ORIGINAL ARTICLE

Validity and Reliability of a Questionnaire Developed to Assess the Knowledge of Pregnant Women about Cord Blood Banking

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ABSTRACT

Introduction: Cord blood (CB) is rich in hematopoietic stem cells. There has been significant growth in cord blood banks (CBBs) throughout the world. In Malaysia, the CB units cryopreserved in public CBB is below its optimal level. Lack of knowledge about CB banking among mothers in other countries influenced their decision to donate CB, however, there is no local data to support this in Malaysia. Moreover, no validated and reliable tool is available for measuring local women's knowledge about CB banking. In this study, a questionnaire to assess pregnant women's knowledge about CB banking was developed and validated. **Method:** Several steps were taken to develop the knowledge items in the questionnaire which includes comprehensive literature review, content validity by a panel of experts, and face validity by a group of pregnant women. The questionnaire was developed in Malay language and contained 18 items. After modifications, the self-administered questionnaire was distributed to 121 pregnant women to assess its psychometric properties using two-parameter logistic item response theory analysis and internal consistency reliability analysis. **Results:** The majority of the knowledge items showed acceptable difficulty and discriminatory values. The Cronbach's alpha and ICC values were 0.831 and 0.887, respectively, indicating good reliability. All 18 knowledge items were retained for the final version of the questionnaire. **Conclusion:** The newly developed questionnaire demonstrated acceptable psychometric properties and can be used as a reliable tool to assess knowledge about CB banking among pregnant women in the local population.
Malaysian Journal of Medicine and Health Sciences (2023) 19(2):151-158. doi:10.47836/mjmhs19.2.23

Keywords: Validity, Reliability, Questionnaire, Knowledge, Cord Blood Banking

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INTRODUCTION

Cord blood (CB) is a rich source of hematopoietic stem cells (HSC) equivalent to that found in the bone marrow (1). It has become an alternative source for hematopoietic stem cell transplantation (HSCT) (2). This discovery changed the world's view of CB from a biological waste to a potentially curative therapy for many hematological diseases (3-8). CB units can be cryopreserved at -196 C in liquid nitrogen for more than 20 years for future transplantation. As a result, cord blood banks (CBBs) have grown exponentially (9). There are two different kinds of CBBs, namely public blood cord bank and private blood cord bank. Public CBBs which are funded by the government, collect, process, and store unrelated CB donation for the use of public who need HSCT. Meanwhile, private banks collect directed CB donation only for the use of the family who bank it and the parents are charged for processing and storing the CB unit. More than 800,000 CB units are currently stored in public CBBs across 45 countries (10), with an average of 4100 units released for cord blood transplantations (CBTs) each year (11).

Among the Southeast Asia countries, Malaysia, Singapore, Thailand, and Vietnam have both public and private CBBs. In other countries such as Indonesia, Brunei, Myanmar, and Philippines, only private CBBs are available (12). Singapore Cord Blood Bank is the largest public CBB in Southeast Asia with about 11,000 transplantable units in its inventory and had facilitated over 282 CBTs in Singapore and 15 other countries across the world as of 1 February 2021 (13). In Malaysia,

the first public CBB housed in National Blood Center (NBC) was launched in 2002, and Hospital Kuala Lumpur was the main cord blood collection centre. The country's largest public CBB has cryopreserved nearly 7500 CB units readily available for clinical use, but to date, there were only 11 cord blood units issued since its establishment.

The reason for the underutilization of cord blood was due to several factors such as unavailability of HLA matched CB units, clinician-related factors, and limited facility. The chances of finding an unrelated HLA-matched cord blood will be higher if the public CBB has an inventory of one or two CB units per 1000 population (14). Unfortunately, due to low clinical conversion rate (rate of stored cord blood from collection) caused by an insufficient or poor quality of the cord blood stem cells, NBC has cryopreserved only around 25% of suggested optimal inventory, which can be improved by increasing the number of cord blood collection.

