ORIGINAL ARTICLE

Knowledge on Informed Consent for Blood Transfusion Among Patients in Hospital Melaka and Its Associated Factors

Mohd Hilmi Senin[1], Bakiah Shaharuddin[1], Nor Amiza Mat Amin[2], Mastura Sopian[3]

[1] Regenerative Medicine Cluster, Advanced Medical and Dental Institute, Universiti Sains Malaysia, 13200, Kepala Batas, Pulau Pinang, Malaysia
[2] Department of Transfusion Medicine, Hospital Melaka, 75460, Melaka, Malaysia
[3] Oncological and Radiological Science Cluster, Advanced Medical and Dental Institute, Universiti Sains Malaysia, 13200, Kepala Batas, Pulau Pinang, Malaysia

ABSTRACT

Introduction: To perform blood transfusion, a physician should obtain informed consent from the patient. However, previous studies have shown a poor transfer of knowledge from the doctor to the patient regarding blood transfusion, with conflicting information as recollected by patients from informed consent discussions. This study aims to describe knowledge of informed consent for blood transfusion from the patients' perspective. **Methods:** A cross-sectional study was performed from October 2019 to May 2020 at Hospital Melaka. The instrument used in this study was a structured, validated questionnaire written in the Malaysian language. Respondents aged 18 and above, who had given their consent for blood transfusion within three days, were recruited using purposive sampling. Logistic regression was used to investigate potential predictors for good knowledge. **Results:** Data analysis was performed on 239 sets of returned questionnaires, which showed that 85.8% of the respondents had good knowledge scores. Additionally, 94.1% of them were aware that informed consent is mandatory before the blood transfusion procedure. The lowest percentage of correct responses (43.9%) was regarding the timing of the informed consent. Respondents with a history of undergoing transfusion more than once (AOR = 2.18; 95% CI = 1.02, 4.65; p = 0.04), and practising Buddhism as a religion (AOR = 0.36; 95% CI = 0.15–0.86; p = 0.02) showed significant associations with knowledge. **Conclusion:** The respondents in this study were relatively knowledgeable about informed consent for blood transfusion. However, further analysis revealed the deficiency of knowledge among the respondents in several aspects of this topic. The findings can help Malaysian health authority plan for interventions that would improve knowledge of informed consent on blood transfusion among patients and the public.

Keywords: Informed consent, Blood transfusion, Knowledge, Ethics

Corresponding Author:
Mastura Mohd Sopian, MMED (Family Medicine)
Email: mastura_sopian@usm.my
Tel: +6012-2652170

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). Traditionally, the patient-doctor relationship is paternalistic, in which the decisions for patient care are made based on a physician's perspective. However, in modern medicine, the paternalistic relationship has shifted to a shared decision-making process between the doctor and the patient. Patients are more knowledgeable and desire more significant involvement in their care by expressing their preferences, values, and goals. "Informed consent" is the best example of shared decision making, which demands mutual respect and participation (2). It requires evident appreciation and understanding of the facts, implications, and future repercussion of action (3). Informed consent also covers three overlapping dimensions, namely, legal, ethical, and administrative (4).

Blood transfusion is a form of tissue transplantation. Thus, in Malaysia, it mandates a special consent form to be signed by the patient (5). This form contains elements of informed consent (5). In the consent taking process, the physician needs to explain the indication, benefits, risks, and alternative to blood transfusion, as well as ensures that the patient understands the issues being discussed, with ample room for discussion. The patient's decision regarding blood transfusion therapy should also be clearly documented.

Regrettably, some studies have shown a poor transfer of knowledge regarding blood transfusion from the doctor to the patient (6,7). A cross-sectional study by

Court et al. (2011) on 164 adult patients, whose blood were crossmatched, demonstrated that only 58.8% of them felt apprised of the blood transfusion procedure (6). 67.0% of these patients remembered that they were informed of the benefits of the procedure (6). Moreover, the risk of blood transfusion was variably recalled by the respondents6. Only 48.2% of patients remembered being told about the possibility of incorrect blood component being transfused, while 55.6% were informed regarding the risk of contracting hepatitis and HIV (6). Additionally, a study involving 25 patients who received blood transfusion for the first time has found a wide variability of information recollected from informed consent discussion (7). This phenomenon was also observed for other forms of medical therapy (8,9).

The suboptimal practice of obtaining informed consent and misconceptions towards the consent form could be the causes of this practical dilemma. The former cause could be linked to the physician factor. Examples of this factor could include time and staff constraints, and inadequately-trained or unauthorised personnel who obtain the consent (10,11). Heterogeneous patient population further complicates this problem, such as a first-timer versus regularly transfused patient, inquisitive versus unconcerned, and educated versus the illiterate patient. This problem could be further compounded by pain, anxiety, and fear of the unknown (12). As for the latter cause, physicians could have misconceived a signed consent form as a sign of complete patient understanding towards the blood transfusion procedure (4,13,14).

