KNOWLEDGE REGARDING INFORMED CONSENT FOR BLOOD TRANSFUSION AMONG PATIENTS IN HOSPITAL MELAKA AND ITS ASSOCIATED FACTORS.

By

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DISCLAIMER

I declare that this dissertation records the results of the study performed by me and that it is my own composition.

Date: 10th May 2021 ----------

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LIST OF ABBREVIATIONS

Abbreviations

ICBT Questionnaire	Informed Consent for Blood Transfusion Questionnaire
HUSM	Hospital Universiti Sains Malaysia
I-CVI	Item-Content Validity Index
S-CVI/UA	Scale-Content Validity Index/Universal Approach
S-CVI/Average	Scale-Content Validity Index/Average
FVI	Face Validity Index
IRT	Item Response Theory
SD	Standard Deviation
CI	Confidence Interval
IQR	Interquartile Range
AOR	Adjusted Odds Ratio
IPPT	Institut Perubatan dan Pergigian Termaju

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ABSTRAK

Pengenalan: Doktor perlu mendapatkan keizinan daripada pesakit untuk menjalankan prosedur transfusi darah. Walaubagaimanapun, kajian terdahulu menunjukkan pesakit tidak mendapat maklumat yang secukupnya mengenai proses transfusi darah daripada doktor. Maklumat yang berjaya diingati oleh pesakit daripada hasil perbincangan bersama doktor adalah tidak seragam. Tujuan kajian ini dijalankan adalah untuk menentukan menilai pengetahuan mengenai keizinan untuk transfusi darah di kalangan pesakit. **Metodologi:** Satu kajian rentas silang telah dilaksanakan daripada Oktober 2019 sehingga Mei 2020 di Hospital Melaka. Instrumen yang digunakan dalam kajian ini merupakan borang kaji selidik yang berstruktur dalam Bahasa Malaysia yang telah menjalani proses validasi. Responden berumur 18 tahun dan ke atas dan telah memberi keizinan transfusi darah dalam masa 3 hari sebelumnya telah direkrut melalui kaedah persampelan bertujuan. Kaedah Regresi logistik digunakan untuk mengkaji peramal yang berpotensi untuk tahap pengetahuan yang bagus. **Keputusan:** Analisa data telah dibuat pada 239 borang kaji selidik yang telah dipulangkan menunjukkan (85.8%) responden mempunyai pengetahuan yang baik. Seramai 225 (94.1%) responden tahu bahawa keizinan pesakit adalah mandatori sebelum prosedur transfusi darah dijalankan. Jumlah peratusan terendah untuk jawapan yang betul (43.9%) ialah berkenaan dengan masa untuk mendapatkan keizinan pesakit. Pesakit yang mempunyai sejarah transfusi darah lebih daripada sekali (AOR=2.18; 95% CI =1.02, 4.65; p = 0.04) dan anutan agama (Buddha,

AOR = 0.36; 95% CI= 0.15-0.86; p= 0.02) menunjukkan hubungkait yang kuat dengan pengetahuan pesakit. **Kesimpulan:** Secara relatifnya, responden dalam kajian ini mempunyai pengetahuan yang baik mengenai keizinan transfusi darah. Walaubagaimanapun, analisa lanjut mendedahkan kelemahan di dalam beberapa aspek pengetahuan tentang keizinan transfusi darah. Dapatan kajian ini akan membantu Kementerian Kesihatan Malaysia untuk merancang langkah-langkah intervensi yang akan meningkatkan tahap pengetahuan tentang keizinan untuk prosedur pemindahan darah di kalangan pesakit dan komuniti.

Kata kunci: Keizinan, transfusi darah, pengetahuan, etika

277 patah perkataan

ABSTRACT

Knowledge Regarding Informed Consent For Blood Transfusion Among Patients In Hospital Melaka And Its Associated Factors.

