

Syazwana Syirin Ibrahim<sup>1</sup>,  
Ernest Mangantig<sup>2</sup>,  
Siti Salmah Noordin<sup>3</sup>

<sup>1</sup>Blood Transfusion Service  
Unit, Hospital Sibul, Batu 5  
½, Jalan Ulu Oya, 96000  
Sibu, Sarawak, Malaysia

<sup>2</sup>Department of Community  
Health, Institut Perubatan  
dan Pergigian Termaju,  
Universiti Sains Malaysia,  
Kepala Batas, 13200, Pulau  
Pinang, Malaysia

<sup>3</sup>Department of Clinical  
Medicine, Institut Perubatan  
dan Pergigian Termaju,  
Universiti Sains Malaysia,  
Kepala Batas, 13200, Pulau  
Pinang, Malaysia

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\*Corresponding author:  
Siti Salmah Noordin  
E-mail: [ssalmah@usm.my](mailto:ssalmah@usm.my)

## Causes and Factors Associated with Temporary and Permanent Blood Donor Deferral at the National Blood Centre

**Abstract**— Blood donor deferral is a critical aspect of ensuring donor and patient transfusion safety. This study aimed to evaluate the causes and factors associated with blood donor deferrals in the National Blood Centre, Malaysia. A retrospective cross-sectional study was conducted on 1,103 whole blood donors who experienced deferral from the 1st of January 2018 to the 31st of December 2020. Data were extracted from donor deferral reports and the Blood Bank Information System. Simple and multiple logistic analyses were used for statistical analysis, and a p-value of < 0.05 was considered significant. Out of 732,756 registered blood donors, 167,855 (22.9%) were deferred during the study period. Among the 1,103 deferrals analysed for this study, 1,053 (95.5%) were temporary deferrals, while 50 (4.5%) were permanent deferrals. Notably, a majority of temporarily deferred donors were female (698, 66.3%), whereas 38 (76%) of permanently deferred donors were male. The most common reason for temporary deferral was low haemoglobin levels (551, 52.3%), followed by high blood pressure (459, 12.3%). Medical illnesses accounted for most permanent deferrals (19, 36%), with high-risk behaviours being the second most common cause (15, 30%). After adjusting for confounding factors, female donors showed a significantly higher risk of deferral (adjusted odds ratio [OR] = 5.220, 95% confidence interval [CI] 2.657–10.25,  $p < 0.001$ ), as did regular donors (adjusted OR = 6.470, 95% CI 1.929–21.70,  $p = 0.002$ ). The study highlights that female and regular donors are more likely to face deferral. Enhancing blood donor education, awareness, and pre- and post-donation support are crucial steps in reducing deferrals and preserving the donor pool.

**Keywords** - Blood donors, deferral, permanent, temporary

### 1 INTRODUCTION

Blood collection remains a critical global endeavour, with approximately 118.5 million units collected annually. Notably, 60% of these units originate from middle-income and low-income countries, which collectively house 84% of the world's population (1). However, the dynamics of the socioeconomic, climate, and human factors make recruiting and retention of blood donors a challenging task in blood transfusion services (2). Furthermore, blood procurement faces additional challenges due to emerging pathogens. For instance, the Zika virus, although rare, has been implicated as a potential transfusion-transmissible agent (3). Similarly, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), responsible for the COVID-19 pandemic, has raised concerns about transfusion safety, despite no confirmed cases of SARS-CoV-2 transmission through blood transfusion (4).

Blood transfusion is an essential component of

medical therapy. While ensuring an adequate blood supply is paramount, it is equally critical to safeguard both recipients and donors. The collection and transfusion protocols must not harm either party. However, certain circumstances render donor's ineligible to donate—either to protect the blood supply or the donor's health. Donor deferral, whether temporary or permanent, plays a pivotal role in this delicate balance (5, 6). The COVID-19 pandemic significantly disrupted blood donation worldwide, with reductions ranging from 12.1% to 67%. Early outbreaks in 2020 saw a decline in blood donation rates (7,8). Furthermore, the establishment of new deferral criteria based on COVID-19 exposure and infection risk further contributed to donor deferrals (9).

