Development and content validation of assessment items for identifying pregnant women of concern by midwives and public health nurses

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Abstract

This study aimed to develop and validate assessment items to help midwives and public health nurses identify pregnant women who may need special attention (pregnant women of concern). The research followed a structured four-step approach consisting of (1) defining the phrase "pregnant women of concern," (2) creating assessment items based on existing research and interviews, (3) verifying these items with experienced professionals, and (4) validating the content of the assessment tool through surveys. Forty-five assessment items were developed based on previous research. To verify the appropriateness of their content, the study surveyed midwives and public health nurses with at least 10 years of experience. Content validity was confirmed using the Item-Level Content Validity Index (I-CVI) and Content Validity Index (CVI) measures. Following this confirmation, a broader questionnaire survey was conducted among midwives and public health nurses actively working with pregnant women to further assess content validity. Based on I-CVI results, some items were removed and others refined, resulting in a final set of 39 assessment items. The Scale-Level Content Validity Index (S-CVI) for the entire tool was 0.901, indicating high validity.

Key Words

pregnant women of concern, assessment items, content validity, midwife, public health nurse

Introduction

In Japan, the number of child abuse cases continues to rise, driven by changes in the childcare environment, the increasing isolation of parenting due to the declining birthrate, and the rising prevalence of nuclear families [1]. Consequently, providing support from the prenatal stage has become increasingly important. The 2009 amendment to the Child Welfare Act designated pregnant women in need of special support before childbirth as "specified expectant mothers," and in 2013, the criteria for identifying these women were clarified [2], leading to integrated support across health, medical, and welfare services.

Furthermore, Mitsuda suggest that pregnant and postpartum women expected to face difficulties in child-rearing due to economic or familial factors, among other challenges, should be considered socially high-risk pregnant and postpartum women, although no precise definition for this category has been established [3]. They emphasize that such individuals require appropriate support. Mitsuda also distinguishes within this group those who do not meet the criteria for specified expectant mothers, referring to them as "pregnant wom-

en of concern" [4].

In clinical practice, cases of pregnant women who do not qualify as specified expectant mothers but are nevertheless expected to require some form of support are an acknowledged issue. These individuals, who elicit a vague sense of concern, are referred to as "pregnant women of concern." Toba emphasizes that this sense of unease is important in medical settings, should be shared among healthcare providers, and contributes to safer perinatal care [5]. However, the concerns that nurses experience regarding certain pregnant women are derived from their individual experiential knowledge [6]. There is no established definition of pregnant women of concern, nor has the concept been explicitly verbalized in a way that allows for shared interpretation among midwives working in hospitals or public health nurses engaged in regional care.

Therefore, to provide coordinated support for pregnant women of concern—similar to specified expectant mothers—across health, medical, and welfare services, it will first be necessary to establish a clear understanding of who falls into this category. This process should begin with assessments conducted based on a common framework of understanding among all relevant stakeholders.

We have previously studied concept derivation to clarify the concept of "pregnant women of concern" [6]. Building on this, we conducted a qualitative study targeting midwives in obstetric medical institutions and public health nurses in maternal and child health departments who support pregnant women.

Based on 89 events (thinking processes) described by the participants, a total of 249 codes and 10 subcategories related to perceptions of pregnant women of concern were extracted, and four main categories were derived: mental and physical maladaptation to pregnancy; personality traits that make adapting to social life difficult; social isolation; and vulnerable family functioning [7]. Based on these results, assessment items for screening pregnant women of concern were developed and reviewed for content validity.

The purpose of this study is to refine assessment items for developing the "Assessment Tool for Pregnant Women of Concern" to help midwives and public health nurses screen for pregnant women who require special attention when issuing Mother and Child Health Handbooks or during prenatal checkups and to verify the content validity of these items.

We believe that if an assessment tool for "pregnant women of concern" who need support can be created, it would enable healthcare professionals to connect many pregnant women to appropriate support services from early pregnancy—not limited to those officially designated as specified expectant mothers—ensuring that no pregnant woman who needs support is overlooked, and facilitating continuous childcare support.

Materials and methods

The methodology follows a systematic approach to content validation [8], described in the following steps:

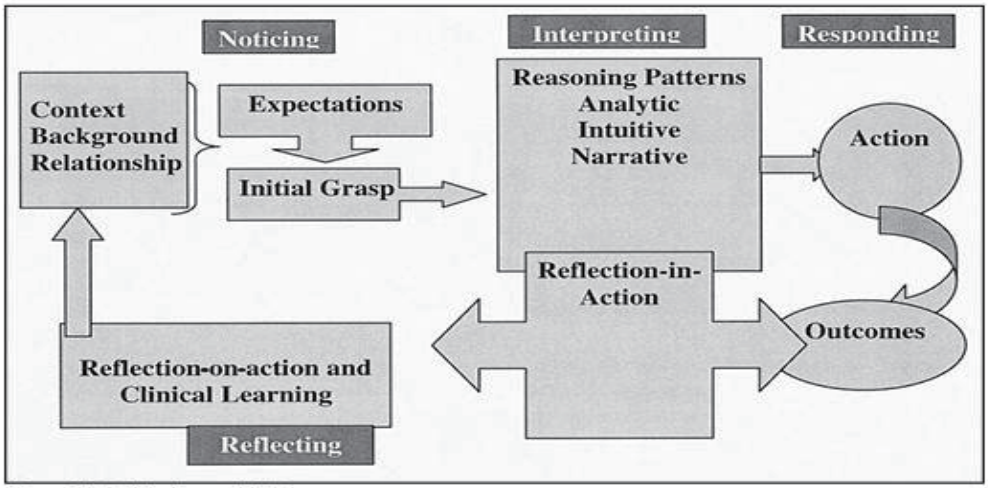
Defining the target domain

Given that "pregnant women of concern" lacks a clear definition, potentially leading to a variety of interpretations even among experts, a definition was proposed for the purposes of this study.

