Original Article

Access this article online

Quick Response Code:

Website: www.ajts.org

DOI: 10.4103/ajts.ajts_176_21

Development and validation of informed consent for blood transfusion questionnaire

Mohd Hilmi Senin[1], Mastura Mohd Sopian[2], Bakiah Shaharuddin[3], Muhammad Jaffri Mohd Nasir[4]

Abstract:

INTRODUCTION: Blood transfusion warrants written informed consent from the patient. However, patients have poor knowledge regarding blood transfusions as evidenced by nonstandardized information retained by patients from the informed consent discussion. The problem stems from suboptimal patient knowledge on the elements of informed consent. This study describes the development and validation of a new questionnaire to assess the knowledge on informed consent for blood transfusion from the patients' perspective.

SUBJECTS AND METHODS: The development phase consisted of literature review, small group discussion, expert review meeting, content, and face validity. We evaluated the psychometric properties of Informed Consent for Blood Transfusion Questionnaire (ICBTQ) using reliability test and item response theory among a sample of 95 patients in Hospital Universiti Sains Malaysia.

RESULTS: ICBTQ was formulated to include sociodemographic and knowledge sections. ICBTQ possessed excellent content validity. The face validity index (FVI) of clarity and comprehension were both 0.97. Thus, the universal FVI was 0.96. One item was added following the advice given by one of the content experts. ICBTQ had excellent face validity. For the validation phase, ICBTQ demonstrated an acceptable Cronbach's Alpha value. One item was omitted in view of low corrected item-total correlation. In the item response theory (IRT) analysis, ICBTQ exhibited good difficulty and discriminatory indexes. Assessments of item-fit indicated that all items of the model were well-fitted.

CONCLUSIONS: Based on the IRT and reliability analysis, the knowledge section of the ICBTQ was psychometrically valid to be used among patients.

Keywords:

Blood transfusion, informed consent, knowledge, questionnaire, validation

[1]Department of Transfusion Medicine, Hospital Sultanah Aminah, 80100, Johor Bahru, Johor, Departments of [2]Community Health and [3]Biomedical Science, Advanced Medical & Dental Institute, Universiti Sains Malaysia, 13200, Kepala Batas, Pulau Pinang, [4]Faculty of Entrepreneurship and Business, Universiti Malaysia Kelantan, City Campus, 16100, Kota Bharu, Kelantan, Malaysia

Address for correspondence:
Mastura Mohd Sopian, Community Health Department, Advanced Medical & Dental Institute, Universiti Sains Malaysia, 13200, Kepala Batas, Pulau Pinang.
E-mail: mastura_sopian@usm.my

Submitted: 06-12-2021
Revised: 29-12-2021
Accepted: 11-01-2022
Published: 28-09-2022

Introduction

"Consent" is defined as "a voluntary and unambiguous agreement by a person with sufficient autonomy and competence, based on adequate comprehensible information and premeditation to make an intelligent decision about a proposed action."[1] It is a professional, legal, and ethical principle that valid consent is acquired before commencing medical intervention, physical examination, or delivering personal care for a patient. There are three types of consent comprising implied, verbal and written, which depend on the invasiveness of the procedure. Blood transfusion is a routine and potentially life-saving medical procedure used in various medical conditions. However, blood transfusion is invasive, which carries significant infectious and noninfectious potential complications, including but not limited to, death or permanent disabilities.[2] Hence, the concern of these hazards warrants patient participation in the decision to transfuse. In Malaysia, the patient must sign

How to cite this article: Senin MH, Sopian MM, Shaharuddin B, Nasir MJ. Development and validation of informed consent for blood transfusion questionnaire. Asian J Transfus Sci 0;0:0.

Table 1: The content validity index of relevance, clarity, simplicity, and ambiguity of the informed consent for blood transfusion questionnaire

Item number	Item	Relevance	Clarity	Simplicity	Ambiguity
C1	Patient aged 18 year old and above can give consent without parents/legal guardian involvement	1.00	1.00	1.00	1.00
C2	Consent which is given by a mentally unstable patient is invalid	1.00	1.00	1.00	1.00
C3	There is a special consent form for blood transfusion, which requires the patient's signature	1.00	1.00	1.00	1.00
C4	The validity of signed informed consent applies throughout patient admission	1.00	1.00	1.00	1.00
C5	The patient can sign the consent form for blood transfusion, regardless of whether the conversation with the physician has taken place or not	1.00	1.00	1.00	1.00
C6	Which of the following must be discussed by the physician during consent taking procedure prior to blood transfusion?				
C6a	Indication for blood transfusion	1.00	1.00	1.00	1.00
C6b	Alternative to blood transfusion	1.00	0.88	0.88	0.88
C6c	Opportunity to ask question	1.00	1.00	1.00	1.00
C6d	Risk of blood transfusion	1.00	0.88	0.88	0.88
C6e	Right to refuse blood transfusion	1.00	1.00	1.00	1.00
C6f	Information regarding blood transfusion procedure	1.00	1.00	1.00	1.00
C6g	Right to show understanding on information received	0.88	0.88	0.88	0.88
C7	Consent obtained from a patient under coercion is invalid	1.00	1.00	1.00	1.00
C8	The patient has the right to change mind even having signed the consent form for blood transfusion	1.00	1.00	1.00	1.00
C9	In general, consent can be obtained after completion of blood transfusion	1.00	0.88	0.88	1.00
C10	Consent for blood transfusion can be obtained using language not understood by the patient	1.00	1.00	1.00	1.00
C11	Consent for blood transfusion is bound by law in Malaysia	1.00	0.88	0.88	0.88
C12	Family members can give consent for blood transfusion if the patient is comatose or unconscious	1.00	1.00	1.00	1.00
S CVI/UA	-	0.94	0.72	0.72	0.78
S-CVI/Ave	-	0.99	0.97	0.97	0.97

a separate consent form for blood transfusion before the procedure.[3] The form outlines the components of the informed consent for blood transfusion that physicians should cover in the consent-taking process, which are:

- Explanation of the indication/s of blood transfusion
- Explanation of the benefits of blood transfusion
- Explanation of the risks of blood transfusion
- Explanation of the alternative to blood transfusion
- Assessment of patient understanding
- Provision of opportunity to ask questions
- Documentation of the procedure.