Despite the abundance of literature on blood donor deferral, there remains a paucity of research focusing on the distinct characteristics of temporary and permanent deferrals within the

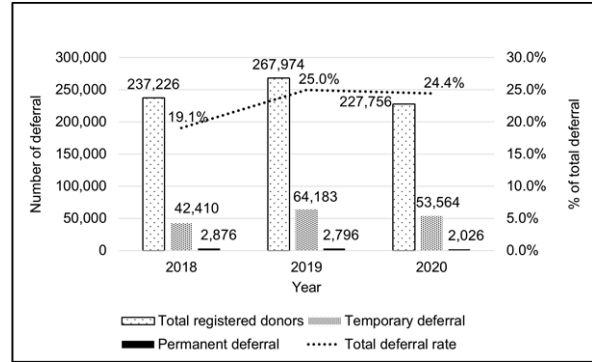
Malaysian context. This study aimed to investigate the prevalence, categorisation (temporary or permanent), underlying causes and factors associated with blood donor deferrals. By delving into the specific reasons for donor deferrals, this study seeks to contribute to the maintenance of an ample, enduring, and secure blood inventory through enhanced comprehension of deferral causes.

**2 MATERIALS AND METHODS**

This is a cross-sectional study involving a retrospective record review from blood donors who were deferred from 1st January 2018 until 31st December 2020 at the National Blood Centre (NBC), Malaysia. The study received approval from the Human Research Ethics Committee of Universiti Sains Malaysia (USM/JEPeM/20080432) and by the Medical Research & Ethics Committee, Ministry of Health Malaysia, (NMRR-20-3293-55883(IIR)). The inclusion criteria encompassed all whole blood donors registered at NBC. Donors deferred due to cancellation of the blood donation procedure, donors who experienced adverse reactions, autologous and apheresis blood donors, and cases with incomplete or missing data were excluded from this study. Additionally, non-Malaysian blood donors were also excluded.

The sample size was determined using a single proportion formula, assuming a deferral rate of 26.8% among blood donors with a 95% confidence interval and a precision of 0.03 (10). This resulted in a final calculated sample size of 1,103, accounting for a 20% dropout rate. Data were extracted through a record review of deferred donors using the Blood Bank Information System version 2 (BBISv2). A systematic random sampling method was employed, selecting every 100th deferred donor listed in the BBISv2 based on the inclusion and exclusion criteria.

Donor was categorised as new, regular (those who donated a minimum of two times within 24 months) or lapsed (those whose last donation was more than 24 months ago). Deferral periods were classified as temporary or permanent, and deferral causes were grouped into categories such as medical illness, bloodletting procedures



**Figure 1:** Blood donor deferral in the National Blood Centre from 2018 to 2020

(e.g., acupuncture, body tattoo, body piercing), high-risk behaviours (e.g., homosexuality, multiple sexual partners, paying for sexual services, intravenous drug use), travel history, and several other causes based on the Malaysia National Blood Donation Guideline (11).

Statistical analysis was conducted using SPSS version 27.0 for Windows software (SPSS, Chicago, Illinois, USA). The prevalence of blood donor deferrals and deferral causes were presented descriptively. Categorical data were expressed as frequency (percentage) and numerical data as mean (standard deviation). The association between blood donors' sociodemographic characteristics and donor deferral was determined using simple and multiple logistic regression analyses. The dependent variables for logistic regression were temporary and permanent deferral, with temporary deferral as the reference group. Variables with a p-value < 0.25 in univariable analysis were selected for multiple logistic regression. A p-value of < 0.05 was considered statistically significant.

**3 RESULTS**

**3.1 Prevalence of blood donor deferrals**

During the study period, the NBC registered a total of 732,756 blood donors. Among these donors, 22.9% (167,855) were deferred from donation (Fig. 1).

### 3.2 Demographic and descriptive analysis of blood donor deferral

Within the selected 1,103 deferrals, 1,053 (95.5%) were temporary deferrals, while 50 (4.5%) were permanent deferrals. Among the total deferrals, 710 (64.4%) were female donors, and 393 (35.6%) were male donors. Male donors exhibited a higher incidence of permanent deferral (38, 76%) compared to female donors (12, 24%). Regular donors constituted 43% (474) of the deferrals, while new donors and lapsed donors accounted for 42.2% (466) and 14.8% (163), respectively. Notably, most permanently deferred donors were new donors (44, 88%), compared to regular (3, 6%) or lapsed donors (3, 6%). Mobile blood donation sites recorded a high deferral rate of 76.1% (839) compared to other donation locations (Table I).

### 3.3 Causes of deferral

Low haemoglobin was the leading cause of temporary deferral (551, 52.3%), with female blood donors comprising the majority (459, 83.3%). High blood pressure was the second most common cause for temporary deferral (130, 12.3%) (Table II). Deferral due to travelling history (24, 2.3%) includes travelling to recent endemic areas especially COVID-19-affected areas in year the 2020. For permanent deferrals, medical illness (36%) and high-risk behaviour (30%) were the most common causes (Table III).