To the best of our knowledge, no study has been conducted on the patient's knowledge regarding informed consent for blood transfusion. Although several studies have evaluated the patient's knowledge regarding informed consent for general procedures, their questions were incomprehensive (15-17), while the respondents were doctors in other studies (18,19). Hence, this study aimed to explore the proportion of good knowledge of informed consent for blood transfusion among patients. It has also determined the relationship between socio-demographic factors with the proportion of good knowledge among patients, especially in a multicultural community, as found in Malaysia.

MATERIALS AND METHODS

A cross-sectional study was performed from October 2019 to May 2020 at Hospital Melaka, a state hospital that provides tertiary care. This research used the Informed Consent for Blood Transfusion (ICBT) questionnaire, a structured and validated questionnaire in the Malaysian language (pending publication of study validation). The respondents' inclusion criteria were medical and surgical patients aged 18 years and above, who were stable and had provided consent for blood transfusion within two days before completing the questionnaire. A shorter interval of two days was selected to reduce the respondents' recall bias while maximising sampling, compared with previous studies (6,7,11). Patients who did not remember the consent-taking process, did not understand Malaysian, had vision problems, who had been discharged from the hospital, illiterate or suffered from mental illnesses were omitted. Patients in the emergency department, operational theatre, high dependency and intensive care units were also not recruited.

The Informed Consent for Blood Transfusion (ICBT) questionnaire went through a rigorous review process by eight multidisciplinary clinical experts, including one transfusion medicine specialist in an expert review meeting. Subsequently, the ICBT questionnaire was submitted for content validation to seven clinical experts, who were routinely involved in the blood transfusion practice, and one legal expert. Then, the ICBT questionnaire underwent face validation among 20 respondents who consented to blood transfusion. Afterwards, a validation study was conducted among 95 respondents at Hospital University Sains Malaysia, Kelantan to determine the reliability, and the discriminatory and difficulty indexes of the scale using Item Response Theory analysis. A Cronbach's alpha value of more than 0.70 was considered satisfactory (20). The reliability of the questionnaire was confirmed with a Cronbach's alpha value of 0.77. Using the Item Response Theory (IRT), the difficulty and discriminatory indexes were acceptable in the range of - 3 to + 3 and 0.35 to 2.5, respectively (21). As evidenced by the IRT analysis, the psychometric properties of the knowledge section were considered good. For further details of the validation study of the ICBT questionnaire.

Table I summarises the construction of domains, measurement of concepts, and categories of responses in the ICBT questionnaire. A scoring scheme for the knowledge section was used which assigned "correct answer" = 1, and "wrong answer" and "do not know" = 0. The total knowledge score for each respondent was calculated by summation of the score of each item. An arbitrary cut-off point of 60% was modified from original Bloom criteria (good, moderate, poor), which classifies the knowledge score into good (11–18 marks) and poor (0–10 marks) (22). This modification converts multinomial outcomes to binary outcomes to maximise the significance of the results.

The sample size was estimated by considering 6% precision and 95% confidence level with an infinite population using a single proportion calculation where 50% of the population have good knowledge (15). A minimum sample size of 294 respondents was needed, accounting for an assumed non-response rate of 10%. The self-administered questionnaire was distributed through purposive sampling to potential respondents. Completion of the ICBT questionnaire took

Table I: Construction of domains, concepts measurement and response categories in the questionnaire

Section	No. of items	Concepts measured	Response category
Socio-demographics	10	Socio-demographic information, history of receiving blood transfusion	Multiple choice question
Knowledge	18	Patient's right in the informed consent process, including components of informed consent, age limit, validity of informed consent and its duration, consent forms, legal aspect of consent, and consent in an unconscious patient.	True/False/Do not know

approximately 20 minutes.

Data on socio-demographic and knowledge of the respondents were analysed using SPSS version 26.0 for Windows (SPSS, Chicago, Illinois, USA) and presented in a descriptive form. The categorical data and numerical data were expressed as frequency (percentage) and mean (SD), respectively. Factors with a P-value less than 0.25 from the univariate models were selected for the multivariate analysis. A multiple logistic regression model was constructed using forward LR and backward LR to determine the association between the socio-demographic parameters and the outcomes. A P-value of less than 0.05 was deemed statistically significant.

Ethical approval was obtained from the Human Research Ethics Committee of Universiti Sains Malaysia (USM/JEPeM/18110727), and from the Medical Research and Ethics Committee of the Ministry of Health, Malaysia (NMRR-18-3156-44688 (IIR)). The questionnaire was designed to preserve anonymity, and informed consent for research participation was attained from every respondent. Data confidentiality was maintained, and the results would not identify the respondents personally. The researchers protect all documents pertaining to this research.

RESULTS

Out of the 294 disseminated ICBT questionnaires, only 280 sets of questionnaires were returned, yielding a 95.2% response rate. We obtained 41 missing data which refer to questionnaires with non-response item/s or multiple responses for item/s. After excluding the missing data, 239 questionnaires were analysed. The mean age of the respondents was 36.75 ± 13.94 years old. Most of the respondents were Malay (74.9%), Muslim (76.6%), female (69.5%), married (66.8%), possessed secondary level education (49.8%), and had transfusion history (58.2%) (Table II).