However, in contemporary medical practice, the process of taking informed consent is variable among practitioners and place of practice and far from theoretical ideals.[4] Informed consent discussions often omit material risks, alternatives and opportunities for the patient to ask questions, which are indispensable to meaningful decision-making.[5] Jukic *et al*. found a significant discrepancy between physicians and patients concerning knowledge of the informed consent process.[6] In the study, most patients (186; 70.2%) reported having partial knowledge of the informed consent process. Another cross-sectional study in Istanbul showed that 38.1% (n = 102) of adult surgical patients do not understand informed consent.[7] Moreover, several studies have shown poor transfer of knowledge regarding informed consent for blood transfusion from the doctor to the patient.[8,9]

At present, there is neither study nor a validated tool to evaluate patient's knowledge regarding informed consent for blood transfusion worldwide. Although several studies evaluated the level of knowledge regarding informed consent for the general procedure, the questions to assess patients' knowledge were incomprehensive.[6,7,10] For example, the item asks, "Are you familiar with the informed consent process?" or "Before the operation, did you know what the informed consent form means?" Moreover, the respondents are doctors.[6,7,11] Additionally, to the best of our knowledge, there is no available local study appraising patient knowledge on informed consent for the general procedure, not to mention for blood transfusion. Hence, this study was intended to develop a valid and reliable tool to evaluate knowledge regarding informed consent for blood transfusion among local patients.

Ethical approval

This study received ethical approval from the Human Ethics Committee of Hospital Universiti Sains Malaysia (HUSM) (ref no: USM/JEPeM/18110727) and

Table 2: The face validity index of clarity and comprehension of the informed consent for blood transfusion questionnaire

Item number	Item	Clarity	Comprehension	Universal
F1	In general, the physician should obtain consent from the patient before blood transfusion	0.95	1.00	0.98
F2	Patient aged 18 year old and above can give consent without parents/legal guardian involvement	0.95	0.95	0.95
F3	Consent which is given by a mentally unstable patient is invalid	0.95	0.95	0.95
F4	There is a special consent form for blood transfusion, which requires the patient's signature	0.95	0.95	0.95
F5	The validity of signed informed consent applies throughout patient admission	0.90	0.90	0.90
F6	The patient can sign the consent form for blood transfusion, regardless of whether the conversation with the physician has taken place or not	0.95	0.95	0.95
F7	Which of the following must be discussed by the physician during consent taking procedure prior to blood transfusion?			
F7a	Indication for blood transfusion	1.00	1.00	1.00
F7b	Alternative to blood transfusion	1.00	1.00	1.00
F7c	Opportunity to ask question	1.00	1.00	1.00
F7d	Risk of blood transfusion	1.00	0.95	0.98
F7e	Right to refuse blood transfusion	1.00	0.95	0.98
F7f	Information regarding blood transfusion procedure	0.90	1.00	0.95
F7g	Right to show understanding on information received	1.00	1.00	1.00
F8	Consent obtained from a patient under coercion is invalid	1.00	0.95	0.98
F9	The patient has the right to change mind even having signed the consent form for blood transfusion	1.00	0.95	0.98
F10	In general, consent can be obtained after completion of blood transfusion	0.90	1.00	0.95
F11	Consent for blood transfusion can be obtained using language not understood by the patient	1.00	1.00	1.00
F12	Consent for blood transfusion is bound by law in Malaysia	0.90	1.00	0.95
F13	Family members can give consent for blood transfusion if the patient is comatose or unconscious	1.00	0.95	0.98
Average	-	0.97	0.97	0.97

the Medical Research Ethics Committee in the Ministry of Health Malaysia (NMRR No: 18-3156-44688). The anonymity and confidentiality of the participants were guaranteed.

Subjects and Methods

This study was conducted in two phases [Figure 1]. Phase 1 involved the development of the questionnaire. Phase 2 consisted of a validation study that assessed reliability and Item response theory (IRT).

Phase 1: Questionnaire development

An extensive literature review encompassing scholarly articles, books, and guidelines was performed to ascertain any existing validated questionnaire regarding informed consent for blood transfusion. Additionally, the literature review attempted to identify any relevant items which could be incorporated into the newly developed questionnaire. Since there is scarce data on informed consent for blood transfusion, the literature review was expanded to include informed consent for general medical or surgical procedures.

A small group discussion (SGD) was organised among hospitalised patients to define the level and scope of new questionnaires on informed consent for blood transfusion. Five participants who had a history of blood transfusion were recruited. These participants were interviewed in a semi-structured manner to explore their basic knowledge regarding the elements of informed consent and blood transfusion procedures. The researcher formulated relevant constructs for the questionnaires based on the conclusion derived from SGD. The preliminary draft of the questionnaire was prepared using the expert review meeting, literature review, and SDG findings. For the expert review meeting, eight experts were recruited, comprising physicians, paediatricians, transfusion medicine specialists, laboratory haematologists and staff nurses who are routinely involved with blood transfusion practices.

