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Development of an Informed Consent Form for Intrauterine Device (IUD) Insertion Using the Delphi Method

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ABSTRACT

Background & Aim: The intrauterine device (IUD) is a widely used reversible contraceptive with risks such as expulsion or infection, necessitating informed consent. There is a gap in studies on informed consent forms for IUD placement. This study uses the Delphi method to create a comprehensive consent form tailored for IUD insertion.

Methods: This research was conducted at Yazd University of Medical Sciences (2019-2018) using the Delphi technique. Thirty experts, including gynecologists, midwives, and reproductive health specialists, participated in three Delphi rounds. A draft consent form was prepared based on literature studies, previous research, and expert opinions. The Delphi rounds aimed to establish necessity, determine item importance, and gauge expert agreement.

Results: Three Delphi rounds were conducted with 28, 24, and 24 participants, respectively. The consent form, designed in nine areas, was reviewed and refined. Items with 75% agreement or more were accepted in the first round, while those with 25% agreement or less were removed. The second and third rounds considered agreement levels above 75% and change rates below 15%. An acceptable consensus above 51% was reached, resulting in a finalized consent form with five sections: demographic characteristics, general IUD placement features, contraindications, patient responsibilities, and declaration of consent.

Conclusion: Implementing the informed consent form in the clinical process of IUD placement is essential for respecting client autonomy, minimizing risks, addressing clinical consequences, and fulfilling legal responsibilities. Research on the use of the designed form in patients desiring an IUD is suggested.

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Introduction

The Intrauterine Device (IUD) is a reversible contraceptive method used worldwide, second only to tubal ligation in terms of popularity (1). Approximately , 14.5% of women in developing countries and 7.6% in developed countries use this method (2). In Iran, 13.57% of women relied on this method in 2011 (3). IUDs offer many health benefits and usually do not interfere with diseases treatment, and it has a low failure rate (less than one percent) (4). Copper IUDs emerged in different types in the late 1960s, of which the Tcu380A model was the most effective (5-6).

Despite its effectiveness, IUD insertion, experienced by approximately 40 million women annually, may cause pain, discomfort, and

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complications such as the risk of uterine rupture and bleeding (7). The rate of uterine perforation or rupture caused by IUS is about 6.1%, 15% of which may cause perforation of hollow organs, and about 1% to 3% of women may suffer from uterine perforation (8) is still the most serious complication of IUD. This complication was first described by Murphy in 1933. Dysmenorrhea and increased bleeding during menstruation are also the causes of the withdrawal of copper IUDs to 10-15% (9). Given these potential complications, IUD insertion is considered invasive, necessitating skilled health care providers who adhere to, ethical standards by full informatingwomen about the procedure and its associated risks (10). Indeed, it seems that women should be able to choose this method with full knowledge and consent. There is no need to say that any medical examination and procedure should be done with the client's consent unless it is an emergency (11).

To uphold the ethical standards, obtaining informed consent is one of the main components of client rights in health care centers and the basis of medical ethics. The importance of informed consent is well known. This matter has been stated in the codes of ethics in medical science research of the Islamic Republic of Iran in clauses 1, 3, 4, 22, and 25 and several other clauses have also implicit references to it (12-13). Informed consent is the free and terminable agreement of a competent person to actively participate in the decision-making process after gaining knowledge of its nature, purpose, and consequences, believing in the effectiveness of the participation in choosing the most effective and beneficial available treatment method (14). Therefore, obtaining informed consent may indicate the characteristics of a clinician and altruistic service provider who respects the client's freedom and rights to choose and does not allow himself/herself to intervene before providing information to the client (12).

Informed consent requires six prerequisites: providing information, understanding, being voluntary, ability to make decisions, signing the informed consent form, factors related to interaction, and the clinician-client relationship. For the first time in 1981, the American Medical Association emphasized informed consent as a social right to empower the client to make an independent choice of treatment or test even against the clinician's decision (15). The World Health Organization has also determined rights for clients, including the rights of informed consent, autonomy, or independence of vote, protest, complaint, and compensation (16). Informed consent is a kind of interaction and relationship between client and clinician to make decisions about a treatment method (17). While implicit or verbal consent suffices for basic medical services, invasive procedures like diagnostic and therapeutic interventionsnecessitate informed consent, detailing procedures, complications, and risks (11-12).

The review of previous studies has indicated a significant relationship between obtaining informed consent and appropriate clinical outcomes including improved mental health, resolution of symptoms and pain, improved client functions and physiological factors. The results of these studies showed that clients cooperated more in taking medications and were more satisfied with the treatment process (18). Mahmoodiyan et al. studied the level of consent obtained from clients undergoing gynecological surgery and showed that the clients' participation in clinical decision-making was 57%. In addition, the client's knowledge about their rights in clinical procedures was in the most inappropriate situation (19). In this regard, Khazaei et al. showed that the form and type of informed consent forms were significantly associated with the clients' understanding and participation in clinical decisions (20). Regarding IUD insertion, several studies have emphasized the need to provide women with information about its advantages and risks, i.e., the main concept of informed consent in IUD insertion. They concluded that this issue can lead to greater satisfaction and prevent IUD expulsion (1, 21-23). The indisputable importance of obtaining informed consent has made medical ethics experts and researchers compile and explain the principles and components so that writing a thorough, standard, and brief informed consent form is an essential principle to observing client rights (12). Since medical ethics knowledge is nascent in the country, some invasive healthcare procedures have no informed consent form, and

the need for such standard forms is felt too much. Therefore, considering the importance of obtaining informed consent before IUD insertion, the present study aimed to design an informed consent form for IUD insertion.

Materials and Methods

The present study is taken from a research project under the ethical code IR.SSU.RSI.REC.1398.049. It was carried out between 2019-2018 using the Delphi method and a descriptive method. The Delphi method is a systematic method mostly used in research, that aims to collect opinions on a particular research question or a specific topic to gain consensus using a series of questionnaires, maintaining the respondents anonymous and providing the feedback to the panel members (24); The process entails gathering professional judgments from homogenous and independent experts on a specific issue is repeated until a consensus is achieved (25).