205 (85.8%) respondents had good knowledge scores, and the remaining 14.2% had poor knowledge scores. Similarly, 225 (94.1%) respondents were aware that informed consent from patients is mandatory prior to the blood transfusion procedure (Table III). A majority of the respondents (92.9%) knew that there is a special consent form for blood transfusion. The lowest percentage of correct responses (43.9%) was obtained for the timing of the informed consent. Only 48.1% of the respondents were mindful of the patient's rights to change his or her mind after signing the informed consent form.

Table II: Socio-demographic characteristics of respondents

Variable		n (%)	Mean (SD)
Age[a]			36.75 (13.94)
Gender	Male	73 (30.5)	
	Female	166 (69.5)	
Race	Malay	179 (74.9)	
	Chinese	48 (20.1)	
	Indian	10 (4.2)	
	Other	2 (0.8)	
Religion	Islam	183 (76.6)	
	Buddha	43 (18)	
	Hindu	9 (3.8)	
	Christian	3 (1.3)	
	Other	1 (0.4)	
Marital Status	Single	71 (29.8)	
	Married	159 (66.8)	
	Divorced	8 (3.4)	
Education	No education	6 (2.5)	
	Primary School	13 (5.4)	
	Secondary School	119 (49.8)	
	Certificate / Diploma	63 (26.4)	
	Degree / Higher educational level	38 (15.9)	
Occupation	Government Servant	32 (13.4)	
	Private Sector	55 (23.0)	
	Unemployed	48 (20.1)	
	Student	18 (7.5)	
	Retiree	15 (6.3)	
	Self-employed	23 (9.6)	
	Housewife	48 (20.1)	
Household Income[b]			
	950 and below	90 (37.7)	
	951 - 3860	122 (51.0)	
	3861 - 8319	25 (10.5)	
	More than 8320	2 (0.8)	
Transfusion History			
	First Time	100 (41.8)	
	More than once	139 (58.22)	

Notes: [a]Age is expressed as mean standard deviation
[b]Household Income was categorised according to the Report of Household Income and Basic Amenities Survey 2016. High income: > RM8,320, Medium income: RM3,861–RM8,319, Low income: RM951-RM3860, Very low income: ≤ RM950 (1,42,44)

Table III: Number of correct and incorrect respondents for each item

Item	Number of correct respondent (%)	Number of incorrect respondent (%)
In general, the physician should obtain consent from the patient before blood transfusion.	225 (94.1)	14 (5.9)
Patient aged 18 years old and above can give consent without parents/legal guardian involvement.	177 (74.1)	62 (25.9)
Consent which is given by a mentally unstable patient is invalid.	113 (47.3)	126 (52.7)
There is a special consent form for blood transfusion, which requires the patient's signature.	222 (92.9)	17 (7.1)
The validity of signed informed consent applies throughout patient admission.	178 (74.5)	61 (25.5)
The patient can sign the consent form for blood transfusion, regardless of whether the conversation with the physician has taken place or not.	171 (71.5)	68 (28.5)
Which of the following must be discussed by the physician during consent taking procedure prior to blood transfusion?		
• Indication for blood transfusion	221(92.5)	18 (7.5)
• Alternative to blood transfusion	155 (64.9)	84 (35.1)
• Opportunity to ask question	225 (94.1)	14 (5.9)
• Risk of blood transfusion	201 (84.1)	38 (15.9)
• Right to refuse blood transfusion	169 (70.7)	70 (29.3)
• Information regarding blood transfusion procedure	204 (85.4)	35 (14.6)
• Right to show understanding on information received	214 (89.5)	25 (10.5)
The patient has the right to change mind even having signed the consent form for blood transfusion	115 (48.1)	124 (51.9)
In general, consent can be obtained after completion of blood transfusion	105 (43.9)	134 (56.1)
Consent for blood transfusion can be obtained using language not understood by the patient	177 (74.1)	62 (25.9)
Consent for blood transfusion is bound by law in Malaysia	145 (60.7)	94 (39.9)
Family members can give consent for blood transfusion if the patient is comatose or unconscious	202 (84.5)	37 (15.5)

Moreover, 64.9% (n = 155) and 70.7% (n = 169) of respondents knew that alternatives to blood transfusion and the patient's rights to refuse should be discussed during the consent-taking process, respectively. Furthermore, only 60.7% (n = 145) of respondents answered correctly that informed consent is bound by law. Slightly over a quarter (28.5%) of respondents were unaware that a doctor is required to explain the procedure prior to having a patient sign the consent form for blood transfusion. Additionally, only 47.3% of respondents were cognizant that consent from a patient with unstable mental health is invalid.