The questionnaire consists of two sections, which are the sociodemographic and knowledge domains. The participants provided information on age, gender, ethnic group or groups, religion, marital status, highest educational attainment, employment, household income and history of receiving blood transfusion. The questionnaire was designed in the Malay language as a self-administered questionnaire, adhering to standard protocols for questionnaire design and testing.

Table 3: Corrected item-total correlation for each item

Item number	Item	Scale mean if item deleted	Scale variance if item deleted	Corrected item-total correlation	Squared multiple correlation	Cronbach's alpha if item deleted
R1	In general, the physician should obtain consent from the patient before blood transfusion	27.41	31.734	0.238	0.239	0.767
R2	Patient aged 18 year old and above can give consent without parents/legal guardian involvement	27.07	30.495	0.184	0.298	0.770
R3	Consent which is given by a mentally unstable patient is invalid	26.71	27.955	0.368	0.330	0.758
R4	There is a special consent form for blood transfusion, which requires the patient's signature	27.24	29.611	0.382	0.512	0.756
R5	The validity of signed informed consent applies throughout patient admission	26.89	27.840	0.437	0.314	0.751
R6	The patient can sign the consent form for blood transfusion, regardless of whether the conversation with the physician has taken place or not	26.60	31.583	0.110	0.169	0.772
R7	Which of the following must be discussed by the physician during consent taking procedure prior to blood transfusion?					
R7a	Indication for blood transfusion	27.31	30.342	0.336	0.416	0.760
R7b	Alternative to blood transfusion	26.86	28.056	0.382	0.301	0.756
R7c	Opportunity to ask question	27.37	31.022	0.310	0.298	0.763
R7d	Risk of blood transfusion	27.08	30.078	0.217	0.257	0.769
R7e	Right to refuse blood transfusion	26.98	26.914	0.570	0.434	0.739
R7f	Information regarding blood transfusion procedure	27.13	27.580	0.576	0.633	0.740
R7g	Right to show understanding on information received	27.13	28.580	0.436	0.350	0.751
R8	Consent obtained from a patient under coercion is invalid	26.39	31.730	0.112	0.148	0.771
R9	The patient has the right to change mind even having signed the consent form for blood transfusion	26.77	28.159	0.387	0.271	0.755
R10	In general, consent can be obtained after completion of blood transfusion	26.51	29.423	0.343	0.320	0.759
R11	Consent for blood transfusion can be obtained using language not understood by the patient	26.45	31.867	0.116	0.249	0.770
R12	Consent for blood transfusion is bound by law in Malaysia	26.97	27.988	0.418	0.347	0.752
R13	Family members can give consent for blood transfusion if the patient is comatose or unconscious	27.28	29.738	0.414	0.401	0.755

Content validity

To validate the questionnaire construct, a cover letter with the drafted questionnaires was submitted to another panel of eight experts, comprising five senior clinicians, one haematopathologist and one clinical matron who routinely deal with blood transfusion practices, and one university legal advisor. Each panel was asked to examine and rate each item for four parameters: Relevance, clarity, simplicity and ambiguity using a 4-point scale. Ratings of 1 and 2 are considered invalid content, while ratings of 3 and 4 are considered valid content and further categorised into dichotomous data 0 and 1, respectively.

Content validity was then determined by calculation of the content validation index (CVI) for each parameter. CVI can be computed using the item (I-CVI) and scale (S-CVI).[12] First, I-CVI describes the proportion of experts who are in agreement with each parameter (or item statement) and its value ranges from 0 to 1.[12] I-CVI is calculated as the number of experts that gave a rating of 3 or 4, divided by the total number of experts.[12] The item has excellent content validity if I-CVI $\geq$0.8 whereas the item needs revisions if I-CVI is between 0.70 and 0.79, and the item is eliminated if the value is below 0.70.[12] Second, S-CVI is calculated using the number of items in a tool that have achieved a rating of "valid content."[12] There are two types of S-CVI, one is the universal agreement (UA) among experts (S-CVI/UA), and the second, the average CVI (S-CVI/Ave).[12] S-CVI/UA is calculated by adding the number of items with I-CVI equal to 1 divided by the total number of items, while S-CVI/Ave is calculated by taking the sum of the I-CVIs divided by the total number of items.[12] When both S-CVI/UA $\geq$0.8 and S-CVI/Ave $\geq$0.9, these indicate excellent content validity.[13]

Face validity

For face validity assessment, an evaluation form was created to help respondents assess each item in terms of the clarity and comprehension of the wording. A column for the free-text suggestion for better item formulation was also provided in the form. The questionnaire was

