ORIGINAL ARTICLE

Validity and Reliability of Knowledge and Perception of Blood Safety Issues Questionnaire Among Blood Donors

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ABSTRACT

Introduction: Unsafe blood products cause transfusion-transmissible infections. A good knowledge and perception about blood safety issues is crucial to ensure safe blood supply. The objective is to develop and validate a questionnaire about the knowledge and perception among blood donors on blood safety issues. **Method:** A cross-sectional study was conducted among 130 blood donors who attended the National Blood Centre, Kuala Lumpur in April and May 2018. The questionnaire was developed in the Malay language after extensive literature search. The self-administrated questionnaire consisted 39 items which required around 20 minutes to complete. The validation involved content validity, construct validity using exploratory factor analysis and reliability using test-retest analysis in IBM SPSS statistics. The same group of respondents was retested after two weeks using the same questionnaire. **Results:** Content validity was established through multidisciplinary expert meeting and two content reviewers. The factors loadings of all questionnaires were more than 0.40. Knowledge questions were divided into three domains; perception questions were divided into four domains. The intraclass correlation (ICC) values of the test-retest were more than 0.80 for the three knowledge domains and more than 0.60 for the four perception domains. The third domain of the perception section which consisted two questions had the lowest ICC value of 0.686 (95% CI 0.583-0.767). One of the questions was restructured to improve clarity. **Conclusions:** The questionnaire on knowledge and perception on blood safety issues has good validity and reliability, with appropriate items which warranted its utilization among blood donors.

Keywords: Validity, Reliability, Questionnaire, Blood safety, Blood donor

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INTRODUCTION

Blood safety is defined as the degree to which the blood supply for blood transfusion is free of harmful substances or infectious agents and properly typed and cross matched to insure serological compatibility between blood donors and recipients (2).

The cost of unsafe blood is immeasurable. Failure to curb the spreading of infection, including human immunodeficiency viruses (HIV) may incur higher healthcare burden and loss of productive labor as reported previously in several countries. A higher prevalence of infection among the donors may increase the risk of patients receiving unsafe blood products. Transfusion of contaminated blood products may cause serious complications or death to the recipients, traumatizing the family members (3). In order to minimize the incidence of unsafe blood transfusion, World Health Organization (WHO) has urged researchers in the developing countries to embark on research projects focusing on specific areas of blood safety, including developing plausible plan to improve blood safety as well as exploring blood donors' behavioral risk factors (14).

In order to tackle this issue, donor screening questionnaires were developed. There are well developed donor questionnaires according to different countries' needs. These questionnaires are used to assess the donor's health status and suitability for donation. Additionally, it helps to keep out the individual with a higher likelihood of spreading blood-borne infectious pathogens from donating blood (1). Blood donor questionnaire depends significantly on the truthfulness of blood donors in giving the particulars of their health condition and risky behaviors which might increase exposure to infections (12).

Not all the blood donors will disclose the deferrable risk behavior during donation. The deferrable risk behaviors include history of male homosexual, intercourse with a HIV-positive person, being a sexual worker, intravenous

drug abuse, history of sex with a bisexual male, prostitution and history of sexual relationship with drug addicts. There was a study found out that 2.8% of the donated-donors reported to have deferrable behaviors in Hong Kong. From the same study, there were 10.2% of the donated donors possibly had deferrable behaviors but they did not disclose it prior to blood donation (21). This indicates the need to explore the donors' perception regarding blood safety.

To our best knowledge, there was neither local study nor validated tool developed to explore blood donor knowledge and perception regarding blood safety. Even though there were studies done regarding blood safety and donation among blood donor, the majority of these studies were done in western and African countries. Hence, this study aimed to develop a valid and reliable tool to assess the knowledge and perception of blood safety issues among local blood donors.

MATERIALS AND METHODS

A cross sectional study was conducted among blood donors at National Blood Centre, Kuala Lumpur, Malaysia. Blood donors who come for donation at National Blood Centre that fulfilled the inclusion criteria were invited to take part. Study recruitment dated from 1st April 2018 to 30th May 2018. The study lasted for a duration of two months. We used purposive sampling method in this study in order to obtain a diverse range of participants for the pilot test.