Background: To perform blood transfusion, a physician is required to 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 evaluate knowledge on informed consent for blood transfusion among patients. **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. 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 of 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 aid Malaysian health authority to 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

276 words

CHAPTER ONE: INTRODUCTION

1.1 Overview

This chapter covers some brief introduction of the patients' knowledge regarding informed consent for the general procedure, and specifically for blood transfusion. This chapter also highlights the research justifications and research questions. Additionally, this chapter concisely explains the study location.

1.2 Background of Study

Consent is defined as an actual willingness that an act or an infringement of an interest shall occur (1). A person with adequate capacity for decision-making exhibits consents by performing an action suggested by another. Traditionally, the patient-doctor relationship is paternalistic, in which the decision for patient care are made based on the physician's perspective. Patients had complete trust in the doctor because they perceived the doctor knows best about their condition. However, in modern medicine, the paternalistic relationship has shifted to shared decision making between the doctor and patient. This phenomenon occurs because patients show more interest and knowledge in their healthcare. Thus, the care plan's decision is more patient-centred, allowing the patient to express patient preferences, values, and goals. When appropriately executed, informed consent is a model of shared decision making.

A well-conducted informed consent process leads to better patients' understanding of their condition and care plan. Informed consent enhances care quality, patient comprehension, and cooperation, which subsequently improves patient outcomes and minimises errors (2). Informed consent served as the standard for protecting patients' legal rights and

steering the ethical practice of medicine. Hall et al. summarise informed consent's roles to three interrelated aspects: legal, ethical, and administrative (3). From a legal perspective, simple informed consent safeguards patients against assault and battery in the manner of undesired medical interventions.

In comparison, the higher standard of informed consent confers protection on patients' rights to self-determination and autonomy (3). Ethically, informed consent pursues to value patients' autonomy by ensuring that given care is agreed and preferred by them (3). Informed consent is the process that occurs before patients signed the consent form. Continual re-evaluation of consent is done to check if patient choice remains relevant. Additionally, the consent form documents the occurrence of the process, which falls into the aspects of administration. This documentation is to ensure adherence of physician to obtain consent before procedure or operation. Consent can be divided into implied, verbal, and written types (1). These types are arranged in the sequence of increased invasiveness of the procedure (4).

Blood transfusion is the transfer of blood or blood components from one person (the donor) into the bloodstream of another person (the recipient) (5). It is a routine and potentially life-saving medical procedure used in various medical conditions. Generally, anaemia warrants packed red blood cell transfusion to enhance oxygen delivery to tissues in patients (6). However, this should be guided by the overall patient's clinical condition. Fresh frozen plasma infusion can be used to replace multiple coagulation factor deficiencies in a bleeding patient (6). It is also incorporated into the regime comprising prothrombin complex concentrate and vitamin K, for reversal of warfarin in patients with life-threatening bleeding (6). Platelet transfusion is administered as a prophylactic or therapeutic measure in patients with quantitative or qualitative deficiency of platelets (6).

Moreover, cryoprecipitate is utilised in cases of hypofibrinogenemia, which most routinely occurs in the setting of massive haemorrhage or consumptive coagulopathy (6).

However, blood transfusion is invasive and carries significant infectious and non-infectious potential complications, including, but not limited to, death or permanent disability. Hence, it warrants consent from the patient in a written format. Consequently, there is a special consent form for blood transfusion in Malaysia to be signed by the patient (7). In the consent-taking process, the physician should explain indications, benefits, risks, and alternatives to blood transfusion and ensure the patient understands the issues discussed with ample room for discussion (7). The patient's decision regarding blood transfusion therapy should be clearly documented (7). Consent taking process precedes blood transfusion procedure. In an emergency, when the patient is unable to provide informed consent, it should be obtained from family members. If no family members available or the need for transfusion leaves no time for consent, it should be made jointly by two registered medical practitioners (7). Each hospital should develop its own policy for regularly transfused patients such as thalassemia or haematological cancer patients (7).