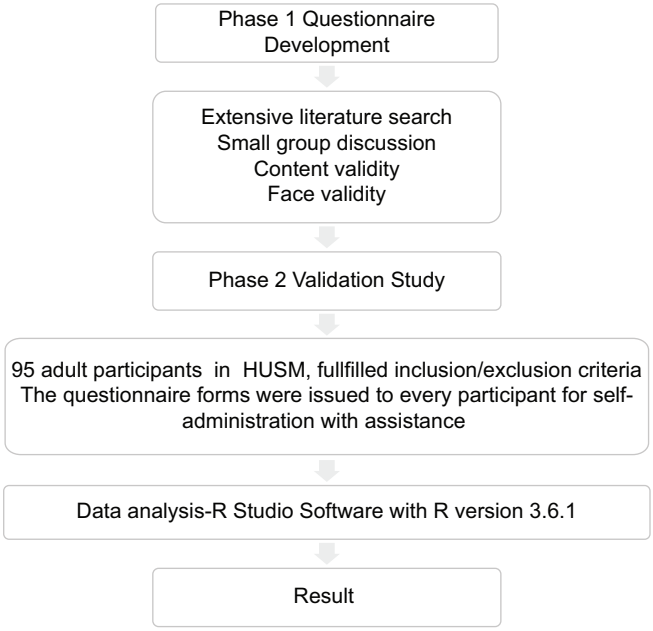

Figure 1: Flow diagram of overall methodology

then pretested for face validity, with 20 participants using purposive sampling. The target study population was patients at the Advanced Medical and Dental Institute, Universiti Sains Malaysia, Penang, who were above 18 years of age and had prior blood transfusion history. The latter is important to imply exposure to the consent-taking process. On a scale of 1-4, each subject was asked to rate each item for clarity (1 - Not clear at all; 4 - Very clear) and comprehension (1 - Unable to understand at all; 4 - Very easy to understand). Ratings of 1 and 2 are considered invalid content, while ratings of 3 and 4 are considered valid content and further categorised into dichotomous data 0 and 1, respectively. The dichotomous data were used to calculate the face validity index (FVI). The universal FVI was computed by averaging clarity and comprehension indices. The cut-off value for a satisfactory level of I-CVI in this study was used to interpret FVI. Therefore, FVI $\geq$0.8 was considered a satisfactory level of face validity.[12] The subjects were provided sufficient time to go through each item to share any thoughts or doubts, if any.

Phase 2: Validation study

The validation study was conducted in September 2019 to explore the psychometric properties of the questionnaire. The sample size for the validation study is calculated based on the respondent-to-item ratio of 5:1.[14] Nineteen items assessed the knowledge domain.[15] Therefore, a total of 95 adult participants was recruited in HUSM, Kelantan through purposive sampling. The inclusion criteria include stable, literate patients who had a history of receiving prior blood transfusions. Blood transfusion history implies the subject's exposure to the informed consent process for the procedure. The questionnaire forms were issued to every participant for self-administration with assistance from the researcher. The data analysis was performed in R studio software with R version 3.6.1 R style Boston, MA (Computer Software v0.98.1074) . As the knowledge section consisted of unidimensional items with dichotomous responses, it was analysed by the two-parameter logistic IRT (2PL) analysis, using the ltm package version 1.0.0. Difficulty index in the range of –3 to +3 and discrimination index in the range of 0.35–2.5 were considered acceptable.[16] The Chi-square goodness-of-fit per item determined item fit, and one-dimensionality was determined by the likelihood ratio method.

For internal consistency reliability, we produced Cronbach's alpha coefficient through the IBM SPSS Statistics version 24.0 (IBM Corporation, New York, USA), where the coefficient equal to or greater than 0.7 is considered acceptable for the consistency. The obtained results were analysed to prepare a revised final version of the questionnaire that is used in the subsequent actual study.

Results

Item development

Through a SGD, extensive literature review and expert review discussion on informed consent for blood transfusion, the concept and relevant knowledge construct were identified to develop a preliminary draft of the questionnaire.

Content validity

All items in the ICBT Questionnaire scored excellent I-CVI ($\geq$0.80) for all four domains [Table 1]. The majority of items had I-CVI = 1.00 while the remaining had I-CVI = 0.88. Overall, all items were considered valid content. The S-CVI/UA results for relevance, clarity, simplicity, and ambiguity were 0.94, 0.72, 0.72 and 0.78, respectively. The results of the S-CVI/Ave for relevance, clarity, simplicity and ambiguity were 0.99, 0.97, 0.97 and 0.97, respectively. The universal agreement (S-CVI/UA) method exhibited moderate content validity, whereas the average approach (S-CVI-Ave) demonstrated high content validity of the ICBT questionnaire. Correction of words on some items was done. An addition of one item was made to address the significant need for informed consent from the patient for blood transfusion. This item was later labelled as F1 in the face validity section.

Face validity

The FVI calculation was for the second version (19 questions) of the ICBT Questionnaire. The FVI of clarity and comprehension were both 0.97. Thus, the universal FVI was 0.96, representing an excellent level of face validity. At the item-level, ten items had FVI = 1.00 in each

parameter. The results of item-level indices demonstrated an excellent level of face validity [Table 2]. Following feedback from respondents, several changes to the wordings, terminologies and layout were made. A brief explanation regarding the blood transfusion procedure was also added to the patient information sheet.

Sociodemographic characteristics of respondents

The mean age of the respondents was 34.15 ± 12.56 years old. Most of the respondents were Malay (84.2%), Muslim (84.2%), male (54.7%), married (66.3%), possessed secondary level education (43.2%), and had transfusion history (61.1%)

Reliability tests

Cronbach's alpha coefficient equal to or greater than 0.7 is considered acceptable for internal consistency. For the third version of the ICBT Questionnaire, the Cronbach's alpha value of the 13 items was 0.769. Table 3 displays that the corrected item-total correlation for 15 out of 19 items were more than 0.2. Four out of 19 items had poor score (≤0.2), including item R2, R6, R8 and R11. Item R8 had the lowest value for corrected item-total correlation with 0.11 and was removed. Items R2, R6 and R11 were retained because these items were deemed crucial, following advice by one of the experts. After R8 removal, the updated Cronbach's alpha value for the scale was 0.771.

