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Development of sexual health promotion package in pregnancy: The Delphi method

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Abstract:

BACKGROUND: The World Health Organization recommendation requires the development and use of effective, brief, clear, and evidence-based education packages to improve health-care outcomes. No comprehensive sexual health improvement package exists for the pregnancy period in the Iranian health system. This study aimed to develop a package to promote sexual health in pregnancy.

MATERIALS AND METHODS: The present study is a qualitative study, which was conducted in 2019 in Tehran, Iran. Sexual health package during pregnancy was developed based on the National Institute for Health and Clinical Excellence (NICE) steps. The first step included reviewing of international guidelines, strategies, handbooks, education packages, and articles in this regard. The package was developed in the second step. In the third step, quality assessment was performed using expert opinion with the Appraisal of Guidelines for Research and Evaluation Instrument II (AGREE II) tool, and validation was performed using Delphi method.

RESULTS: Package content was designed in two sections: for midwives and health-care providers and for pregnant mothers in three sessions (in each trimester of pregnancy). The quality assessment using the AGREE II guidelines revealed excellent quality (>89%). The package was validated based on expert opinion (>95%).

CONCLUSION: The sexual health promotion package during pregnancy was designed with high quality and validity based on NICE steps. It is recommended, midwives be performed this designed and validated package in routine pregnancy care to promote the couple's sexual health.

Keywords:

Delphi, national institute for health and clinical excellence, package, pregnancy, sexual health

Introduction

Women experience a biological pass with physiological, anatomical, and behavioral changes during pregnancy,^[1] then sexual and partner relations undergo changes during pregnancy due to physical, hormonal, social, cultural, and psychological alterations.^[2,3] Therefore, evaluating sexual issues is a necessary part of pregnancy care.^[4] Health-care providers can have an important role in providing sexual health information to pregnant women during pregnancy. Guidance and consultation

regarding sexual relations during pregnancy can improve sexual function, and sexual health, and can reduce stress, psychological, and emotional pressures and reduce couple worries in pregnancy.^[5] Sexual health guidelines exist in the health-care system of different countries in the world including the guideline and recommendations for sexual health in women in Canada,^[6] comprehensive sexual education guidelines in the United States,^[7] guidelines for sexual and reproductive health for women in Australia,^[8] and framework for improving sexual health in England.^[9]

Integration of sexual health education in primary health care is important to increase

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individuals knowledge and equip them with adequate information in sexual health to enable them to control their health.^[10] In this regard, in 2010, the World Health Organization (WHO) proposed the design and use of efficient, clear, and evidence-based education packages to improve health-care processes and outcomes. Globally, and in middle-income countries, specialized packages are usually designed based on basic service packages and primary health care.^[11]

Designing service packages is a necessity and is among the priorities of the health division of the Iran Ministry of Health. In the national safe maternity program, questions are asked from pregnant mothers about unsafe sexual behaviors and partner abuse (physical and psychological violence) during the routine pregnancy care in the first, second, and third trimesters. In high-risk sexual behavior, only human immunodeficiency viruses (HIVs) test is performed for the mother. Furthermore, based on the recommendations and guidelines of safe maternity program book, only one sentence was used to describe sexual health “sexual health: sexual relations and its issues and high-risk behaviors with the emphasis on HIV transmission.” However, no further information was provided regarding the issues and how the consult and education should be provided in pregnancy care visits and what should be done in case of a problem and the method for diagnosis of the problems.^[12,13] Education is one of the basic principles for promoting sexual health.^[14] Sexual health education during pregnancy can improve marital satisfaction in the postpartum period.^[15] Furthermore, Rahimi *et al.*,^[15] Schulz *et al.*,^[16] and Masoumi *et al.*^[17] achieved these results during their studies.

According to the booklets and routine pregnancy care guidelines of the Iranian health system, lack of a valid package for sexual health promotion in pregnancy is sensed in the current national pregnancy health-care recommendations; so the researchers aimed to conduct a study to design an education package to promote sexual health in two sections including a section for health-care providers (midwives and related specialties) and pregnant women, without adding a new service to pregnancy care with the aim of the promotion and enrichment of sexual health and marital relations and consequently promoting the sexual health quality in pregnancy for pregnant women.

