

ORIGINAL ARTICLE

THE DEVELOPMENT AND VALIDATION OF A HEALTH BELIEF MODEL QUESTIONNAIRE FOR MEASURING FACTORS INFLUENCING ADHERENCE DURING PREGNANCY

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ABSTRACT

This study aimed to develop and validate a Health Belief Model (HBM) questionnaire to measure adherence to drug, vitamin, and supplement use in pregnant women. This cross-sectional study was conducted over a duration of one month at one of the advanced type B health facilities in Surabaya, namely the obstetrics and gynecology clinic of Airlangga University Hospital. The respondents were pregnant women who took drugs, vitamins, and/or supplements, using convenience sampling. Reliability was analyzed using Cronbach's alpha, whereas validity was analyzed using the content validity index, Pearson's product-moment correlation, and exploratory factor analysis (EFA). The analysis was conducted using IBM SPSS software (version 26). A total of 135 respondents participated in this study. Construct validation was performed using exploratory factor analysis (EFA). The result of the Kaiser-Meyer-Olkin (KMO) test was 0.806, and Bartlett's test showed a value of 0.000. We deleted two items because the loading factor value was less than 0.5. The results showed that the Health Belief Model questionnaire had a Cronbach's alpha value > 0.7 and Pearson's correlation above the r-table with a significance of < 0.05. The 25-item questionnaire, based on the Health Belief Model theory, is a valid and reliable instrument for measuring adherence factors for the use of drugs, vitamins, and/or supplements by pregnant women.

Keywords: Health Beliefs Model; Pregnancy; Medication adherence; Validity and Reliability

INTRODUCTION

The prevalence of medication use during pregnancy in developed countries has shown that approximately 73.1% of pregnant women receive at least one prescription¹. Consistent with findings from developed countries, prevalence studies in Indonesia have reported a relatively high rate of medication use among pregnant women (35.3%)². The prevalence of this drug prescription increases with gestational age³. Inappropriate drug use during pregnancy can cause fetal abnormalities⁴. The high prevalence in pregnant women at risk is also caused by inadequate vitamin and supplement use⁵. Noncompliance is one of the factors that cause pregnant women to experience risks during pregnancy⁶.

Nonadherence to medications, including vitamins and supplements, is one of the most important global health issues, and it is estimated that almost half of the patients do not take their medications according to the prescribed therapeutic regimen⁷. In Indonesia, medication adherence during pregnancy remains

low, with adherence rates of only 53.8% for chronic condition medications and 46.2% for symptomatic medicines⁸. Medication adherence plays an important role in improving the quality of pregnancy and reducing the risk of adverse events in pregnant women and fetuses⁹. Some studies have mentioned that adherence to the use of drugs, vitamins, and supplements in pregnant women is influenced by several factors, such as low knowledge, perception of risk, and limited access to health facilities⁶. These factors increase the risk of complications during pregnancy, including anemia, low birth weight (LBW), and premature birth⁵.

The Health Belief Model (HBM) is a health behavior theory suitable for identifying factors that influence adherence¹⁰. This theory explores the relationship between individuals' perceptions of health risks, benefits, and perceived barriers. The addition of cues to action encourages changes in a person's behavior. Although studies have shown that health beliefs significantly affect medication adherence in various patient populations, validated adherence measurement tools

specifically designed for pregnant women remain limited^{11,12}. Therefore, the HBM approach in this study was used to explain the factors influencing pregnant women's adherence to drugs, vitamins, and supplements. By understanding these factors, more effective and focused interventions can be designed to improve adherence among pregnant women's adherence¹³.

To date, reports related to evidence of adherence to the use of drugs, vitamins, and supplements, especially in pregnant women, are still limited because most existing studies primarily focus on the prevalence and patterns of medication use rather than adherence behavior and its underlying determinants. In addition, only a limited number of studies have employed validated, theory-based instruments, and evidence from low- and middle-income countries, including Indonesia, remains scarce. Therefore, this study aimed to develop a questionnaire based on the Health Belief Model theory and measure its validity and reliability to determine the factors that influence compliance with the use of drugs, vitamins, and supplements in pregnant women. A validated questionnaire grounded in the Health Belief Model will provide a reliable tool for health professionals and researchers to assess and address adherence to antenatal care.

METHODS

The development and validation of the Health Belief Model questionnaire in this study were divided into several stages: The first stage involved designing the HBM questionnaire in accordance with the HBM theory domains. The second stage involved seeking expert opinions. The third stage involved constructing validity using Exploratory Factor Analysis (EFA). The details of each phase are outlined as follows.