1.3 Literature review

A thorough search of the relevant literature yielded no study, specifically evaluates knowledge among patients regarding informed consent for blood transfusion and associated factors. Thus, related studies which explored knowledge among patients regarding consent for the general procedure are referred. Studies that explored physician practice in obtaining consent, based on patients' responses were also referred.

In contemporary medical practice, informed consent is variably practised and far from theoretical ideal (3). Informed consent discussions are often lacking material risks, benefits and alternatives, which are indispensable to meaningful decision making (8). There is significant variability in the information regarding informed consent for blood transfusion, retained by the patients. A cross-sectional study done by Court et al. on 164 adult patients whom the blood was cross-matched demonstrated that only 58.8% patients were informed of blood transfusion process, of which 67.0% patients remembered that they were told benefits and 27.8% were told risks (9). In the risk itself, only 48.2% of patients were told regarding incorrect blood component transfused, whereas 55.6% of patients were informed regarding hepatitis and HIV. Although the absolute risk of receiving incorrect blood component or transfusion-transmitted infection is small, they are likely highly important to patients (9). Moreover, only 30.9% of patients in the study recalled being allowed to ask questions.

Similar findings were found in another cross-sectional study involving 25 patients who received the blood transfusion for the first time (10). In the study, information recollected from informed consent discussion was variable and incomplete. While 85% of patients were informed about the benefits of blood transfusion, only 33% and 24% claimed that infectious risks and alternative options were discussed, respectively. Information about

the risk of blood transfusion was also variably recalled. For instance, 45.8% and 12.5% of patients reported that they remembered the discussion about the allergic reaction and lung injury, respectively.

Moreover, there is a significant proportion of poor knowledge among patients towards informed consent. A total of 269 physicians and 265 patients were recruited for self-administered questionnaire in a multi-centre cross-sectional study to appraise the difference in knowledge between physician and patient regarding informed consent process for the general procedure (11). The findings revealed a significant disagreement between physicians and patients concerning knowledge of the informed consent process (11). Most patients (186; 70.2%) reported to possess limited knowledge of the informed consent process (11). A cross-sectional study in Istanbul involving 102 adult surgical patients showed that 38.3% of patients did not understand informed consent towards surgical procedure (12). Additionally, several studies have shown a poor transfer of knowledge regarding informed consent for blood transfusion from the doctor to the patient (9, 10). For instance, slightly over 30% of 164 patients were unsure if the informed-consent discussion for blood transfusion took place (9).

Furthermore, there are several factors associated with knowledge among patients regarding the informed consent process. According to Erkan et al., gender and employment status are independent predictors of the proportion of good knowledge regarding the informed consent process (12). A higher proportion of female patients (76.5%) are associated with good knowledge than male patients (47.5%) because female patients perhaps are more interested in disease and care. Additionally, unemployed patients (76.3%) demonstrated a higher proportion of good knowledge than employed and retired patients (54%). Age and educational status were deemed not statistically significant. The study also highlighted a statistically significant difference between the

educational status and the refusal of treatment upon learning the operation's adverse effect and risks. A higher refusal rate among high school and university graduates to surgical treatment was observed than elementary school graduates (12). In another study conducted in Iran, the authors found that patient education level has a significant relationship to understanding information on informed consent (13).

1.4 Research justification

As described in the literature review, the suboptimal practice of informed consent is evidenced by poor patient's knowledge regarding informed consent, and wide variability of information retained by patients on blood transfusion. This practical dilemma could be linked to the physician factor and patient factor. Examples of the former factor could include time and staff constraints, and inadequately-trained or unauthorised personnel who obtain the consent (14, 15). 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 (16).

Poor knowledge transfer from the doctor to the patient can result in several negative implications. First, it jeopardises the patient's autonomy to be involved in decision making. This violation of autonomy contradicts the modern doctor-patient relationship and hinders efforts for patient empowerment in transfusion practice. The patient also had little to no recollection of details regarding the procedure after consent taking process (9, 10). Next, there is a higher risk of patient dissatisfaction following poor doctor-patient communication and breach of trust, which leads to a higher number of litigation cases.