The method used in this study was multistage. The final consensus was reached by collecting written comments and free speech and modified versions with numerical estimates.. In this method, the repetition of a series of rounds was done in a procedural, systematic, and written form by using questionnaires to reach a consensus. The experts were asked about their opinions in three stages, resulting in the development of group work regardless of others' opinions (26). The rounds were considered to be three; previous studies have reported between 2 and 10 rounds. However, the classic Delphi method consisted of 4 rounds, reduced to two or three by researchers to achieve the goals (27, 28). Finally, the experts' opinions were aggregated and the responses were analyzed, and a consensus was achieved. Consensus refers to reaching an agreement about an idea and simply shows the agreement of the participants at a certain level on a certain issue. The review of studies in this regard shows different levels between 51% and 100% (28). In this study, in the second and third rounds, the level of agreement above 75% and the change level less than 15% were accepted.

The population consisted of experts in the fields of gynecology and obstetrics, forensic medicine, medical ethics, sociology, and law, who were selected using the purposive method. It consisted of 30 people who were interested in the subject, had knowledge and experience in the subject, and had enough time to participate. The review of studies showed that there is no explicit rule on the way of selecting and the number of experts; the number of participants depended on factors such as homogeneity or heterogeneity of samples, the purpose of Delphi or the extent of the problem, the ability of the research team in conducting the study, the time of data collection and available resources, the scope of the problem, etc. The number of participants has been usually less than 50 people and mostly between 15 and 20 people. In homogenous groups, 10-15 people are enough (29). At first form draft was prepared using bibliographic studies, the literature, and opinions of experts in reproductive health, medical ethics, ethics, sociology, and law.

In the first round of Delphi, the draft of the informed consent form for IUD insertion was sent to the experts via email, and their opinions were asked about each item in the form of yes and no answers, as well as the relevance of items. Also, the overall adequacy level of each section was examined. In the end, an open-ended question asked the participants to write any necessary item that they thought was ignored, as well as any opinion or suggestion. The form was prepared for the second round after examining the analyzed questionnaires.

In the second round of Delphi, the revised form was sent for the experts to rate the level of their agreement with the proposed items based on a 5-point Likert scale (not very important=1 to very important 5), as well as their corrective opinions and suggestions. Then, statistical analysis was performed, and the items with 75% agreement and more were approved, the items with 25% agreement and less were removed, and items between 25-75% agreements were sent to the third round of Delphi if necessary. Also, the percentage of agreement for each item was reported to experts.

Similar to the second round, the revised form was sent to the experts to rate their agreement based on a 5-point Likert scale and provide their opinions and suggestions. In this round, an agreement above 75% and a change level of less than 15% were accepted, and the results were reported based on the maximum agreement

(consensus) with the items of the informed consent form. Then, in a group discussion, the researchers summarized their opinions, and the final informed consent form for IUD insertion was approved. To conduct the research, conclude, and report the consensus, descriptive statistical methods and SPSS 18 were used.

Results

A number of 17 clinical guidelines related to the research topic were found in the first stage and 9 were usable according to the AGREE tool criteria. Finally, 65 clinical recommendations were selected from the mentioned guidelines and used in the localized clinical guideline. The general content of the recommendations include having a preparedness plan, all-round support of key decision makers, physical and psychological support of those injured in the crisis, attention to the main functions of reproductive health in natural disasters, providing and strengthening access to reproductive health services, increasing the technical-skills of service providers, providing equipment needed by vulnerable groups, providing minimum basic reproductive health services in disasters, and public education through mass media.

The present study was conducted in three Delphi rounds with the presence of 28, 24, and 24 experts, respectively. According to the results of the study, the mean age of the participants in the first round was 42.43 years, and in the second and third rounds, it was 42.33 years. The average working experience of the participants was about 17 years, who had the following degrees: associate's degree in midwifery, expert in midwifery, doctor of reproductive health, and obstetricians. Table 1 shows the number of people in terms of their expertise and the number of monthly IUD insertions. In addition, according to the analysis of the results of Delphi round 1 and experts' opinions, the overall adequacy in all sections was on average higher than 91% and was calculated in all sections at 100%, indicating desired overall adequacy of the sections (Table 2).

After analyzing the questionnaires of the first round, a new modified form was sent to 28 experts and the importance of the items was determined. Then, statistical analysis was performed, and the items with 75% and above agreement were accepted, the items with 25% and below agreement were removed and the items between 25-75% agreements were sent to the third round of Delphi if necessary. The agreement percentage obtained by each item was reported to the experts (Table 3). The highest agreement percentage (92%) in the second round was related to the item stating "IUD insertion is a method that immediately loses its contraceptive effect when the device is removed".

Then in a group discussion, researchers summarized the opinions, and the final form of IUD insertion informed consent was approved. The form included 5 sections: demographic characteristics, general components of the IUD insertion method, contraindication, client responsibilities, and expressing consent. The final form contained 42 items in 5 sections. The section of general component included 22 items, the section of contraindication had 2 items, the section of client responsibilities had 15 items, and the section of expressing consent had 3 items (appx. 1).