Materials and Methods

Study design and setting

The present study is a qualitative study, which was conducted in 2019 in Tehran, Iran.

As the main objective of this study was to design and develop a sexual education package, one of the most

validated references for developing guidelines and clinical recommendations is the National Institute for Health and Clinical Excellence (NICE) guidelines.^[18]

The NICE guideline has four steps as follows:

1: Scoping phase:

the required information regarding the subject is collected, and the content and framework of the project are identified.^[18] At this stage of the present study, the term “assessment of sexual health guidelines in pregnancy based on pregnant mothers’ needs” was searched in published literature. In order to collect information about the findings of other studies and to assess the experience of other researchers, a systematic review was performed and the guidelines, handbooks, and education packages in this field were assessed in the world based on the development level, commitment to 1994 WHO conference action plan in Cairo, availability of definable pattern for sexual health in pregnancy, and information accessibility. Therefore, based on the inclusion criteria, countries similar to Iran regarding midwifery services and their documents were available in English language and were committed to the action plan of the WHO conference in Cairo, were selected. The search keywords included Sexual health promotion, Training, health-care provider, practitioner, sexual health, skill education, pregnancy, and antenatal care.

2: Development phase:

The first draft of the protocol or clinical guideline, including the condition of the receivers of the services and principals and clinical guidelines for need assessment and provision of different types of services and evaluation indices based on the present evidence are prepared and presented.^[18] In this phase, the primary draft of the protocol and sexual health promotion package during pregnancy were developed based on the current evidence and pregnancy care table, by the Ministry of Health as the Mother friendly book, in three sessions at each trimester.^[12]

3: Validation phase:

The specialists and experts in the field evaluated and assessed the first draft of the protocol. This group assesses the collected data, reviews the clinical guideline briefly, and can comment on the content, re-evaluate the references, and finally provide suggestions for the final draft of the clinical guideline.^[18] Regarding the hardship in collecting experts in a field at a time, the use of the Delphi technique will be one way to collect expert’s opinions and knowledge.^[19] Regarding the number of experts for the Delphi method based on the availability of time, resources, and broadness, mainly <50 experts, usually between 15 and 20 experts, are reported.^[20]

Study participants and sampling

In this phase of the study, in order to assess the validity of the designed intervention package based on Delphi, a draft of the first version was E-mailed to 25 experts, including university scholars, reproductive health specialists, obstetricians and gynecologists, psychologists, midwives and skilled personnel of health care and medical care facilities, hospitals, sexual health-related clinics, and private medical offices from different cities (Tehran, Rasht, Karaj, Qom, Isfahan, Yazd, Shiraz, and Hamadan) who had a history of scientific or practical skills and research and accurate knowledge in the topic under study and were willing to participate in the study. The information collection form was sent to them through e-mail after coordinating with them. After receiving the opinions and suggestions of the experts, the necessary improvements were made to the draft by the research team based on the experts' comments, and the revised intervention package was resent to the experts to receive their feedback. The intervention package was prepared after exchanging numerous opinions and continuous corrections according to the opinions of experts.

To assess the quality of the package, experts answered the Persian version of the Appraisal of Guidelines for Research and Evaluation Instrument II (AGREE II) questionnaire. The final intervention package was developed based on the obtained and re-evaluation scores. Twenty experts and specialists cooperated until the completion of the final package.

Data collection tool and technique

In order to assess the quality and the level of agreement between specialists regarding the practicality of the intervention package, the AGREE II questionnaire was used. This tool both evaluates the quality of content presentation method and the quality of some aspects of the recommendations and also assesses the probability of success of the package and guidelines in achieving the desired behavioral outcomes but does not evaluate patient outcomes. This tool is designed for the assessment of guidelines and packages that are regional, national, or international. It includes 23 key criteria in six sections (first section is scope and purpose [3 questions], stakeholder involvement [4 questions], rigor of development [7 questions], clarity and presentation [3 questions], applicability [4 questions], and editorial independence [2 questions]) and each section assesses one aspect of the quality of the guide. It is noteworthy that in terms of presenting the results of the AGREE II tool, the scores for each section are independent and therefore, should not be summed up to get a total score for the guide.^[21,22]