Recent studies from other countries have reported that a lack of knowledge regarding CB banking and CBT in general makes expectant parents not motivated and hesitant to donate CB (15,16). Locally, there is no data regarding pregnant women's knowledge about CB banking which is important as current practice in the public CB collection centre in Malaysia approaches pregnant women regarding CB donation in the labour room, and decision whether to donate or not is largely decided by the expectant mother. To maximise the number of cord blood repositories for public banks, it is essential to assess the knowledge level about CB banking in our local population and the quality of the disseminated information about CB banking. A study which assess the respondents' knowledge level must use a valid and reliable tool to provide high quality and accurate results. Hence, a valid and reliable questionnaire was developed for Malaysian population to assess pregnant women's knowledge about CB banking.

MATERIALS AND METHODS

This study consisted of Part 1 for development of questionnaire items and Part 2 for validation of the questionnaire. Ethical approval from Human Research Ethics Committee Universiti Sains Malaysia (study protocol code: USM/JEPeM/18110728) and Medical Research and Ethics Committee of the Ministry of Health (reference no: NMRR-18-3100-44622) were obtained before conducting this study.

Part 1: Questionnaire development

Several steps were taken to develop the questionnaire. A comprehensive literature review regarding knowledge and attitude of expectant mothers towards CBB was done to identify relevant items used in the previous studies. Educational tools and brochures provided by the Ministry of Health Malaysia on CB banking were also reviewed. Several items from questionnaires used in earlier studies (17-20) were adapted and modified after obtaining permission from the relevant authors. To appropriately address the aims of this study, other newly created items have been included in the questionnaire. The questionnaire was constructed in Malay language to be used as a self-administered tool because it is used as a national language and majority of the pregnant women at the CB collection centre were of Malay ethnicity. After the initial items of questionnaire were created, five content experts from various background (Obstetrician and Gynecologist, Family Medicine Specialist, Haematopathologist, Transfusion Medicine Specialist, and Pediatrician) reviewed the items in a formal group discussion to ensure that the items are relevant and accurate. After the expert panel discussion, some items that were found unnecessary were excluded from the questionnaire and new items were added.

The questionnaire consisted of 34 questions and composed of three primary sections: (i) demographic information (10 items), (ii) knowledge measure (18 items), and (iii) attitude determinant (6 items). The first section capture demographic details such as age, race, gravidity, number of children, gestational age, education level, occupation, household income, and source of cord blood banking information. The second section assess the respondents' CB banking knowledge and consisted of 18 close-ended questions with 'True, False, and Don't know' responses. This part covered questions on the definition of CB, its collection, storage, and applications, as well as the concept of CB banking. The third section contained six closed-ended questions to determine the participant's attitude towards CB banking which includes willingness to donate CB (Yes/ No), reasons if not willing to donate (Not interested/ Family member do not agree/Information not adequate to make decision/ Religion do not allow for donation/ Other reason), preferred cord blood bank if willing to donate CB (Public CB bank/ Private CB bank), reasons for the preference to donate to public bank (For the benefit of patients in need/ High cost for CB storage at private bank/ Child is less likely to require umbilical cord blood transfusion/ Lack of confidence in standards and quality of private CB bank/ Other reason), reasons for the preference to donate to private bank (For health protection in the future/ Using own umbilical cord blood is safer than using others'/ Reasonable cost/ Worry that umbilical cord blood stored at public CB bank will be used for other purposes/ Other reason), and lastly willingness to donate CB for research purpose (Yes/ No).

The first draft of the questionnaire was then subjected to content validity by another five panel of experts consisting of a Transfusion Medicine Specialist, a Family Medicine Specialist, a Clinical Hematologist, an Obstetrics & Gynecology Specialist and a Pediatrician. The purpose of the content validity was to evaluate

the relevance (using 4-scale scoring system from 1 'Not relevant' to 4 'Extremely relevant'), clarity (using 4-scale scoring system from 1 'Not understandable' to 4 'Extremely understandable'), simplicity (using 4-scale scoring system from 1 'Not simple' to 4 'Extremely simple'), and ambiguity (using 4-scale scoring system from 1 'Doubtful' to 4 'Extremely clear') of each item developed in the questionnaire. The panel indicated their decision for each item whether to eliminate, retain, or amend and also commented on the items amended. The item-level content validity index (I-CVI) for relevancy, scale-level content validity index based on the average (S-CVI/Ave), and scale-level content validity index based on the universal agreement (S-CVI/UA) were calculated, and the acceptable CVI values must be ≥0.8 (21-23). All items in the knowledge and attitude section have I-CVI values of 1, except 3 items in the attitude section with I-CVI values of 0.8. The S-CVI/Ave and S-CVI/UA were 0.99 and 0.93, respectively. Hence. all items were considered appropriate. Following the content validity, all initial items in the first draft were retained after minor wording modifications based on the panel's suggestions.