All blood donors, male or female, eligible or temporary deferred for blood donation within the study period were eligible for the study. The blood donors must be able to understand Malay language. The exclusion criteria included illiterate donor, non-Malaysian citizen, donor who had any known mental disorder and medical personal e.g. doctors, nurses, health allied student. We explained the study to the participants verbally before their enrolment in the study. Afterwards, we obtained a signed informed consent from the participants.

Developing the Questionnaire (Item Pool)

The questionnaire consisted of 39 items. Section A consisted 10 items which captured sociodemographic data; Section B consisted 20 items initially regarding blood safety knowledge while Section C consisted nine items regarding perception toward blood safety issues. The knowledge section consisted three domains including infections related to blood transfusion (five item), blood screening (six item) and safe donor criteria (nine item). The perception section contained four domains; donor`s responsibilities (two item), donor criteria (one item), safe donor (two item) and risky donor (four item). The respondents were required to answer the questionnaire based on a three point Likert scale for blood transfusion and blood screening (yes/no/unsure); five point scale for safe donor criteria (eligible, not eligible/permanent deferral, not eligible/temporary deferral, not eligible/unsure, unsure); five point Likert scale for perception items (strongly disagree/disagree/unsure/agree/strongly agree). Each correct response was given one mark. The knowledge score was categorised using an arbitrary cut-off point, good: 60%-100% (12-20 marks) and poor: ≤59% (0-11marks). The perception items were not scored and were reported on per-item basis.

We conducted extensive literature review including WHO guidelines and scientific articles (7, 9, 12, 13, 16-18, 21) to identify important components of the questionnaires. A panel of expert consisted of multidisciplinary background (one anesthesiologist, one public health specialist, one clinical anatomy physician, one biostatistician, one pediatrician, two haematopathologist, one transfusion medicine specialist, one radiologist and one family medicine specialist) was invited to discuss about the content of the questionnaire. Then, two independent content reviewers who were transfusion medicine specialists reviewed the questionnaire to finalize the content. By doing so, we could optimize the content validity of the questionnaires, to ensure the representativeness of the selected items.

The questionnaire was in Malay language. This study employed a self-administered questionnaire which required an estimated time of 20 minutes to complete. The questionnaire was generally well received. The same group of respondents was retested after two weeks using the same questionnaire.

Ethical Approval

We obtained ethical approval from the Human Ethics Committee at the Hospital University Sains Malaysia [ref no: USM/JEPeM/18010091] and the Medical Research Ethics Committee, Malaysia in the Ministry of Health Malaysia (NMRR No:17-3338-39479). The confidentiality of the participants was strictly protected.

Factor Analysis

We used the IBM SPSS Statistics version 24.0 (IBM Corporation, New York, USA) to perform the data analysis.

The construct validity of our questionnaire was verified using factor analysis. To ensure sampling sufficiency and compatibility for factor analysis, we ran the test of Kaiser-Meyer-Olkin Measure of Sampling Adequacy (KMO) and Bartlett's Test of the Sphericity (8). With a KMO value of > 0.5 and a significant Bartlett's test ($p<0.001$), the sample was sufficient and suitable for factor analysis.

We extracted the component using the Principal Component Analysis (PCA). Items with Eigenvalues exceeding one were remained. Items which did not fit

the construct would have a loading factor less than 0.3, which we excluded from the questionnaires (6,8).

Reliability Analysis

Reliability was an important measures of the probability of the questionnaires to provide consistent outcome (8), and we employed two different ways of analysis to evaluate the reliability. As commonly known, a Cronbach's alpha value of more than 0.70 showed that the questionnaires have acceptable reliability. We also examined the statistical reliability of each individual component, in which we have removed the components with a corrected-item total correlation value of less than 0.2 and those with a high if items deleted value.

We employed the one-way random effects model with single measures in our ICC model by using the test-retest results. Intraclass correlation was one of the most commonly used approach to evaluate the reliability of study instruments with continuous outcomes (22).

An ICC value of less than 0.4 was considered poor, ICC value between 0.4 to 0.75 was considered acceptable, while an ICC value of ≥ 0.75 was considered as excellent (15).

