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# Development and Validation of a Questionnaire Assessing the Knowledge and Perception of Pregnant Women about Oral Iron Consumption

Nurulhuda Abd Kadir[1], Ahzad Hadi Ahmad[1], Nur Arzuar Abdul Rahim[1], Nik Ahmad Zuky Nik Lah[2], Ernest Mangantig[1]

[1] Regenerative Medicine Cluster, Advanced Medical and Dental Institute, Universiti Sains Malaysia, 13200 Kepala Batas, Pulau Pinang, Malaysia
[2] Department of Obstetrics and Gynaecology, School of Medical Sciences, Universiti Sains Malaysia, 16150 Kubang Kerian, Kelantan, Malaysia

## ABSTRACT

**Introduction:** Good knowledge and perception regarding iron supplementation are crucial to ensure adherence to iron therapy. This study aims to develop and validate a questionnaire on the knowledge and perception among pregnant women about oral iron consumption. **Method:** A self-administrated questionnaire was developed in Malay language through extensive literature search and a face and content validation process. The questionnaire validation involved two parts; Validation Study 1 included item response theory (IRT) and exploratory factor analysis (EFA) for the knowledge and perception items, respectively. Validation Study 2 comprised a repeat IRT analysis for the knowledge items and confirmatory factor analysis (CFA) for the perception items. **Results:** For the knowledge section, the initial 22 items in Validation Study 1 were reduced to 19 items after the repeat IRT analysis. The remaining 19 items had difficulty and discrimination parameters close to or within the acceptable values. For the perception section, the original 16 items were reduced to 14 in the EFA as two items had a factor loading ≤0.3. The CFA model showed poor fit of items (chi-square p-value <0.05; $CFI_{robust}$=0.73; $TLI_{robust}$=0.68; $RMSEA_{robust}$=0.20; and SRMR=0.12). The Cronbach's alpha for both sections were >0.7, and the intra-class correlation coefficient value in the knowledge and perception sections were 0.74 and 0.87, respectively. **Conclusion:** The results illustrate good psychometric properties for the knowledge items. However, further confirmatory validation is needed for the perception items. This questionnaire can be a valid and reliable assessment tool for assessing the knowledge of pregnant women regarding oral iron consumption.

**Keywords:** Validity, Reliability, Iron supplements, Pregnant Women, Anaemia

**Corresponding Author:**
Ernest Mangantig, PhD
Email: e.mangantig@usm.my
Tel: +604-5622289

## INTRODUCTION

Anaemia in pregnancy is an important public health issue worldwide, especially in developing countries. In 2011, the prevalence of anaemia in pregnancy is estimated to be 38.2%, globally (1). Anaemia in pregnancy is defined as a haemoglobin level under 11.0 g/dL at sea level in the first and third trimester and reduces by approximately 0.5 g/dL in the second trimester of pregnancy (2). Pregnant women are more vulnerable to iron deficiency anaemia because of the substantial increase in iron demand during pregnancy to support foetal–placental growth as well as the expansion of red cell mass and plasma volume (3). Anaemia in pregnancy is associated with various detrimental effects to the mother and foetus. These effects include maternal fatigue, decreased exercise tolerance, increased risk of preterm birth and reduced foetal birth weight (4,5).

Iron deficiency is the major cause of anaemia worldwide and causes up to 50% of anaemia cases (1,6). Iron supplementation is the main strategy currently used to control iron deficiency anaemia in low-, middle- and high-income countries (7). To date, a low dose of oral iron therapy with 30 to 60 mg of elemental iron has become a standard treatment for all pregnant women as iron-deficiency anaemia prophylaxis. Oral iron supplements are extensively prescribed to all pregnant women, but poor compliance to the treatment remains a challenge (8,9,10). A prior investigation identified forgetfulness, side-effects of the medication, non-affordability and misconception about iron tablets as the main reasons for non-compliance (10). Knowledge and perception of the pregnant women regarding oral iron supplementation are the possible missing links and

are important elements as motivation for or hindrance to treatment compliance. Previous studies have shown that the knowledge of anaemia was significantly associated with compliance to oral iron therapy (11, 12).