Results for item response theory

Table 4 describes the average difficulty and discrimination parameter estimates of the dichotomous 2PL model for the IRT. The items had overall difficulty ranging from −3.6 to 0, indicating that the questions were either considered easy (Difficulty <−2.0), or average in difficulty (−2.0 ≤ Difficulty <2.0). For discriminatory index, seven out of 18 items (Q2, Q3, Q6, Q8, Q9, Q10, and Q11) had overall discriminant values below 1, suggesting that these items may have a low-to-moderate ability to differentiate among individuals with different levels of the latent trait being measured by the scale. Item Q7f had the highest value of overall discriminant value, indicating that it was the best at differentiating among individuals with different latent trait levels (ability level).

Figure 2 shows item characteristic curve (ICC) plots for each item. The Q7f had the steepest S-shaped curve in the range of −0.7 to −0.3 ability level from the ICC plots, indicating the best discrimination capability to

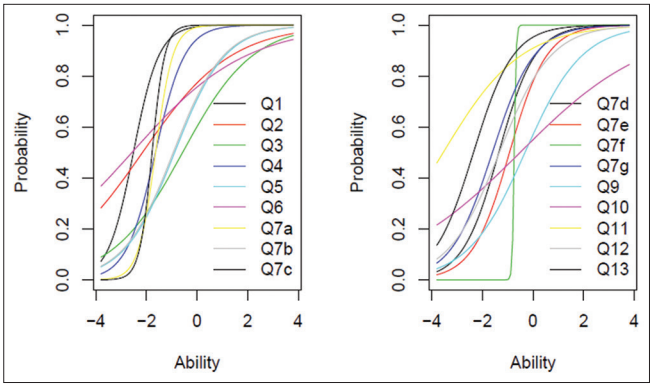

Figure 2: Item characteristic curves

Table 4: Difficulty index and discriminatory index

Item number	Item	Difficulty index, *P*	Discriminatory index, *D*
Q1	In general, the physician should obtain consent from the patient before blood transfusion	−2.52	1.99
Q2	Patient aged 18 year old and above can give consent without parents/legal guardian involvement	−2.16	0.57
Q3	Consent which is given by a mentally unstable patient is invalid	−0.57	0.72
Q4	There is a special consent form for blood transfusion, which requires the patient's signature	−1.65	1.73
Q5	The validity of signed informed consent applies throughout patient admission	−0.89	1.00
Q6	The patient can sign the consent form for blood transfusion, regardless of whether the conversation with the physician has taken place or not	−2.57	0.44
Q7	Which of the following must be discussed by the physician during consent taking procedure prior to blood transfusion?		
Q7a	Indication for blood transfusion	−1.64	2.92
Q7b	Alternative to blood transfusion	−0.94	1.00
Q7c	Opportunity to ask question	−1.78	4.00
Q7d	Risk of blood transfusion	−1.35	1.39
Q7e	Right to refuse blood transfusion	−0.93	1.36
Q7f	Information regarding blood transfusion procedure	−0.74	27.05
Q7g	Right to show understanding on information received	−1.61	1.21
Q8	The patient has the right to change mind even having signed the consent form for blood transfusion	−0.32	0.88
Q9	In general, consent can be obtained after completion of blood transfusion	−0.51	0.39
Q10	Consent for blood transfusion can be obtained using language not understood by the patient	−3.55	0.65
Q11	Consent for blood transfusion is bound by law in Malaysia	−1.33	0.98
Q12	Family members can give consent for blood transfusion if the patient is comatose or unconscious	−2.35	1.28

distinguish those with lower and higher abilities, and the item might be considered hard for those with lower ability. Items Q1, Q4, Q7a and Q7c had substantial steep S-shaped curve and had an inflexion point near ability level of −2, indicating that those with lower ability can correctly answer the items. Items Q2 and Q6 were two of the easiest to be correctly answered for most people, but with low capability of segregating between low and high ability persons. Besides, item Q9 was considered the hardest for those with high ability to answer, with maximum probability of 0.8 at the ability level of 4.

Figure 3 displays the item information curve (IIC) values for each item. The figure shows that item Q7f provided very high information in the small range of −0.7 to −0.3 ability level and was almost flat for the remaining value range. Meanwhile, Q7 g, Q9, Q10, Q11, Q12 and Q13 had information peak values of <0.5 indicating that these items were the least useful to estimate the true ability levels with reliable precision. We also observed that Q1, Q5 and Q7a, had a peak approximately at the ability level of − 2.0 and had a broader curve than Q7f, suggesting that these items have wider distribution of information.

The total/test information curve (TIC) [Figure 4] was used to assess how well the questionnaire estimated respondents' ability for the whole item. The curve was almost flat, except for the two peaks, suggesting that small value ranges of ability cover extensive information on the questionnaire, and some ranges had very little information. Combined with the results of R function information (), the ability level above zero only covered 5.54% of all information provided by the 2PL model of the questionnaire. Conversely, approximately 94.46% of the information in this test was provided for ability levels below 0. These results implied that very little information could be obtained for those with higher ability. Furthermore, we observed that the ability range of −1.0 to 0 already covered 61.17% of the information.

Finally, the item fit and unidimensionality assumption of the 2PL model were assessed [Table 5]. Items were considered fit under the 2PL model if the corresponding $P \geq 0.05$. From the results, all the $P > 0.05$, indicating all items were well-fitted for the model.