The selected factors from univariate analysis ($p < 0.25$) were race, religion, occupation, household income, and transfusion history. However after systematic variable selection by SPSS, only history of transfusion and race were included in our final model. In multiple logistic regression analysis, history of receiving transfusion of more than once (AOR = 2.18; 95% CI = 1.02, 4.65; p = 0.04), and practicing Buddhism (AOR = 0.36; 95% CI = 0.15-0.86; p = 0.02) showed significant associations with knowledge of informed consent for blood transfusion (Table IV).

DISCUSSION

The majority of the respondents (85.8%) in this study have a good knowledge regarding informed consent before receiving blood transfusion. Previous studies in Turkey and Croatia have reported low percentages of 61.7% and 24.9% of respondents possessing a good knowledge regarding informed consent before surgery, respectively (15,16). However, the evaluation of patients' knowledge regarding informed consent was not comprehensively done. For instance, similar questions on this matter simply ask whether the respondent knows the meaning of informed consent. Further comparison cannot be made because of the paucity of other similar studies.

In this study, 94.1% of respondents correctly answered that informed consent for blood transfusion is mandatory. This finding agrees with studies conducted in Nigeria and Ethiopia, which found that 97.5% and 78.8% of patients, respectively, were aware of informed consent prior to undergoing surgical procedures (23,24). This finding is reassuring because blood transfusion carries substantial risks of deleterious outcomes, whether through infectious or non-infectious complications. These risks are related to the sources and processes involved in their issuances (25,26). In Malaysia, the incidence of adverse transfusion reaction was 1.2% in 2017 (25). Serious Hazard of Transfusion (SHOT) reported the risk of severe morbidity to be 1 in 17,884 blood components issued in the United Kingdom (26). This risk could be higher if the

Table IV: Associated socio-demographics factors for knowledge regarding informed consent for blood transfusion by Multiple Logistic Regression Model

Variables		Crude Odd Ratio (OR)	(95 % Confidence Interval, CI)	P-value*	B	Adjusted OR	(95 % Confidence Interval, CI)	P-value^
Age		1.02	(0.99,1.04)	0.29				
Gender	Male	1						
	Female	1.29	(0.60,2.77)	0.52				
Race	Other	1						
	Malay	7.950	(0.48,132.12)	0.15				
	Chinese	3.800	(0.22,66.22)	0.36				
	Indian	2.333	(0.11,50.98)	0.59				
Religion	Islam	1				1		
	Buddha	0.41	(0.17,0.94)	0.04	-1.02	0.36	(0.15,0.86)	0.02
	Hindu	0.25	(0.06,1.06)	0.06	-1.44	0.24	(0.05,1.05)	0.06
	Christian & Other	0.37	(0.04,3.71)	0.40	-1.18	0.31	(0.03,3.21)	0.32
Marital Status	Divorced	1						
	Single	0.70	(0.08, 6.25)	0.75				
	Married	0.94	(0.11,8.02	0.95				
Education	No education	1						
	Primary School	32	(0.001,1)	0.99				
	Secondary school	0.93	(0.10,8.41)	0.95				
	Certificate/Diploma	1.38	(0.14,13.33)	0.78				
	Degree/Master/PhD	1.70	(0.16,18.44)	0.66				
Occupation	Housewife	1						
	Government Servant	0.23	(0.06,0.84)	0.03				
	Private Sector	0.47	(0.13,1.62)	0.23				
	Unemployed	0.64	(0.17,2.42)	0.51				
	Student	1.55	(0.16,14.84)	0.71				
	Retiree	1.27	(0.13,12.35)	0.84				
	Self-employed	0.43	(0.10,1.91)	0.27				
Household Income	More than 8320	1						
	950 and below	5.43	(0.32,91.97)	0.24				
	951 - 3860	6.63	(0.39,111.28)	0.19				
	3861 - 8319	7.33	(0.36,150.71)	0.20				
History of Transfusion	First Time	1				1		
	More than Once	1.94	(0.93,4.03)	0.08	0.78	2.18	(1.02,4.65)	0.04

*Simple Logistic Regression
^ Multiple Logistic Regression
Constant = 1.73
Forward LR, Backward LR and manual method were applied
No multicollinearity and no interaction
Hosmer Lemeshow test, p-value=0.64
Classification table 85.8% correctly classified
Area under Receiver Operating Characteristics (ROC) curve was 67.8%

transfusion safety management system is less established, especially in developing countries. Although 84.1% of the respondents in this study knew that the risks of transfusion should be discussed, a study by Court et al. revealed that only 27.8% of patients were informed of the risks of blood transfusion (6). The physician's failure to advise patients regarding blood transfusion's specific hazards might lead to a negligence or battery claim, should an adverse transfusion reaction occur. An example of such occurrences would be in Chatterton v Gerson's case, where the patient sued the surgeon over the loss of her lower limb sensation following a sensory nerve blocking procedure (27).

