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## The Effect of New Model PREPARED on Obtaining Informed Consent Skill in Midwifery Students of Shahid Sadoughi University of Medical Sciences

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### Abstract

#### Background:

Professional ethics culture should be taught to students appropriately. Studies have shown that midwifery students are not entirely familiar with the skill of obtaining informed consent. Using a new and applicable model to teach this skill to midwifery students is necessary. This study was conducted to determine the effect of a new standard model, PREPARED, on the skill of obtaining informed consent in midwifery students of Shahid Sadoughi University of Medical Sciences.

#### Materials and Methods:

This interventional study was conducted on 37 5<sup>th</sup> semester midwifery students through a census method. After determining psychometric indices, in two phases with a 4-week interval (before and after the training), the PREPARED checklist was completed by the professors of the research team in the presence of students in the delivery room while they were performing midwifery care considering their compliance to the checklist. Descriptive statistics paired *t*-test were used for data analysis.

#### Results:

The lowest mean score before the training belonged to alternative methods (1.00) and treatment expenses (1.00). After the training, treatment plan had the highest mean score (3.54 (0.69)). The mean and standard deviation of scores before and after training the students were 9.12 (2.00) and 30.6824 (5.25), respectively. Based on the results of the paired *t*-test ( $P = 0.001$ ), the difference was statistically significant.

#### Conclusion:

Results showed that the implementation of the new model of PREPARED would increase the skill of obtaining informed consent in midwifery students and could be applied for educating students of other medical majors in Iran.

**Keywords:** Education, informed consent, Iran, medical professionalism, midwifery

### Introduction

Informed consent is an important ethical and clinical part of patient's care, and has legal, juridical, and medical requirements in all countries including Iran. According to the law, treating a patient without their consent is considered assault and battery.[1] Informed consent is a series of activities which would be applied for sharing information, making decisions, retention of information, and answering patient's questions regarding their treatment and care.[1,2,3]

Students must learn many academic and practical skills such as making effective professional communication, team work, and providing services for the patients based on the principles of professional ethics.[4] Considering the standards of care, such as understanding the principles of professional ethics, of which taking informed consent is considered as one of the most important ethical and legal principles, is of significant importance and has been extensively emphasized in scientific references of obstetrics and gynecology.[5] Recently, in the standard health care plan of the joint commission of Medicare, the method of declaration or speak up has been used, and one of the inventions of the University of California is designing the PREPARED checklist, where each letter of the name refers to a specific action that is a part of the informed consent process.[5] Previous studies have shown that executing this educational model would improve the process of taking informed consent, and 80% of the health providing organizations which participated in this project have evaluated this educational program as good or excellent.[6,7]

Considering the emphasis on distributing professional ethical culture as a principle in the documents of comprehensive scientific map of the country and presenting the modern package of healthcare reform by ministry of health and medical educations,[8] ethical professionalism, including taking informed consent, must clearly be taught to the students and evaluated.[9] Some of the professors do not have the sufficient knowledge and skill for teaching subjects, for which they need specific educational courses.[10] In addition, there are few data about students' experiences, comfort, and access to such trainings.[11] The effectiveness of the process of taking informed consent has not been well realized and studied.[12]

Based on the results of previous studies which indicate students' lack of knowledge about taking informed consent from patients, which is a legal and ethical action, and not conducting it would not only harm the patient but can also have consequences in prosecution and other undesirable results, it seems that previous methods has not been appropriate; using a simple, modern, applicable, and integrated method for training students is necessary. This study was conducted to determine the effect of training the modern pattern of PREPARED on the skill of obtaining informed consent among midwifery students.