Table 1. The participants' demographic characteristics

Delphi Round	Round 1	Round 2	Round 3
Number of experts	28	24	24
Mean age	42.9±43.35	42.33±9.91	42.33±9.91
Average working experience (year)	17.75±9.16	17.38±9.49	17.38±9.49
Education			
Associate's in Midwifery	1 (3.6%)	0(0)	0(0)
Bachelor in Midwifery	11 (39.3%)	10 (41.7%)	10 (41.7%)
Master's in Midwifery	5 (17.9%)	5 (20.8%)	5 (20.8%)
Ph.D. in Reproductive health	9 (32.1%)	8 (33.3%)	8 (33.3%)
Obstetrician	2 (7.1%)	1 (4.2%)	1 (4.2%)
Non-faulty member	16 (57.1%)	15 (62.5%)	15 (62.5%)
Educator	6 (21.4%)	5 (20.8%)	5 (20.8%)
Scientific rank			
Associate professor	3 (10.7%)	3 (12.5%)	3 (12.5%)
Assistant professor	1 (3.6%)	0 (0)	0 (0)
Professor	2 (7.1%)	1 (4.2%)	1 (4.2%)
Employment in midwifery office			
Yes	10 (35.7%)	7 (29.2%)	7 (29.2%)
no	18 (64.3%)	17 (70.8%)	17 (70.8%)
Average no. of IUD insertions in a month	2.75±3.28	2.42±3.12	2.42±3.12

Table 2. Necessity, relevance, appropriateness, and adequacy of the IUD insertion informed consent form sections in the 1st round

Section	Item	Necessity (%)	Relevance (%)	Appropriateness (%)	Necessity (%)	Relevance (%)	Appropriateness (%)
		Yes	No	Yes	No	Yes	No
General components of the method	IUD insertion is a type of reversible contraception method with 99.2% effectiveness, i.e., less than one case of pregnancy per 100 women using it.	91.3	8.7	95.7	4.3	91.3	8.7
	The short-acting copper IUD prevents pregnancy .for 5 years	87	13	82.6	17.4	87	13
	Standard copper IUD prevents pregnancy for 10 years.	91.3	8.7	95.7	4.3	95.7	4.3
	IUD can be inserted at any time, but the best time is during the menstrual period.	86.4	13.6	90.9	9.1	86.4	13.6
	If IUD is used as a contraceptive method, a condom should be used to protect against sexually transmitted diseases.	82.6	17.4	91.3	8.7	73.9	26.1
Overall adequacy of the section (%)		95.7					
Benefits	IUD is a contraceptive device that will not interfere with your intercourse and will not cause any problems in this regard.	86.4	13.6	95.5	4.5	95.5	4.5
	IUD insertion is an effective contraceptive method.	87	13	91.3	8.7	91.3	8.7
	A copper IUD is a contraceptive method that does not interfere with breastfeeding and will cause no problems in this regard.	5.5	4.5	95.5	4.5	100	0
	IUD is a cheap contraceptive method because one device can prevent pregnancy for several years. IUD is an economic contraceptive method that prevents pregnancy for many years.	91.3	8.7	95.7	4.3	91.3	8.7
	IUD is a reversible contraceptive method, i.e., it stops working immediately after removal. IUD stops working immediately after removal.	100	0	95.5	4.5	95.5	4.5
	A copper IUD is a good choice for women looking for non-hormonal contraceptive methods.	91.3	8.7	95.7	4.3	95.7	4.3
	This method can be used to prevent pregnancy within 5 days after suspected sexual intercourse or at most the first 12 days of the menstrual period.	86.4	13.6	82.6	17.4	82.6	17.4
	IUDs can prevent pregnancy immediately after insertion.	82.6	17.4	86.4	13.6	86.4	13.6
	Overall adequacy of the section (%)	95.6					
Complications	The complications caused by this device include increased menstrual blood loss and days (about a half times of previous periods) during menstrual periods.	100	0	91.3	4.3	100	0
	Since the IUD is an external device, women are more likely to experience infections, so they need to observe proper personal hygiene.	95.5	4.5	5.95	4.5	90.9	9.1
	This device increases the volume of menstrual blood loss and the number of bleeding days;	100	0	91.3	4.3	95.7	4.3

Section	Item	Necessity (%)	Relevance (%)	Appropriateness (%)	Necessity (%)	Relevance (%)	Appropriateness (%)
		Yes	No	Yes	No	Yes	No
	however, these changes are resolved after 3-6 months.						
Overall adequacy of the section (%)		91.3					
Risks	IUD insertion may cause pain during and shortly after insertion; however, painkillers can be used one hour before insertion.	100	0	100	0	95.7	4.3
	Bleeding may be experienced during and after the IUD is placed	95.7	4.3	100	0	95.7	4.3
	The uterus may expel the IUD. This may occur in 1 in 20 women, with the highest risk in the first year after it is placed.	95.7	4.3	100	0	100	0
	Infection, which may spread from the uterus to the pelvis, is rare. One (out of 300 women) may experience the infection within 20 days of IUD insertion.	87	13	95.7	4.3	91.3	8.7
	Uterine perforation during IUD insertion; may occur in approximately 2 out of every 1000 cases. This rate may increase if the woman has breastfed or given birth in the past 9 months.	87	13	87	13	91.3	8.7
	Unwanted pregnancy. Although it is rare, it may occur. If conception occurs, there is the risk of increased ectopic (tubal) pregnancy, miscarriage, and premature delivery.	100	0	95.7	4.3	95.7	4.3
Overall adequacy of the section (%)		100					
Effectiveness	I know about the effectiveness of IUD, and that this method is more efficient than other contraceptive methods.	95.7	4.3	100	0	95.7	4.3
	I know that no birth control method is 100% effective at preventing pregnancy; however, IUD decreases the risk of pregnancy.	95.7	4.3	100	0	95.7	4.3
	I know that copper IUD is 99.2% effective in preventing pregnancy; that is, fewer than 1 in 100 women who use this method will get pregnant.	95.7	4.3	100	0	95.7	4.3
Overall adequacy of the section (%)		100					
IUD removal time	I know that the IUD should be removed after 5-10 years of insertion.	95.7	4.3	100	0	100	0
	In women aged over 45, IUDs can remain longer. However, the decision should be made after consulting the clinician or midwife.	82.6	17.4	82.6	17.4	78.3	21.7
	Although the IUD can be removed at any time, the most appropriate time is during the menstrual cycle.	86.4	13.6	95.5	4.5	90.9	9.1
	If I am over 40 years old, I will consult a midwife or clinician to remain on the IUD for a longer time.	82.6	17.4	91.3	8.7	82.6	17.4
	I know that the use of the IUD for longer than recommended may increase the chance of unwanted pregnancy, and I am responsible for	82.6	17.4	91.3	8.7	91.3	8.7