The lowest number of correct responses (43.9%) was observed for an item that asked the timing of informed consent in relation to the blood transfusion procedure. This finding is alarming because under no circumstances can consent be obtained retrospectively (3). Once transfusion is decided, informed consent discussion should happen immediately. This practice provides the patient ample time to internalise the information and arrange for transfusion alternatives, such as haematinics or autologous blood donation, if necessary. In emergency settings, consensus between the primary physician and the registered medical doctor should be sought to institute blood transfusion, if family members

and advance directives to the contrary are unavailable (3). In this study, 28.5% of respondents did not know that a doctor's explanation is required before signing the consent form for blood transfusion. Doctor's explanation encompasses the central tenet of the informed consent procedure, which will then fulfil the moral, legal, and professional duty of the doctor (28).

In this study, 65% of respondents correctly thought that the doctor should communicate information on blood transfusion alternatives during the consent-taking process. The Patient Blood Management adoption at health centres worldwide has successfully reduced the rate of allogeneic blood transfusion while improving patient outcomes (29). Alternative treatments to blood transfusion, such as intravenous iron, tranexamic acid, and autologous blood transfusion are employed in surgical and non-surgical settings with demonstrable success (29). Physicians need to discuss transfusion alternatives with their patients, even if they deem these alternatives less desirable, such as the use of perioperative acute normovolaemic haemodilution (30). Parallel with the notion of proportionality in ethics, the greater the risk a patient is exposed to, the greater obligation the physician has to disclose transfusion alternatives (28). The absence of information on transfusion alternatives limits a patient's autonomy to choose. Chan et al. (2005) discovered that 88% of patients did not remember discussing transfusion alternatives with their physician (11).

This current study found that 30% of respondents were unaware that they have the rights to refuse blood transfusion in the consent process. This inadequate awareness could be due to lesser attention given to the notion of informed refusal in practice and the literature (31). The current blood transfusion consent form in Malaysia does not explicitly address the refusal statement to be signed by the patient (5). Indeed, informed refusal is a newer doctrine that could be considered as the reverse of informed consent (32). A legally competent individual is entitled to refuse medical procedure regardless of the rationality of their belief if any (3). Properly informed refusal process ensures that the patient is cognizant of the potential risks and adverse reactions that may ensue following his or her refusal. Motives prompting patient refusal should be elicited, such as religion (Jehovah Witness), fears of infection, prior negative experience and practical consideration (28). Informed refusal should be documented, signed, and dated by the patient (3). The omission of information regarding the informed refusal by the physician violates the patient's autonomy (28). Furthermore, patients can revoke their consent at any point during the course of their treatment, even after signing the consent form. However, less than 50% of respondents in this study believed this statement to be true. A study in India found that a higher percentage of surgical patients (88%) thought they were not entitled to the right to rethink and change their mind after signing the surgical consent form (33). The latter findings could be explained by cultural factors, in which the paternalistic doctor-patient relationship still dominates in Indian society (34).

This study also found that 145 respondents (60.7%) had correctly answered that informed consent is bound by law. The right of a person to control his or her body is a concept that has long been acknowledged in Malaysia under Tort law, and has been incorporated into the Ethical code of the Malaysian Medical Council (35). There is an absence of a specific comprehensive statute on consent to medical treatment in Malaysia, except for the Malaysian Mental Health Act 2001, which involves cases of mental health patients (36). Nevertheless, since Malaysia is a Commonwealth country, any legal dispute regarding consent to medical treatment, including blood transfusion, can be referred to the English common law (36). Additionally, in this study, less than half (47.3%) of the respondents correctly answered the validity of consent from unstable mental health patients. If the patient's legal guardian or relative is unavailable, consent should be sought from two psychiatrists, one of whom shall be the attending psychiatrist (3). However, the Mental Health Act 2001 does not include blood transfusion as a procedure that warrants informed consent from patients with mental illnesses, an area which needs to be amended (3).

Good communication in the informed consent process can be hindered by linguistic factors (28). This current study found that 25.9% of respondents wrongly thought that consent could be obtained using a language not understood by the patient. Even the physician's most comprehensive explanation regarding consent will be unsuccessful if the patient cannot understand due to the language barrier. Furthermore, the choice of words needs to be tailored to fit the patient's health literacy, with the appropriate omission of complex medical jargons. This process can be more difficult when physicians are inept at the essential aspects of transfusion medicine (37,38). Incomprehension or misunderstanding of medical information can reduce patients' involvement in their own health care (39). Patients' understanding of the risks and benefits of blood transfusion will improve if a transfusion physician provides the explanation (40). A completed consent form can still be dropped as a piece of supportive evidence if the prosecutor finds the process of consent taking is suboptimal, as in the controversial case of Williamson v East London & City Health Authority (41). The patient claimed that she had not consented to a mastectomy in an operation that was initially planned to remove her breast implant. Availability and accessibility of written materials in various languages or an interpreter can facilitate patients' understanding during the consent-taking process (42). Slightly less than three-quarters of the respondents (74.5%) correctly answered the validity of the given consent. Consent for a medical procedure is valid if

the patient's condition remains unchanged. Hence, generally, consent for blood transfusion will remain valid throughout hospital admission. Once the indication for blood transfusion changes, fresh consent must be sought from the patient (3). The frequency of consent for chronically transfused patients is subjected to the local institution's policy, although it has to be contemporaneous with the blood transfusion procedure (3). A study in Croatia found that more than half (63%) of the physicians were unaware of the validity period of the signed informed consent form (18).