As mentioned previously, there is no study conducted on patients worldwide to evaluate patient's knowledge regarding informed consent for blood transfusion to our best literature reviewed. Although several oversea studies assess the level of knowledge regarding informed consent for the general procedure, the questions to evaluate patients' knowledge were not comprehensive. One study employed a postal questionnaire two months after the consent process, resulting in memory bias (15). Moreover, the study subjects were doctors (11, 12, 17). Additionally, there is no available local study assessing patient knowledge towards informed consent for the general procedure; even more so with blood transfusion. Hence, this study is conducted to fill the research gap. This study provided background data for the proportion of good knowledge among patients regarding informed consent for blood transfusion. It also intended to determine associated socio-demographic factors for the proportion of good knowledge among patients, especially in Malaysia's multicultural community.

1.5 Research questions

i. What is the proportion of patients with good knowledge regarding informed consent for blood transfusion among patients?
ii. What are the socio-demographic factors associated with good knowledge among patients regarding informed consent for blood transfusion?

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CHAPTER TWO: OBJECTIVES

2.1 General Objective

To study the knowledge regarding informed consent for blood transfusion among patients in Hospital Melaka.

2.2 Specific Objectives

i. To determine the proportion of patients with good level of knowledge on informed consent process for blood transfusion among patients.
ii. To describe the socio-demographic characteristics of patients involved in this study sample.
iii. To determine the factors associated with proportion of patients with good level of knowledge on informed consent process for blood transfusion among patients.

2.3 Alternative Hypotheses

There are associated factors for good knowledge among patients regarding informed consent for blood transfusion.

2.4 Null Hypotheses

There are no significant associated factors for good knowledge among patients regarding informed consent for blood transfusion.

CHAPTER THREE: METHODOLOGY

3.1 Study background

This study focused on knowledge regarding informed consent for blood transfusion among patients in Hospital Melaka. This study was divided into two phases. The first phase comprised of development and validation of Informed Consent for Blood Transfusion (ICBT) questionnaire. In the second phase, the validated ICBT questionnaires were distributed to eligible subjects for data collection for the actual study.

3.2 Study design

This study was an observational cross-sectional study using assisted self-administered questionnaires.

3.3 Study area

Hospital Melaka is a 1091-bedded state hospital which provides tertiary care. There are approximately 8000 transfusion recipients of blood or blood component per year. About 60 to 80 blood transfusion procedures are performed daily. There is a daycare centre for regularly transfused patients such as patients with thalassemia and haematological malignancies.

3.4 Study population

i. Reference population: Patients in Melaka

ii. Source population: Patients admitted to hospital Melaka

iii. Target population: Patients admitted to hospital Melaka who receives blood transfusion of blood or blood component/s.

iv. Sampling frame: Patients admitted to hospital Melaka who receives blood transfusion of blood or blood component/s within last 24 hours.

3.5 Subject criteria

3.5.1 Inclusion criteria

i. Adult medical or surgical patient (18 years old and above) who had received transfusion of any blood component/s within last 24 hours.

ii. Stable patient.

   a. Patient was conscious, comfortable, not in respiratory distress and able to speak in full sentences. Vital signs were normal and Glasgow Coma Scale score were 15 out of 15.

iii. Malaysian citizen.

3.5.2 Exclusion criteria

i. Patient who took consent form beyond two days before answering the questionnaire.

ii. Patient who had altered conscious level during consent-taking process for blood transfusion.

iii. Patient with psychiatric illness.

iv. Patient who did not understand Malay and instructions.

v. Patient who could not read the questionnaire due to illiteracy or vision problem.

vi. Patient who had been discharged from hospital.

vii. Patient suffered from transfusion reaction during questionnaire distribution.

   a. Transfusion reaction could cause discomfort and might impair the patient's concentration, judgement, and response during questionnaire session.

viii. Patient who did not remember the consent process.