Section	Item	Necessity (%)	Relevance (%)	Appropriateness (%)	Necessity (%)	Relevance (%)	Appropriateness (%)
		Yes	No	Yes	No	Yes	No
	this.						
Overall adequacy of the section (%)		100					
Allergic reaction	I will tell my doctor about my allergic reactions to chemicals, metals (e.g., copper), or any of the ingredients or products in the copper IUD.	91.3	8.7	91.3	8.7	91.3	8.7
Overall adequacy of the section (%)		95.7					
IUD contraindication	I know that IUD insertion is prohibited in the following medical conditions; If I: - Am pregnant or suspect pregnancy. -Have serious pelvic infection. -have a uterus with an abnormal shape. -have been allergic to copper (Wilson's disease) -have an immune system deficiency. -have cured cervical cancer. -have a myoma that has changed the size and shape of the uterus. -have heavy menstrual blood loss. -have severe anemia. - have abnormal uterine bleeding. -have coagulation disorders. -have a history of ectopic pregnancy. -am suspected of cervical cancer (abnormal pap smear). -have had a mole pregnancy and I am undergoing treatment and a follow-up process.\ -have no history of childbirth. -have pelvic tuberculosis. I know that I should use another contraceptive method than IUD; If I -have had a pelvic infection but have not been hospitalized. -have multiple sexual partners. -my husband has multiple sexual partners. -have valvular heart disease that I need to take medicine for. -have recently got a uterine infection and it has not been treated. -am in the post-partum stage and have a postpartum uterine infection. -have had a septic miscarriage in the last 3 months.	100	0	100	0	91.3	8.7
Overall adequacy of the section (%)		95.5	4.5	100	0	100	0
Responsibilities of women	I know that it is not important to be pregnant while inserting an IUD.	100					
	I have told the clinician and midwife about the medications that increase the risk of bleeding (e.g., warfarin), the medical conditions that increase the risk of bleeding (e.g., hemophilia), and previous gynecological or obstetric surgeries	87	13	91.3	8.7	91.3	8.7
		95.7	4.3	95.7	4.3	95.7	4.3

Section	Item	Necessity (%)	Relevance (%)	Appropriateness (%)	Necessity (%)	Relevance (%)	Appropriateness (%)
		Yes	No	Yes	No	Yes	No
	(such as cesarean) section						
	I have told my midwife or doctor about the medications I take.	91.3	8.7	91.3	4.3	91.3	4.3
	I know that IUD can affect some other medical conditions; therefore, in case of other diseases, I will inform the doctor and other health professionals that I have placed an IUD.	95.7	4.3	91.3	8.7	91.3	8.7
	I understood the information about the copper IUD and ask the midwife or doctor to answer my questions.	100	0	91.3	0	100	0
	I will call the midwife or doctor for any further consultation.	91.3	8.7	95.7	4.3	95.7	4.3
	The midwife or doctor has provided me with a pamphlet on the IUD.	87	13	95.7	4.3	95.7	4.3
	I have read the pamphlet.	86.4	13.6	95.5	4.5	95.5	4.5
Overall adequacy of the section (%)		100					
Consent declaration	According to the above information, I, ……., consent to the insertion of an IUD as a contraceptive method. By signing this consent form, I acknowledge that I have discussed the benefits, risks, and side effects of using an intrauterine device (IUD) with the midwife or clinician, and the information above has been checked with and understood by me. Name…….. date ……..	100	0	100	0	95.7	4.3
	According to the above information, I,……., consent to the insertion of an IUD as a contraceptive method for my wife. Name…….. date…….. Midwife or clinician: I have discussed the benefits, risks, and side effects of using an IUD with the client. Name…….. date……..						
Overall adequacy of the section (%)		100					

Table 3. The results of 2nd and 3rd rounds

Section	Item	Consensus frequency percentage of items	
		2nd round	3rd round
General components of IUD insertion	-IUD is an effective and reversible method of birth control, with an effectiveness of 99.2%; that is, fewer than 1 in 100 women (2nd round) - IUD is an effective and reversible method of birth control, with an effectiveness of 99.2%; that is, fewer than 1 in 100 women using this method gets pregnant (revised version of 3rd round)	87	86
	Short-acting copper IUD prevents pregnancy for 5 years.	84.5	-