RESULTS

A total of 130 blood donors which comprised of 70 males (53.8%) and 60 females (46.2%) donors participated in this study. Most of the blood donors were Malay (n=72, 55.4%), worked in private sector (n=61, 46.9%) with degree education and above (n=73, 56.2%). More than half (n=70, 53.8%) of the respondents have household income more than RM3000. The demographic characteristics of the respondents were shown in Table I.

Table I: Demographic and socio economic characteristics of blood donors (n=130)

Characteristics	n (%)	Mean (SD)
Gender		
Male	70 (53.8)	
Female	60 (46.2)	
Age		32.48 (8.86)
Race		
Malay	72 (55.4)	
Chinese	43 (33.1)	
Indian	13 (10.0)	
Others	2 (1.5)	
Marital Status		
Single	64 (49.2)	
Married	63 (48.5)	
Divorced	3 (2.3)	
Educational level		
No formal education	0 (0)	
Primary	0 (0)	
Secondary	24 (18.5)	
Diploma	33 (25.4)	
Degree and above	73 (56.1)	
Occupational level		
Government employee	23 (17.7)	
Private employee	61 (46.9)	
Self employed	19 (14.6)	
Student	21 (16.2)	
Unemployed	6 (4.6)	
Household income		
< 675	15 (11.5)	
675 - 1000	2 (1.5)	
1001 - 2000	12 (9.2)	
2001 - 3000	31 (23.9)	
> 3000	70 (53.9)	
Donor status		
First time donor	22 (16.9)	
Regular donor	89 (68.5)	
Lapsed donor	19 (14.6)	

Results of Factor and Reliability Analyses

The KMO value for data in this study is 0.704 (>0.5) and Bartlett's test of Sphericity is significant (P<0.001) which indicates sampling adequacy and data is suitable for factor analysis.

Results from the principal component analysis showed nine components with eigenvalues more than one and explained a total variance of 68%. However, for meaningful interpretation, only seven components were considered for the 29 items in the questionnaire. Forcing for seven components account for 52% variance. Table II shows three domains were identified for knowledge (knowledge about infection related to blood transfusion, knowledge about blood screening, and knowledge about safe donor criteria) and table III shows four domains identified for perceptions (donor's responsibility, donor criteria, safe donor, and risky donor). The items in knowledge domains have moderate to high loading ranging from 0.4 to 0.88 whereas the loading for items in perception domains ranged from 0.53 to 0.81.

The internal consistencies for knowledge and perceptions domains were shown in Table II and III, respectively. The Cronbach's alpha values for knowledge domains were all high (0.71, 0.88, 0.83) which were considered to be reliable. The corrected item total correlations for all items in the knowledge domains were more than 0.2. For item Q1, the total Cronbach's alpha if item deleted is 0.79, which is higher than the overall Cronbach's alpha value of 0.71 for knowledge about infection related to blood transfusion domain. However, considering the clinical importance of this item, Q1 was not deleted from knowledge domains.

On the other hand, the Cronbach's alpha values for

Table II : Final questionnaire of blood safety knowledge and perception among donors