Definition of terms

This study aimed to develop and validate the content of items for an Assessment Tool for Pregnant Women of Concern to help midwives and public health nurses screen for pregnant women who may require special attention when issuing Mother and Child Health Handbooks or during prenatal checkups. The moment when nursing professionals identify a pregnant woman of concern rep-

resents what Tanner describes as the initial recognition stage in the clinical judgment process [9]. Tanner describes nurses' clinical judgment as a process of noticing, interpreting, responding, and acting, with the initial recognition stage grounded in anticipatory awareness (Figure 1). This ability to recognize concerning situations is built upon a contextual foundation that develops through accumulated clinical judgment experiences. Our previous research also confirmed that a nursing professional's capacity to identify pregnant women of concern is fundamentally dependent on their own clinical experience. Based on these insights, in the present study, the term "pregnant woman of concern" is defined as a pregnant individual who has triggered the nurse's professional intuition. This occurs through a process in which nursing professionals perceive characteristics through their senses, then draw from past learning and clinical experiences, search for information from others, and



Tanner CA: Thinking like a nurse: A research-based model of clinical judgment in nursing. Journal of Nursing Education, 45: 204-211, 2006.

Figure 1. The process that experienced midwives and public health nurses initially use to identify pregnant women who may need special attention

Table 1. Definition of pregnant women of concern as identified by experienced midwives and public health nurses

Pregnant women identified through the following four-step process:

1. Recognizing characteristics of the pregnant woman through sensory perception.
2. Drawing on past learning, clinical experience, and information obtained from others.
3. Selecting the most similar pregnant woman from past cases.
4. Inferring potential risks in physical, psychological, or social aspects that may arise during pregnancy, childbirth, or childrearing.

Adapted from Nishimura et al, "Concept derivation of concerns that nurses observe in pregnant women," J. Jpn. Soc. Matern. Nurs., 22, 2022.

identify the closest analogous case they have encountered. From this, they infer potential problematic situations that might arise in physical, psychological, or social aspects during pregnancy, childbirth, or child-rearing [6] (Table 1).

Conceptual framework

We previously conducted a concept analysis. In light of the results, the present study aimed to clarify the characteristics of "pregnant women of concern" as identified by experienced midwives and public health nurses, and a qualitative descriptive study was conducted involving semi-structured interviews with 22 midwives and public health nurses (15 midwives and 7 public health nurses) with at least 4 years of nursing experience. The results indicated that "pregnant women of concern" can be positioned as those who might transition into specified expectant mothers. The conceptual framework is illustrated in Figure 2.

Development of assessment items for pregnant women of concern

Literature review

A literature review was conducted using the academic databases ICHUSHI-Web, PubMed, and CINAHL. The keywords used for the search included pregnant or postpartum women AND concern OR worry OR socially high-risk, mother and child AND concern OR worry, as well as specific terms such as pregnant women requiring attention, pregnant women of concern, socially high-risk pregnant women, specified expectant mothers, and mother and child of concern. For articles written in English, the search used the keywords "pregnant women AND concern OR anxiety OR social high-risk."

The search period covered publications from 2000 to June 2021. The year 2000 was chosen because it marked the enactment of the Child Abuse Prevention Act, which defined "child abuse" in Japan. In 2009, revisions to the Child Welfare Act in-

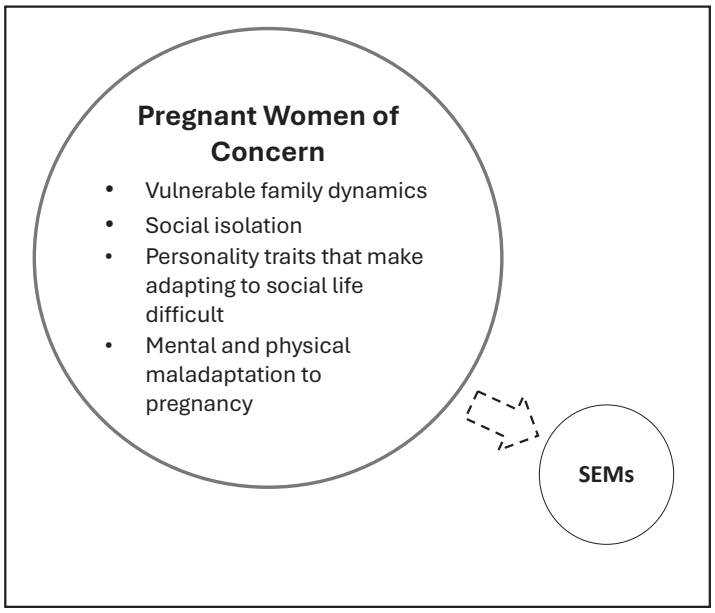


Figure 2. Conceptual framework for pregnant women of concern

troduced the definition of "specified expectant mothers," drawing attention to the need for supporting pregnant women.