Section	Item	Consensus frequency percentage of items	
		2nd round	3rd round
	Standard copper IUD prevents pregnancy for 10 years.	93	-
	Depending on its type, copper IUD can prevent pregnancy between 5-10 years.	-	90
	IUD can be inserted at any time, but the best time is during the menstrual period.	94.8	-
	Long-term or continuous use of anti-inflammatory drugs in the non-menstrual period, including mefenamic acid and ibuprofen, may reduce the effectiveness of an IUD.	-	80
	In the case of using an IUD as a contraceptive method, it is recommended to use a condom to prevent sexually transmitted diseases (2nd round).	78.2	90
	In the case of using an IUD as a contraceptive method, it is recommended to use a condom against sexually transmitted diseases if the woman or her husband has high-risk sexual behaviors (extramarital affairs) (3rd round).		
	An IUD is a contraceptive method that will not interfere with your intercourse and causes no problems in this regard.	96.6	-
	A copper IUD is a contraceptive method with no hormonal side effects (Delphi 2nd round).	94.8	90
	A copper IUD is a good alternative for women who prefer non-hormonal methods of birth control (revised version of the 3rd round).		
	An IUD as a contraceptive method does not interfere with breastfeeding.	96.6	-
	An IUD is an economic method to prevent pregnancy for several years.	91.4	90
	An IUD is a contraceptive method with reversible effects immediately after expulsion.	98.2	-
	A copper IUD is a good alternative for women who prefer non-hormonal methods of birth control.	98.8	90
	An IUD prevents pregnancy from the same day of insertion if properly placed (2nd round).	81.8	83
	The contraceptive effect of copper IUD starts from the same day of insertion if properly placed (revised version of the 3rd round).		
	It is recommended to use another contraceptive method in the first month (2nd round)	90.4	81
	To endure the proper placement of the copper IUD, it is recommended to use another contraceptive method such as a condom until the first menstrual period after insertion (revised version of the 3rd round).		
	The complications caused by this device include increased menstrual blood loss and days (about a half times of previous periods) during menstrual periods.	91.4	86
	An IUD causes some complications such as increased blood loss during the menstrual period.		
	Since the IUD is an external device, women are more likely to experience infections, so they need to observe proper personal hygiene.	92.2	89
	This device increases the volume of menstrual blood loss and the number of bleeding days; however, these changes are resolved after 3-6 months.	88.6	94
	IUD insertion may cause pain during and shortly after insertion; however, painkillers can be used one hour before insertion.	80	85
	Bleeding may be experienced during and after the IUD is placed	75.6	85
	The uterus may expel the IUD. This may occur in 1 in 20 women, with the highest risk in the first year after it is placed.	78.2	83
	Infection, which may spread from the uterus to the pelvis, is rare. One (out of 300 women) may experience the infection within 20 days of IUD insertion.	78.2	74

Section	Item	Consensus frequency percentage of items	
		2nd round	3rd round
	Uterine perforation during IUD insertion; may occur in approximately 2 out of every 1000 cases. This rate may increase if the woman has breastfed or given birth in the past 9 months.	80.8	76
	Unwanted pregnancy. Although it is rare, it may occur. If conception occurs, there is the risk of increased ectopic (tubal) pregnancy, miscarriage, and premature delivery.	79.2	82
	IUD can be inserted at any time, but the best time is during the menstrual period.	85.2	82
Contraindications	I know that IUD insertion is prohibited in the following medical conditions; If I: - Am pregnant or suspect pregnancy. -Have serious pelvic infection. -have a uterus with an abnormal shape. -have been allergic to copper (Wilson's disease) -have an immune system deficiency. -have cured cervical cancer. -have a myoma that has changed the size and shape of the uterus. -have heavy menstrual blood loss. -have severe anemia. - have abnormal uterine bleeding. -have coagulation disorders. -have a history of ectopic pregnancy. -am suspected of cervical cancer (abnormal pap smear). -have had a mole pregnancy and I am undergoing treatment and a follow-up process.\ -have no history of childbirth. -have pelvic tuberculosis.	97.4	-
	I know that I should use another contraceptive method than IUD (2nd round); If I -have had a pelvic infection but have not been hospitalized. -have multiple sexual partners. -my husband has multiple sexual partners. -have valvular heart disease that I need to take medicine for. -have recently got a uterine infection and it has not been treated. -am in the post-partum stage and have a postpartum uterine infection. -have had a septic miscarriage in the last 3 months. ********	90.4	92
	I know that I should use another contraceptive method than the IUD (revised version of the 3rd round); If I -have had a pelvic infection but have not been hospitalized. -have multiple sexual partners. -my husband has multiple sexual partners. -have valvular heart disease that I need to take medicine for. -have recently got a uterine infection and it has not been treated. -am in the post-partum stage and have a postpartum uterine infection. -have had a septic miscarriage in the last 3 months.		
	I understand that it is important not to be pregnant while inserting an IUD.	94	-
	I have told the clinician and midwife about the medications that increase the risk of bleeding (e.g., warfarin), the medical conditions that increase the risk of bleeding (e.g., hemophilia), and previous gynecological or obstetric surgeries (such as cesarean) section	94.8	-

Section	Item	Consensus frequency percentage of items	
		2nd round	3rd round
	I have told my midwife or doctor about the medications I take.	94.8	-
	I know that IUD can affect some other medical conditions; therefore, in case of other diseases, I will inform the doctor and other health professionals that I have placed an IUD.	92.2	-
	I understood the information about copper IUDs and asked the midwife or doctor to answer my questions.	93	-
	I know about the effectiveness of the IUD		
	I know about the effectiveness of IUD, and that this method is more efficient than other contraceptive methods.	92.2	90
	I know that no birth control method is 100% effective at preventing pregnancy; however, IUD decreases the risk of pregnancy.	91.4	-
	I will tell my doctor about my allergic reactions to chemicals, metals (e.g., copper), or any of the ingredients or products in the copper IUD.	89.6	86
	I know that the IUD should be removed after 5-10 years of insertion.	94	-
	I know that the use of the IUD for longer than recommended may increase the chance of unwanted pregnancy, and I am responsible for this.	96.6	-
	I will call the midwife or doctor for any further consultation.	90.4	88
	The midwife or doctor has provided me with a pamphlet on the IUD.	86	90
	I have read the pamphlet.	88.6	84
	I have received the couple's counseling about this procedure and we decided to go on long-term contraception.	82.6	86
	I understand that I am responsible for the lack of adherence to the health recommendations, such as forgetting timely visits for control, etc.	85.2	87
Consent declaration	Woman's consent (2nd round) According to the above information, I, ……., consent to the insertion of an IUD as a contraceptive method. By signing this consent form, I acknowledge that I have discussed the benefits, risks, and side effects of using an intrauterine device (IUD) with the midwife or clinician, and the information above has been checked with and understood by me. Name…….. date ……..		
	Woman's consent (revised version of the 3rd round) According to the above information, I, ……., consent to the insertion of an IUD as a contraceptive method. By signing this consent form, I acknowledge that I have discussed the benefits, risks, and side effects of using an intrauterine device (IUD) with the midwife or clinician, and the information above has been checked with and understood by me, and I declare clearly that the midwife or clinician is not liable for any complications, including pregnancy and damages to the uterus. Name…… date…….. Husband's consent (2nd round of Delphi) According to the above information, I,……., consent to the insertion of an IUD as a contraceptive method for my wife. Name…….. date…….. Woman's consent (revised version of the 3rd round of Delphi) I, ……., have agreed with my husband to place an IUD and I am responsible for any claim from him. Name…… date…… Woman's unwillingness (2nd round) According to the above information, I,……., do not want to use an IUD. Name…….. date……..	94.8	97

