourage dependence, rendering females unable to develop their autonomy even later in life as adults. To maintain cultural integrity, female patients should choose if they wish to consult with their family members; however, the final decision on consent should be hers alone.

While respecting the freedom patients have to consult family when making high-stakes choices, healthcare providers should maintain a patient-centred approach. The focus should remain on the patient, and the healthcare provider should remind the family and the public that competent individuals are responsible for their own decisions as they are the ones who will be most affected by the consequences. However, some cultural limitations in Oman affect the validity of female consent. Especially in cases of tubal ligations or hysterectomies, for example, the consent of both the male and female partner should be sought. Education plays a role in mediating this cultural norm of female reliance on male family members.¹⁸ However, if a female child learns that her opinions do not matter, she may stop expressing them.

Standardising Informed Consent Forms in Oman

Informed consent documents are legal contracts. In Oman, these forms need improvement to enforce the autonomy and decision-making ability of competent patients. The standardisation of forms and procedures should apply to both genders as this would enforce equality of care regardless of the patient's gender. Document standardisation should be carried out nationally and across medical and surgical specialities. Different specialties might be encouraged to design preset forms for common procedures in their departments. Some departments of some hospitals in Oman have accomplished document standardisation through individual and team efforts. Standard forms might include a description of the procedure, indications, steps, complications and post-operative care. These forms can be given to patients during the pre-operative period and preferably in the outpatient department prior to admission, which would help them make an informed decision.19 However, there should be sufficient time between the patient receiving such a form and the procedure itself.

To ensure comprehension in complex interventions, patients might need to be informed on multiple occasions. For example, patients might be informed both at the outpatient clinic visit and pre-operatively as an inpatient. Complex medical terminology must not be used in the informed consent document or during discussion.19 Moreover, the informed consent document should be written in the language used most commonly in the country or region. If a patient cannot read or understand the language, a translation should be provided by professional medical translators. The current practice in Oman regarding translation is to acquire help of any willing and available person from the medical team regardless of the level of experience in translation. Using inexperienced individuals for translations might lead to gaps in information or the use of incorrect terminology which may affect the meaning of the consent form and, therefore, the patient's understanding of the procedure.

Standardised forms should be accessible to the public through the Ministry of Health's website as resources for patients so they have ample time to review the information in the consent form, including how the procedure is performed and specific side effects. It is important to actively involve patients in preparing these standardised forms as they will be the end users. In addition, patient input and feedback should also be sought after publishing these documents to ensure their usability. These forms and their accompanying educational information could be supplemented with an animated video; Flory et al. have shown that this improves patient comprehension.²⁰

Furthermore, special attention should be given to who is receiving the consent from the patient. Commonly, consent is taken by junior members of the team, such as residents or interns; however, this task should not be delegated to a junior doctor and the surgeon performing the procedure should be the one to obtain consent.²¹

Conclusion

Female patients should be empowered to make their own health-related decisions. Paternalistic practices on the part of family and healthcare providers should be discouraged. Decisions need to be made free from coercion or pressure and without any imposed limitations on the patient's decisions by family members; this needs to be made clear to the public. While advice and guidance from family members may be sought, the final decision needs to be made by the patient. Literature reporting on this issue in the Middle East is scarce. In Oman, investigations of informed consent and female patients should start by assessing the perceptions and practices of female patients regarding informed consent. Research should be directed toward addressing the gap in the literature in the area of female consent not only in Oman, but internationally.

ACKNOWLEDGEMENTS

The author would like to thank Dr Abeer Al Mamari (Director of Patients' Services and Clients at the Ministry of Health, Oman) for her input and valuable comments and Ms Lesley Carson for her assistance in editing the manuscript.

