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Designing and Psychometric Evaluation of a Questionnaire for Health Needs of Hepatitis B Affected Women: A Mixed Method Study in Reproductive Health Domain

Shiva Khayatimotlagh [1], Elham Ebrahimi [2,*], Seyed Moayed Alavian [3], Maryam Hassani [4], Masud Yunesian [5], Afsaneh Keramat [6], Marjan Hassani [7] and Nahid Bolbolhaghighi [8]

[1] Department of Midwifery, Maragheh Branch, Islamic Azad University, Maragheh, Iran
[2] Reproductive Health Department, School of Nursing and Midwifery, Tehran University of Medical Sciences, Tehran, Iran
[3] Baqiyatallah Research Center for Gastroenterology and Liver Diseases, Baqiyatallah University of Medical Sciences, Tehran, Iran
[4] Reproductive Health Department, School of Nursing and Midwifery, Lorestan University of Medical Sciences, Khorramabad, Iran
[5] Environmental Health Department, School of Public Health, Tehran University of Medical Sciences, Tehran, Iran
[6] Reproductive Health Department, School of Nursing and Midwifery, Shahroud University of Medical Sciences, Shahroud, Iran
[7] School of Medicine, Baqiyatallah University of Medical Sciences, Tehran, Iran
[8] Midwifery Department, School of Nursing and Midwifery, Shahroud University of Medical Sciences, Shahroud, Iran

[*] *Corresponding author*: Reproductive Health Department, School of Nursing and Midwifery, Tehran University of Medical Sciences, Tehran, Iran. Email: ebrahimi_308@yahoo.com

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Abstract

Background: Hepatitis B is a problematic condition which can affect both patients and health systems. The fetus health effect, transmissibility of infection, disease screening during pregnancy and confronting the disease during pregnancy as a new diagnosis case have made this disease close to the reproductive health domain. A health need assessment is a first step in designing an equality health service, the aim of this study was the development and validation of the health need questionnaire of hepatitis B affected women in the reproductive health domain.

Methods: Based on the specific design, this study had two phases. At the first step to develop the instrument, we conducted some qualitative interviews with hepatitis B affected women and reproductive health care providers. After analyzing, we developed a health need questionnaire, the psychometric characteristics of which were determined in the second phase.

Results: After analyzing the data, we received 88 codes and 186 items. The research team removed 9 items during the face and content validity based on the cut off point of Impact Score, CVR and CVI. To elucidate, the questionnaire with 79 items developed in the psychometric evaluation phase. Internal consistency of the total scale was good with Cronbach alpha coefficient 0.87, and Spearman correlation coefficient of 0.84 that indicated good stability. In the construct validity by exploratory factor analysis, the Kaiser-Meyer-Olkin (KMO) index was higher than 0.90 and also the Bartlett test of sphericity was significant ($P < 0.001$). Concerning the cumulative percentage of the variance, the 4 factors determined 54.99% of the total variance.

Conclusions: This study lead to development and validation of a questionnaire to evaluate the health needs of hepatitis B affected women in the reproductive health domain.

Keywords: Hepatitis B, Need Assessment, Psychometry, Reproductive Health

1. Background

The family health foundation is based on its member health (1). Among the members of family, women's health is an important issue and a world concern. Policymakers wholeheartedly believe that the health of some vulnerable women such as those handicapped, villagers or some who are affected by some stressful diseases such as HIV and hepatitis is more important than the others (2). Hepatitis B is one of the health problems that may lead to a lot of health costs (3). In fact, the specific status of its affected population has received the warning state in the subject of life qualification (4-7). Indeed, high levels of psychological issues such as stigma deteriorate their personal communication, performance, their chores and perhaps intention to access health facilities (8, 9). Based on the best knowledge of disease transmission to the fetus, spouse, and the importance of its screening during pregnancy which are main concerns in reproductive health, this disease is near to this domain (4, 10, 11). Also these women as well as the other ones have the right to have safe and desirable sexual rela-

tionships and access to need-based sexual and reproductive health care for themselves, their child and their sexual partners (4, 11, 12). Paying attention to health costs and determining the need priority prompted us to do a health need assessment in this field as a first step for designing a health service model for hepatitis B affected women.

2. Objectives

We aimed to evaluate the health needs of hepatitis B affected women when they referred to the reproductive health centers.

3. Methods

Based on the specific design, this study had two phases. At the first step, to develop the instrument, we conducted some qualitative interviews with hepatitis B affected women and reproductive health care providers. In sum, we developed a questionnaire that its psychometric characteristics was evaluated in the second phase.