Domain & components	Final items	Factor loading
Knowledge of donor towards blood safety		
Infection related to blood transfusion	1. Pesakit boleh mendapat jangkitan kuman melalui penerimaan darah	0.403
	2. Penyakit berikut boleh dijangkiti melalui proses penerimaan darah:	
	a) Demam denggi	0.621
	b) Zika	0.641
	c) Penyakit "lembu gila"	0.531
Blood screening	1. Kesemua darah yang diderma akan disaring untuk:	
	a) HIV	0.798
	b) Sifilis	0.761
	c) Kolestrol	0.759
	d) Hepatitis B	0.857
	e) Para gula dalam darah	0.650
	f) Hepatitis C	0.816
Safe donor criteria	1. Berikut adalah individu yang dibenarkan menderma darah:	
	a) Individu yang bertukar-tukar pasangan seks	0.806
	b) Lelaki yang mempunyai hubungan seks sejenis (homoseksual).	0.875
	c) Individu yang mempunyai hubungan seks biseksual (mempunyai pasangan lelaki dan perempuan).	0.776
	d) Individu yang mengambil suntikan kecantikan pada hari pendermaan darah.	0.446
	e) Individu yang pernah mengambil dadah larangan melalui suntikan.	0.647
	f) Berbekam (cupping)	0.539
	g) Akupuntur (acupuncture)	0.547
	h) Bertindik di mana-mana bahagian badan (body piercing)	0.868
	i) Bertatu (tattooing)	0.838
Perception of donor towards blood safety		
Donor's responsibility	1. Penderma bertanggungjawab sekiranya darah yang didermanya menyebabkan jangkitan kuman kepada pesakit.	0.628
	2. Penderma darah yang memberi pengakuan palsu wajar didakwa di mahkamah.	0.780
Donor's criteria	1. Seseorang yang sedang demam boleh menderma darah.	0.560
	2. Penderma boleh menderma darah untuk memeriksa status penyakit HIV untuk diri sendiri.	0.732
Safe donor	1. Penderma tidak seharusnya menderma darah jika beliau ketahui lebih awal darahnya tidak selamat untuk diberi kepada pesakit.	0.531
	2. Darah penderma adalah 100% selamat setelah keputusan saringan adalah negatif.	0.737
Risky donor	1. Darah penderma adalah selamat dari jangkitan dan boleh diderma sekiranya:	
	a) Penderma memakai kondom semasa melanggani pelacur atau mempunyai hubungan seks rambang	0.771
	b) Penderma berkongsi sudu yang sama semasa makan dengan pesakit HIV	0.717
	c) Penderma tinggal serumah dengan pesakit Hepatitis B	0.806
	d) Penderma melakukan seks oral sahaja semasa melanggani pelacur	0.755

perception domains were low to medium (0.46, 0.14, 0.38, and 0.56). Statistically, only items with Cronbach's alpha value of more than 0.7 is acceptable. The domain with the lowest Cronbach alpha value (α=0.14) consisted of two questions, including Q22 "Feverish blood donor are allowed to donate blood" and Q23 "The donors can donate blood to check their status of HIV disease. The corrected item total correlation for this domain was 0.155.

The intraclass correlation (ICC) values of the test-retest for all the three knowledge domains of the questionnaire are more than 0.80, indicating good reliability. Despite the low Cronbach's alpha value in some perception domains, the intraclass correlation (ICC) values for all

Table III: Summary of the factor analysis and reliability of final questionnaire on blood safety among donors

Domains and components	Initial items	Final items	Factor loading	Overall ICC value
Knowledge	(20)	(19)	0.403-0.868	
Infection related to blood transfusion		4		0.817
Blood screening		6		0.839
Safe donor criteria		9		0.884
Perception	(9)	(10)	0.531-0.806	
Donor's responsibility		2		0.843
Donor's criteria		2		0.759
Safe donor		2		0.686
Risky donor		4		0.828

perception domains were acceptable. The intraclass correlation (ICC) values of the test-retest for all the 4 perception domains of the questionnaire are more than 0.60, indicating moderate and acceptable reliability. The third domain of the perception section had the lowest ICC value of 0.686 (95% CI 0.583-0.767). The two questions in this domain were Q24 "The donor should not donate blood if he knows early that his blood is not safe for the patient" and Q25 "The donated blood is safe if the screening results are negative".

DISCUSSION

Assessment of knowledge and perception of blood safety issues among donor is essential for safe blood supply for transfusion. Thus, a reliable and valid tool was important to assess the knowledge and perception of donors for future planning of blood donation program among public. We developed a new structured questionnaire to evaluate the blood donors' perception and knowledge of blood safety issues. The current study illustrated the reliability and validity of this questionnaire.

The appropriateness of sample size to be used in pilot study was equivocal as reported by previous literatures. A study by Johanson and Brooks suggested that a sample size of 24 to 36 was sufficient to provide maximum information and minimum cost (11). Viechtbauer and colleagues estimated the sample size of a pilot study by looking at the probability of a particular problem in a study participants (20). On the other hand, Hertzog et al. argued that a sample size of 40 per group might be sufficient for test-retest reliability (10). Costello & Osborne reported studies with subject ratio ranged from 2:1, 5:1, 10:1 and 20:1 (5). Our questionnaires consisted 39 item before the pilot test. The minimum sample size required for reliability using Intraclass Correlation Coefficient (ICC) was 28 (4). On the other hand, the sample size for factor analysis was calculated based on a 1:3 ratio, giving a minimum sample size of 117. The larger sample size of 117 was used to test both the ICC and the factor analysis in order to prevent selection bias in choosing different pool of subjects for both the tests.