As the term "pregnant women requiring attention" is not clearly defined, a comprehensive literature search was conducted, including all relevant articles published in English and Japanese between 2000 and June 2021, excluding conference proceedings. Literature that lacked descriptions or insights relevant to understanding this concept was excluded. Additionally, studies focusing on clearly defined criteria—such as young maternal age, economic hardship, non-issuance of Maternal and Child Health Handbooks, lack of prenatal checkups, and multiple pregnancies—as outlined in the Ministry of Health, Labour and Welfare guidelines, were excluded. These criteria were deemed outside the scope of the present study, which focuses on how nurses intuitively identify pregnant women of concern.

After excluding duplicates, the literature search identified 305 Japanese papers and 2,256 English papers (627 from CINAHL and 1,629 from PubMed). Two additional papers were identified through non-database sources, bringing the total to 26 papers from which assessment criteria for "pregnant women of concern" were extracted.

Qualitative descriptive study

We have previously conducted a qualitative descriptive study to clarify how midwives and public health nurses identify pregnant women of concern as part of efforts to develop an Assessment Tool for Pregnant Women of Concern. The study focused on the awareness and insights of experienced midwives and public health nurses who provide care to pregnant women.

Study participants

The study included 22 midwives and public health nurses with at least 4 years of experience as nurses.

Analysis methods and results

Semi-structured interviews were conducted, and the collected data were analyzed using qualitative descriptive methods. Based on the 89 events (thinking processes) described by the participants, a total of 249 codes and 10 subcategories related to perceptions of pregnant women of concern were extracted, and four main categories were derived: mental and physical maladaptation to pregnancy; personality traits that make adapting to social life difficult; social isolation; vulnerable family functioning[7] (Table 2).

Refinement of assessment items

To refine the assessment items, the findings from the literature review and qualitative descriptive study were compared. As a result, seven additional items were incorporated into the assessment, even though they were not explicitly identified in the qualitative study, because they were considered necessary for screening pregnant women of concern.

The seven additional items derived from prior research included lack of affect[10], extremely negative statements[11], a noticeable smell of cigarettes from the pregnant woman[5, 12], mood swings and emotional instability[13], a noticeable smell of alcohol from the pregnant woman[13], statements indicating a desire to prioritize personal time even after childbirth[11], and the woman's parents not accepting the pregnancy[12]. These seven additional items, combined with those from the qualitative research, resulted in a total of 45 assessment items. These items were reviewed by seven faculty members who held master's degrees or higher, had experience in tool-development research, and specialized in maternal nursing, public health nursing, and/or pediatric nursing education.

Expert validation of assessment items

Expert panel

Based on the results of the qualitative descrip-

tive study, the 45 extracted assessment items were presented to a panel of four experts, consisting of two midwives and two public health nurses. These experts were asked to evaluate whether the items were appropriate for assessing pregnant women of concern. All four participants were experienced nurses specializing in maternal and child support, each with at least 10 years of professional experience.

Table 2. Pregnant women of concern as identified by proficient and expert midwives and public health nurses

Category	Subcategory	Codes
Vulnerable family functioning	Poor relationship with the family	・Frightened of her husband and asking his opinion every time. ・The accompanying family members answer before she can respond to questions from the medical staff. ・During the conversation, the pregnant woman looks at her own mother's expression before answering. ・Poor family relationship and the lack of a family member to rely on. ・Finds it difficult to express her thoughts to her husband or mother. ・Moves to a new home during the pregnancy for reasons other than work. ・Pregnant women who are single, young, or in stepfamilies and cannot rely on family members due to complex family relationships. ・Couples who have had children in a superficial relationship.
	Lack of support from the family	・Even if family members are around, the woman is likely to spend much time parenting on her own. ・There is unlikely to be anyone in the family she can ask about childcare. ・The pregnant woman's parents are elderly and she cannot get support from them. ・Unemployed, receiving welfare benefits, or likely in financial difficulty based on state of clothing.
Social isolation	No one to turn to in the community	・Not much interaction with the community and society. ・Not voluntarily seeking connections with other people.
	Avoids involvement with government services and hospitals	・Keeps things to herself and does not express her feelings. ・There is an air of reluctance to delve deeper into personal matters. ・Seems not to want to get involved; seems reluctant to visit or be connected with government services. ・There is a history of refusing medical intervention or a seeming unwillingness to accept support from medical professionals.
Personality traits that make adapting to social life difficult	Learning difficulties	・Characterized intellectually by how she writes and looks up words. ・Comprehension is poor and the same things need to be repeated many times during the conversation.
	Developmental difficulties	・Unable to sit still in a chair and wait; seems restless. ・Fixates on the same questions repeatedly during the conversation. ・A feeling that the woman is not taking care of herself, based on disheveled appearance or dirty clothing.
	Emotional instability	・She asks too many trivial questions. ・Easily upset by unexpected things. ・Worried about various things without any clear reason. ・Cries while talking.
	Difficulty establishing communication	・Does not make eye contact. ・Doesn't respond to questions. ・Difficulty conversing and communicating.
Mental and physical maladaptation to pregnancy	Maternal health concerns	・The pregnant woman has a chronic illness and there is a risk that this would deteriorate during the course of pregnancy, childbirth, and childcare. ・In geriatric pregnancies, there are concerns about the physical burden of the pregnancy process as well as the mental and physical burden after birth. ・There is a history of mental illness or predisposition to depression, and concern about postpartum deterioration of mental health after childbirth. ・There is mental illness but it is untreated or treatment has been stopped by the patient.
	No progress in accepting the pregnancy	・The pregnant woman feels something other than happiness upon discovering that she is pregnant. ・The partner does not accept the pregnancy. ・Poor awareness of herself as a pregnant woman. ・Makes negative comments about the fetus during pregnancy, such as its movements are uncomfortable or it is not cute.