In order to validate the designed package based on Delphi, expert opinion was used. The extracted

recommendations based on applicability (1: very low, 2: low, 3: much, 4: very much), being scientific (from 1: completely disagree to 4: completely agree) and necessity (from 1: completely disagree to 4: completely agree) of the sexual health promotion package in pregnancy was given to 20 experts in the field. Finally, after collecting the specialists' opinion, data were analyzed. The presented ideas and suggestions are considered a consensus of 50%–70% and a consensus of 70% indicates higher confidence.^[23] In this study, 70% consensus on the acceptability was considered as valid.

4: Publication and dissemination:

The finally accepted draft is published and disseminated.^[18]

Statistical analysis

To extract the results of the AGREE II questionnaire, the data were analyzed through SPSS version 23 (SPSS Inc., Chicago IL, USA) statistical software. Descriptive statistics were used to describe the data (frequency and percentage).

Ethical consideration

The Ethics Committee of Shahid Beheshti University of Medical Sciences approved this study (IR.SBMU.PHARMACY.REC.1399.064), and written consent was obtained from the subjects.

Results

The findings of the first phase of the NICE steps included a literature search regarding sexual health improvement. Guidelines of countries such as Australia;^[24-27] England;^[28-31] Canada,^[32-36] the United States;^[37-39] Norway;^[40] Turkey,^[41] and the WHO^[42-44] were thoroughly evaluated using appropriate keywords and considering the inclusion criteria. Furthermore, articles published in reputable scientific databases (in Persian or English) in the field of sex education for pregnant women were searched using appropriate keywords. The two books, "Your Orgasmic Pregnancy"^[45] and "Counseling couples before, during, and after pregnancy"^[46] were used to design the sexual health package in this study.

In the second phase, the sexual health promotion package was designed based on the findings of the first phase for three sessions (in each pregnancy trimester) [Table 1].

In the third phase, after the initial design of the package by the research team, to validate the package for pregnant mothers, the booklet was given to ten pregnant mothers at different levels of education (under diploma-diploma-university education). After receiving the opinions of pregnant mothers and making the necessary editions, the entire package for quality evaluation was given to

Table 1: Content of the sexual health improvement package during pregnancy

Session	Content
First session (first trimester)	Female and male reproductive system, physiological changes in mother during pregnancy, psychological-emotional changes during pregnancy, personal and sexual hygiene in the first trimester of pregnancy, presex preparation, and sexual intimacy and following that marital satisfaction, sexual behavior limitations in pregnancy especially in the first trimester, describing various intercourse positions and conditions in the first trimester, correct beliefs and attitudes regarding sexual function and correcting wrong beliefs and attitudes, domestic violence during pregnancy
Second session (second trimester)	Describing sexual response cycle and the physical and psychological differences between men and women in sexual cycle, sexual activity and its changes in pregnancy and the factors that influence sexual activity in pregnancy, personal and sexual hygiene in the second trimester of pregnancy, presex preparation, and sexual intimacy and following that marital satisfaction, sexual behavior limitations in pregnancy especially in the second trimester, describing various intercourse positions and conditions in the second trimester, describing a summary of the correct beliefs and attitudes regarding sexual function and correcting wrong beliefs and attitudes
Third session (third trimester)	Patterns of sexual changes in pregnancy, personal and sexual hygiene in third trimester of pregnancy, presex preparation, sexual intimacy and following that marital satisfaction, sexual behavior limitations in pregnancy in the third trimester, describing various intercourse positions and conditions in the third trimester, sexual changes after delivery, and the best time to begin sexual activity after delivery

the specialists. To assess the quality of the package, the AGREE II questionnaire was used based on expert opinion. The results of validity assessment and the quality of the designed package were as follows the score for scope and purpose: 95%, the score for stakeholder involvement: 93.1%, the score for rigor of development: 94.04%, the score for clarity of presentation: 95.5%, the score for applicability: 92.29%, the score for editorial independence: 89.16% [Table 2].