Development Questionnaire

The Health Belief Model (HBM) and cues to action questionnaires were developed using the HBM theory approach, which consists of five domains: perceived susceptibility, perceived severity, perceived benefits, perceived barriers, and self-efficacy, coupled with the concept of cues to action. A questionnaire was created using various sources from the literature. Keywords such as "Health Belief Model", "Pregnancy", "Development Questionnaire", "Validation Questionnaire", "Medication Adherence", "Supplement in Pregnancy", and "Vitamins in Pregnancy" were used. All questionnaire items were organized based on knowledge, attitude, and action variables. The HBM and cues-to-action questionnaires were developed using a Likert scale to calculate the scores for each variable. Scores were 1 for "strongly disagree," 2 for "disagree," 3 for "neutral," 4 for "agree," and 5 for "strongly agree."

Content Validity Index (CVI)

At this stage, the content validity of the HBM and cues to action questionnaire was assessed by seven experts selected based on their expertise in maternal health, patient adherence and instrument development. The experts included one obstetrician, two pharmacists with experience in patient adherence and maternal health, and four professionals, including university faculty members experienced in survey design and health behavior research. The content validity was quantitatively assessed. Experts assessed the content validity index (CVI) of the questionnaire. The item validity index (I-CVI) of each item was calculated by dividing the number of experts who gave a score of '3' or '4' by the total number of experts, so that the I-CVI value ranged from 0 to 1. With the number of experts in the range of 5-10 (seven in this study), an item is said to be relevant if the I-CVI value is ≥ 0.78 , and the item should be revised if the I-CVI value is < 0.78 . The average content validity index (S-CVI) is the average of the S-CVI, and the questionnaire is considered relevant if the S-CVI is at least 0.90¹⁴.

Construct Validity

Construct validity was assessed using exploratory factor analysis (EFA). Exploratory factor analysis was used to group instrument items into factors that the researcher wanted or in accordance with theory (Gaskin & Happell, 2014). Exploratory factor analysis also determines whether the data collected can be tested with further factor analysis tests using Kaiser-Meyer-Olkin (KMO) and Bartlett's test values. KMO and Bartlett's tests were used to determine whether the sample used was sufficient for factor analysis. Factor analysis can be carried out if the KMO value is > 0.5 , and the Bartlett's test is < 0.05 .

Study Design and Data Collection

This was an observational cross-sectional study. The inclusion criteria for this study were pregnant patients who were taking medications, vitamins, and supplements; able to communicate with the researchers; and willing to participate in the study by providing informed consent. The exclusion criteria were pregnant women who suffered from other diseases that would affect the results of the study (e.g., severe dementia, schizophrenia, or depression) and interfere with pregnancy conditions.

This study measured the validity of the HBM questionnaire, which consisted of 27 items. Based on this rule of thumb, the number of samples used versus the questionnaire items was 5:1. Therefore, this study used a minimum of 135 samples. Convenience sampling was used to collect samples from patients who sought treatment at the obstetrics and gynecology clinic at Universitas Airlangga Hospital in Surabaya City from November 20, 2024, to December 20, 2024, who met the predetermined criteria.

Reliability Test

A reliability test was conducted to analyze the consistency of the items. The reliability test was conducted by testing internal consistency, and the value was represented using Cronbach's alpha coefficient. Cronbach's alpha was in the range of 0.00-1.00. Item reliability was considered acceptable if the Cronbach's alpha value was above 0.70. For social science research, Cronbach's alpha values above 0.60 are acceptable¹⁵.

Pearson's Product-moment Correlation

Pearson's product-moment correlation was performed to ensure consistency between components within the construct¹⁶, where a coefficient of 0 indicated no correlation and a coefficient of 1 indicated a perfect positive correlation¹⁷. The reliability test process and Pearson's product-moment correlation were conducted using IBM SPSS software version 26.

Ethical approval

This study was approved by the Research Ethics Committee (KEP) of the Universitas Airlangga Hospital (number: 145/KEP/2024; date of approval: 26th August 2024).

RESULTS

Content Validity Index

Seven experts rated the HBM and cues in the action questionnaire as relevant to the study. The I-CVI for each item was in the range from 0.86-1.00. The mean S-CVI score was 0.984.