To date, various questionnaires have been developed to assess the knowledge of anaemia and its prevention. Queries regarding awareness about the causes, signs and symptoms of anaemia as well as its general prevention and management are among the commonly posed questions. However, questionnaires that focused specifically on knowledge and perception regarding the intake of oral iron supplements are still limited and not psychometrically evaluated. To address this issue, a structured and validated questionnaire is necessary to evaluate the knowledge and perception of pregnant women about oral iron supplements. Using a validated questionnaire with good psychometric properties is salient in ensuring high-quality and accurate results. Consequently, this study aimed to develop and validate a new questionnaire assessing the knowledge and perception of pregnant women about oral iron consumption.

## MATERIALS AND METHODS

The development of a new questionnaire involves two phases: questionnaire development (Phase 1) and questionnaire validation (Phase 2).

### Phase 1: Developing a new questionnaire

An extensive review of literature regarding knowledge and perception of oral iron consumption among pregnant women was conducted to identify relevant items in previous questionnaires (13–19). Brochures and educational tools about dietary iron advice and iron supplementation produced by the Ministry of Health Malaysia were also reviewed. A discussion with obstetricians was conducted to obtain their expert opinion on the important items to be included in the questionnaire. Interviews with 10 pregnant women were also held to explore their knowledge on oral iron supplement intake, the factors that may influence iron absorption, as well as their choices of foods that are rich in iron. The perception aspects were also explored during the interviews to assess their views on the importance of oral iron therapy during pregnancy and their negative beliefs about iron supplements. The information from the literature and interviews were used to create relevant constructs in the questionnaire.

The questionnaire was constructed by a panel of experts consisting of an obstetrician and gynaecologist, a family medicine specialist, a haematopathologist, a transfusion medicine specialist and a paediatrician. Moreover, the questionnaire was designed in the Malay language and was a self-administered one. The first draft was subjected to content validation by another panel of experts which include an obstetrician and gynaecologist, a family medicine specialist, a clinical haematologist and a haematopathologist so as to evaluate the clarity, relevance, simplicity and ambiguity of each item. The level of agreement between the experts was assigned as a content validity index (CVI). A CVI exceeding 0.80 indicates a high level of agreement which, in turn, suggests that most of the experts agreed that the constructs are relevant to the concepts being investigated (20).

The questionnaire comprises two sections, namely, the knowledge and perception sections. The knowledge section consists of 22 items including knowledge of iron requirement during pregnancy (two-items), effects of anaemia on the mother and foetus (two-items), foods with high iron content (five-items), benefits of iron supplements (two-items), daily iron supplement consumption (four-items), factors that may influence iron absorption (four-items) and side effects of iron supplements (three-items). The perception section comprises 16 items exploring negative beliefs about iron supplements. Each item in the knowledge section can be answered by one of three responses (True/False/ Don't know). One mark was assigned for each 'Correct' answer and zero marks were awarded for 'Wrong' or 'Don't know' responses. For items in the perception section, the responses were based on a five-point Likert scale (strongly agree/agree/ unsure/disagree/strongly disagree).

To assess the face validity of the questionnaire, pre-testing was conducted with 30 pregnant women at the Obstetrics and Gynaecology Clinic, Hospital Universiti Sains Malaysia (HUSM). An open-ended discussion was included to assess their understanding of the items as well as the readability, clarity and ambiguity of the questionnaire. The results were employed in the revision of the questionnaire, which was then subjected to a validation study to determine the psychometric property of the items.

### Phase 2: Validation studies

The validation study consisted of two parts. Part 1 includes item response theory (IRT) and exploratory factor analysis (EFA). Part 2 includes repeat IRT and confirmatory factor analysis (CFA).