## Materials and Methods

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This interventional study was conducted in the nursing and midwifery faculty of Shahid Sadoughi University. From 38 5<sup>th</sup> semester bachelor midwifery students, 37 met the inclusion criteria (being a student of the 5<sup>th</sup> semester for bachelor of nursing and midwifery at Shahid Sadoughi University of Yazd, not being a guest or transfer student, having passed the theoretical courses on pregnancy and delivery at nursing and midwifery faculty of Shahid Sadoughi University, and having practiced at clinical skills center of nursing and midwifery faculty of Shahid Sadoughi University with relevant professors) who were selected through census method. Data were collected through a two-part questionnaire including personal information and the PREPARED questionnaire (Berk 2012);[5] its translated version published by Golban publications was used. Qualitative face validity of the checklist was first evaluated through a pilot study on midwifery students of different semesters who did not participate in the main study, and the level of difficulty, ambiguity, and relevance to the subject of the study for all the 8 items of the checklist were defined as appropriate and comprehensible. Then, its content validity index was defined by 6 professors of nursing and midwifery faculty to be content validity index (CVI) = 0.93 and its correlation coefficient was  $r = 0.88$ . Then, after training the members of the research team and conducting the necessary coordination regarding the method of completing the checklist, the checklist was completed for all the 37 students who participated in the study imperceptibly regarding their level of conformity. After a 60-minute training, the PREPARED model was taught to the students through speech and PowerPoint presentation by the main researcher. Four weeks after the training, the checklist was completed again at the same time by the researchers at delivery room to evaluate participants' level of conformity. Scoring was based on a 4-point scale, where 1 was equal to nonconformity, 2 was low conformity, 3 was medium conformity, and 4 was complete conformity.

The lowest possible score was 8 and the highest was 32. Because of imperceptible evaluation, informed

consent was gained from the students after the study. Data analysis was conducted through descriptive and inferential statistics such as paired *t*-test. The level of statistical significance was set at 0.05.

### Ethical considerations

All participants were made alert of the purposes of the study, and their complete informed consent was gotten based on the Ethics Committee of Shahid Sadoughi University of Medical Sciences (ir.ssu.rec.1394.159).

### Results

The mean and standard deviation of students' age was 21 (0.3) years. The mean of total grade point average of the students was 15.72. The mean score of theoretical courses about pregnancy and delivery was 17 (2.3). A total of 24.3% of the students were married, 78% were highly interested in the major of midwifery, and 73% of them were highly passionate about delivery and pregnancy courses. The lowest mean scores before the training belonged to lateral methods (1.0000) and treatment costs (1.0000). After training, the highest mean score belonged to treatment plan (3.5405 (0.69100)). The mean scores of students before and after training were 9.1250 (2.00607) and 30.6824 (5.25352), respectively, and the difference between them was statistically significant according to paired *t*-test ( $P = 0.001$ ) [Table 1].

### Discussion

In the present study, the lowest score of students before the training belonged to mentioning lateral methods and treatment costs, followed by treatments' expectations and risks. In this regard, in a study, only 60% of the patients realized the aim and nature of the informed consent process, and 55% were able to mention one of the risks or side effects of the treatment.[13] In another study, the lowest level of awareness belonged to patient's knowledge about the advantages and disadvantages of lateral therapeutic methods.[14]

In most of the previous studies, informing patients about lateral therapeutic methods was one of the unmentioned items in obtaining informed consent; these results are similar to the results of the present study. Not mentioning the costs of treatment had the lowest score in the present study, which despite its importance, has not been mentioned in any of the other studies. It seems that the differences in the gained scores between the present study and other similar studies could be due to effective variables on taking consent such as patients' educational level, the time of taking the consent, the person who takes the consent, and other factors relevant to taking consent. The process and methods of taking informed consent should fundamentally change based on spatial and temporal conditions and patients' educational level.[14]

Although ethics lesson plan exists in almost all medical educational programs around the world, its contents and presentation methods have not been clearly discussed.[15] In a study, only 5% of the residents reported talking to patients about the 5 main parts of informed consent.[3] In another study, most of the residents mentioned that they were not prepared to talk about the risks of processes such as draining the cerebrospinal fluid.[11]

It seems that informed consent form rarely contains all the key points, advantages, therapeutic processes, risks, possible consequences, and alternative therapies.[3] Hence, it is considered to use one comprehensive consent form which, while being brief, contains all the key points and is simple and comprehensible. Interventions that constantly improve the necessary knowledge and skills for taking informed consent must widely be used and promoted.[2]

Audiovisual interventions by themselves or along with other methods such as written forms, internet, CDs, video recordings or verbal speaking could be helpful.[16] One simple consent form would cause less fear in patients and could be understood by them more easily. In this regard in a study two consent forms of Southwestern Oncology Group (SWOG) and Louisiana State University (LSU) were used. Participants preferred the LSU form to the SWOG form and believed that it was simpler to understand.[17]

This study tried to evaluate the effect of PREPARED checklist, which was applicable and practical for all the receivers of consent forms and did not have problems inherent in other forms such as being long, not being able to recall all the important points of the consent, and being difficult in use for all the patients, nurses, and students. Results of the present study indicated the effect of the educational intervention using

PREPARED checklist, and it was revealed that this method could easily be used by the students. Among the items of the PREPARED checklist, the highest score after the intervention belonged to conformity to treatment plan. Because no relative Iranian studies were available on this subject, the present results would be compared with the results of foreign studies.