Pre-Testing

In this study, the results of the pre-testing suggested eliminating the word "vulnerable" in items with the perceived susceptibility domain, namely item number 1-4. Therefore, items 1-4 were previously "I feel vulnerable to the risk of nutritional deficiencies if I do not comply with the use of drugs, vitamins, or supplements", "I feel vulnerable to the risk of infection or disease if I do not comply with the use of supplements and vitamins during pregnancy", "I feel vulnerable to possible side effects if I do not comply with the use of drugs, supplements, and vitamins during pregnancy", "I feel vulnerable to serious health threats to my fetus if I do not comply with the use of drugs, supplements and vitamins" were changed to "I feel at risk of nutritional deficiencies if I do not comply with the use of drugs, supplements, and vitamins" was changed to "I feel at risk of nutritional deficiencies if I do not adhere to the use of drugs, vitamins or supplements", "I feel at risk of infection or illness if I do not adhere to the use of supplements and vitamins during pregnancy", "I feel at risk of possible side effects if I do not adhere to the use of drugs, supplements, and vitamins during pregnancy", "I feel a serious health threat to my fetus if I do not adhere to the use of drugs, supplements, and vitamins". The reduction of the word "vulnerable" emphasizes the statement of each item, is easier to understand, and does not reduce the meaning of each item statement itself.

After the evaluation phase of the Content Validity Index and Pre-testing, the researchers agreed to release the final version of the HBM and cues-to-action questionnaires, as presented in Table 1.

Table 1a. Health Belief Model and Adherence Questionnaire

Domain: <i>Perceived Susceptibility</i>	
Q1	I feel at risk of nutritional deficiencies if I do not adhere to the use of medications, vitamins, or supplements.
Q2	I feel at risk of infection or illness if I do not adhere to the use of supplements and vitamins during pregnancy.
Q3	I feel at risk of possible side effects if I do not comply with the use of medications, supplements, and vitamins during pregnancy.
Q4	I feel that there is a serious health threat to my fetus if I do not adhere to the use of medications, supplements, and vitamins.
Domain: <i>Perceived Severity</i>	
Q5	I was worried about having serious complications during pregnancy if I did not adhere to the use of medications, supplements and vitamins.
Q6	I am worried about my health condition and that of my fetus if I am not compliant with the use of medication, vitamins or supplements.
Q7	I am worried about complications in my labor if I do not adhere to the use of medications, vitamins, or supplements during pregnancy.
Q8	I feel fine if I am not compliant in taking medications, vitamins, or supplements during pregnancy.

Table 1b. Health Belief Model and Adherence Questionnaire

Domain: <i>Perceived Benefit</i>	
Q9	I feel that the benefits of being compliant with my medication, vitamins, and supplements can help me have a healthy pregnancy.
Q10	I feel that the benefits of adhering to the use of medications, vitamins, and supplements will enhance the healthy development of my fetus.
Q11	I feel that the benefits of adhering to the use of supplements and vitamins as advised by doctors, pharmacists, pharmacies, and other health professionals will help prevent complications during pregnancy.
Q12	I feel that the benefits of adhering to the recommended use of medications, vitamins, and supplements can help me recover quickly after giving birth.
Domain: <i>Perceived Barrier</i>	
Q13	I feel that the large number of medications to be taken is an obstacle to medication adherence.
Q14	I feel that the side effects of medications, supplements and vitamins discourage me from using them regularly.
Q15	I have trouble remembering to take my medication, vitamins, and supplements.
Q16	I have trouble remembering whether I have taken my medications, vitamins and supplements.
Q17	I don't understand how to use medicines, vitamins, supplements properly.
Q18	I don't understand the correct timing of medications, vitamins, supplements.
Q19	I feel that the cost of buying medicine, supplements and vitamins is too expensive.
Domain: <i>Perceived Self Efficacy</i>	
Q20	I didn't trust the drugs, vitamins, and supplements I was getting.
Q21	I feel capable of being compliant in using medications, vitamins and supplements.
Q22	I feel able to take my medication, vitamins, and supplements on time.
Q23	I feel capable of using medications, vitamins and supplements properly.
Q24	My confidence in the drugs, vitamins, and supplements I was getting increased.
Domain: <i>Cues to action</i>	
Q25	Information and education from my doctor, pharmacist, and other health professionals will be very important to help me adhere to the use of supplements and vitamins during pregnancy.
Q26	Information and education from the pharmacist will be very important to help me adhere to the use of supplements and vitamins during pregnancy.
Q27	Support from my family encouraged me to adhere to the use of supplements and vitamins during pregnancy.