Adapted from Nishimura et al, "Pregnant women of concern as identified by proficient and expert midwives and public health nurses," Journal of Wellness and Health Care, 48, 2024.

Analysis method

Content validity was evaluated by calculating values for the Content Validity Index (CVI) and the Item-Level Content Validity Index (I-CVI). Because a panel of four experts was used, the evaluation criteria required that both I-CVI and CVI reach a value of 1 for an item to be considered valid. Only items meeting this threshold were deemed content-valid for inclusion.

Content validity and overall validity assessment through a questionnaire survey

Study participants

The study participants were midwives and public health nurses working in facilities that provide maternal health services, including prenatal checkups, maternal health guidance, and the issuing of Mother and Child Health Handbooks.

Participants were recruited from 16 maternity facilities and 22 maternal health departments that had received approval from their respective department heads or nursing administrators. A total of 114 participants were invited, and three midwives or public health nurses were selected from each facility.

As noted in the definition of "pregnant women of concern," identifying such women requires a certain level of nursing expertise and experiential knowledge. Therefore, based on Benner's nursing theory, which classifies nurses with at least 4 years of experience as proficient practitioners, only participants with 4 or more years of experience in maternal support were included in the study. Those with less than 3 years of experience were excluded [14].

Participating research facilities

The participating research facilities included all 16 maternity facilities that handle deliveries in a single Japanese prefecture, as well as all 22 municipal maternal and child health centers listed in the prefectural directory of municipal maternal and child health departments.

Data collection method

Data were collected from October to November 2024, using an anonymous, self-administered questionnaire distributed by mail. The survey consisted of two parts: six demographic questions about participants (age, professional role, workplace setting, years of nursing experience, years of experience supporting pregnant women, and number of pregnant women managed per month) and an assessment of the content validity of the 45 assessment items. For the latter, participants responded using a four-point Likert scale: "Does not apply," "Rarely applies," "Applies," and "Strongly applies."

Analysis method

For the calculation of CVI, values were determined for both I-CVI and Scale-Level Content Validity Index (S-CVI). Following previous research recommendations, items with an I-CVI of 0.78 or higher and a scale with an S-CVI/Ave of 0.90 or higher were considered to have excellent content validity [15]. SPSS Statistics ver. 29 (IBM Corp., Armonk, NY) was used for the analysis.

Ethical considerations

The research request documents mailed to potential participants included information about the research purpose, methodology, voluntary nature of participation, assurance that refusal would not result in any disadvantages, and details about the publication of research findings. The documents clearly stated that returning the completed questionnaire would be considered as an affirmation of consent to participate in the study.

The study was conducted after obtaining approval from the Ethics Review Committee of Toyama Prefectural University (approval no. R6-8)

Results

Of the 114 questionnaires distributed, responses were received from 74 participants (response rate

64.9%). Three respondents had less than 3 years of nursing experience and were therefore excluded. Of the remaining 71 participants, 68 completed all questionnaire items (valid response rate 59.6%); these 68 participants constituted the analysis dataset for this study.

Assessment of content validity by the expert panel

An assessment of content validity by four expert nurses resulted in an I-CVI value of 1 for all 45

Table 3. The relevance ratings on the item scale by four experts

	Expert 1	**Expert 2**	**Expert 3**	**Expert 4**	**Expert in Agreement**	**I-CVI**	**UA**
Item							
Q1	1	1	1	1	4	1	1
Q2	1	1	1	1	4	1	1
Q3	1	1	1	1	4	1	1
Q4	1	1	1	1	4	1	1
Q5	1	1	1	1	4	1	1
Q6	1	1	1	1	4	1	1
Q7	1	1	1	1	4	1	1
Q8	1	1	1	1	4	1	1
Q9	1	1	1	1	4	1	1
Q10	1	1	1	1	4	1	1
Q11	1	1	1	1	4	1	1
Q12	1	1	1	1	4	1	1
Q13	1	1	1	1	4	1	1
Q14	1	1	1	1	4	1	1
Q15	1	1	1	1	4	1	1
Q16	1	1	1	1	4	1	1
Q17	1	1	1	1	4	1	1
Q18	1	1	1	1	4	1	1
Q19	1	1	1	1	4	1	1
Q20	1	1	1	1	4	1	1
Q21	1	1	1	1	4	1	1
Q22	1	1	1	1	4	1	1
Q23	1	1	1	1	4	1	1
Q24	1	1	1	1	4	1	1
Q25	1	1	1	1	4	1	1
Q26	1	1	1	1	4	1	1
Q27	1	1	1	1	4	1	1
Q28	1	1	1	1	4	1	1
Q29	1	1	1	1	4	1	1
Q30	1	1	1	1	4	1	1
Q31	1	1	1	1	4	1	1
Q32	1	1	1	1	4	1	1
Q33	1	1	1	1	4	1	1
Q34	1	1	1	1	4	1	1
Q35	1	1	1	1	4	1	1
Q36	1	1	1	1	4	1	1
Q37	1	1	1	1	4	1	1
Q38	1	1	1	1	4	1	1
Q39	1	1	1	1	4	1	1
Q40	1	1	1	1	4	1	1
Q41	1	1	1	1	4	1	1
Q42	1	1	1	1	4	1	1
Q43	1	1	1	1	4	1	1
Q44	1	1	1	1	4	1	1
Q45	1	1	1	1	4	1	1
					S-CVI/Ave	1	
Proportion relevance	1	1	1	1	**S-CVI/UA**		1
	Average proportion of items judged as relevance across the four experts			1			