In a study the effectiveness of PREPARED model was approved and it was recommended that wide use of similar interventions could be families, health care providers, and patients.[6] In a study, an innovative educational tool which was named speaking book was used for the intervention group. Comparing the level of awareness between the intervention and the control group revealed that the participants of the intervention group were more aware about the content of the consent from.[18] In another study which studied obtaining informed consent before surgery, one group received verbal trainings whereas the other group received pamphlets along with verbal trainings. Result showed that educational intervention, regardless of age, sex, and educational level, would improve information recall.[19] In another study, group educational intervention before surgical consultation was able to significantly improve the quality of decision making for selecting treatment and informed consent compared to the usual trainings before surgery.[20]

Studying related researches to training students showed that, in an interventional study which was conducted among two groups of students, the group that received communicational skills training at the end of the course had higher recall of information for taking informed consent.[21] One study used skills-based training for interns for taking informed consent, which resulted in statistically significant difference in the method of taking informed consent and also the total knowledge about the content of informed consent after training.[15]

In general, it could be stated that according to all the conducted studies, effective interventions and different interventional and educational methods could improve the skills for taking informed consent, which is in line with the results of the present study. It appears that training has an undeniable role in improving the process of taking informed consent and new, easy to use, with more capacity for learning methods should be used to train students who are responsible for taking informed consent from patients. It appears that PREPARED model has all of these characteristics.

One of the limitations for this study could have been students' absence during pre-intervention and post-intervention duration; however, in the present study no student was absent.

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## Conclusions

It seems that the modern model of PREPARED, which is designed based on new scientifically validated sources, could be used as a standard, low cost, effective, and simple method; because it does not need any specific training equipment, it could be used in midwifery, other medical majors, private practices, local regions, and internationally. It is recommended to evaluate the comprehensibility of this checklist by patients in further studies.

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## Conflicts of interest

There are no conflicts of interest.

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## References

1. Parsapoor MB, Ghasemzadeh SR. Legal and Jurisprudential study of patients' informed consent and physicians' duty of notification: A comparison between Iranian, English and French law. *J Med Ethics History Med.* 2012;5:39–50.