In order to validate the final package based on Delphi method, expert opinion was used. The extracted recommendations were obtained from applicability and usability (97.5%), being scientific (95%) and necessity (95%).

In the fourth phase of the study, the designed package that was approved by the experts was published under the supervision of the Shahid Beheshti University Press.^[47]

Discussion

In this study, the sexual health promotion package in two sections (for midwives and health-care providers as well as pregnant mothers) was designed and developed based on the NICE method, and based on guidelines, and literature review; then its quality was validated based on experts' opinions from all over Iran (Delphi method) and using the AGREE II tool.

Compared to the package designed in the present study for Iranian pregnant women with other areas studied, it should be said: In all reliable sexual health websites and guidelines in various countries, such as Australia, England, Canada, the United States have an emphasis on adolescent sexual health education at the school level. Therefore, educating sexual issues should be started from a younger age, and the incorrect taboos, attitudes, and knowledge should be corrected, and sexual education

is recommended only in case of need at other periods like pregnancy.

Regarding the clinical guidelines

Australian pregnancy care states that education should be provided to pregnant women with uncomplicated pregnancies about the health and safety of sexual relationships during pregnancy and that no complications occur if these behaviors are performed. Sexual intercourse is not recommended for pregnant women with high-risk pregnancy. Education should be provided to pregnant women regarding domestic violence and its signs and symptoms during regular pregnancy care sessions. All health-care providers should be educated regarding the detection of domestic violence in the first place. In case an individual experiences domestic violence, counseling and support should be provided to the affected women through education programs, clinical supervision, and counseling. Proper guidance and management should be provided and the documents should be recorded in their medical records, not pregnancy care records. This education should be provided by a midwife, general physician, obstetrician and gynecologist, health-care specialist, health-care workers, and sexual health-care providers.^[24]

Furthermore, in England, sexual education is provided by presenting questions and answers on the National Health Service (NHS) website, and it was stated that having sexual intercourse is safe during pregnancy. The contraindications for sexual intercourse in pregnancy were stated. It was stated that if sexual intercourse is not performed, marital intimacy should be maintained through other methods and changes in sexual intercourse positions should be occasionally made during pregnancy.^[31] As well as, The British Columbia federal guidelines for pregnancy care and neonatal general health care book states that: education on the use of safe methods should be provided to vulnerable pregnant women to prevent

Table 2: Results of validity assessment of the package based on Appraisal of Guidelines for Research and Evaluation Instrument II tables

Expert	Item																						
	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	Q21	Q22	Q23
	Scope and purpose			Stakeholder involvement				Rigour of development					Clarity of presentation			Applicability				Editorial independence			
1	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
2	7	7	7	7	7	7	6	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
3	7	7	7	6	6	7	4	7	7	7	7	7	7	7	7	7	7	7	7	6	7	7	7
4	7	6	7	6	6	7	6	7	6	7	6	6	6	7	7	7	7	7	7	6	7	6	6
5	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
6	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	5	7
7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
8	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	6	7	7	7	7	7
9	7	6	7	6	6	7	7	7	7	6	7	6	6	7	6	6	7	7	5	6	6	6	6
10	7	6	7	7	6	7	7	6	6	7	7	6	6	6	7	7	7	7	6	6	6	7	6
11	3	5	2	4	2	3	6	2	4	3	5	4	4	4	5	4	3	4	4	3	2	-	-
12	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
13	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
14	7	7	7	7	6	7	7	7	7	7	7	5	7	7	7	7	7	7	7	7	7	7	7
15	6	6	7	6	6	7	7	6	7	6	6	6	6	7	7	7	7	5	6	6	6	6	7
16	7	7	7	6	7	7	7	7	7	7	7	7	7	6	7	7	7	7	7	6	6	6	7
17	7	7	7	7	7	7	5	6	7	6	7	6	6	7	7	6	6	6	6	6	6	6	6
18	6	6	7	7	7	6	7	7	7	6	6	7	7	6	7	6	6	7	7	6	7	6	7
19	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
20	7	7	7	6	6	7	7	7	7	7	7	7	7	7	6	7	7	7	7	7	7	7	7
quality score (%)	95			93/1				94/4					95/5			92/29				89/16			