items. Consequently, the overall CVI was also 1 (Table 3).

Assessment of content validity by the questionnaire survey

The demographic characteristics of the study participants are shown in Table 4. The sample included 40 midwives and 28 public health nurses. The mean duration of nursing experience was 17.6 ± 8.1 years, and the mean duration of experience in maternal and child support was 14.3 ± 6.9 years (Table 4).

The content validity results for each of the 45 items are presented in Table 5. The S-CVI for all 45 items was 0.873. Four items failed to meet the content validity threshold of I-CVI ≥ 0.78: item (6) "Moves to a new home during pregnancy for reasons other than work," item (13) "Limited interaction with the community and society," item (14) "Not voluntarily seeking connections with other people," and item (44) "Expresses a desire to enjoy personal time even after childbirth."

After excluding these four items with I-CVI <0.78, the S-CVI for the remaining 41 items was 0.897. Upon further examination of content, items with similar expressions or content as well as items whose meaning was difficult to interpret were modified or excluded. Specifically, item (15) "Keeps things to herself and does not express her feelings" was removed because its content was encompassed within item (5) "Finds it difficult to express her thoughts to her husband or mother," and item (45) "Parents not accepting the pregnancy" was removed because its content was encompassed within item (36) "The partner does not accept the pregnancy." Following these revisions, a final set of 39 items was established (Table 6). The S-CVI for the final 39-item scale was 0.901, indicating high content validity.

Table 4. Characteristics of study participants (N = 68)

Category	N	%
Age		
20s	5	7.4
30s	20	29.4
40s	29	42.6
50s	13	19.1
60s	1	1.5
Occupation		
Public health nurse	28	41.2
Midwife	40	58.8
Workplace		
General hospital	19	27.1
Clinic	18	25.7
Public health center	28	41.4
Other	3	4.3
No. of pregnant women handled per month		
Fewer than 10	25	37.1
10–49	32	45.7
50–99	6	8.6
100 or more	5	7.1
Years of nursing experience (mean ± SD)	17.6 ± 8.1	
Years of experience in maternal and child support (mean ± SD)	14.3 ± 6.9	

Table 5. Content validity of the Assessment Tool for Pregnant Women of Concern（N = 68）