#### *Validation Study 1: IRT and EFA*

Validation Study 1 was performed from June to July 2019 and involved 124 pregnant women at the Obstetrics and Gynaecology Clinic, HUSM. This hospital was chosen because it is one of the largest hospitals in Kelantan State, has various sub-speciality services and serves a high influx of patients. The participants were recruited according to systematic random sampling that selected every third registered patient. Pregnant women who fulfilled the inclusion criteria were invited to participate in this study voluntarily. The participants must understand Malay language and be willing to

take part in the investigation. Respondents who were illiterate, non-Malaysian citizens and had known mental disorders were excluded from this work. After obtaining informed consent, the respondents were given the self-administered questionnaire form which takes approximately 20 minutes to complete.

The statistical analysis was performed using R software version 4.0.2. R package ltm was used to perform the two-parameter logistic item response theory (2-PL IRT) analysis for the knowledge section which consisted of unidimensional items with dichotomous responses (21). The pre-defined acceptable values for difficulty index was between –3 to +3, and the acceptable values for discrimination index was 0.35 to 2.5 (22). The chi-square goodness-of-fit per item was used to assess the item fit individually. The assumption of unidimensionality was checked by modified parallel analysis (22,23).

R package *psych* was used to perform the EFA for the perception section which consisted of ordinal responses. The Kaiser–Meyer–Olkin measure of sampling adequacy (KMO) and Bartlett's test of the sphericity were utilised to evaluate the adequacy and suitability of the samples for factor analysis. A KMO value above 0.5 and a significant Bartlett's test ($P < 0.001$) indicates that the data are suitable for factor analysis (24). The EFA was performed using the principal axis factoring extraction method with oblimin rotation. The number of extracted factors were determined by scree plot inspection and eigenvalues > 1. The pre-defined acceptable factor loading value was > 0.4 (25). For internal consistency reliability, the acceptable Cronbach's alpha coefficient value was > 0.7 (26). For the reliability of each individual item, items with a corrected-item total correlation value of < 0.3 were removed. The ICC was employed to evaluate the level of test–retest reliability in this study. An ICC value between 0.4 to 0.75 was considered acceptable, and such a value ≥ 0.75 is excellent (27).

The minimum sample size of 1:3 ratio is required for EFA to produce a construct with relatively high factor loadings (28,29). For Validation Study 1, the sample size was calculated according to a 1:6 ratio for the 16 items in the perception section. Thus, the final sample size required with an additional 30% non-response rate was 124. The minimum sample size for the IRT analysis follows the sample size for EFA as no definitive sample size for IRT is known, although a previous study recommends 100 to 500 samples (30). Conversely, 50 participants were invited for a test–retest analysis after two weeks of using the same questionnaire.

### *Validation Study 2: Repeat IRT and CFA*

Validation Study 2 was conducted from August to September 2019 to further evaluate and confirm the psychometric properties of the questionnaire. A revised questionnaire was distributed to a similar number of pregnant women as in Validation Study 1 and similar sampling strategy and inclusion criteria were applied. A total of 124 pregnant women at the Obstetrics and Gynaecology Clinic, HUSM and who did not already take part in Validation Study 1 were invited to participate in Validation Study 2 voluntarily.

R software version 4.0.2 was also used for the data analysis. The 2-PL IRT analysis as explained in Validation Study 1 were repeated for the knowledge section. R package lavaan was used to perform CFA for the perception section. The model fitness was assessed according to the following indices with their respective cut-off values: chi-square p-value > 0.05; robust comparative fit index (CFI) and Tucker-Lewis fit index (TLI) ≥ 0.95; and robust root mean square error of approximation (RMSEA) and standardized root mean square residual (SRMR) ≤ 0.08 (31,32). R package *semTools* was used to assess the composite reliability based on the Raykov's rho, with an acceptable value of ≥ 0.7 (33,34).