Subsequently, face validity was conducted by administering the second draft questionnaire to 30 pregnant women at the Obstetrics and Gynecology Clinic, Hospital Kuala Lumpur (HKL) to assess the understanding and interpretation about the items in the questionnaire using 4-scale scoring system for clarity and comprehension (from 1 'Not clear and understandable to 4 'very clear and understandable'). The respondents were also requested to give their suggestion and opinion on overall readability and simplicity of the items. All the suggestions and opinions were noted and reviewed with experts. The item-level face validity index (I-FVI), scale-level face validity index based on the average (S-FVI/Ave), and scale-level face validity index based on the universal agreement (S-FVI/AUA) were calculated, and FVI values of ≥ 0.8 were considered acceptable (24). Each item in the questionnaire have I-FVI values of 1 and have S-FVI/Ave and S-FVI/UA values of 1, respectively. At the end of the content validity and face validity process, the revised questionnaire was then used in the validation study to assess the items' psychometric properties.

Part 2: Validation Study

The validation study was conducted using a cross-sectional design approach from April 2019 until May 2019 involving 121 pregnant women at Obstetrics and Gynecology Department of HKL. HKL was selected as the study location since it is the largest contributor of cord blood units to Malaysia's public collection centre with nearly 11,000 births per year. The respondents were recruited through a convenience sampling method. Pregnant women who fulfilled the inclusion criteria were invited to take part in this study voluntarily. Participants must be 18 years or older, understand Malay language, and be willing to participate in the study. Respondents who were illiterate, non-Malaysian citizen and had any known mental disorder were excluded from this study. After obtaining informed consent, the respondents were given a set of the self-administered questionnaire form which takes about 15 to 20 minutes to complete.

Data was coded for entry in the SPSS statistical software version 24.0 (IBM Corporation, New York, USA). Descriptive statistics were used to summarise the respondents' characteristics. The data was then analysed to assess the items' psychometric properties for items in the knowledge section using R software version 4.0.2 in R Studio environment. Items in the attitude section were not evaluated for psychometric properties since only one clear-cut item from this section was used to assess the respondents' attitude towards CB banking, which is willingness to donate cord blood. The two-parameter logistic item response theory (2-PL IRT) analysis using R package ltm was performed for the knowledge section as it consisted of unidimensional items with dichotomous responses (25). The acceptable range values for difficulty and discrimination index were -3 to +3 and 0.35 to 2.5, respectively (26). Item fit was assessed by chi-square goodness-of-fit per item and assumption of unidimensionality was checked by modified parallel analysis (26-27). For internal consistency reliability, R package psych was used for analysis. A Cronbach's alpha coefficient of > 0.7, corrected-item total correlation (for each individual item) of > 0.3, and an intra-class correlation coefficient (ICC) (for test-retest) of > 0.4 were the acceptable values referred in the analysis (28).

There is no sample size calculation for the IRT analysis (29), hence the validation study sample size was calculated by means of an estimation for internal consistency. To get a minimum expected Cronbach's alpha of 0.8 with 95% CI, the study required 136 respondents for 18 items in the knowledge section. However, only 121 participants were recruited due to time constrain. For the test-retest analysis, a minimum sample size of 46 was adequate to detect an ICC value of 0.80. However, only 30 respondents successfully completed the second questionnaire.