Section	Item	Consensus frequency percentage of items	
		2nd round	3rd round
	Consent of the midwife or clinician who inserted the IUD (2nd round) I have explained the benefits and risks of IUD insertion to the client. Name…….. date…….. Consent of the midwife or clinician who inserted the IUD (revised version of the 3rd round) I,……., declare that I observed all items of this consent form and then placed an IUD for the client. Midwife's or clinician's name…….. date…….. Client's name……. date……..	94	87

Discussion

The present study aimed to design an informed consent form for IUD insertion in three Delphi rounds in the presence of experts. The informed consent was developed in 5 sections of demographic characteristics, general components of IUD insertion, contraindications, clients' responsibilities, and consent declaration, in 42 items.

Obtaining informed consent in medical practices has become a new matter in client rights in medical ethics. Obtaining informed consent before any diagnostic and therapeutical procedure will lead to clinical and ethical positive results (30). Informed consent is of great importance in all dimensions of medical care, and the important issues of medical ethics, such as truth-telling and client-clinician relationships, are closely related to the notes mentioned in informed consent (31). It is also one of the most important components of client rights in healthcare centers, and it is indeed the foundation of medical ethics (32).

Today, due to complex healthcare processes, providing information to clients about the outcome of a treatment, possible risks, side effects, etc. is considered a necessary part of treatment and care. Failure to provide such information to the client can be considered an important obstacle to making communication with the client. Informed consent requires several conditions such as providing information to clients, understanding, being voluntary, being competent, ability to make decisions, signing the informed consent form, and the factors related to interaction and the clinician-client relationship (33-34).

Today, the importance of clients' autonomy is well known. Obtaining informed consent requires necessary and sufficient information about risks, benefits, and alternative treatments that involve the clients in making appropriate decisions. Indeed, informed consent is a document indicating that the clinician-client conversation has led to mutual understanding (35-36). According to the results of the present study, obtaining informed consent, in the first place, is associated with providing general information about the methods and contraindications. Such information involves the clients in appropriate decision-making, and according to the principle of autonomy in medical ethics, they can choose a contraceptive method relying on the provided information about the risks, benefits, and consequences of the method. In this regard, a study conducted in Sanandaj showed that empowering women and emphasizing counseling before IUD insertion, educating, and providing sufficient information to women about the side effects of IUD has played an important role in continuing the use of this method and reducing women's worries (37). Greenberg's study also emphasized that since health providers must have sufficient knowledge of the risks and benefits of IUD insertion to provide optimal counseling before and after insertion because some women have never had a pelvic examination or may have had only once, they are supposed to conduct conversations with the client in a smooth, step-by-step manner that optimizes client education and comfort, to explain the risks and benefits of IUD according to the items of the informed consent form. Therefore, this not only informs

the clients about the procedure and able to decide but also prevents side effects and risks as much as possible, and increases the period of IUD maintenance in women (38). Rubin et al., (2016) conducted an exploratory study to investigate women's decision-making process of using an IUD and found that women introduced their healthcare providers as the most influential persons during the IUD insertion decision process by providing reliable and accurate contraceptive information and real descriptions (39). In this regard, the results of the studies were in line with the results of the present study, emphasizing the role of empowering women in making an informed decision to use this method. Considering the results of studies on obtaining informed consent, as well as other informed items, the informed consent form designed in this study provided the latest scientific information about IUD insertion to women to empower them to make an accurate decision, which was confirmed by women in the form. It is suggested that healthcare providers use educational pamphlets and brochures to achieve more desired results in transferring the required knowledge because, according to previous studies, the person can make informed and logical decisions about treatment methods if s/he has sufficient knowledge (40-41).

The informed consent form designed in this study included the benefits, risks, and consequences of the method so that healthcare providers can explain the benefits and risks of the method based on the latest studies. After gaining sufficient information about IUD insertion, the woman and her husband are required to study and accept the "responsibilities" part that shows they were provided with sufficient information about the method and willingly consented to use the method, and the clinician provided information about their responsibilities. They also acknowledge that they have discussed and checked the information provided to them and declare that the midwife and clinician have no responsibility, within the scientific and technical standards, to them in the event of any of the explained complications and side effects, including pregnancy and damage to the uterus. The husband also acknowledges this and permits to use IUD for his wife. The husband's information about using this method plays an important role in sustaining it because many women consult with their husbands or partners about this matter. In this regard, Divakar et al., (2019) examined the opinions of 66508 women who used an IUD about selecting this method as a contraceptive method and showed that 86.1% of women discuss with their husbands/partners before making decisions on family planning options, and the opinions of their husbands/ partners play an important role in choosing and staying with this method. They suggested healthcare providers ask the opinions of husbands/partners as well to provide the grounds for an informed and accurate decision (42). This result was in line with the results of the present study.

To increase the comprehensibility and clarity of the informed consent form items, the experts in Persian literature were asked to edit the form designed in this study, since many studies revealed a lack of comprehensibility of the informed consent form as an important obstacle to completing a quality questionnaire. According to Kurt and Vucemilo, “informed consent forms” are too complex for clients to read and understand. Indeed, many clients sign the form with no proper understanding or studying (43-44).