### Ethical Approval

We obtained ethical approval from the Human Ethics Committee of Universiti Sains Malaysia [ref no: USM/JEPeM/19010047]. The data used for this work do not identify the participants personally, and data confidentiality was strictly protected.

## RESULTS

A total of 124 questionnaires were distributed for each validation study, but only 122 respondents completed the questionnaires. Table I presents the socio-demographic details, pregnancy profiles and oral iron supplementation information of the respondents in Validation Study 1. The mean age of the respondents was 31.15 ± 4.63 years. Most of the respondents were Malay (n = 118, 96.7%), married (n = 121, 99.2%), worked in the government sector (n = 69, 56.6%) and had certificate/diploma education (n = 54, 44.3%). The respondents were predominantly multigravida (n = 99, 81.1%), in the third trimester of pregnancy (n = 81, 66.4%) and had a previous history of iron consumption (n = 89, 73%).

### Item Development and Content and Face Validation

Information from previous literature was primarily used to create items in the first draft of the questionnaire. A small group discussion with a few pregnant women were helpful in identifying relevant constructs for inclusion. The questionnaire was then revised on the basis of the suggestions and inputs from the panel of experts. All items with low CVI scores (<0.8) were rephrased or removed. In line with the feedback from face validation, minimal changes were subsequently made to terminologies and wordings. Most respondents understood the questionnaire well. At this stage, the final draft of the questionnaire consisted of two sections

**Table I: Demographic, pregnancy characteristics and iron supplementation information of the pregnant women in Validation Study 1**

| Characteristics | n (%) |
|---|---|
| **Age** | 31.15 ± 4.63[a] |
| **Race** | |
| Malay | 118 (96.7) |
| Chinese | 3 (2.5) |
| Indian | 1 (0.8) |
| Others | 0 (0) |
| **Marital status** | |
| Married | 121 (99.2) |
| Unmarried | 1 (0.8) |
| **Education level** | |
| No formal education | 0 (0) |
| Primary school | 0 (0) |
| Secondary school | 29 (23.8) |
| Certificate/Diploma | 54 (44.3) |
| Degree/master/PhD | 39 (32.0) |
| **Occupation** | |
| Government | 69 (56.6) |
| Private | 12 (9.8) |
| Self-employed | 0 (0) |
| Student | 13 (10.7) |
| Unemployed | 28 (23.0) |
| **Household income[b] (RM)** | |
| < 4360 (B40 - Bottom 40%) | 73 (59.8) |
| 4360 – 9619 (M40 – Middle 40%) | 43 (35.2) |
| 9619 (T20 – Top 20%) | 6 (4.9) |
| **Maternal Gravidity** | |
| Primigravida | 23 (18.9) |
| Multigravida | 99 (81.1) |
| **Maternal Parity** | |
| 0-1 | 69 (56.6) |
| >2 | 53 (43.4) |
| **Gestational Age** | |
| First trimester (≤ 12 weeks) | 5 (4.1) |
| Second trimester (13 – 27 weeks) | 36 (29.5) |
| Third trimester (≥ 28 weeks) | 81 (66.4) |
| **History of anaemia during previous pregnancy** | |
| Yes | 24 (19.7) |
| No | 74 (60.7) |
| Missing info | 24 (19.6) |
| **History of oral iron supplementation** | |
| Yes | 89 (73.0) |
| No | 31 (25.4) |
| Missing info | 2 (1.6) |
| **Blood disorders during current pregnancy** | |
| Yes | 8 (6.6) |
| No | 113 (92.6) |
| Missing info | 1 (0.8) |
| **Advised for iron pills intake last 4 weeks** | |
| Yes | 119 (97.5) |
| No | 2 (1.6) |
| Missing info | 1 (0.8) |
| **Frequency of missed iron pills in last 4 weeks** | |
| Never | 25 (20.5) |
| 1-7 days | 52 (42.6) |
| >7 days | 20 (16.4) |
| Unsure | 22 (18.0) |
| Missing info | 3 (2.5) |
| **Factors of non-compliance** | |
| No available pills | 3 (2.5) |
| Forgetfulness | 82 (67.2) |
| Side effects | 7 (5.7) |
| Others | 2 (1.6) |
| Missing | 28 (23.0) |

[a] *Age is expressed as mean ± standard deviation*
[b] *Household income was categorised based on the 2018 report from Khazanah Research Institute (35)*

and 38 items (22 items in the knowledge and 16 items in the perception sections).