Assessment Tool for Pregnant Women of Concern (draft items)	Does not apply	Rarely applies	Applies	Strongly applies	Item CVI
Vulnerable family functioning					
	n (%)	n (%)	n (%)	n (%)	
(1) Frightened of her husband and asking his opinion every time.	3(4.4%)	2(2.9%)	13(19.1%)	50(73.5%)	0.93
(2) The accompanying family members answer before she can respond to questions from the medical staff.	1(1.5%)	6(8.8%)	44(64.7%)	17(25.0%)	0.90
(3) During the conversation, the pregnant woman looks at her own mother's expression before answering.	2(2.9%)	6(8.6%)	38(55.9%)	22(32.4%)	0.88
(4) Poor family relationship and the lack of a family member to rely on.	0	3(4.4%)	33(48.5%)	32(47.1%)	0.96
(5) Finds it difficult to express her thoughts to her husband or mother.	0	3(4.4%)	43(63.2%)	22(32.4%)	0.96
(6) Moves to a new home during the pregnancy for reasons other than work.	10(14.7%)	25(36.8%)	25(36.8%)	8(11.8%)	**0.49**
(7) Pregnant women who are single, young, or in stepfamilies and cannot rely on family members due to complex family relationships.	1(1.5%)	1(1.5%)	24(35.3%)	42(61.8%)	0.97
(8) Couples who have had children in a superficial relationship.	1(1.5%)	5(7.4%)	20(29.4%)	42(61.8%)	0.91
(9) Even if family members are around, the woman is likely to spend much time parenting on her own.	0	12(17.6%)	46(67.6%)	10(14.7%)	0.82
(10) There is unlikely to be anyone in the family she can ask about childcare.	1(1.5%)	7(10.3%)	37(54.4%)	23(33.8%)	0.88
(11) The pregnant woman's parents are elderly and she cannot get support from them.	0	14(20.6%)	46(67.6%)	8(11.8%)	0.79
(12) Unemployed, receiving welfare benefits, or likely in financial difficulty based on state of clothing.	1(1.5%)	3(4.4%)	8(11.8%)	56(82.4%)	0.94
Social isolation					
(13) Not much interaction with the community and society.	0	21(30.9%)	37(54.4%)	10(14.7%)	**0.69**
(14) Not voluntarily seeking connections with other people.	2(2.9%)	24(35.3%)	39(57.4%)	3(4.4%)	**0.62**
(15) Keeps things to herself and does not express her feelings.	0	15(22.1%)	45(66.2%)	8(11.8%)	0.78
(16) There is an air of reluctance to delve deeper into personal matters.	0	6(8.8%)	45(66.2%)	17(25.0%)	0.91
(17) Seems not to want to get involved; seems reluctant to visit or be connected with government services.	0	7(10.3%)	30(44.1%)	31(45.6%)	0.90
(18) There is a history of refusing medical intervention or a seeming unwillingness to accept support from medical professionals.	1(1.5%)	5(7.4%)	33(48.5%)	29(42.6%)	0.91
Personality traits that make adapting to social life difficult					
(19) Characterized intellectually by how she writes and looks up words.	1(1.5%)	11(16.2%)	25(36.8%)	31(45.6%)	0.82
(20) Comprehension is poor and the same things need to be repeated many times during the conversation.	1(1.5%)	4(5.9%)	34(50.0%)	29(42.6%)	0.93
	1(1.5%)	7(10.3%)	33(48.5%)	27(39.7%)	0.88
(21) Unable to sit still in a chair and wait; seems restless.	1(1.5%)	6(8.8%)	30(44.1%)	31(45.6%)	0.90
(22) Fixates on the same questions repeatedly during the conversation.	1(1.5%)	10(14.7%)	29(42.6%)	28(41.2%)	0.84
(23) A feeling that the woman is not taking care of herself, based on disheveled appearance or dirty clothing.	0	6(8.8%)	39(57.4%)	23(33.8%)	0.91
	0	5(7.4%)	48(70.6%)	15(22.1%)	0.93
(24) She asks too many trivial questions.	0	8(11.8%)	44(64.7%)	16(23.5%)	0.88
(25) Easily upset by unexpected things.	0	9(13.2%)	24(35.3%)	35(51.5%)	0.87
(26) Worried about various things without any clear reason.	1(1.5%)	2(2.9%)	38(55.9%)	27(39.7%)	0.96
(27) Cries while talking.	2(2.9%)	2(2.9%)	23(33.8%)	41(60.3%)	0.94
(28) Does not make eye contact.	2(2.9%)	3(4.4%)	29(42.6%)	34(50.0%)	0.93
(29) Doesn't respond to questions.					
(30) Difficulty conversing and communicating.					
Mental and physical maladaptation to pregnancy					
(31) The pregnant woman has a chronic illness and there is a risk that this would deteriorate during the course of pregnancy, childbirth, and childcare.	0	5(7.4%)	36(52.9%)	27(39.7%)	0.93
	0	8(11.8%)	43(63.2%)	17(25.0%)	0.88
(32) In geriatric pregnancies, there are concerns about the physical burden of the pregnancy process as well as the mental and physical burden after birth.	1(1.5%)	2(2.9%)	20(29.4%)	45(66.2%)	0.96
	1(1.5%)	1(1.5%)	16(23.5%)	50(73.5%)	0.97
(33) There is a history of mental illness or predisposition to depression, and concern about postpartum deterioration of mental health after childbirth.	1(1.5%)	9(13.2%)	32(47.1%)	26(38.2%)	0.85
	1(1.4%)	4(5.9%)	20(29.4%)	43(63.2%)	0.93
(34) There is mental illness but it is untreated or treatment has been stopped by the patient.	2(2.9%)	6(8.8%)	31(45.6%)	29(42.6%)	0.88
(35) The pregnant woman feels something other than happiness upon discovering that she is pregnant.	2(2.9%)	6(8.8%)	10(14.7%)	50(73.5%)	0.88
(36) The partner does not accept the pregnancy.					
(37) Poor awareness of herself as a pregnant woman.					
(38) Makes negative comments about the fetus during pregnancy, such as its movements are uncomfortable, or it is not cute.					
Previous Studies					
(39) Lack of affect	0	6(8.8%)	38(55.9%)	24(35.3%)	0.91
(40) Extremely negative statements	0	6(8.8%)	34(50.0%)	28(41.2%)	0.91
(41) A noticeable smell of cigarettes from the pregnant woman	1(1.5%)	9(13.2%)	30(44.1%)	28(41.2%)	0.85
(42) Mood swings and emotional instability	1(1.5%)	7(10.3%)	30(44.1%)	30(44.1%)	0.88
(43) A noticeable smell of alcohol from the pregnant woman	2(2.9%)	6(8.8%)	17(25.0%)	43(63.2%)	0.88
(44) Statements indicating a desire to prioritize personal time even after childbirth	4(5.9%)	16(23.5%)	34(50.0%)	14(20.6%)	**0.71**
(45) The woman's parents not accepting the pregnancy	1(1.5%)	9(13.2%)	27(39.7%)	31(45.6%)	0.85

Items (6), (13), (14), and (44) did not meet the I-CVI threshold of 0.78.
Items (6), (13), (14), and (44) were removed due to an I-CVI below 0.78.
Item (15) was removed due to redundancy with item (5).
Item (45) was removed due to ambiguity and overlap with item (36).