3.1. Phase 1: Qualitative Study of Development of the Health Needs Questionnaire of Hbs Ag Positive Women in the Reproductive Health Domain

We used purposive sampling methods. A total of 40 hepatitis B affected women and 30 reproductive health care providers were individually interviewed. The written informed consent was obtained from participants and data collection continued until data saturation was achieved. We used content analysis method to extract the data. Finally we received 124 items that decreased to 70.

3.2. Phase 2: Validity and Reliability

3.2.1. Face Validity

We used both qualitative and quantitative methods for evaluating the face validity. A total of 15 hepatitis B affected women determined the relevance, ambiguity and difficulty of the items. Also we calculated the impact scores of each item. In order to examine the quantitative face validity of the questionnaire, 20 other women with hepatitis B were asked to rate the necessity of the items based on the Likert scale.

3.2.2. Content Validity

In this stage, the variables were investigated on a three-part scale "Essential", "Useful, but not necessary" and "Unnecessary" by 10 specialists. The obtained data were used to determine the content validity through determining the content validity ratio (CVR) and the content validity index (CVI).

3.2.3. Construct Validity

To reach this goal, we used the exploratory factor analysis (EFA). Appropriateness and sufficiency of the number of samples was evaluated by the Bartlett test and Kaiser-Mayer-Olkin (KMO), respectively.

3.2.4. Reliability

Internal consistency, which calculates an agreement between the responses among the respondents, was used to determine the reliability (13). Moreover, the test- retest method was done to check the stability of the questionnaire. At each stage, we used the views of 10 members of the target group.

3.2.5. Setting and Samples

The study population were the hepatitis B carrier women from the five health centers, as well as two hepatitis B research centers in Tehran. We found the patients through their health record data in the hospitals or health centers. The inclusion criteria in this part were being married, hepatitis B carrier, in the age range 15 - 45 years old and willingness to participate in the study. The other section of sampling was related to the health care providers. In this regards we selected those of them that had any experience of providing reproductive health to these types of women.

3.2.6. Statistical Analysis

We used SPSS version 18.0 for the statistical analyses. Item- and dimension-level analyses were specified by descriptive statistics (frequencies, means, and standard deviations). The acceptable Impact Score were assumed higher than 1.5. Also the CVR and CVI scores upper than 0.62 and 0.70 (based on Lawshe's critical values) were acceptable (14). The acceptable Cronbach's alpha coefficient and Spearman coefficient values for the new instrument were -0.70 and 0.80, respectively. In factor analysis, KMO -0.9 and a significant Bartlett test (-0.05) were acceptable. In Varimax rotation, factor loadings -0.3 were considered suitable.

3.3. Ethical Consideration

This study was approved by the Ethics Committee of the Shahrood University of Medical Sciences, Shahrood, Iran (code: 22122). The written consent forms were obtained from the all participants.

4. Results

After analyzing the qualitative interviews, we received 88 codes and 186 items. The research team assessed and reviewed the items in 3 phases. Accordingly, after integrating and eliminating, the questionnaire with 79 items entered to the psychometric evaluation phase.

4.1. Face and Content Validity

Based on our study participants, we eliminated 3 items during the face validity process. These items were omitted because of their irrelevance and ambiguity. Also in CVR, 9 items were removed. The CVR mean value was < 0.91 (0.62). We did not have any item reduction during CVI. At that time, the questionnaire had 70 items.

4.2. Construct Validity

In this regard, we collected 350 hepatitis B affected women (5 times the number of the items that were in the questionnaire) that have the specific characteristic based on study inclusion criteria. The majority of participants (53.4%) had 25 - 35 years of age (Table 1) The amount of KMO was 0.931 that was higher than cut off point (0.9). This means that the data were suitable for factor analysis. Also the result of the Bartlett test was significant. ($P < 0.001$) In this regard, principle component analysis via Varimax rotation indicated that all factors are compatible with the desire factor, so that no items were eliminated. The result showed that 4 factors that involved the dimensions of this questionnaire (with the total variance of 54.99%) (Table 2).

4.3. Reliability

The value of Cronbach's alpha of the instrument for 300 samples was 0.878. Also the amount of Spearman correlation coefficient was 0.84. Based on these results that indicate a good stability. The reliability of this questionnaire was confirmed.