### Validation Study 1: IRT and EFA

Table II shows the psychometric properties of the items in the knowledge section from IRT analysis. In terms of the difficulty index, 18 of 22 items were within or close to the acceptable range of –3 and +3. Four items (K1, K12c, K13b and K13c) were out of the acceptable range, with K13c exceeding the cut off by a large margin. The amount of information tapped by the items for the pre-defined difficulty range was 90.1%. As for the discrimination index, only 9 of 22 items were within the acceptable range of 0.35 to 2.5. Five items (K5b, K5d, K5e, K7, and K8) were above the 2.5 cut off value and 8 items (K1, K11, K12a, K12b, K12c, K13a, K13b, and K13c) were below the 0.35 cut off value, with K1 and K13c having very small discrimination index values. The item goodness-of-fit showed that four items (K1, K5a, K5c, and K11) did not fit well ($p < 0.05$). The modified parallel analysis indicates that the unidimensionality assumption was fulfilled ($p = 0.119$). Thus, the items were suitable to be summed as a final score. The Cronbach's alpha of 0.736 demonstrates acceptable internal consistency reliability. After discussion with the experts, all items in the knowledge section were considered important and were retained for a repeat IRT analysis, with some revisions.

Table III lists the psychometric properties of the perception section from the EFA analysis. The KMO value of 0.82 and Bartlett's test of sphericity of $p < 0.05$ indicates the sufficiency of samples for factor analysis. According to the scree plot, the EFA suggested a one-factor solution. Among the items, 12 out of 16 have acceptable factor loadings. Four items (P1, P3, P6c and P7) have factor loadings below the 0.4 cut-off value. Two items (P6c and P7) were dropped given their very low factor loadings (≤0.3). The Cronbach's alpha for the remaining 14 items was 0.883. The corrected item-total correlation for all the items exceeded 0.3. Only 30 of the 50 respondents invited for the test–retest participated. The ICC value from the test–retest was 0.74 for items in the knowledge section and 0.87 for items in the perception section, an outcome which indicates good reliability of all items in the questionnaire.

The final version of the questionnaire contained 22 items in the knowledge section and 14 items in the perception section. After revisions, the questionnaire was subjected to Validation Study 2 which includes repeat IRT and CFA.

### Validation Study 2: Repeat IRT and CFA

The repeat IRT results are also presented in Table II. With regard to the difficulty index, most items were within or close to the pre-defined acceptable range, except for two items (K1 and K5a) with a large margin difference. For the discrimination index, most of the items were also within or close to the pre-defined acceptable range, except for four items (K5a, K5b, K12b and K12c). As K1, K5a and K13b exceeded the cut-off by a very large margin, these three items were excluded, thereby leaving only 19 final items. The amount of information tapped by the 19 items for the pre-defined acceptable range was 90.14%. All items demonstrates a good fit to the model. The unidimensionality assumption was also fulfilled (p = 0.110). The Cronbach's alpha for the 19 items was 0.703, a result which demonstrates acceptably good