3.6 Sample size

Objective 1: To determine the proportion of patients with good level of knowledge on informed consent process for blood transfusion among patients.

The current estimated sample size for this objective was based on 6% precision and 95% confidence level with infinite population, using single proportion calculation where 62% of the population had good knowledge, according to Erkan et. al (1). 6% precision was selected for feasibility of subjects sampling due to cost and time constraint.

The expected proportion value, p, was obtained from this study because there was no existing study from literature which assesses the knowledge regarding informed consent prior to blood transfusion. Hence, research assessing knowledge regarding informed consent before surgical operation was used.

Single proportion : $n = (z/\Delta)^2 p (1-p)$

n = sample size

z= z statistic for a level of confidence = 1.96 (95% confidence interval)

p=expected prevalence or proportion (in proportion of one; if 100%, p=1) = 0.62

Δ = precision (in proportion of one; if 6%, $\Delta = 0.06$)

Where,

$n=(1.96/0.06)^2 \times 0.62 (1-0.62)$

= 251 + 10% drop out = 277

A minimum sample size of 277 was needed for this objective.

Objective 2: To describe the demographic characteristics of patients involved in this study sample.

The current estimated sample size for this objective was based on 6% percent precision and 95% confidence level with infinite population, using single proportion calculation where 50% of the population are male, according to Erkan et. al (1). 6% precision was selected for feasibility of subjects sampling due to cost and time constraint.

Single proportion : $n = (z/\Delta)^2 p (1-p)$

n = sample size

z= z statistic for a level of confidence = 1.96 (95% confidence interval)

p=expected prevalence or proportion (in proportion of one; if 100%, p=1) = 0.5

Δ = precision (in proportion of one; if 6%, Δ = 0.06)

Where,

$n= (1.96/0.06)^2 \times 0.5 (1-0.5)$

= 266 + 10% drop out = 294

A minimum sample size of 294 was needed for this objective.

Objective 3: To determine the factors associated with proportion of patients with good level of knowledge on informed consent process for blood transfusion among patients.

The current estimated sample size for this objective was calculated based on comparing two proportion formula. The sample size estimation of socio-demographic factor which of good knowledge was based on gender from the study by Erkan et al, in 77% of females and 48% of the males had good knowledge.

The p_1 and p_2 value, were obtained from study by Erkan et al. because there was no existing study from literature which assesses the knowledge regarding informed consent prior to blood transfusion (1). Hence, research assessing knowledge regarding informed consent before surgical operation was used.

Two proportions :

$n=[[p_1(1-p_1) + p_2(1-p_2)] / (p_1-p_2)^2] (z_\alpha + z_\beta)^2$

n=sample size

p_1=proportion of the associated factor among higher risk

p_2=proportion of the associated factor among lower risk

z_α = 1.96 for α = 0.05 (two tailed) or 2.58 for α =0.01 (two tailed)

z_β = 0.84 for 80% power or 1.28 for 90% power

Where,

n=calculated sample size

p1=proportion of female patients with good knowledge =0.77 (Erkan et al., 2017)

p2=proportion of male patients with good knowledge =0.48 (Erkan et al., 2017)

$z\alpha$ = 1.96 for α = 0.05 (two tailed)

$z\beta$ = 0.84 for 80% power

$n=[[0.77\ (1-0.77) + 0.48\ (1-0.48)]/\ (0.77-0.48)^2\ ]\ x\ \ (1.96\ +\ 0.84)^2$

n= 40 + 10% drop out = 44

A minimum sample size of 44 was needed for this objective.

Conclusion of Sample Size

The highest number of sample was 294 according to specific objective no. 1, obtained from Erkan et al., Assessment of patients' knowledge level regarding the informed consent from the ethical aspect (1).

Thus 294 was the total number of sample for this study, including a 10% drop-out rate (at 95% CI with an expected 6% precision).