Table 1. Demographic Data[a]

Variables	No. (%)
Age	
15 - 25	36 (10.3)
25 - 35	187 (53.4)
> 35	127 (36.3)
Education	
Under primary school	74 (21.1)
Primary school	107 (30.6)
Secondary - high school	121 (34.6)
University	48 (13.7)
Job	
Student	17 (4.9)
Clerk	23 (6.6)
Household	223 (63.1)
Other	89 (25.4)
Parity	
Nulliparous	56 (16)
Primiparous	81 (23)
Multiparous	213 (61)

[a] Characteristics of the study participants (n = 350).

5. Discussion

The results of current study verified the psychometric characteristics of the health need questionnaire of hepatitis B affected women in reproductive health domain. We used a well defined procedure (alternative between qualitative and quantitative methods). Item generation started with a qualitative method and tracked by quantified judgments in the quantitative process. In this study we evaluated the necessity by CVR. Also CVI examined the simplicity and clarity. Nine items were removed in this level. Based on the exploratory factor analysis results we did not remove any items. Finally, we found a validated questionnaire with 70 items. Reliability and stability was confirmed by the value of the Cronbach's alpha (0.878) and spearman correlation coefficient (0.84). The final version of the questionnaire had four subscales (supportive, information, health service and capacity building needs). Unfortunately, our literature review showed that a few studies have been conducted in this area. Maybe it means that the health needs of these people were neglected in this part. But our study results were consistent with those of the studies on validating the health need questionnaire in the reproductive health domain. For instance recently Behboodi-Moghadam et al. developed and validated the Reproductive Health Assessment Scale for HIV-Positive Women. This tool had 36 items in 6 subscales (disease-related concerns, life instability, coping with the illness, disclosure status, responsible sexual behaviors, and the need for self-management support) (15). Although most domains of this questionnaire (coping with the illness, disclosure status, need for self-management support) were similar to the items of our instrument, some domains such as disease-related concerns, life instability and responsible sexual behaviors were different. Perhaps these differences might be related to the differences in the type of disease and its stigma burden in our society. Asadi-Lari et al.'s instrument for analyzing the health needs of cardiac patients is another instrument for need assessment. This tool had 49 items and 5 subscales (physical, satisfaction, information, social and worries needs) (16). They only evaluated face and content validity. As a tool in the health needs of patients, some of the items in this questionnaire were near to our instrument items and domains such as information and social needs. But there were some differences which may be related to the different conditions of the two diseases. Also Fallahi and colleagues developed a tool with an approach to the reproductive health and HIV. Exploratory factor analysis revealed the 7 subscales for this tool (the need for controlling the excitement and condom use negotiation, social support, environmental factors, the power of men in sexual decision making. Although the object of these two studies were completely different but as full

validated tools had similarity in the items and domains (social support, environmental factors) and psychometric characteristics with our study. This study had some limitations. The first limitation was associated with the hepatitis B stigma in our country. Because of this reason, some of our patients didn't accept in-person interview. In our country, we didn't have any formal registration systems for hepatitis B affected people and we found our participants via informal resources. Therefore, the other patients may have some needs that didn't reflect in our study results.

5.1. Conclusions

This study lead to development and validation of a questionnaire to evaluate the health needs of hepatitis B affected women in the reproductive health domain. This tool showed the essential needs of these women. It can help health providers to deliver better quality services.

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Footnotes

Conflict of Interests: The authors declared no conflict of Interest.

Ethical Approval: This study was approved by the Ethics Committee of the Shahrood University of Medical Sciences, Shahrood, Iran (code: 22122).

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Patient Consent: The constant written forms were obtained from the all participants.

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Table 2. Results of Exploratory Factor Analysis Using Rotated Component Matrix