RESULTS

Respondents' sociodemographic characteristics

The sociodemographic characteristics of the respondents are represented in table I. In the validation study, 121 pregnant women with a mean age of 30.87 (4.85) years participated. Most of the women were of Malay ethnicity (78.5%), multigravida (69.4%) and in their third trimester (63.6%). The majority of them had a diploma level of education (36.4%), followed by secondary education (32.2%) and degree or higher education level (29.8%). A large proportion were private employees (44.6%), while 19.8% were government employees, 5.8% self-employed and 29.8% unemployed. The mean family income of the pregnant women was RM3882.73

Table I: Respondents' socio-demographic characteristics in the validation study

Socio-demographic characteristics	n (%)
Age (years)	30.87 (4.85)[a]
Race	
Malay	95 (78.5)
Chinese	7 (5.8)
Indian	17 (14.0)
Others	2 (1.7)
Gravidity	
Primigravida	37 (30.6)
Multigravida	84 (69.4)
Gestational age	
≤12 weeks	2 (1.7)
13-27 weeks	42 (34.7)
≥28 weeks	77 (63.6)
Education level	
No formal education	1 (0.8)
Primary school	1 (0.8)
Secondary school	39 (32.2)
Diploma	44 (36.4)
Degree or higher level	36 (29.8)
Occupation	
Government	24 (19.8)
Private	54 (44.6)
Self-employed	7 (5.8)
Unemployed	36 (29.8)
Student	0 (0.0)
Household income (Ringgit Malaysia)	3882.73 (2062.07)[a]

[a] Mean (Standard deviation)

(2062.07).

Psychometric properties of the knowledge items

Table II present the psychometric properties of the knowledge items based on IRT analysis. The difficulty index of all items was between -3 and +3 except for item 11(d) which exceeded the cut-off limit by a small difference of 1.81. The information gathered by items between the pre-determined acceptable -3 and +3 difficulty range was 91.6%. As for the discrimination index, 13 items ranged between 0.35 to 2.5. Five items (2, 3, 9, 11b, and 11c) were above the 2.5 cut-off value but by a small margin. The item goodness-of-fit showed all items fit well, except item 5 (P value < 0.05). The modified parallel analysis (P value = 0.118) indicates that the unidimensionality assumption was supported and items were suitable to be summed as a total score. Considering the importance of all items in assessing pregnant women's knowledge about CB banking, all items with out-of-range difficulty and discrimination values were retained. Item 5 which have poor fit was also retained as both difficulty and discrimination values were acceptable.

Reliability of the knowledge items

Table III shows internal consistency reliability of the knowledge items. For all the 18 items, the Cronbach's alpha was 0.831, indicating an acceptable internal consistency. The corrected item-total correlation for all the items were more than 0.3, except item 1 and 11d. However, both items were retained as removing the two items does not show a huge improvement in the Cronbach's alpha. Meanwhile, the ICC value for the test-retest reliability was 0.887, which exhibits good reliability.

DISCUSSION

This study was conducted with the aim of designing a validated questionnaire to assess the knowledge level of the local population about CB banking, with concern that pregnant women's decisions on CB banking are greatly influenced by their knowledge level and the quality of information they received. Using a validated and reliable tool is important to ensure accurate results when measuring the respondents' knowledge. Overall, the items assessing knowledge about CB banking demonstrated acceptable psychometric properties based on the difficulty and discriminatory values and the reliability parameters. Of the 18 items developed, five items with out-of-range difficulty and discrimination parameters were retained as the values were close to the acceptable range and only exceeded the range by a small margin. Moreover, the five items (2, 3, 9, 11b, and 11c) were considered core components by the panel in the assessment of knowledge regarding CB banking as these items were about the usage of CB, collection procedure and its application, which are important information that may influence women's decision whether to donate cord blood or not. The final version of the questionnaire retained all the 18 items that was initially developed to assess pregnant women's knowledge about CB banking.

The current study is one of the first to report in detail on the development and validation of a questionnaire to measure pregnant women's cord blood banking knowledge. The newly developed questionnaire was evaluated for content validity by an expert panel, face validity by a group of pregnant women, and uses IRT and reliability analysis to assess the items' psychometric properties. While there were several studies reporting on pregnant women's or the general public's awareness, knowledge, and attitudes concerning CB banking, the development and validation of the questionnaires used in these studies (30-34) were mostly inadequate or not described at all. For instance, a study in Arab Saudi that reported the public's awareness on cord blood banking did not described the validity of questionnaire used in the study. Their survey instrument contained questions surrounding CB and its applications and also questions concerning attitudes towards CB donation (17). Another study was done in India to analyse potential donors' awareness, attitudes, and expectations, with attempts made to establish the validity of the survey questionnaire. The authors reported that content and face validity were conducted. However, items' reliability wasn't reported (18). Several items from these studies that were relevant to our construct were included into the questionnaire