Despite many attempts, the bootstrap modified parallel analysis test (BMPAT) approach through R function unidimTest was unsuccessful in generating any result due to an unexpected error, which was difficult to fix. However, the EFA through R function ANOVA was working fine, and the corresponding result of the likelihood ratio test was given. Since the P value of the likelihood was < 0.05, the unidimensionality assumption was not met for the single latent 2PL IRT model implying that a multiple latent 2PL-IRT can provide a better fit.[17]

Discussion

Evaluation of patient knowledge regarding informed consent for blood transfusion is vital to identify whether patients are aware of their rights before consenting to the blood transfusion procedure. Hence, a reliable and valid tool was crucial to assess patient's knowledge to improve future blood transfusion practice. We developed a new structured and validated questionnaire as an assessment tool of patients' knowledge of the elements of informed consent for

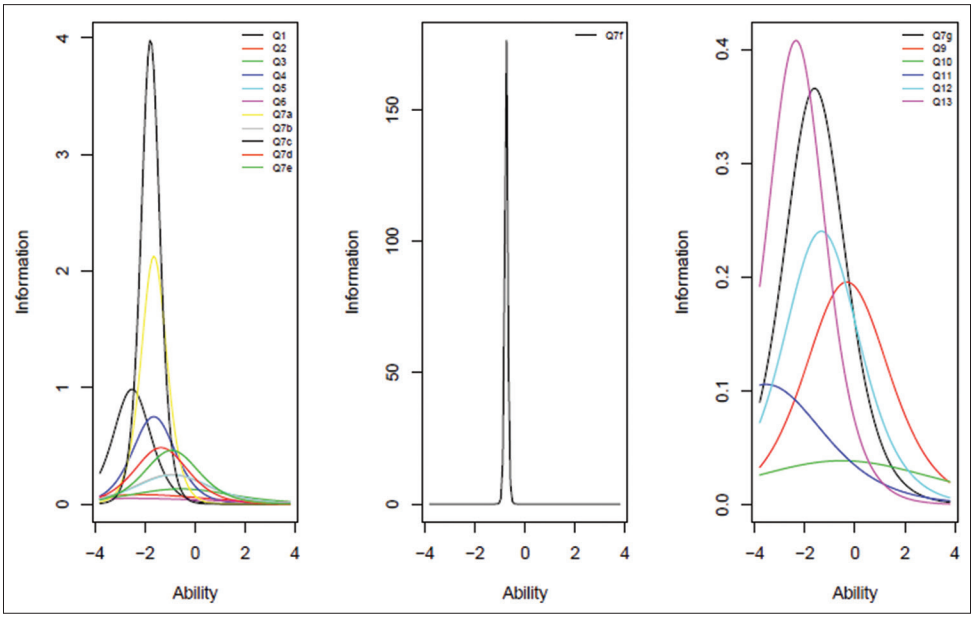

Figure 3: Item information curves

Table 5: Item fit statistics for binary-two-parameter logistic item response theory model

Item number	Item	χ^2	*P*
Q1	In general, the physician should obtain consent from the patient before blood transfusion	5.280	0.727
Q2	Patient aged 18 year old and above can give consent without parents/legal guardian involvement	4.394	0.820
Q3	Consent which is given by a mentally unstable patient is invalid	8.854	0.355
Q4	There is a special consent form for blood transfusion, which requires the patient's signature	5.190	0.737
Q5	The validity of signed informed consent applies throughout patient admission	5.763	0.674
Q6	The patient can sign the consent form for blood transfusion, regardless of whether the conversation with the physician has taken place or not	2.964	0.937
Q7	Which of the following must be discussed by the physician during consent taking procedure prior to blood transfusion?		
Q7a	Indication for blood transfusion	2.791	0.947
Q7b	Alternative to blood transfusion	13.344	0.101
Q7c	Opportunity to ask question	2.280	0.971
Q7d	Risk of blood transfusion	12.338	0.137
Q7e	Right to refuse blood transfusion	7.080	0.528
Q7f	Information regarding blood transfusion procedure	5.941	0.654
Q7g	Right to show understanding on information received	6.160	0.629
Q8	The patient has the right to change mind even having signed the consent form for blood transfusion	5.377	0.717
Q9	In general, consent can be obtained after completion of blood transfusion	13.461	0.097
Q10	Consent for blood transfusion can be obtained using language not understood by the patient	12.033	0.150
Q11	Consent for blood transfusion is bound by law in Malaysia	9.081	0.336
Q12	Family members can give consent for blood transfusion if the patient is comatose or unconscious	7.908	0.443

blood transfusion. A validated questionnaire with good psychometric properties is essential to ensure a reliable and high-quality result. Our questionnaire went through a rigorous process of content validity assessment by eight experts; face validity by a group of patients who had a history of blood transfusion which is analogous to the target population; IRT analysis to determine the difficulty and discriminatory parameters of the items for knowledge domain; and assessment of reliability by measurement of the internal consistency.

CVI is a form of consensus estimate in which the experts share a mutual agreement on the rating of each item of the construct.[18] The recommended number of experts to review an instrument varies from 2 to 20 individuals.[19] A minimum number of five experts is enough to provide adequate levels of control for chance agreement.[19,20] Although the maximum number of experts is not established, it is unlikely to exceed ten experts.[20] ICBT questionnaire was submitted to eight content experts, which allows one disagreement and the instruments will have valid content.[20] The ICBT questionnaire was shown to have good overall content validity at both the scale and item levels. However, there is concern of inflated values of CVI due to chance agreement. This concern warrants a modified kappa statistics, a consensus index of interrater agreement, to adjust for chance agreement.[21] However, we do not consider this statistic here. The addition of one item, F1, which addresses the significant need for informed consent from the patient for blood transfusion, was performed since it was deemed crucial by one of the content experts.