References

- Sherlock A, Brownie S. Patients' recollection and understanding of informed consent: A literature review. ANZ J Surg 2014; 84:207-10. https://doi.org/10.1111/ans.12555.
- Berger, K. Informed consent: Information or knowledge? Med Law 2003; 22:743-50.
- Friedman M, Arja W, Batra R, Daniel S, Hoehn D, Paniz AM, et al. Informed consent for blood transfusion: What do medicine residents tell? What do patients understand? Am J Clin Pathol 2012; 138:559-65. https://doi.org/10.1309/AJCP2TN5 ODILYGOR.
- Court EL, Robinson JA, Hocken DB. Informed consent and patient understanding of blood transfusion. Transfus Med 2011; 21:183-9. https://doi.org/10.1111/j.1365-3148.2011.01069.x.
- Sahin N, Oztürk A, Ozkan Y, Demirhan Erdemir A. What do patients recall from informed consent given before orthopedic surgery? Acta Orthop Traumatol Turc 2010; 44:469-75. https://doi.org/10. 3944/AOTT.2010.2396.
- Lee WH, Kim IS, Kong BH, Kim S, Lee S. Probing the issue of informed consent in health care in Korea-Concept analysis and guideline development. Asian Nurs Res (Korean Soc Nurs Sci) 2008; 2:102-12. https://doi.org/10.1016/S1976-1317(08)60034-1.
- Egbert N, Nanna KM. Health Literacy: Challenges and Strategies. OJIN: The Online Journal of Issues in Nursing 2009; 14:3. From: http://ojin.nursingworld.org/MainMenuCategories/A NAMarketplace/ANAPeriodicals/OJIN/TableofContents/Vol 142009/No3Sept09/Health-Literacy-Challenges.html. Accessed: Nov 2018.
- Directorate General of Quality Assurance Centre, Ministry of Health. Policy & procedure of informed consent. From www. moh.gov.om/documents/10181/667459/Policy+%2 6+Procedure+of+Informed++CConse.pdf/ae580ace-5afe-4035-89a0-8898569d2b01 Accessed: Nov 2018.

- 9. Slovenko R. Informed consent--A ploy? Med Law 1997; 16:651-3.
- 10. Eyal N. Informed consent. From: plato.stanford.edu/archives/ fall2012/entries/informed-consent/ Accessed: Nov 2018.
- 11. Charland LC. Decision-making capacity. From: https://plato. stanford.edu/archives/fall2015/entries/decision-capacity/ Accessed: Nov 2018.
- 12. Ganzini L, Volicer L, Nelson WA, Fox E, Derse AR. Ten myths about decision-making capacity. J Am Med Dir Assoc 2004; 5:263-7. https://doi.org/10.1097/01.JAM.0000129821.34622.A2.
- 13. Women in Oman. From: https://www.oman.om/wps/wcm/con nect/EN/site/home/gov/gov12/gov1204/ Accessed: Nov 2018.
- Sherwin S. No longer patient: Feminist ethics and healthcare. Philadelphia, Pennsylvania, USA: Temple University Press, 1992. P17.
- 15. Li X, Xing Y, Lin Q, Wei L, Dong M, Ma X, et al. Female cancer patients' awareness and role in family-based medical decision making mode in Confucian area. J Clin Oncol 2016; 34:237. https://doi.org/10.1200/jco.2016.34.26_suppl.237.
- 16. Mobeireek AF, Al-Kassimi F, Al-Zahrani K, Al-Shimemeri A, al-Damegh S, Al-Amoudi O, et al. Information disclosure and decision-making: The Middle East versus the Far East and the West. J Med Ethics 2008; 34:225-9. https://doi.org/10.1136/ jme.2006.019638.

- 17. Tong R, Williams N. Feminist ethics. From: plato.stanford.edu/ archives/win2016/entries/feminism-ethics/ Accessed: Nov 2018.
- 18. McGinn KL, Eunsil O. Gender, social class, and women's employment. Current Opinion in Psychology 2017; 18:84-8. https://doi.org/10.1016/j.copsyc.2017.07.012.
- Anderson OA, Wearne IM. Informed consent for elective surgery--What is best practice? J R Soc Med 100:97-100. https://doi.org/10.1258/jrsm.100.2.97.
- Flory J, Emanuel E. Interventions to improve research participants' understanding in informed consent for research: A systematic review. JAMA 2004; 292:1593-601. https://doi.org/10. 1001/jama.292.13.1593.
- 21. Department of Health. Reference guide to consent for examination or treatment. From: assets.publishing.service.gov.uk/g overnment/uploads/system/uploads/attachment_data/ file/138296/dh_103653__1_.pdf Accessed: Nov 2018.