Table II: IRT analysis for knowledge items

	Items	%	Difficulty index	Discrimination index	Chi-square value	P value
1.	Umbilical cord blood is the blood that remains in the umbilical cord and the placenta after the birth of a baby. *Darah tali pusat ialah darah yang ada di dalam tali pusat dan uri selepas kelahiran bayi.*	0.72	-1.13	0.98	10.53	0.23
2.	Umbilical cord blood is rich in blood stem cells. *Darah tali pusat kaya dengan sel stem/sel induk darah.*	0.59	-0.20	3.16	8.91	0.35
3.	Blood stem cells have the potential to form different types of blood components such as red blood cell, white blood cell and platelet. *Sel stem darah berpotensi membentuk pelbagai komponen darah seperti sel darah merah, sel darah putih dan platlet.*	0.45	0.19	3.18	14.08	0.08
4.	Cord blood is usually discarded as a medical waste if not collected and stored in cord blood bank. *Darah tali pusat biasanya dibuang sebagai sisa perubatan sekiranya tidak diambil dan disimpan di tabung darah tali pusat.*	0.31	1.00	1.00	12.16	0.14
5.	Cord blood is collected before delivery. *Darah tali pusat diambil sebelum bersalin.*	0.47	0.17	0.87	17.09	0.03
6.	Cord blood can be collected from natural births. *Darah tali pusat dapat diambil daripada kelahiran normal.*	0.33	0.65	1.70	7.41	0.49
7.	Cord blood can be collected from caesarean sections. *Darah tali pusat dapat diambil daripada kelahiran melalui pembedahan.*	0.28	0.82	1.80	14.72	0.06
8.	Placenta and umbilical cord will not be returned to the donor after cord blood collection. *Uri dan tali pusat tidak akan dikembalikan kepada penderma selepas pengambilan darah tali pusat.*	0.26	1.70	0.69	4.60	0.80
9.	Cord blood collection procedure is safe and not harmful for the mother and the baby. *Prosedur pengambilan darah tali pusat adalah selamat dan tidak membahayakan ibu dan bayi.*	0.44	0.24	2.56	11.25	0.19
10.	Cord blood can be preserved in cord blood bank for less than 10 years only. *Darah tali pusat dapat disimpan di tabung darah tali pusat selama 10 tahun sahaja.*	0.05	2.76	1.32	6.48	0.59
11.	The following are diseases that can be treated with cord blood: *Darah tali pusat dapat membantu dalam rawatan penyakit-penyakit seperti berikut:*					
	a) Thalassemia *Talasemia*	0.23	0.98	2.01	13.14	0.11
	b) Leukemia *Kanser darah*	0.19	1.05	2.67	4.87	0.77
	c) Diabetes *Kencing manis*	0.10	1.44	3.19	9.35	0.31
	d) Hemophilia *Hemofilia*	0.02	4.81	0.83	7.14	0.52
	e) Bone fracture *Patah tulang*	0.07	1.98	1.84	4.21	0.84
12.	Cord blood is one of the options for patients who need bone marrow transplant. *Darah tali pusat adalah salah satu pilihan untuk pesakit yang memerlukan pemindahan sumsum tulang.*	0.22	1.08	1.74	7.51	0.48
13.	Pregnant women who did not register for antenatal checkup (no pink book) are eligible to donate cord blood. *Ibu mengandung yang tidak mendaftar untuk pemeriksaan prenatal (tiada buku pink) adalah layak untuk menderma darah tali pusat.*	0.21	1.45	1.16	4.00	0.86
14.	Public cord blood bank is for the use of donor's family members only. *Tabung darah tali pusat awam adalah untuk kegunaan ahli keluarga penderma sahaja.*	0.21	1.49	1.06	1.92	0.98