According to the results of the study and considering that so far the procedure of IUD insertion in Iran has been conducted through obtaining and completing a consent form with poor explanations of legal aspects, risks, and consequences, and given that the informed consent form in Iran is considered a fundamental right of client and the basis of ethics in medicine, obtaining informed consent should be based on ethical and legal processes that promote clients’ health and respect their independence (12,45). Therefore, it is recommended to explain the risks, diagnostic and treatment benefits, as well as side effects and complications, and prognosis along with any information required in the decision-making process to the client before placing an IUD. The informed consent form designed in this study clearly explained the legal issues, risks, and consequences of the method. In addition, the use of this form has an important position in the

clinical training of IUD insertion under ethical principles. Also, it is expected that this form to be a basis for further studies on respecting the principle of autonomy and independence of clients to make an informed decision about choosing a contraceptive method. The most important limitation of the present study was insufficient studies on designing and investigating the effectiveness of different forms of designing informed consent forms for IUD insertion. In this regard, the opinions of experts and bibliographic studies were used. To evaluate the quality and effectiveness of the designed form, research the opinions of healthcare providers about the obstacles to completing the form, and studies on the effect of obtaining informed consent on continuing the use of the IUD and preventing its early expulsion.

Conclusion

According to the results of previous studies and since the IUD insertion process is considered a high-risk procedure, after designing the informed consent form in this study, the consensus of the relevant experts was reached on a draft by using the Delphi method. It included five sections: demographic characteristics, general components of IUD insertion, contraindications, patients' responsibilities, and consent declaration. Then, the final version was presented by an expert in literature. Considering the necessity of obtaining the informed consent form, the designed form will be suggested to the Ministry of Health to be sent to all health centers, clinics, and Midwidery/ Gynecologist offices to use the form before placing an IUD. The limited number of scientific sources to prepare and analyze the dimensions of the consent form was one of the most important limitations of the present study. Therefore, it is suggested to conduct research on the use of the designed form in patients who want to have an IUD.

Declerations

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Conflicts of interest

Authors declared no conflicts of interest.

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Ethical approval

The present study is the result of a research project approved at the Research Center for Nursing and Midwifery Care affiliated to Shahid Sadougi University of Medical Sciences in Yazd and with the code of ethics approvalIR.SSU.RSI.REC.1398.049.To collect data in this researchAfter explaining the objectives of the study to the participants, a informed consent form was completed by them and their spouses. The principle of confidentiality was assured.

Authors' contributions

BE, LA, and AS contributed to the conception and design of the study. BE, and LA drafted the first version of the manuscript. BE, LA, and AS revised the manuscript. LA critically reviewed the manuscript for important intellectual content. All authors approved the final version.

References

1. Asker C, Stokes-Lampard H, Wilson S, Beavan J. What is it about intrauterine devices that women find unacceptable? Factors that make women non-users: a qualitative study. BMJ Sexual & Reproductive Health. 2006; 32(2): 89.
2. D'Arcangues C. Worldwide use of intrauterine devices for contraception. Contraception. 2007; 75(6): S2-S7.
3. Nourani Saadodin S, Goudarzi M, Peyman N, Esmaily H. Prediction of intrauterine device insertion among women of childbearing age based on the theory of planned behavior. The Iranian Journal of Obstetrics, Gynecology and Infertility. 2013; 16(45): 13-19.
4. Bilian X. Intrauterine devices. Best Practice & Research Clinical Obstetrics & Gynaecology. 2002; 16(2): 155-168.

5. Hubacher D, Cheng D. Intrauterine devices and reproductive health: American women in feast and famine. Contraception. 2004; 69(6): 437-446.
6. Kulier R, O'Brien P, Helmerhorst FM, Usher-Patel M, d'Arcangues C. Copper containing, framed intra-uterine devices for contraception. Cochrane Database of Systematic Reviews. 2007; 31(4): 123-131.
7. Hubacher D, Reyes V, Lillo S, Zepeda A, Chen P-L, Croxatto H. Pain from copper intrauterine device insertion: randomized trial of prophylactic ibuprofen. American Journal of Obstetrics and Gynecology. 2006; 195(5): 1272-1277.
8. Zakin D, Stern WZ, Rosenblatt R. Complete and partial uterine perforation and embedding following insertion of intrauterine deives. I. Classification, complications, mechanism, incidence, and missing string. Obstetrical & Gynecological Survey. 1981; 36(7): 335.
9. Saremi A. Rotating Withdrawal as an Effective Technique to Decrease Complications of IUD. Sarem Journal of Medical Research. 2017; 1(1): 9-15.
10. Asadi L, Dafei M, Mojahed S, Safinejad H. Clinical error management training for midwifery students in Shahid Sadoughi University of Medical Sciences, Yazd. Journal of Education and Health Promotion. 2021; 10(5): 21-32.
11. Ghafourian M, Safaei S, Abbasi M. Analyzing the Role of Patient Autonomy in Informed Consent. Bioethics Journal. 2018; 8(29): 43-51.
12. Ghaderi A, Malek F. Principles of informed consent in medicine. Koomesh. 2014; 15(2): 133-137.
13. Asadi L, Beigi M, Valiani M, Mardani F. Evidence-based draft guideline for prevention of midwifery malpractices based on referred cases to the forensic medicine commission and the medical council from 2006–2011. Iranian Journal of Nursing and Midwifery Research. 2017; 22(4): 313.
14. Parsapour A, Parsapour MB, Larijani B. Informed consent, contents, conditions and practical methods. Iranian Journal of Diabetes and Metabolism. 2005; 5(3): 1-14.
15. Gattellari M, Voigt KJ, Butow PN, Tattersall MH. When the treatment goal is not cure: are cancer patients equipped to make informed decisions?. Journal of Clinical Oncology. 2002; 20(2): 503-513.
16. Hall DE, Prochazka AV, Fink AS. Informed consent for clinical treatment. Canadian Medical Association Journa. 2012; 184(5): 533-540.
17. Daugherty CK. Impact of therapeutic research on informed consent and the ethics of clinical trials: a medical oncology perspective. Journal of Clinical Oncology. 1999; 17(5): 1601-174.
18. Grossman SA, Piantadosi S, Covahey C. Are informed consent forms that describe clinical oncology research protocols readable by most patients and their families?. Journal of Clinical Oncology. 1994; 12(10): 2211-2215.
19. Mahmoodian H, Barzegar H. Evaluation of obtained informed consents from patients undergoing gynecological surgery in a hospital in shiraz during 2014. Iranian Journal of Medical Ethics and History of Medicine. 2017; 10(1): 78-90.
20. Khazaei T, Hedayati H, Baratzadeh Z. Investigating the degree of informed consent obtained from patients undergoing surgery in the hospitals of Birjand University of Medical Sciences. Medical Ethics. 2014; 6(21): 169-185.
21. Amico JR, Bennett AH, Karasz A, Gold M. She just told me to leave it: women's experiences discussing early elective IUD removal. Contraception. 2016; 94(4): 357-361.
22. Edwards C, Panjwani D, Pendrith C, Ly A, Dunn S. Knowledge of and interest in the copper intrauterine device among women seeking emergency contraception. Journal of Obstetrics and Gynaecology Canada. 2018; 40(1): 41-47.
23. Moreau C, Bohet A, Hassoun D, Ringa V, Bajos N. IUD use in France: women's and physician's perspectives. Contraception. 2014; 89(1): 9-16.
24. Kennedy HP. Enhancing Delphi research: methods and results. Journal of Advanced Nursing. 2004; 45(5): 504-511.
25. Avella JR. Delphi panels: Research design, procedures, advantages, and challenges. International Journal of Doctoral Studies. 2016; 11(2): 305.
26. Farajkhoda T, Bokaie M, Abbasi M, NajafiHedeshi S, Alavi Z, Rahimdel M. The effect of new model PREPARED on obtaining informed consent skill in midwifery students of Shahid Sadoughi University of Medical Sciences. Iranian Journal of Nursing and Midwifery Research. 2017; 22(4): 267.
27. Jones J, Hunter D. Consensus methods for medical and health services research. British Medical Journal. 1995; 311(7001): 376.
28. Powell C. The Delphi technique: myths and realities. Journal of Advanced Nursing. 2003; 41(4): 376-382.
29. Avella JR. Delphi panels: Research design, procedures, advantages, and challenges. International Journal of Doctoral Studies. 2016; 11(1): 305-321.