In this study, knowledge was associated with the history of prior blood transfusion and religion. For the former, a patient who had a history of transfusion more than once had 2.18 odds compared to a patient who received the first transfusion, when all religion factors were adjusted. Repeated exposure to the consent process might have stimulated information searching and discussion on the topic among patients. An association between the patient's surgical history and the knowledge on informed consent for surgery was observed in a study in Ethiopia (24). A similar effect was recognised in other studies exploring the association of repeated exposure and knowledge level. For example, a study done on breastfeeding knowledge among mothers demonstrated that greater breastfeeding exposure leads to a more comprehensive breastfeeding knowledge (43).

As for the association between knowledge and religion, it was an interesting new finding to observe that a Buddhist had 0.36 less chance to acquire good knowledge than a Muslim when the history of transfusion and other religions were adjusted. This result was not observed in previous studies, perhaps due to scarcity of the literature regarding good knowledge for informed consent itself, more so, pertaining to the associated factors. Some of the available studies were conducted in countries which has less religious diversity or which Buddhism was not a major religion (15,16,23,24,44). Additionally, these studies did not have sociodemographic data on religion. However, from the literature, there was example of religion impact towards consent process in the settings of Jehovah witness who refuses blood product because of biblical injunctions (1). Furthermore, impact of differences on the extent of information and autonomy patients desire might explain the association (28). For example, from a Buddhist perspective, the paternalistic model of physician-patient relationship is not always perceived as something disruptive to informed consent (45). These findings illustrate the need to better understand religious diversity during the informed consent-taking process.

Erkan et al. identified female and unemployment as important predictors to having good knowledge of informed consent (15). Furthermore, a study in Ethiopia found positive associations between living in urban areas, having a higher education level, and a history of prior surgery with having good knowledge of informed consent (24). However, the associations between these factors and good knowledge were not demonstrable in this current study. Different patient demographics, topic covered (informed consent for surgery), and depth of items assessed in the questionnaire might have contributed to this observation.

Poor knowledge transfer from doctor to patient can result in several negative implications. First, it jeopardises the patient's autonomy in making a decision. This situation contradicts the modern doctor-patient relationship and hinders the patient's empowerment efforts in the blood transfusion practice. Patients have also reported little to no recollection of details regarding the procedure after the consent-taking process (6,7). Furthermore, there is a higher risk of patient dissatisfaction following poor doctor-patient communication and breach of trust, leading to a higher number of litigation cases.

This study has provided a comprehensive evaluation of a patient's knowledge of informed consent for blood transfusion. Additionally, this study has highlighted the importance of good communication skills in the informed consent process for shared decision-making. The effective communication skills, such as tailoring the explanation to fit the patient's background by describing transfusion risks in relative terms, and encouraging two-way communication in the consent-taking process, must be acquired by clinicians. Interventions, such as standardised leaflets, authorised multimedia materials, consent-checklist, and involvement of transfusion liaison officers, have been shown to improve the consent-taking process (6,7,14,40,46). Growing awareness and understanding among the patient and physician communities on the principle of informed consent for blood transfusion were observed throughout this study. The empowerment of both parties complements Patient Blood Management which ultimately improves blood transfusion practice (47).

Nonetheless, there are some limitations to this study. First, purposive sampling, which was employed in the later part of sampling process, might have the residual risk of researcher bias, despite carefully selected respondents (48). Additionally, combining good (≥80%) and moderate (≥60%) knowledge from original Bloom criteria into an arbitrary cut-off point (60%) for good knowledge only might explain the high percentage of respondents with good knowledge (85.8%) (22). Moreover, the 0-3 days interval between consent taking process for blood transfusion and completion of the ICBT questionnaire might still lead to recall bias. This problem was aggravated by anxiety and pain experienced by the patients. Furthermore, this study may not represent other hospitals in Malaysia, both government and private because of different patient demographics. Since this study focused only on patients, the knowledge of the general public was not represented.

CONCLUSION

Overall, the patients in this study possessed good knowledge of informed consent for blood transfusion. Nevertheless, the lack of knowledge was observed in several aspects related to this topic upon further scrutiny. The findings can facilitate the Malaysian health authority to plan for interventions that could improve knowledge of informed consent on blood transfusion among patients and the general public. Subsequently, the planned interventions can be extended to include general medical procedures as well. A nationwide multicentre study could be conducted to evaluate knowledge regarding informed consent for blood transfusion among a wider patient pool.