Table 6. Revised Assessment Tool for Pregnant Women of Concern（39 items）

	Original 39 Items from the Assessment Tool for Pregnant Women of Concern	Revised wording
Vulnerable family functioning	(1) Frightened of her husband and asking his opinion every time. (2) The accompanying family members answer before she can respond to questions from the medical staff. (3) During the conversation, the pregnant woman looks at her own mother's expression before answering. (4) Poor family relationship and the lack of a family member to rely on. (5) Finds it difficult to express her thoughts to her husband or mother. (6) Pregnant women who are single, young, or in stepfamilies and cannot rely on family members due to complex family relationships. (7) Couples who have had children in a superficial relationship. (8) Even if family members are around, the woman is likely to spend much time parenting on her own. (9) There is unlikely to be anyone in the family she can ask about childcare. (10) The pregnant woman's parents are elderly and she cannot get support from them. (11) Unemployed, receiving welfare benefits, or likely in financial difficulty based on state of clothing.	
Social isolation	(12) There is an air of reluctance to delve deeper into personal matters. (13) Seems not to want to get involved; seems reluctant to visit or be connected with government services. (14) There is a history of refusing medical intervention or a seeming unwillingness to accept support from medical professionals.	＊ ＊
Personality traits that make adapting to social life difficult	(15) Characterized intellectually by how she writes and looks up words. (16) Comprehension is poor and the same things need to be repeated many times during the conversation. (17) Unable to sit still in a chair and wait; seems restless. (18) Fixates on the same questions repeatedly during the conversation. (19) A feeling that the woman is not taking care of herself, based on disheveled appearance or dirty clothing. (20) She asks too many trivial questions. (21) Easily upset by unexpected things. (22) Worried about various things without any clear reason. (23) Cries while talking. (24) Does not make eye contact. (25) Doesn't respond to questions. (26) Difficulty conversing and communicating. (27) Lack of affect (28) Extremely negative statements	＊
Mental and physical maladaptation to pregnancy	(29) The pregnant woman has a chronic illness and there is a risk that this would deteriorate during the course of pregnancy, childbirth, and childcare. (30) In geriatric pregnancies, there are concerns about the physical burden of the pregnancy process as well as the mental and physical burden after birth. (31) There is a history of mental illness or predisposition to depression, and concern about postpartum deterioration of mental health after childbirth. (32) There is mental illness but it is untreated or treatment has been stopped by the patient. (33) The pregnant woman feels something other than happiness upon discovering that she is pregnant. (34) The partner does not accept the pregnancy. (35) Poor awareness of herself as a pregnant woman. (36) Makes negative comments about the fetus during pregnancy, such as its movements are uncomfortable or it is not cute. (37) A noticeable smell of cigarettes from the pregnant woman (38) Mood swings and emotional instability (39) A noticeable smell of alcohol from the pregnant woman	

＊Indicates items with revised wording.

Discussion

Content validity of assessment items for pregnant women of concern

We examined the content validity of the 45 items in our proposed assessment tool. First, we conducted a content validity assessment using I-CVI with four experts: midwives and public health nurses. According to the guidance for an acceptable cutoff score when using 3–5 experts, the value should be 1.0 [8]. Our results showed that all 45 items achieved an I-CVI of 1 and a CVI of 1, confirming the content validity of these items.

Next, we conducted a survey to examine the content validity of the proposed assessment tool consisting of the 45 items whose content validity had been confirmed by the expert panel. The results showed that 41 items satisfied the content validity criterion of I-CVI ≥ 0.78, confirming their content validity.

Four items failed to meet the I-CVI ≥ 0.78 criterion: "Moves to a new home during pregnancy for reasons other than work," "Limited interaction with the community and society," "Not voluntarily seeking connections with other people," and "Says she wants to enjoy her own time even after the child is born."

Regarding "Moves to a new home during pregnancy for reasons other than work," the Mother and Child Health Handbook used during prenatal checkups remains valid regardless of relocation. Although prenatal checkup examination forms are issued together with the Mother and Child Health Handbook, they are issued by individual local governments [16]. Because pregnant women handle relocation procedures privately, midwives or public health nurses cannot easily identify a pregnant woman's relocation status during the initial assessment. Similarly, "Limited interaction with the community and society" indicates the pregnant woman's community status. This information is difficult to assess for public health nurses involved in issuing the Mother and Child Health Handbook or for midwives conducting prenatal checkups.

Furthermore, today's pregnant women largely belong to the smartphone generation born after the 1990s. This generation's interpersonal relationships are characterized by their online connectivity, allowing them to function without direct personal interactions while still accessing desired information. Research indicates that this generation often struggles with face-to-face communication and expressing opinions [17, 18]. Therefore, the item "Not voluntarily seeking connections with other people" likely reflects characteristics of the digital era rather than being a specific concern for pregnant women. Additionally, mothers maintain multiple aspects of identity: as family members, as professionals/working individuals, and as individuals in their own right. When the individual aspect diminishes in real life, parenting anxiety can emerge [19]. Previous research also shows that the desire to maintain personal autonomy after becoming a mother contributes to parental growth [20]. Consequently, "Says she wants to enjoy her own time even after the child is born" should not be considered an indicator for identifying pregnant women of concern. Considering the above, it is reasonable to exclude these four items from the assessment tool for identifying pregnant women of concern.