Demographic Characteristic

The sociodemographic characteristics of the 135 participants who agreed to participate in this study are presented in Table 2. The mean age of the participants was 28.42 (SD: 4.80), and as many as 60% of the participants were pregnant women with a gestational age > 28 weeks (trimester 3).

Construct Validation

Test construct validation was performed using exploratory factor analysis (EFA). The result of the Kaiser-Meyer-Olkin (KMO) test was 0.806, and Bartlett's test showed a value of 0.000. The results of the factor analysis with varimax rotation produced loading factor data, as shown in Table 3.

Table 2a. Characteristics of the respondent (n=135)

Characteristics	n (%)
Age (years)	
17-20	7 (5.2)
21-30	84 (62.2)
31-40	43 (31.9)
>40	1 (0.7)
Occupations	
None	70 (51.9)
Private	24 (17.8)
Public officer	9 (6.6)
Other	32 (23.7)

Table 2b. Characteristics of the respondent (n=135)

Education	
None	3 (2.2)
Elementary school	7 (5.2)
Junior high school	23 (17.0)
Senior high school	78 (57.8)
Diploma	22 (16.3)
Bachelor and above	2 (1.5)
Total number of pregnancies (including current pregnancy)	
1	50 (37.0)
2	43 (31.9)
3	30 (22.2)
4	5 (3.7)
Other	7 (5.2)
Trimester of Pregnancy	
1	18 (13.3)
2	36 (26.7)
3	81 (60.0)
Source of Healthcare Financing	
National Health Coverage (BPJS/JKN/KIS)	126 (93.3)
Private Insurance	9 (6.7)
Out of Pocket	0 (0.0)
Illness during Pregnancy	
None	99 (73.3)
Chronic	36 (26.7)

Table 3. Rotated Factor Matrix

Item	Loading Factor					
	1	2	3	4	5	6
Q1				0.798		
Q2				0.727		
Q3				0.746		
Q4				0.470		
Q5					0.706	
Q6					0.682	
Q7					0.760	
Q8		0.090*				
Q9		0.742				
Q10		0.777				
Q11		0.727				
Q12		0.508				
Q13	0.385					
Q14	0.649					
Q15	0.648					
Q16	0.673					
Q17	0.791					
Q18	0.834					
Q19	0.760					
Q20			0.054*			
Q21			0.340			
Q22			0.419			
Q23			0.531			
Q24			0.618			
Q25			0.777			
Q26			0.870			
Q27			0.754			

Table 4. Reliability and Validity Result

Item	Significance	Coefficient Pearson's Correlation	Cronbach's alpha if item deleted
Q1	0.000	0.405	0.871
Q2	0.000	0.586	0.865
Q3	0.000	0.629	0.864
Q4	0.000	0.525	0.866
Q5	0.000	0.584	0.865
Q6	0.000	0.629	0.864
Q7	0.000	0.526	0.867
Q9	0.000	0.603	0.865
Q10	0.000	0.531	0.867
Q11	0.000	0.604	0.865
Q12	0.000	0.541	0.867
Q13	0.000	0.348	0.875
Q14	0.000	0.475	0.872
Q15	0.000	0.351	0.876
Q16	0.000	0.437	0.873
Q17	0.000	0.384	0.876
Q18	0.000	0.399	0.874
Q19	0.000	0.406	0.874
Q21	0.000	0.579	0.866
Q22	0.000	0.501	0.867
Q23	0.000	0.559	0.866
Q24	0.000	0.562	0.866
Q25	0.000	0.505	0.868
Q26	0.000	0.432	0.870
Q27	0.000	0.472	0.868

DISCUSSION

This instrument was developed based on prior studies to identify factors influencing pregnant women's beliefs about consuming drugs, vitamins, and supplements during pregnancy. The first version of the questionnaire was subjected to a content validity index assessment and pretesting. The CVI was assessed by seven experts, who provided results that met the criteria, where the I-CVI value was ≥ 0.78 , and the S-CVI value was $\geq 0.90^{14}$. In the pre-testing stage, it was recommended that the word "vulnerable" from items 1-4 of the perceived susceptibility domain. The removal of the word "vulnerable" emphasizes the question but does not eliminate its meaning of the question itself. The evaluation and adjustment results from the pre-testing stage resulted in the final version of the HBM-Cues-to-Action Questionnaire.