**Table II: IRT analysis for the knowledge section in the Validation Study 1 and 2**

| Items | Validation Study 1 (IRT) | | | | Validation Study 2 (Repeat IRT) | | | |
|---|---|---|---|---|---|---|---|---|
| | ***b*** | α | **Chi-square value** | **P-value** | ***b*** | α | **Chi-square value** | **P-value** |
| K1. Keperluan zat besi bagi wanita hamil adalah lebih tinggi berbanding wanita tidak hamil | -9.12 | 0.08 | 17.46 | 0.026 | -9.13 | 0.27 | 3.84 | 0.871 |
| K2. Keperluan zat besi bagi wanita hamil meningkat mengikut usia kandungan | -1.54 | 0.39 | 8.2 | 0.415 | -2.46 | 0.52 | 11.55 | 0.173 |
| K3. Kekurangan sel darah merah (anemia) boleh menyebabkan wanita hamil menjadi cepat letih | -2.22 | 1.35 | 10.13 | 0.256 | -4.91 | 0.74 | 9.79 | 0.280 |
| K4. Kekurangan sel darah merah (anemia) semasa hamil boleh meningkatkan risiko kelahiran bayi pra-matang | -1.54 | 1.34 | 8.91 | 0.350 | -2.37 | 0.91 | 11.38 | 0.181 |
| K5. Berikut adalah sumber makanan yang kaya zat besi: | | | | | | | | |
| K5a. Ikan bilis | -1.34 | 1.06 | 16.33 | 0.038 | -17.3 | 0.06 | 13.25 | 0.104 |
| K5b. Telur | 0.10 | 2.56 | 9.22 | 0.324 | -0.94 | -0.14 | 3.97 | 0.860 |
| K5c. Kerang | -1.98 | 1.55 | 18.11 | 0.020 | -3.99 | 0.44 | 10.87 | 0.209 |
| K5d. Tauhu | 0.49 | 4.58 | 8.97 | 0.345 | 3.10 | 0.18 | 9.71 | 0.286 |
| K5e. Ubi kentang | 0.50 | 3.63 | 11.32 | 0.184 | 3.40 | 0.14 | 9.43 | 0.307 |
| K6. Pengambilan pil zat besi boleh mencegah masalah kekurangan sel darah merah (anemia) | -1.65 | 1.27 | 10.95 | 0.205 | -2.61 | 0.81 | 7.26 | 0.509 |
| K7. Pengambilan pil zat besi boleh membantu janin membesar dengan baik | -2.21 | 6.16 | 5.99 | 0.648 | -4.45 | 1.04 | 7.11 | 0.525 |
| K8. Wanita hamil perlu mengambil pil zat besi setiap hari | -1.97 | 2.70 | 4.57 | 0.803 | -2.83 | 1.05 | 6.42 | 0.600 |
| K9. Wanita hamil perlu meneruskan pengambilan pil zat besi sehingga 6 minggu selepas bersalin | -0.53 | 0.46 | 10.52 | 0.231 | -0.88 | 0.34 | 8.52 | 0.384 |
| K10. Dos/ sukatan pil zat besi yang perlu diambil meningkat mengikut tahap keterukan kekurangan zat besi | -0.70 | 0.81 | 14.12 | 0.079 | -1.12 | 0.84 | 5.54 | 0.699 |
| K11. Pil zat besi adalah paling baik diambil ketika perut kosong (contoh: 2 jam selepas makan) | -2.93 | 0.19 | 20.91 | 0.007 | -1.08 | 1.06 | 7.30 | 0.504 |
| K12. Makanan/minuman yang membantu penyerapan pil zat besi: | | | | | | | | |
| K12a. Air teh | -3.19 | 0.31 | 13.18 | 0.106 | -0.96 | 1.17 | 11.5 | 0.175 |
| K12b. Air kopi | -3.56 | 0.28 | 14.29 | 0.074 | -0.93 | 1.24 | 13.77 | 0.088 |
| K12c. Susu | 6.90 | 0.12 | 7.2 | 0.515 | 1.31 | 0.89 | 14.95 | 0.060 |
| K12d. Buah oren | -3.10 | 0.66 | 6.94 | 0.543 | -2.63 | 0.97 | 10.44 | 0.235 |
| K13. Kesan sampingan pil zat besi: | | | | | | | | |
| K13a. Sembelit | -0.17 | 0.21 | 4.84 | 0.774 | 0.25 | 1.84 | 11.83 | 0.159 |
| K13b. Cirit-birit | 6.19 | 0.32 | 6.97 | 0.539 | 0.89 | 13.17 | 0.68 | 0.999 |
| K13c. Sakit perut | 71.6 | 0.02 | 5.41 | 0.713 | 1.13 | 3.64 | 14.47 | 0.070 |

*b Difficulty index  Discrimination index*

internal consistency reliability.