Through expert evaluation of content validity, questionnaire survey assessment of item validity and overall tool validity, and subsequent content modifications, we reduced the original 45 items to a final set of 39 items. The S-CVI of the 39-item assessment tool was 0.901, exceeding the standard criterion of 0.90 and confirming the tool's content validity [15].

Features of the assessment tool for pregnant women of concern

Among the 39 items in our final assessment tool, the categories with the highest number of items

were: “Personality traits that make adapting to social life difficult” with 14 items, followed by “Vulnerable family functioning” and “Mental and physical maladaptation to pregnancy” with 11 items each.

The items in “Personality traits that make adapting to social life difficult” consisted of content related to learning and communication problems and emotional instability. After childbirth, mothers develop relationships with their infants through interaction, and mothers bear the responsibility for regulating these interactions[21]. Social adaptability and responsiveness are identified as characteristics necessary for fulfilling this role[22, 23]. In other words, when mothers have communication problems or emotional instability, interaction with their infants is likely to be difficult. Based on this experiential knowledge, midwives and public health nurses identify such women as pregnant women of concern.

Next, the items in “Vulnerable family functioning” consisted of family relationships and support situations. Pregnancy causes adaptations and role changes for each family member, so if basic family dynamics are weak, this restructuring may not proceed smoothly. Good family dynamics emerge from joint decision-making and support from family members[22]. Therefore, pregnant women with poor family relationships or insufficient family support may have difficulty restructuring family member roles during childbirth. For this reason, midwives and public health nurses identify women with vulnerable family functioning as pregnant women of concern.

The items in “Mental and physical maladaptation to pregnancy” consisted of how pregnant women and their partners accepted the pregnancy, as well as the pregnant women’s lifestyle habits and history of complications involving physical and mental disorders. The acceptance of pregnancy by both the pregnant woman and her partner influences childrearing and the couple’s relationship during the childrearing period[24], and lifestyle behaviors during pregnancy are related to attachment to the fetus and infant imagery[25]. Furthermore, given the contemporary trend for women to marry later in life, there is an increase in pregnancies at an advanced maternal age, which carries a higher risk of complications such as gestational diabetes and chronic hypertension[26]. Furthermore, from a demographic perspective, the global prevalence of clinical depression has increased from 13% to approximately 17.7%[27]. Based on these factors, midwives and public health nurses assess situations of “mental and physical maladaptation to pregnancy” not only for health during pregnancy but also in anticipation of childcare after birth.

In summary, the key feature of the Assessment Tool for Pregnant Women of Concern is that while it comprises the pregnant woman’s personal characteristics and her surrounding environment, its purpose is to identify women who may experience difficulties in the transition to motherhood or in raising children.

These results suggest that the content validity of the assessment tool developed in this study has been confirmed. Content validity refers to the extent to which the items of a measurement tool conceptualize and capture the full content of what is being measured[15]. The content of the assessment tool items developed in this study is considered to capture an overview of pregnant women of concern. Because the Assessment Tool for Pregnant Women of Concern proposed in this study is still under development, it will be necessary to conduct further research using questionnaires targeting midwives and public health nurses to verify its validity and reliability.

Conclusion

A preliminary set of 45 assessment items was developed to assist midwives and public health nurses in identifying pregnant women of concern.

To confirm content validity, a survey was conducted among midwives and public health nurses with over 10 years of experience. Content validity was established using the Item-Level Content Validity Index (I-CVI) and Content Validity Index (CVI). Based on these findings, a broader survey was conducted among midwives and public health nurses actively engaged in maternal care. Following a review of the I-CVI results, items were refined or removed, resulting in a final set of 39 assessment items with confirmed content validity.

Conflict of interest

There is no conflict of interest.

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気になる妊婦のアセスメント項目の開発と内容妥当性の検証
－助産師と保健師が気になる妊婦を把握するために－

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要　旨

本研究は，助産師と保健師が気になる妊婦を把握するための，気になる妊婦のアセスメント項目を開発し妥当性を検証することを目的とした．内容妥当性の体系的アプローチを参考に，①概念領域の決定②先行研究と質的研究による気になる妊婦のアセスメント項目案の作成③専門家による質問項目妥当性の検証④質問紙調査によるアセスメントツールの内容妥当性の検証を行った．

先行研究と質的研究から作成した助産師と保健師が気になる妊婦を把握するためのアセスメント 45 項目の内容妥当性確認のため，10 年以上の経験がある助産師，保健師に専門家による調査を行った．I-CVI と CVI により内容妥当性を確認し，アセスメントツール案として妊婦支援に携わる助産師，保健師に質問紙調査を行った．I-CVI の結果に基づき，項目の削除と表現の修正を行い内容妥当性のある 39 項目のアセスメントツールを作成した．ツール全体としての S-CVI は 0.901 であり妥当性の高い結果が示された．

キーワード

気になる妊婦，アセスメント項目，内容妥当性，助産師，保健師