Before a questionnaire can be used, it must be tested for validity and reliability¹⁸. This study was conducted using a sample of pregnant women from the Airlangga University Hospital. A total of 135 pregnant women participated in this study. The age group and educational characteristics of the participants reflect those commonly observed among pregnant women in urban clinical settings such as Surabaya. The participants in this study were pregnant women with an average age range

of 21-30, which is the reproductive age for pregnancy and childbirth¹⁹. Educational background did not prevent the participants from completing the questionnaire, proving that the questionnaire was used in various demographic layers of pregnant women.

We developed a questionnaire based on the Health Belief Model theory and validated it through content validity, construct validity, and reliability testing. The constructs of the HBM Cues to Action questionnaire were validated or explored using Exploratory Factor Analysis (EFA). The loading factor for all items showed two items $< 0.3^{20}$. The final version contained 25 items across the HBM domains after removing two items with low factor loadings. The two deleted items had loading factor values of < 0.3 . Therefore, we tested the reliability and validity of the 25 questionnaire items using Pearson's product-moment correlation.

The results of the final reliability test showed that the HBM cues for action and the final version of the questionnaire were reliable and valid. This was evidenced by the value of each domain and a total Cronbach's alpha value of > 0.70 . In the same research related to adherence using the health belief model approach, the total Cronbach's alpha value of this questionnaire was slightly smaller than that of other studies. Cronbach's alpha values were slightly lower than those of other HBM-based

adherence questionnaires (for example, 0.89 for patients) but still within an acceptable range²¹. This slightly lower reliability may be due to differences in the target population, number of items, and contextual factors specific to pregnant women in Indonesia. Meanwhile, the validity test with Pearson's product-moment correlation showed that this questionnaire is valid because each item has a significance value of <0.05 , and the Pearson's correlation or r -value is smaller than the r table (r table = 0.1441). It should be noted that adherence was self-reported, which may be subject to social desirability bias, potentially leading participants to overreport their adherence behaviors.

The questionnaire addressed this gap by focusing specifically on medication/supplement adherence during pregnancy using the HBM framework. The results of the reliability and validity tests showed that this questionnaire can be used to assess the various factors affecting adherence among pregnant women in Indonesia. The questionnaire was developed by examining perceptions related to pregnancy risks, risk prevention, and prevention of benefits to perceived benefits. This study has some strengths, including the rigorous development process in which the questionnaire was developed using a comprehensive approach, including expert review and pretesting, enhancing its content validity. In addition, the study included a sufficient number of participants to conduct the validation analyses, strengthening the reliability of the results. The questionnaire incorporated cues to the action domain in addition to core Health Belief Model (HBM) constructs, providing a more comprehensive assessment of the factors influencing medication adherence during pregnancy. Additionally, the questionnaire addressed a specific gap, focusing on medication/supplement adherence during pregnancy using the HBM framework, filling a void in the existing literature.

A few limitations were found, including the use of convenience sampling from a single hospital, which restricted the generalizability of the findings to broader populations and different health care settings. The limited duration of the study may not reflect long-term behavioral change. The number of respondents who reported their use of drugs, vitamins, and supplements may have been underestimated. As the study was conducted in Indonesia, the questionnaire may require further validation and adaptation for use in other cultural contexts or healthcare systems.

Future research should focus on validating the questionnaire across diverse populations and healthcare settings to enhance generalizability. Longitudinal studies can assess the instrument's predictive validity and ability to capture changes in adherence behaviors over time. Investigating the performance of the questionnaire in different cultural contexts and languages will broaden its

applicability further. Additionally, exploring the relationship between questionnaire scores and objective measures of medication adherence could further strengthen its validity. The developed questionnaire has potential implications for clinical practice, enabling healthcare providers to identify pregnant women at risk of nonadherence and to tailor interventions accordingly. It may also serve as a valuable tool for researchers studying medication adherence during pregnancy, facilitating comparisons across studies and contributing to the development of targeted adherence-promoting strategies. In antenatal care settings, healthcare providers can use this tool to identify pregnant women at risk of nonadherence and provide tailored counseling, education, and interventions to improve adherence to medications, vitamins, and supplements.

CONCLUSIONS

The conclusion of this study shows that the questionnaire based on the Health Belief Model theory is a valid and reliable instrument for measuring factors that influence adherence to the use of drugs, vitamins, and/or supplements in pregnant women.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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