2. Kinnerley P, Phillips K, Savage K, Kelly MJ, Farrell E, Morgan B, et al. Interventions to promote informed consent for patients undergoing surgical and other invasive healthcare procedures. *Cochrane Database Syst Rev.* 2013;7:CD009445.
3. Binder AF, Huang GC, Buss MK. Uninformed consent: Do medicine residents lack the proper framework for code status discussions? *J Hosp Med.* 2016;11:111–6. [PubMed: 26471452]
4. Levi A. The ethics of nursing student international clinical experiences. *J Obstet Gynecol Neonatal Nurs.* 2009;38:94–9.
5. Berek JS. *Novak's Gynecology.* 15th Edition. Amazon: Lippincott Williams and Wilkins; 2012. p. 42.
6. Ephraim PL, Powe NR, Rabb H, Ameling J, Auguste P, Lewis-Boyer L, et al. The providing resources to enhance African American patients' readiness to make decisions about kidney disease (PREPARED) study: Protocol of a randomized controlled trial. *BMC Nephrol.* 2012;12:135. [PMCID: PMC3489555]
7. The joint commission. *Speak Up program.* 2010. [Last accessed on May 2015]. Available at: <http://www.the Joint Commission.org/general public/Speak Up/about- Speak Up.htm> .
8. Ministry of Health and Medical Education. *New innovation packages in medical education.* [Last accessed on 2015 May 14]. Available at: <http://behdasht.gov.ir/uploads/basteha%20%20v12.pdf> .
9. Gadre VN, Kelkar KV, Kelkar VS, Jamkar MA. Introducing a teaching module to impart communication skills in the learning anaesthesiologists. *Indian J Anaesth.* 2015;59:369–75. [PMCID: PMC4481757] [PubMed: 26195834]
10. Steinert Y, Mann K, Centeno A, Dolmans D, Spencer J, Gelula M, et al. A systematic review of faculty development initiatives designed to improve teaching effectiveness in medical education: BEME Guide No.8. *Med Teach.* 2006;28:497–526. [PubMed: 17074699]
11. Nickels AS, Tilburt JC, Ross LF. Pediatric resident preparedness and educational experiences with informed consent. *Acad Pediatr.* 2016;16:298–304. [PubMed: 26459695]
12. Jimison HB, Sher PP, Appleyard R, LeVernois Y. The Use of Multimedia in the Informed Consent Process. *J Am Med Inform Assoc.* 1998;5:245–56. [PMCID: PMC61298] [PubMed: 9609494]
13. Cassileth BR, Zupkis RV, Sutton-Smith K, March V. Informed consent: Why are its goals imperfectly realized? *N Engl J Med.* 1980;302:896–900. [PubMed: 7360175]
14. Nematolahei M, Sakhdari A. Amount of obtained informed consent from the hospitalization patient to selected hospitals in Shiraz city. *Health Information Manag.* 2015;6:689–98.
15. Moon MR, Hughes MT, Chen JY, Khaira K, Lipsett P, Carrese JA, et al. laboratory experience for surgery interns. *J Surg Educ.* 2014;71:829–38. [PubMed: 25012607]
16. Ryan RE, Prictor MJ, McLaughlin KJ, Hill SJ. Audio-visual presentation of information for informed consent for participation in clinical trials. *Cochrane Database Syst Rev.* 2008:CD003717. [PubMed: 18254029]
17. Davis TC, Berkel HJ, Holcombe RF. Informed Consent for Clinical Trials: A Comparative Study of Standard Versus Simplified Forms. *J Natl Cancer Inst.* 1998;90:668–74. [PubMed: 9586663]
18. Castelnovo B, Newell K, Manabe YC, Robertson G. Multi-Media Educational Tool Increases Knowledge of Clinical Trials in Uganda. *J Clin Res Bioeth.* 2014;5:165. [PMCID: PMC4004932] [PubMed: 24795832]
19. Chan Y, Irish JC, Wood SJ, Rotstein LE, Brown DH, Gullane PJ, et al. Patient Education and Informed Consent in Head and Neck Surgery. *Arch Otolaryngol Head Neck Surg.* 2002;128:1269–74. [PubMed: 12431168]
20. Causarano N, Platt J, Baxter NN, Bagher S, Jones JM, Metcalfe KA, et al. Pre-consultation educational group intervention to improve shared decision-making for postmastectomy breast reconstruction: A pilot randomized controlled trial. *Support Care Cancer.* 2015;23:1365–75. [PubMed: 25351455]

21. Werner A, Holderried F, Schäffeler N, Weyrich P, Riessen R, Zipfel S, et al. Communication training for advanced medical students improves information recall of medical laypersons in simulated informed consent talks: A randomized controlled trial. *BMC Med Educ.* 2013;1:13:5. [PMCID: PMC3598682]

### Figures and Tables

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**Table 1**

Items of checklist	Mean and SD of scores before training	The least scores before training	The most scores before training	Mean and SD of scores after training	The least scores after training	The most scores after training	P
P: Plan	1.48 (0.60)	1.00	3.00	3.54 (0.69)	2.00	4.00	P=0.001*
R: Reasons	1.67 (0.66)	1.00	3.00	3.48 (0.73)	2.00	4.00	P=0.001
E: Expectation	1.08 (0.27)	1.00	2.00	3.16 (0.98)	1.00	4.00	P=0.005
P: Preferences	1.62 (0.86)	1.00	3.00	3.51 (0.65)	2.00	4.00	P=0.001
A: Alternatives	1.00 (0.00)	1.00	1.00	3.05 (0.97)	1.00	4.00	P=0.005
R: Risks	1.08 (0.27)	1.00	2.00	3.48 (0.76)	2.00	4.00	P=0.001
E: Expenses	1.00 (0.00)	1.00	1.00	3.21 (0.67)	1.00	4.00	P=0.001
D: Decision	1.43 (0.68)	1.00	3.00	3.48 (0.50)	3.00	4.00	P=0.001
Total	9.12 (2.00)			30.68 (5.25)			

Paired Samples t-test; \*

Comparison of means scores before and after education of PREPARED to midwifery students

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