ACKNOWLEDGEMENTS

We want to thank all respondents in this study for taking the time to fill in the questionnaire. We wish to extend our sincere appreciation to the Director-General, Ministry of Health Malaysia, for his approval to publish this article. Our deepest gratitude to Dr Noryati Abu Amin, Prof. Madya Dr Wan Mohd Zahiruddin Wan Mohammad, and Dr Siti Salmah Noordin, for their assistance in the overall study management.

REFERENCES

1. Rathor MY, Rani MF, Shah AM, Akter SF. Informed consent: a socio-legal study. The Medical journal of Malaysia. 2011;66(5):423-428.
2. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. Making Health Care Decisions: A Report on the Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship. Volume One: Report. Washington, DC: US Government Printing Office; 1982. https://repository.library.georgetown.edu/bitstream/handle/10822/559354/making_health_care_decisions.pdf?sequence=1&isAllowed=y. . Accessed August 1, 2020.
3. Malaysian Medical Council. Malaysian Medical Council Guideline: Consent for Treatment of Patients by Registered Medical Practitioners 2016. 2016.
4. Hall DE, Prochazka AV, Fink AS. Informed consent for clinical treatment. CMAJ : Canadian Medical Association Journal. 2012;184(5):533-540.
5. National Blood Centre. Transfusion Practice Guidelines for Clinical and Laboratory Personnel 4th Edition National Blood Centre, Malaysia; 2016.
6. Court EL, Robinson JA, Hocken DB. Informed consent and patient understanding of blood transfusion. Transfusion medicine (Oxford, England). 2011;21(3):183-189.
7. Cheung D, Lieberman L, Lin Y, Callum J. Consent for blood transfusion: do patients understand the risks and benefits? Transfusion medicine (Oxford, England). 2014;24(5):269-273.
8. Weckbach S, Kocak T, Reichel H, Lattig F. A survey on patients' knowledge and expectations during informed consent for spinal surgery: can we improve the shared decision-making process? Patient Safety in Surgery. 2016;10(1):15.
9. Kiss CG, Richter-Mueksch S, Stifter E, Diendorfer-Radner G, Velikay-Parel M, Radner W. Informed Consent and Decision Making by Cataract Patients. Archives of Ophthalmology. 2004;122(1):94-98.
10. Truog RD. Patients and Doctors — The Evolution of a Relationship. New England Journal of Medicine. 2012;366(7):581-585.
11. Chan T, Eckert K, Venesoen P, Leslie K, Chin-Yee I. Consenting to blood: what do patients remember? Transfusion Medicine. 2005;15(6):461-466.
12. Everett CR, Novoseletsky D, Cole S, Frank J, Remillard C, Patel RK. Informed consent in interventional spine procedures: how much do patients understand? Pain physician. 2005;8(3):251-255.
13. Tengku Z, Tengku NA, Abdul Rahim A. Peranan Borang Keizinan dalam Menentukan Sama Ada Pesakit Telah Memberi Keizinan kepada Rawatan Perubatan. Jurnal Undang-undang dan Masyarakat. 2014;18:59-65.
14. Ripley BA, Tiffany D, Lehmann LS, Silverman SG. Improving the Informed Consent Conversation: A Standardized Checklist that Is Patient Centered, Quality Driven, and Legally Sound. Journal of vascular and interventional radiology : JVIR. 2015;26(11):1639-1646.
15. Erkan I, Mayadagli Y, Akbaba M. Assessment of patients' knowledge level regarding the informed consent from the ethical aspect. Romanian Journal of Legal Medicine. 2017;25:121-125.
16. 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. Medicinski glasnik : official publication of the Medical Association of Zenica-Doboj Canton, Bosnia and Herzegovina. 2011;8(1):39-45.
17. Sulaiman A, Rabiu A, Diggol I, Haruna I. Knowledge, attitude and perception of patients towards informed consent in obstetric surgical procedures at Aminu Kano Teaching Hospital. Nigerian Journal of Basic and Clinical Sciences. 2015;12:45.
18. Jukić M, Kvolik S, Kardum G, Kozina S, Tomić A, Juraga. Knowledge and Practices of Obtaining Informed Consent for Medical Procedures among Specialist Physicians: Questionnaire Study in 6 Croatian Hospitals. Croatian Medical Journal. 2009;50(6):567-574.
19. Puwackwaththa Arachchige N, Ranawaka N, Pinto V. An audit on knowledge and practice of obtaining informed consent for invasive procedures among intern medical officers. Sri Lankan Journal