Factors and Items (% of Cumulative Variance = 54.99%)	Rotated Component Matrix			
	1	2	3	4
Supportive needs (Factor 1) (% of cumulative variance = 42.36)				
1. Not be separated from the other patients in the delivery sectors.	0.784			
2. Be respected in the health centers	0.717			
3. Be consulted about disease disclosure	0.759			
4. Be advised about the problems that may occur after disclosure.	0.725			
5. Be declared my test result with confidentiality.	0.751			
6. Do not expose my disease for everyone in the health centers	0.735			
7. To have the right to have or not have an accompaniment at the time of admission.	0.716			
8. Be aware of my baby's health status immediately after delivery.	0.703			
9. Have done my baby's vaccine and immunoglobulin injections in my presence.	0.697			
10. Be supportive of the health care providers if they faced a risk during health care providing	0.684			
11.Be emotionally supported for adaptation to disease	0.580			
12. To have a clean and equipped room during the hospital stay.	0.655			
13. Introduced to trained people with similar disease situation.	0.628			
14. Be supported by the community members after disclosing my disease.	0.645			
15. Get a grant to pay for the essential tests and medicines	0.644			
16. Get a grant to pay for the reproductive health cares	0.638			
17. To pay my life expenses for essential needs.	0.651			
18. To have no difference between me and other patients at the women's clinic, maternity ward or other health care provider centers	0.603			
19. To be questioned about my willingness to do a hepatitis B diagnostic test	0.490			
20. Be tracked for my illness related cares regularly.	0.494			
21. Be tracked for my family related cares regularly.	0.511			
22. Be tracked my pregnancy related cares regularly	0.537			
Information needs (Factor 2) (% of cumulative variance = 3.12)				
1. Be explained to about the need for hepatitis B diagnostic test before applying it.				0.597
2. Be educated about hepatitis B disease, before applying hepatitis B diagnostic test.				0.581
3. To tell me about the probable results of hepatitis B diagnostic test, before applying it.				0.624
4. Simply be interpreted for me the result of the hepatitis B diagnostic test				0.559
5. To give me the correct and adequate information about the disease progression when receiving the test result				0.547
6. To give me the correct information about the disease effects on the both fetus and newborn.				0.537
7. To give me the enough information about the health and nutrition tips to improve the condition of the baby during pregnancy				0.457
8. To give me information on how to track my condition				0.438
9. To give me the necessary information about the disease as soon as possible				0.424
10. Be tough about the care tips that help my health and well-being				0.495
11. Be aware of how to prevent the transmission of disease to the fetus and family		.		0.490
12. Be aware of the health services that are being provided at hepatitis B care centers				0.488
13. Be trained my health care providers about the health services that are being provided at hepatitis B care centers				0.469
14. To give the adequate information about the hepatitis B disease to my family				0.465
15. Be informed by my country's immigrations of the disease and prevention transmission methods.				0.447
16. Be correctly educated about my disease through the media (correct material throughout the correct educational method).				0.548
17. Train the health care providers on how to provide a proper health services to people with hepatitis B				0.432
Health service needs (Factor 3) (% of cumulative variance = 3. 90)				

1. Be consulted properly to solve my sexual problems.		0.790
2. Be referred to the appropriate specialized centers to treat my genitourinary problems.		0.746
3. Be regularly evaluated regarding sexually transmitted disease when I refer to the health centers.		0.735
4. Be consulted about the recommendations that increase my fertility rate.		0.689
5. To guide me about how to prepare and maintain hepatitis B immunoglobulin (during my prenatal care)		0.683
6. Be consulted about the lactation.		0.428
7. Be referred to a precise laboratory to conduct the hepatitis B diagnostic test		0.442
8. Be consulted to choose the right contraception method based on my situation		0.567
9. Be referred to the psychologist after knowing the positive result of the hepatitis B diagnosis test		0.559
10. After receiving the test result, referred to the specialist centers with an easy admission to track my pregnancy and illness , maternity, dentistry or other health services		0.547
Capacity building needs (Factor 4) (% of cumulative variance = 5. 59)		
1. Be planned to change inappropriate behaviors of some health care providers at the time of service providing via professional programs	0.556	
3. Be Increased the number and capacity of the free or low cost specialized health centers.	0.534	
48. Be planed for hepatitis B control program according to the needs of each province in my country	0.508	
5. Be considered the sufficient budget for the implementation of hepatitis B programs in Iran.	0.501	
6. Planned to change the wrong beliefs of people in our society towards people with hepatitis B	0.498	
7. Be created the security against disclosure rules for hepatitis B in Iran.	0.496	
8. Be facilitated my admission in the health centers	0.790	
9. Increased the insurance coverage to receive my health cares.	0.746	
10. Be Increased the number and capacity of the free or low- cost specialized health centers.	0.735	
11. Be increased the capacity of government health centers to replay our needs.	0.689	
12. Be supervised the costs and quality of health services that are provided to me.	0.683	
13. Be created a comprehensive program for diagnosing, treating, advising and tracking my illness.	0.681	
14. Be created and informed the official websites for hepatitis B by the ministry of health.	0.666	
15. Be financially supported by my country's immigrations as a means of disease control strategies.	0.667	
16. To get integrated reproductive and disease health services.	0.652	
17. Be used the capacity of social networks to teach me	0667	
18. Be planed to reduce the hepatitis B related stigma in our country.	0.547	
19. To get support from the key people in hepatitis B programs	0.537	
20. Be in partnership with other countries to control hepatitis B	0.464	
21. Be started the mandatory screening program of hepatitis for all pregnant women in my country as soon as possible.	0.541	