30. Moosavi SM, Mohammadnejad SM. The informatory of the inpatients' informed consent: a survey in selected hospitals. Iranian Journal of Medical Ethics and History of Medicine. 2009; 2(3): 61-70.
31. Spier RE. Science and technology ethics. Spier R, editor. London: Routledge; 2002 Nov 1. Atashdehghan N, Meraji M, Jamali J, Yousefi M, Fazaeli S. Comparison of the Quality of Informed Consent in Angiography Patients in Selected Hospitals in Mashhad from The Perspective of Patients and Physicians. Journal of Paramedical Sciences & Rehabilitation. 2021; 10(1): 58-70.
32. Sheikhtaheri A, Farzandipour M. Quality of informed consent process and factors affecting it among patients undergoing surgery, an empirical study in hospitals of Kashan, Iran. Hakim Research Journal. 2010; 12(4): 33-41.
33. Joolaee S, Faghanipour S, Hajibabaee F. The quality of obtaining surgical informed consent: Case study in Iran. Nursing Ethics. 2017; 24(2): 167-176.
34. Spatz ES, Krumholz HM, Moulton BW. The new era of informed consent: getting to a reasonable-patient standard through shared decision making. Jama. 2016; 315(19): 2063-2064.
35. Negash W, Assefa N, Baraki N, Wilfong T. Practice and factors associated with informed consenting process for major surgical procedures among health-care workers, south eastern Ethiopia. International Journal of General Medicine. 2021; 12(2): 7807-7817.
36. Rezaie M, Karamei R, Shahoei R. Factors Associated with Discontinuation of Intra Uterine Devices among women referred to Sanandaj Health centers. Iran Journal of Nursing. 2013; 26(82): 34-41.
37. Greenberg KB. Consenting and Pre-procedural Counseling for IUD Insertion: What to Expect and What to Talk About. Optimizing IUD Delivery for Adolescents and Young Adults. 2019; 31(5): 83-90.
38. Rubin SE, Felsher M, Korich F, Jacobs AM. Urban adolescents' and young adults' decision-making process around selection of intrauterine contraception. Journal of Pediatric and Adolescent Gynecology. 2016; 29(3): 234-239.
39. Killawi A, Khidir A, Elnashar M, Abdelrahim H, Hammoud M, Elliott H, et al. Procedures of recruiting, obtaining informed consent, and compensating research participants in Qatar: findings from a qualitative investigation. BMC Medical Ethics. 2014; 15(1): 1-13.
40. Spertus JA, Bach R, Bethea C, Chhatriwalla A, Curtis JP, Gialde E, Guerrero M, Gosch K, Jones PG, Kugelmass A, Leonard BM. Improving the process of informed consent for percutaneous coronary intervention: patient outcomes from the Patient Risk Information Services Manager (ePRISM) study. American Heart Journal. 2015; 169(2): 234-241.
41. Kurt E, Ucar M, Atac A. Quality of an informed consent prior to a surgical intervention? Experience of a teaching hospital. Pakistan Journal of Medical Sciences. 2016; 32(1): 206.
42. Vučemilo L, Borovečki A. Readability and content assessment of informed consent forms for medical procedures in Croatia. PloS One. 2015; 10(9): e0138017.
43. Davoudi N, Nayeri ND, Zokaei MS, Fazeli N. Challenges of obtaining informed consent in emergency ward: A qualitative study in one Iranian hospital. The Open Nursing Journal. 2017; 11(6): 263.