of Anaesthesiology. 2014;22.
20. DeVellis R. Scale development: theory and applications. Vol 3. California: Sage publications; 2012.
21. Arifin WN, Yusoff MSB. Item Response Theory for Medical Educationists. Education in Medicine Journal. 2017;9:69-81.
22. Bloom B. Taxonomy education. New York: David McKay; 1956.
23. 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. Nigerian Journal of Basic and Clinical Sciences. 2015;12(1):45-50.
24. Nurhusien NY, Anteneh YB, Senetsehuf MJ. Knowledge and perception of surgical informed consent and associated factors among adult surgical patients in Gondar University Comprehensive and Specialized Hospital Ethiopia. BMC Medical Ethics. 12 September 2019.
25. Abu Amin N, Nor Mohamed I. Haemovigilance Report 2016-2017. Pusat Darah Negara;2019.
26. Shruthi Narayan DP, on behalf of the Serious Hazards of Transfusion (SHOT) Steering Group. Annual SHOT Report 2019. United Kingdom2019.
27. Chatterton v Gerson ((1981) 1 QB 432).
28. Christopher P. Stowell KS. Informed Consent in Blood Transfusion and Cellular Therapies: Patients, Donors, and Research Subjects Bethesda, Maryland AABB Press; 2007.
29. Franchini M, Marano G, Veropalumbo E, et al. Patient Blood Management: a revolutionary approach to transfusion medicine. Blood Transfus. 2019;17(3):191-195.
30. Liang BA. Informed consent: Know rules and exceptions, when they apply. 2003. https://www.reliasmedia.com/articles/29540-informed-consent-know-rules-and-exceptions-when-they-apply.
31. Klauer K. Informed Refusal: Just as Important as Informed Consent. 2013. https://www.reliasmedia.com/articles/64232-informed-refusal-just-as-important-as-informed-consent.
32. American College of Obstetricians and Gynecologists: Refusal of Medically Recommended Treatment During Pregnancy. In:2016: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2016/06/refusal-of-medically-recommended-treatment-during-pregnancy.
33. Dr R, Singh A, Chopra M, et al. Patient's awareness, attitude, understanding and perceptions towards legal nature of informed consent. Journal of Indian Academy of Forensic Medicine. 2013;35:40-43.
34. Yousuf RM, Fauzi AR, How SH, Rasool AG, Rehana K. Awareness, knowledge and attitude toward informed consent among doctors in two different cultures in Asia: a cross-sectional comparative study in Malaysia and Kashmir, India. Singapore medical journal. 2007;48(6):559-565.
35. Che Ngah A. Informed consent in Malaysia: an overview. Journal international de bioethique = International journal of bioethics. 2005;16(1-2):143-161, 199.
36. Zainudin T, Rahim A, Rajamanickam R. Consent to Medical Treatment and the Autonomous Power of Adult Patients: The Malaysian Legal Position. Mediterranean Journal of Social Sciences. 2015;6.
37. Zeller MP, Sherbino J, Whitman L, Skeate R, Arnold DM. Design and Implementation of a Competency-Based Transfusion Medicine Training Program in Canada. Transfusion Medicine Reviews. 2016;30(1):30-36.
38. Ait Bouchrim SA, Haddad A, Bou Assi T, et al. Residents' knowledge in transfusion medicine and educational programs: A pilot study. Transfusion Clinique et Biologique. 2020;27(1):18-24.
39. Derevianchenko N, Lytovska O, Diurba D, Leshchyna I. Impact of medical terminology on patients' comprehension of healthcare. Georgian medical news. 2018(284):159-163.
40. Furumaki H, Fujihara H, Yamada C, et al. Involvement of transfusion unit staff in the informed consent process. Transfusion and Apheresis Science. 2016;54(1):150-157.
41. Williamson v. East London and City Health Authority, 41BMLR 85 (Lloyds's Rep Med 6 1998).
42. Sherlock A, Brownie S. Patients' recollection and understanding of informed consent: a literature review. ANZ Journal of Surgery. 2014;84(4):207-210.
43. Abdul Hamid SB, Yahya N. Knowledge, Attitude, Prior Exposure and Intention to Breastfeed among Undergraduate University Students. Journal of Clinical and Health Sciences. 2018(2):26-35%V 23.
44. Religious Diversity Index. Pew Research Center; 2010. https://www.pewresearch.org/wp-content/uploads/sites/7/2014/04/Religious-Diversity-appendix-1.pdf.
45. Zhang E. Informed consent – A Critical Response from a Buddhist Perspective. Studia Bioethica. 2019;11(2).
46. Schenker Y, Fernandez A, Sudore R, Schillinger D. Interventions to improve patient comprehension in informed consent for medical and surgical procedures: a systematic review. Medical Decision Making. 2011;31(1):151-173.
47. Bolcato M, Russo M, Rodriguez D, Aprile A. Patient blood management implementation in light of new Italian laws on patient's safety. Transfusion and Apheresis Science. 2020;59(4):102811.
48. Sharma G. Pros and cons of different sampling techniques. Int J Appl Res 2017.3(7):749-752.
49. Department of Statistics Malaysia: Report of household income and basic amenities survey 2016. https://dosm.gov.my/v1/index.

php?r= column/cthemeByCat&cat=120&bul_id=RUZ5REwveU1ra1hGL21JWVlPRmU2Zz09&menu_id=amVoWU54UTl0a21NWmdhMjFMMWcyZz09. Accessed Date Accessed 13th August 2019.