3.7 Sampling method and subject recruitment

To capture subjects who underwent consent-taking process for blood transfusion, a list of in-patients who received blood transfusion one day before, was extracted from Blood Bank Information System version 2 (BBIS v2) in transfusion medicine laboratory in Hospital Melaka. Initially, systematic random sampling was employed. A starting number was randomly generated by a phone application called Random Number Generator (UX Apps). Then, every second patient in the list was selected. All selected patients who fulfilled the subject criteria was approached and invited to participate in the study.

However, the sampling method was switched to purposive sampling after 30 subjects to increase the response rate. All in-patients in the extracted list from BBIS v2 who received blood transfusion one day prior, were approached and assessed on their eligibility criteria. The eligible subject was recruited to take part in the study. Additionally, patients who attended daycare for blood transfusion were approached and recruited, if eligible.

Date of the consent form for blood transfusion in the patient file was checked and recorded. The patients who underwent consent-taking process more than three days prior answering questionnaire were excluded from the study.

To avoid repeated respondent, the patient's name was checked against the compiled list before patient recruitment. The patient also was verbally asked on any prior participation in this study.

3.8 Research Tool

Informed Consent for Blood Transfusion (ICBT) questionnaire is a structured and validated questionnaire in the Malaysian language. ICBT questionnaire went through a rigorous review of the validation process. ICBT questionnaire was initially drafted through extensive literature review, small group discussion with patients and expert review meeting with eight multidisciplinary clinical experts, including one transfusion medicine specialist. 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. A validation study was conducted afterwards 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(2). 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(3). As evidenced by the IRT analysis, the psychometric properties of the knowledge section were considered good. **Table 3.1** summarises the construction of domains, measurement of concepts, and categories of responses in the ICBT questionnaire

For further details of the validation study of the ICBT questionnaire, please refer to the validation study results in Chapter 5. The ICBT questionnaire and other proforma were included in the Appendix.

Table 3.1 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 form, legal aspect of consent, and consent in an unconscious patient.	True/False/Do not know

3.9 Data Collection method

Respondents were provided with a written summary of information about the study and were allowed to ask questions. The research consent form and questionnaire are in Malaysian language. The completion of the questionnaire was voluntary. The respondents were assured on their right to withdraw from the survey at any moment, and that failure of returning the questionnaire would not affect their hospital care. Written consent for participation was obtained. The names of respondents were not documented in the questionnaire to ensure anonymity. The self-administered questionnaire was distributed to respondents for them to complete in approximately 20 minutes. Respondents could ask the researcher if there is any unclear question regarding ICBT questionnaire. The questionnaires were returned to the researcher on the same day. The data was statistically analysed. Completed questionnaires and consent forms were stored in a locked cabinet in IPPT while any electronic data generated during analysis was stored in password protected and encrypted USB drive for ten years after completing the study. Research data will be destroyed after the retention period.

3.10 Statistical analysis

Statistical analysis was performed using SPSS version 26.0 for window-software (SPSS, Chicago, Illinois, USA). Each respondent was assigned a code for data entry. Data were entered, checked for data entry errors, explored, and cleaned. The alpha (α) of 0.05 was taken as the level of significance at a 95% confidence interval. Descriptive statistics were applied for the analysis of the socio-demographic data. Categorical data such as gender, race, religion, marital status, education level, occupation and household income were

presented as frequency (percentage). Numerical data such as age were presented as mean (SD) or median (IQR) based on their normality distribution.

The first objective (proportion of patients with good level of knowledge) were analysed using descriptive statistics. 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. The score ranges from zero to eighteen. The proportion of patients with good knowledge was categorical data and was presented as frequency (percentage). Good knowledge was determined from the modified Bloom criteria when the arbitrary total score was more than 60%, i.e. 10 out of 18. The original Bloom criteria (**Table 3.2**) was modified (**Table 3.3**) by combining good and moderate into one domain. This modification converts multinomial outcomes to binary outcomes to increase the analysis's power and ensure assumptions for logistic regression were met. Additionally, a cut-off of 60% was also adopted in a study done by Tan et al. to differentiate between good and poor knowledge (4).