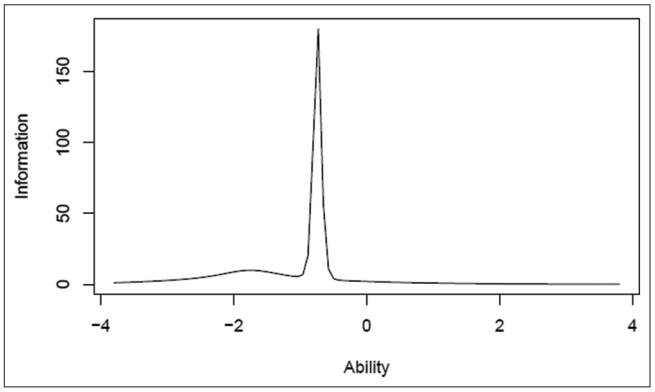

Figure 4: Total information curve

The pretest for face validity aims to attest that the target audience comprehends the questions and can answer meaningfully, as desired by the researcher.[22] Face validity reduces respondents' cognitive burden by revising tricky words and omitting poorly worded words.[23] The ICBT questionnaire had an excellent face validity at both the scale and item levels. Different studies cite different sample sizes for face validity ranging between 5 and 75, whereas other studies cite "as many as researchers can recruit."[22,24] In this study, 20 participants were recruited.

There is no absolute rule from the literature for the sample size of a validation study, although the larger sample size is often better than smaller samples. The respondent-to-item ratio is an excellent tool to strengthen the rationale for a large sample size. However, the range or respondent-to-item ratio varies from 5:1 to 30:1.[25] We

adopted a subject-to-item ratio of 5:1 for the reliability test. Reliability is the degree of consistency exhibited when a measurement is repeated under identical conditions.[26] Cronbach's alpha is a widely used test of reliability.[26] Higher values imply items are measuring the same dimension.[14] After removing Q8, which addresses the validity of informed consent if provided under coercion, the Cronbach's Alpha value increased to 0.771.

The minimum sample size for the IRT analysis follows the sample size for reliability analysis, as there is no gold standard for the former. However, some authors recommend that a minimum of 200 samples will suffice for the 2PL model.[27] The IRT, also known as the latent response theory, denotes a family of mathematical models which underpins scale development. IRT attempts to explore the relationship between latent traits (i.e., knowledge) and their manifestations (i.e., performance).[23,28] IRT ascertains a link between properties of the items on an instrument, individuals responding to these items, and the underlying traits being measured simultaneously.[28] In essence, it identifies functional item which is defined as having good correlation with each other, good discriminatory properties and significant contribution to the construct.[23]

Item difficulty index, *P*, is the proportion of correct answers on a given item.[29] Although lower *P* suggests modification or omission of a particular item, consideration should be given to the intended difficulty level. ICBT Questionnaire is designed for the general patient population, so the focus was on low-to-medium index.[23] Item discriminatory index, *D*, is the degree to which an item correctly discriminates between respondents on a construct of interest.[29] Higher values such as Q7f indicate the greater discriminatory ability of an item.[23] The nondiscriminatory or negative discriminatory item should be revised or omitted. In this study, all items had acceptable *D*, scoring more than 0.34.

The ICC plot provides a way to check the item difficulty and item discrimination according to a person's ability in a graphical way.[30,31] The two properties in ICC does not measure validity.[30,31] The *S*-shaped curves describe the relationship between the probability of correct response to an item and the ability level.[30,31] The steeper the *S*-curve, the better the item can discriminate between different persons' latent traits (e.g., low and high knowledge levels).[30,31] Furthermore, an item is considered easy overall if the probability of correct response is high for those with lower ability and approaches 1.0 for those with higher ability, otherwise, considered hard overall if the probability of correct response is very low for those with lower ability, and remains low for those with higher ability.[30,31]

The IIC plot provides a way to evaluate at which levels of ability of a given item provides the most (and least) information.[30,31] In particular, if the amount of information is large at a particular ability level or range, it means that a person whose true ability is at that level can be estimated or determined with high precision.[30,31] Otherwise, if the amount of information at a particular ability level or range is small, it means that a person's ability level cannot be estimated or determined with reliable precision.[30,31]

In the TIC plot, a spike in the ability range of −1.0 to 0 was observed, which covered 61.17% of the information. Overall, the graph provided the best information for those with moderate ability. While the ideal test information function often maybe a horizontal line, it may not be the best for a specific purpose.[30,31] ICBT Questionnaire assessed knowledge for the general patient population. Hence, the focus was for low-to-medium ability.

One of the IRT model assumptions is the unidimensionality, where only a single latent trait is being measured by the set of items in the model.[30,31] If the assumption is not met, then a higher number of latent traits may better fit the instruments.[30,31] Two known methods to determine unidimensionality are exploratory factor analysis (EFA) and the BMPAT approaches; which are both currently available in R.[30,31] In the EFA approach, a single latent 2PL model is tested against a two latent 2PL model using a likelihood ratio test.[30,31]

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. Furthermore, we could not perform test-retest reliability as it was not feasible to capture the same patients over different time intervals.

This study showed that this newly developed 18-item questionnaire is a valid and reliable tool for assessing informed consent for blood transfusion among patients. Other researchers can use this instrument in the future with larger sample sizes. Additionally, health policymakers can use this instrument to assess patients' knowledge level regarding the area of interest and formulate interventions to empower the patients in this respect. In terms of further analysis of the psychometric properties of the instrument, descriptive statistics can be used.

Conclusions

The final version of the questionnaire in this study contains 18 items assessing the knowledge domain.