sexually transmitted diseases. Furthermore, education should be provided to pregnant women without complications about the health and safety of sexual intercourse during pregnancy. Sexual intercourse should be avoided in the case of placenta previa, bleeding, or preterm delivery.^[36] The 7th edition of the pregnancy care booklet in the United States indicates that: education should be provided to pregnant women with no complications about the safety of sexual intercourse during pregnancy and that it has no complications in pregnancy. Pregnant women who are at risk for preterm delivery should avoid sexual intercourse.^[37]

Several intervention studies have been conducted in the field of sexual health education in pregnancy in Iran (Riazi *et al.*,^[48] Afshar *et al.*,^[49] Bahadoran *et al.*,^[50] and Rostamkhani *et al.*^[51]), in which pregnant women have been trained one to a maximum of three sessions in one trimester in pregnancy. Although the interventions were valuable and effective, interventions of these studies were not designed content for all pregnancy. Therefore, the strength and difference of this study with other studies mentioned is the content design, which has been evaluated and validated in the opinions of pregnant mothers and experts in different parts of Iran, based on scientific and accurate methods. On the other hand, the study designed based on this package showed its feasibility and effectiveness.^[52]

In the Iranian national care for maternal safety during pregnancy, no valid package was present regarding sexual health.^[12] Therefore, the package designed in this study can meet this need.

The evaluation of the guidelines and recommendations found no sexual health package assessed using the AGREE tool and validated based on the Delphi method. In line with this methodology, some packages have been developed for some diseases or conditions. Validation based on Delphi method has been used in other valid international packages such as: “Design and development of a decision support package for low back pain,”^[53] “Construction of perioperative oral care program for elderly patients with oral cancer based on Delphi method.”^[54]

Similar to this study, these studies assessed the quality of their packages using AGREE questionnaire and validated the packages based on expert opinion: “The Scandinavian guidelines for the management of mild and moderate injuries in children” used the methodology based on guides on AGREE II and Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) assessment systems.^[55] In the development of “The evidence-based recommendations for curing urinary incontinence in nursing home residents,” the adaptive process-based methodology (ADAPTE) approach was used based on systematic review, quality assessment of

the guidelines by evaluating guidelines using AGREE II tool and evaluation and validation based on expert opinion.^[56]

The high scores for package evaluation using the AGREE II tool and specialist opinion with Delphi indicate high credibility and appropriateness of the developed package in this study. In the current study, the scores for evaluation and quality assessment of the sexual health promotion package based on the AGREE II tool were higher than 89%. Of the study's remaining criteria in the study, all sections achieve scores higher than 60%.^[22] In this study, the assessment of the specialists' opinions based on Delphi was above 95%. The ideas and recommendations are considered based on 51%–70% consensus and a consensus of higher than 70% is considered valid.^[23]

One of the strengths of the study is that this study was designed based on the valid guidelines of the world and with a review of studies conducted in the world and Iran, as well as Iranian guidelines based on Iranian culture (according to pregnant mothers and specialists' opinions), and it was validated by experts in different parts of Iran using the Delphi method. Therefore, it is a package that covers all trimesters of pregnancy and can be easily used in providing prenatal care.

Limitation and recommendation Limitations of this study

A validly designed package can be implemented with the existing conditions of providing services during pregnancy, but there are no communication instructions in this field yet.

Recommendation for future studies

In a study, this developed package should be educated to pregnant mothers and its effectiveness on relationships and quality of sex life should be measured.

Conclusion

Sexual health promotion package in pregnancy was designed and validated in two sections (for midwives and health-care providers as well as pregnant mothers). This package can be used by midwives in regular national pregnancy care services (such as breastfeeding education and personal hygiene) in various pregnancy months, along with other care services to pregnant mothers without creating new services to improve knowledge, positive attitudes, and correct behaviors regarding sexual health of couples during pregnancy.

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Conflicts of interest

There are no conflicts of interest.

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