Table 3.2 Original Bloom Criteria

Level of knowledge	Percentage
80 – 100%	Good
60 – 79%	Moderate
0 – 59%	Poor

Table 3.3 Modified Bloom Criteria

Level of knowledge	Percentage
60 – 100%	Good
0 – 59%	Poor

The third objective (factors associated with proportion of patients with good level of knowledge) were analysed using univariable and multivariable logistics regression. 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, backward LR and manual 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.

3.11 List of variables

Table 3.4: List of independent and dependent variables

Independent variable	**Dependent variable**
Age	Good Knowledge
Gender	
Race	
Religion	
Marital Status	
Education Level	
Occupation	
Household income	

History of transfusion	

3.12 Variable definition

i. Household Income:

Household Income was categorised according to the Report of Household Income and Basic Amenities Survey 2016 by the Department of Statistics Malaysia. The categorisation of the income is as follow:

- High income: > RM8,320
- Medium income: RM3,861–RM8,319
- Low income: RM951-RM3860
- Very low income: ≤ RM950

ii. History of Blood Transfusion:

Receipt of blood or blood component previously regardless of any clinical indication. The receipt implies a prior experience of patient underwent consent-taking process for blood transfusion. Receipt of plasma-derived medicinal product such as albumin and prothrombin complex concentrate was not included in this definition.

iii. Good Knowledge:

The total knowledge score for each respondent was calculated by summation of the score of each item. Good knowledge was determined according to Modified Bloom Criteria when the total score was more than 60%, i.e. 10 out of 18 (Refer item 3.10)

3.13 Ethical Issue

Ethical approval was obtained from the Human Research Ethics Committee of Universiti Sains Malaysia and the Medical Research and Ethics Committee of the Ministry of Health, Malaysia. Further details of the ethical board approval are as follow:

i. Human Research Ethics Committee (HREC), of Universiti Sains Malaysia

   JEPeM Code: USM/JEPeM/18110727

ii. National Medical Research Review [NMRR, Ministry of Health]

   Protocol Number: 44688

   Ethical Approval Letter No: NMRR-18-3156-44688 (IIR)

The informed consent for research participation was obtained from the respondents before questionnaire administration.

Privacy and Confidentiality

All questionnaires were anonymous. Data were presented as grouped data and would not identify the responders individually. All the written research documents, including study data (demographic and clinical data), were kept confidential by the researcher and were

not publicly available unless disclosure is required by law. The data were only allowed to be reviewed by the principal investigator and research supervisors. Researcher has archived all data for ten years for any enquiries. The data will be destroyed after the period of storage.

Conflict of Interest

There was no conflict of interest throughout study duration by the investigator.

Subject vulnerability

The Principal Investigator was not directly related to patient care. All respondents were explained about the aim and method of the study. The patients were informed that study participation is voluntary and that they may choose to withdraw from the study at any time, for any reason without prejudice. Right to refuse participation was also clarified. They still received standard medical treatment even when they refused to provide consent for this study. These were to ensure the patients would not feel obliged to take part in the study.

Risk

1. **Physical risks**

   Nil

2. **Psychological or social risks**

The questionnaire contains item/s that might cause emotional distress to the patient, as the item/s might provide clues towards the ideal practice of consent-taking process for

blood transfusion by the healthcare worker. The item/s might prompt the patient to compare his or her experience against the ideal practice. However, the issue is unlikely to arise because the item/s assess knowledge domain only, instead of practice domain. Additionally, the researcher did not provide feedback on the correct answer to the respondent.

The questionnaires would not trigger social stigma and were not socially sensitives.

Honorarium and incentives

Token of appreciation were given to all participants.