The CFA results for the perception section are also shown in Table III. Given the skewed data distribution, robust maximum likelihood ratio was utilised in the CFA. Most items have acceptable standardized loadings (> 0.4), except for items P3 and P6a. The composite reliability for the 14 items were 0.90, an outcome which indicates adequate reliability. However, the model did not show a good fit (chi-square p-value < 0.05; $CFI_{robust}$ = 0.72; $TLI_{robust}$ = 0.67; $RMSEA_{robust}$ = 0.19; and SRMR = 0.11). The model was then reanalysed to exclude item P3 which had a low factor loading (< 0.3) and high correlation (> 0.85). However, the model continued to have a poor fit (chi-square p-value < 0.05; $CFI_{robust}$ = 0.73; $TLI_{robust}$ = 0.68; $RMSEA_{robust}$ = 0.20; and SRMR = 0.12). Further removal of item P6a (factor loading = 0.38) did not improve model fitness. No other items also showed a high correlation with each other. Thus, only item P3 was removed from the perception section.

## DISCUSSION

Evaluation of the knowledge and perception of pregnant women about oral iron supplements is crucial to ensure compliance with the treatment. Consequently, we

**Table III: EFA and CFA for the perception section in the Validation Study 1 and 2**

| Items | Validation Study 1 (EFA) | | Validation Study 2 (CFA) | |
|---|---|---|---|---|
| | Factor loading | Reliability[a] | Factor loading | Reliability[b] |
| P1. Kekurangan sel darah merah (anemia) semasa hamil tidak memerlukan rawatan | 0.35 | | 0.57 | |
| P2. Pil zat besi tidak penting untuk diambil semasa hamil | 0.52 | | 0.53 | |
| P3. Pil zat besi tidak perlu diambil sekiranya wanita hamil mengambil makanan yang kaya zat besi | 0.35 | | 0.14 | |
| P4. Pil zat besi perlu diambil pada awal kehamilan sahaja | 0.69 | | 0.55 | |
| P5. Pil zat besi hanya perlu diambil oleh wanita hamil yang mengalami masalah kekurangan sel darah merah (anemia) | 0.48 | | 0.47 | |
| P6. Pengambilan pil zat besi boleh dihentikan sekiranya: | | 0.883 | | 0.900 |
| P6a. Paras hemoglobin sudah mencapai tahap normal | 0.46 | | 0.38 | |
| P6b. Berasa bosan untuk mengambilnya | 0.61 | | 0.54 | |
| P6c. Mengalami kesan sampingan suplemen/vitamin | 0.23 | | - | |
| P6d. Rasa pil tidak sedap | 0.66 | | 0.50 | |
| P7. Sering kali terlupa untuk mengambil pil zat besi tidak akan menjejaskan kesihatan janin | 0.30 | | - | |
| P8. Pengambilan pil zat besi akan menyebabkan: | | | | |
| P8a. Wanita hamil menjadi obes/gemuk | 0.67 | | 0.74 | |
| P8b. Wanita hamil mendapat tekanan darah tinggi | 0.78 | | 0.87 | |
| P8c. Janin menjadi sangat besar | 0.72 | | 0.88 | |
| P8d. Kecacatan kepada janin | 0.78 | | 0.93 | |
| P8e. Keguguran janin dalam kandungan | 0.59 | | 0.93 | |
| P8f. Bayi menjadi kuning (jaundice) selepas lahir | 0.74 | | 0.78 | |

[a]*Cronbach's alpha* [b]*Raykov rho*

developed a structured and validated questionnaire to assess the knowledge of pregnant women regarding oral iron consumption. A validated questionnaire with good psychometric properties is essential to ensure reliable and high-quality results. Our questionnaire underwent content validity assessment by an expert panel; face validity by a group of pregnant women with similar characteristics as the target population; IRT analysis to determine the difficulty and discriminatory parameters of the items in knowledge section; construct validity by EFA and CFA for items in the perception section; and reliability assessment by measuring the internal consistency and ICC values.