%: Percentage of correct responses

Table III: Reliability analysis for knowledge items

	Items	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted	Cronbach's Alpha (95% CI)
1.	Umbilical cord blood is the blood that remains in the umbilical cord and the placenta after the birth of a baby. *Darah tali pusat ialah darah yang ada di dalam tali pusat dan uri selepas kelahiran bayi.*	0.276	0.830	0.831 (0.789, 0.873)
2.	Umbilical cord blood is rich in blood stem cells. *Darah tali pusat kaya dengan sel stem/sel induk darah.*	0.627	0.812	
3.	Blood stem cells have the potential to form different types of blood components such as red blood cell, white blood cell and platelet. *Sel stem darah berpotensi membentuk pelbagai komponen darah seperti sel darah merah, sel darah putih dan platlet.*	0.650	0.811	
4.	Cord blood is usually discarded as a medical waste if not collected and stored in cord blood bank. *Darah tali pusat biasanya dibuang sebagai sisa perubatan sekiranya tidak diambil dan disimpan di tabung darah tali pusat.*	0.394	0.827	
5.	Cord blood is collected before delivery. *Darah tali pusat diambil sebelum bersalin.*	0.379	0.829	
6.	Cord blood can be collected from natural births. *Darah tali pusat dapat diambil daripada kelahiran normal.*	0.552	0.818	
7.	Cord blood can be collected from caesarean sections. *Darah tali pusat dapat diambil daripada kelahiran melalui pembedahan.*	0.571	0.817	
8.	Placenta and umbilical cord will not be returned to the donor after cord blood collection. *Uri dan tali pusat tidak akan dikembalikan kepada penderma selepas pengambilan darah tali pusat.*	0.311	0.831	
9.	Cord blood collection procedure is safe and not harmful for the mother and the baby. *Prosedur pengambilan darah tali pusat adalah selamat dan tidak membahayakan ibu dan bayi.*	0.615	0.812	
10.	Cord blood can be preserved in cord blood bank for less than 10 years only. *Darah tali pusat dapat disimpan di tabung darah tali pusat selama 10 tahun sahaja.*	0.366	0.829	
11.	The following are diseases that can be treated with cord blood: *Darah tali pusat dapat membantu dalam rawatan penyakit-penyakit seperti berikut:*			
	a) Thalassemia *Talasemia*	0.568	0.818	
	b) Leukemia *Kanser darah*	0.562	0.818	
	c) Diabetes *Kencing manis*	0.635	0.821	
	d) Hemophilia *Hemofilia*	0.244	0.833	
	e) Bone fracture *Patah tulang*	0.484	0.827	
12.	Cord blood is one of the options for patients who need bone marrow transplant. *Darah tali pusat adalah salah satu pilihan untuk pesakit yang memerlukan pemindahan sumsum tulang.*	0.458	0.822	
13.	Pregnant women who did not register for antenatal checkup (no pink book) are eligible to donate cord blood. *Ibu mengandung yang tidak mendaftar untuk pemeriksaan prenatal (tiada buku pink) adalah layak untuk menderma darah tali pusat.*	0.400	0.826	
14.	Public cord blood bank is for the use of donor's family members only. *Tabung darah tali pusat awam adalah untuk kegunaan ahli keluarga penderma sahaja.*	0.431	0.824	

and subjected for detailed validation and reliability assessment.

The current study have several limitations. First, the respondents were recruited from a single centre in HKL, hence the sample included only the urban population. Second, majority respondents in this study had good education level and may have exposure to information about cord blood banking, and this may affect the IRT analysis results. A repeat validation study elsewhere should be conducted to confirm the items' IRT and reliability results when administered to all populations. Lastly, the total respondents included in the study was lower than the calculated sample size as it was not possible to extend the data collection period for the validation study due to time constrain. Nonetheless, this study obtained the acceptable values for the reliability results.

CONCLUSION

The final version of newly developed questionnaire to assess knowledge of pregnant women about cord blood banking contained 18 items. All items had acceptable psychometric properties based on the IRT and reliability analysis and can be used as a reliable tool to assess the knowledge of local pregnant women about cord blood banking.

ACKNOWLEDGEMENTS

The authors are grateful to Dr. Siti Suzaina Binti Mohd Zain, Dr. Narul Aida Binti Salleh, Dr. Nor Rosidah Ibrahim, Dr. Ho Kim Wah, Dr. Noraihan Binti Nordin, and Dr. Aznizasuriati Burfan for their expert advice. We would also like to express our appreciation to the participants of the research and Cord Blood Collection Unit staffs from National Blood Centre for their assistance in data collection.

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