A previous study in Hong Kong (21) employed an anonymous survey to assess self-disclosure of deferrable risk behaviors among donors. Similar to ours, their questionnaires explored the practice of deferrable behaviors associated with TTI and attitude towards blood donation. In the United States, two studies (16,17) focused specifically on the knowledge of donors on HIV transmission, including whether donating blood in order to test HIV virus is an acceptable practice and whether all donated blood were tested for HIV virus. Similarly, we have included these content related to HIV knowledge in our questionnaire. Additionally, we identified local studies reported on the seroprevelance of hepatitis C among blood donors (9, 13) and incorporated this in the questionnaire. While there was a wide range of literatures reporting blood safety, majority of the papers did not include the reliability and validity of their instrument. Hence, we were unable to make any comparison with our validation results.

The initial questionnaires consisted of 20 items in the knowledge domain and 9 items in the perception domain. One item in the knowledge domain, Q2 "Feverish blood donor are allowed to donate blood" item has a low factor loading (<0.2) in the knowledge domain as shown in the rotated component matrix but has a high factor loading in the perception domain (factor loading=0.560). Hence, this question was not dropped, but shifted into the perception domain and become Q22. The final version of the questionnaire contained 19 items in the knowledge domain.

The initial questionnaire consisted of 9 items in the perception domains. As described above, one item in the knowledge domain was shifted into the perception domain. Hence, the final version of the questionnaire contained 10 items. Overall, no item was dropped from the questionnaire, as removal of any question will affect the content validity of the questionnaire.

The second domain of the perception section had the lowest Cronbach's alpha (α=0.140). This indicated poor internal consistency. However, the ICC value of this domain was 0.759. Internal consistency or Cronbach's alpha was an important but not a perfect predictor to measure homogeneity. The basic assumption of internal consistency was that homogeneity existed in a sample of test items. If the assumption was violated, it would underestimate the reliability. Therefore, Cronbach's alpha should not be interpreted as a sole index to measure the internal consistency of a test (19).

Based on this evidence, we decided not to drop the two questions in this domain (Q22 and Q23), given the fact of its high ICC value, which is also the most widely use parameter to measure reliability (11) and dropping the question may affect content validity of the questionnaire. The third domain of the perception section had the lowest ICC value (ICC=0.686), with Q24 and Q25. Discussion took place and decision was made to restructure Q25 to become "The donated blood are hundred percent safe if the screening results are negative", in order to improve question clarity. No further modification was made to the other questions.

There were several limitations in this study. One of it was that we only employed exploratory factor analysis to measure the reliability and validity; no confirmatory factor analysis was performed. Hence, we suggest that in future studies, a confirmatory factor analysis should be performed to measure the knowledge and perception of blood safety among donors. As we are developing a new tool, two-way random effect model is more appropriate. However, we only employed one-way random effect model with single. Test-retest was conducted for reliability purpose. However, the respondents were sampled using purposive sampling method rather than randomly from a sample frame. The exploratory factor analysis sample size was based on a 1:3 ratio, however a 1:5 ratio was suggested by recent literature.

CONCLUSION

In conclusion, our questionnaires regarding knowledge and perception of blood safety issues among blood donors have acceptable validity and reliability. Hence, it can be utilized to assess the knowledge and perception of blood safety issues among blood donor.

ACKNOWLEDGEMENTS

We would like to thank the Director General of Health Malaysia for his permission to publish this article. The authors of this study wish to thank the National Blood Centre, Malaysia particularly the officers and health staff of the Blood Bank Unit, for their assistance during this study. We would like to send our deepest thanks to all the participants who participated in this study for taking time to fill in the questionnaire. My gratitude to Dr. Noryati Abu Amin, Dato Dr Faraizah Abdul Karim, Dr Nor Hafizah Ahmad and Dr Sharifah Azdiana Tuan Din for their help of the overall study management.

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