Overall, the knowledge section illustrated acceptable psychometric properties according to the difficulty and discriminatory index in Validation Study 2. The initial questionnaire comprised 22 items in the knowledge section. Following Validation Study 1, several items outside the range of the difficulty and discrimination parameters were rephrased and revised to improve the clarity of the items. In Validation Study 2, several items with difficulty and discrimination values close to the acceptable range were retained given their importance in the assessment of knowledge about iron supplementation. Two items (K1 and K5a) with minimal difficulty indexes were removed as these questions were considered to be very easy. Another item K13b with a large discrimination index was also removed. The final 19 items in the knowledge section were shown to have good reliability in assessing the knowledge of pregnant women about iron supplementation.

Items in the perception section were shown to have good reliability in the EFA and CFA. The initial questionnaire had 16 items for the perception section. According to the EFA, two items (P6C and P7) were removed due to low factor loadings, thereby leaving only 14 items for CFA. Results in the CFA however, showed poor fit for the model. One item (P3) with a very low factor loading and high correlation was removed from the model, but this development did not improve the model fit. Further removal of an item with low factor loading also did not improve model fitness. Apart from item P3, no other items in the model had very low factor loading and a multicollinearity problem. One of the causes for poor fit in CFA is a small sample, as the model may be unsupported by the data (31). For Validation Study 2, only 122 women agreed to participate in the study. Kline recommends 200 as the minimum sample size for CFA because such an analysis for complex models typically necessitates a large sample size (36).

Adznam et al. (13) conducted a survey to assess the knowledge of pregnant women in Putrajaya, Malaysia about anaemia. Several studies (14,15,19) in India reported on the knowledge and attitude of pregnant women regarding anaemia and oral iron supplementation.

Several items from those studies which were relevant to our construct were incorporated in the questionnaire. A research in Nepal focused mainly on the knowledge and perception of pregnant women in regards to the compliance of oral iron and folate supplementation (17). Similar to our study, their questionnaire explored knowledge on the benefits of oral iron supplements and negative beliefs about iron supplementation. A local study (37) explored the knowledge and attitude of pregnant women towards oral iron supplementation in Terengganu but employed a non-validated questionnaire. Furthermore, only four items assessed the knowledge of oral iron supplementation which includes the reason for oral iron consumption and the benefit of iron supplements. To the best on our knowledge, none of these prior works explored the knowledge about the dose, timing and duration of iron supplementation as well as the side effects of iron pills. Nevertheless, we were unable to compare the psychometric properties of items in our questionnaire with those of previous studies because the development and validation processes of their assessment tools were not included or clearly described in most of the articles.

Several limitations were identified in our study. Firstly, the respondents were selected only from Kelantan, and thus the results herein may not represent the entirety of the Malaysian population. Cross-validation studies are necessary for other Malaysian states. Secondly, the sample size for CFA was considered small as 200 is the minimum sample size for assessing the model fitness of CFA (36). This situation results in unsatisfactory model fitness for the items in the perception section.

## CONCLUSION

The final version of the questionnaire in this study contained 19 items in the knowledge section and 13 items in the perception section. Our questionnaire exhibited acceptable psychometric properties for the knowledge section. However, the perception section requires further confirmatory validation with a larger sample. This questionnaire can be a valid and reliable assessment tool for assessing the knowledge of pregnant women regarding oral iron consumption.

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