Our questionnaire exhibited acceptable psychometric properties. This questionnaire is a valid and reliable assessment tool for assessing patients' knowledge regarding informed consent for blood transfusion.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1. Rathor MY, Rani MF, Shah AM, Akter SF. Informed consent: A socio-legal study. Med J Malaysia 2011;66:423-8.
2. Shruthi Narayan DP, on Behalf of the Serious Hazards of Transfusion (SHOT) Steering Group. Annual SHOT Report 2019. United Kingdom; 2019.
3. National Blood Centre. Transfusion Practice Guidelines for Clinical and Laboratory Personnel. 4th ed. Malaysia: National Blood Centre; 2016.
4. Hall DE, Prochazka AV, Fink AS. Informed consent for clinical treatment. CMAJ 2012;184:533-40.
5. Spatz ES, Krumholz HM, Moulton BW. The new era of informed consent: Getting to a reasonable-patient standard through shared decision making. JAMA 2016;315:2063-4.
6. Jukic M, Kozina S, Kardum G, Hogg R, Kvolik S. Physicians overestimate patient's knowledge of the process of informed consent: A cross-sectional study. Med Glas (Zenica) 2011;8:39-45.
7. Erkan I, Mayadagli Y, Akbaba M. Assessment of patients' knowledge level regarding the informed consent from the ethical aspect. Rom J Legal Med 2017;25:121-5.
8. Court EL, Robinson JA, Hocken DB. Informed consent and patient understanding of blood transfusion. Transfus Med 2011;21:183-9.
9. Cheung D, Lieberman L, Lin Y, Callum J. Consent for blood transfusion: Do patients understand the risks and benefits? Transfus Med 2014;24:269-73.
10. Sulaiman A, Ayyuba R, Diggol I, Haruna I. Knowledge, attitude and perception of patients towards informed consent in obstetric surgical procedures at Aminu Kano Teaching Hospital. Niger J Basic Clin Sci 2015;12:45-50.
11. Jukic M, Kvolik S, Kardum G, Kozina S, Tomic Juraga A. Knowledge and practices of obtaining informed consent for medical procedures among specialist physicians: Questionnaire study in 6 Croatian hospitals. Croat Med J 2009;50:567-74.
12. Zamanzadeh V, Ghahramanian A, Rassouli M, Abbaszadeh A, Alavi-Majd H, Nikanfar AR. Design and implementation content validity study: Development of an instrument for measuring patient-centered communication. J Caring Sci 2015;4:165-78.
13. Shi J, Mo X, Sun Z. Content validity index in scale development. Zhong Nan Da Xue Xue Bao Yi Xue Ban 2012;37:152-5.
14. Bujang MA, Omar ED, Baharum NA. A review on sample size determination for Cronbach's alpha test: A simple guide for researchers. Malays J Med Sci 2018;25:85-99.
15. Gorusch R. Factor Analysis. Hillsdale, NJ: Lawrence Erlbaum Associates; 1983.
16. Arifin WN, Yusoff MS. Item response theory for medical educationists. Educ Med J 2017;9:69-81.
17. Oberski DL. A review of latent variable modeling with R. J Educ Behav Stat 2016;41:226-33.
18. Stemler S. A comparison of consensus, consistency, and measurement approaches to estimating interrater reliability. Pract Assess Res Evalu 2004;9:1-11. Available from: http://PAREonline.net/getvn.asp?v=9&n=4. [Last retrieved on 2006 Oct 05].
19. Rodrigues IB, Adachi JD, Beattie KA, MacDermid JC. Development and validation of a new tool to measure the facilitators, barriers and preferences to exercise in people with osteoporosis. BMC Musculoskelet Disord 2017;18:540.
20. Lyn MR. Determination and quantification of content validity. Nurs Res 1986;35:382-5.
21. Polit DF, Beck CT, Owen SV. Is the CVI an acceptable indicator of content validity? Appraisal and recommendations. Res Nurs Health 2007;30:459-67.
22. Perneger TV, Courvoisier DS, Hudelson PM, Gayet-Ageron A. Sample size for pre-tests of questionnaires. Qual Life Res 2015;24:147-51.
23. Boateng GO, Neilands TB, Frongillo EA, Melgar-Quiñonez HR, Young SL. Best practices for developing and validating scales for health, social, and behavioral research: A primer. Front Public Health 2018;6:149.
24. Converse JM, Presser S. Survey Questions: Handcrafting the Standardized Questionnaire. Newbury Park: Sage Publications Inc.; 1986.
25. Bujang MA, Puzziati AG, Soelar SA. Sample Size Guideline for Exploratory Factor Analysis When Using Small Sample: Taking into Considerations of Different Measurement Scales. International Conference on Statistics in Science, Business and Engineering (ISCCBE); 2012.
26. Miquel P. Dictionary of Epidemiology. New York: Oxford University Press; 2008.
27. Hambleton RK, Cook LL. Robustness of item response models and effects of test length and sample size on the precision of ability estimates. In: Bock DJ, editor. New Horizons in Testing: Latent Trait Test Theory and Computerized Adaptive Testing. New York: Academic Press; 1983.
28. Item Response Theory: Columbia University Mailman School of Public Health; 2019. Available from: https://www.publichealth.columbia.edu/research/population-health-methods/item-response-theory#readings. [Last retrieved on 2020 May 12].
29. Raykov T, George AM. Introduction to Psychometric Theory. New York: Routledge, Taylor & Francis Group; 2011.
30. Baker F. The Basics of Item Response Theory Using. 2nd ed. ERIC Clearinghouse on Assessment and Evaluation Publishers; 2001.
31. Finch H, French B. Latent Variable Modeling with R. Routledge Publishers; 2015.