### 3.4 Factors associated with donor deferral

A simple logistic regression (SLR) analysis was conducted to identify factors associated with donor deferral. The variables included age, gender, ethnicity, donor type, and donation location. A significant association was found between female gender and regular donor ( $p < 0.001$  and  $p = 0.004$ , respectively).

A multiple logistic regression analysis, controlling for all variables, revealed that only gender and donor type remained significant factors associated with donor deferral. Female blood donors had 5.2 times higher odds of being deferred compared to male blood donors (adjusted OR = 5.220, 95% CI 2.657 – 10.25,  $p < 0.001$ ). Regular donors had 6.5 times higher odds of being deferred compared to new donors (adjusted OR = 6.470, 95% CI 1.929 – 21.70,  $p = 0.002$ ) (Table IV).

## 4 DISCUSSION

This study delineates the prevalence, causes, and factors associated with blood donor deferral

**Table I:** Demographics and type of donor deferral, (N=1,103)

Variables	Total n (%)	Types of deferrals, n (%)	
		Temporary (n=1,053)	Permanent (n=50)
Age (years) <sup>a</sup>	32.4 ± 10.08	32.3 ± 9.93	34.1 ± 13.93
Gender			
Male	393 (35.6)	355 (33.7)	38 (76.0)
Female	710 (64.4)	698 (66.3)	12 (24.0)
Ethnicity			
Malay	677 (61.4)	650 (61.7)	27 (54.0)
Chinese	313 (28.4)	296 (28.1)	17 (34.0)
Indian	97 (8.8)	93 (8.8)	4 (9.0)
Others	16 (1.4)	14 (1.3)	2 (4.0)
Donor Type			
New	466 (42.2)	422 (40.1)	44 (88.0)
Regular	474 (43.0)	471 (44.7)	3 (6.0)
Lapsed	163 (14.8)	160 (15.2)	3 (6.0)
Donation Place			
Mobile sites	839 (76.1)	796 (75.6)	43 (86.0)
Blood Centre	168 (15.2)	163 (15.5)	5 (10.0)
Donation suites <sup>b</sup>	96 (8.7)	94 (8.9)	2 (4.0)

<sup>a</sup>mean ± SD

<sup>b</sup>Donation suites include two static blood donation centres in two different shopping complexes and one in Federal Government Administrative Centre.

**Table II:** Causes of temporary blood donor deferral in National Blood Centre, (N=1,053)

Causes of temporary deferral	Frequency n (%)
Low haemoglobin	551 (52.3)
Male	92 (16.7)
Female	459 (83.3)
High blood pressure	130 (12.3)
Medical illness	95 (9.0)
Low blood pressure	46 (4.4)
On medication	44 (4.2)
Bloodletting procedure	42 (4.0)
Sleep less than 5 hours	36 (3.4)
Others <sup>a</sup>	34 (3.2)
Travelling history	24 (2.3)
Operation	20 (1.9)
Menstruation	12 (1.1)
Immunisation/ Injection	5 (0.5)
Pregnant/ Breast feeding	5 (0.5)
Dental treatment	4 (0.4)
Weight less than 45kg	2 (0.2)
High haemoglobin	1 (0.1)
Alcohol intake less than 24 hours	1 (0.1)
Donation less than three months	1 (0.1)

<sup>a</sup>The deferral causes include age less than 18 years old without written consent, donors who did not bring their documents for identification, and other reasons which are not specified.

**Table III:** Causes of permanent blood donor deferral in National Blood Centre, (N=50)

Causes of permanent deferral	Frequency n (%)
Medical illness	19 (38.0)
High-risk behaviour	15 (30.0)
Family history of Hepatitis B <sup>a</sup>	13 (26.0)
Age more than 60 years old <sup>a</sup>	2 (4.0)
Lived in United Kingdom/ Europe <sup>b</sup>	1 (2.0)

<sup>a</sup>For first time donor

<sup>b</sup>For risk of variant Creutzfeldt-Jakob disease. The donors are deferred permanently if they visited or lived in the United Kingdom for a cumulative period of 6 months or more between 1st January 1980 to 31st December 1996, or if they visited or lived in the European countries (eg. Austria, Belgium, Denmark, Finland, France, Germany, Greece, Holland, Italy, Liechtenstein, Luxembourg, Norway, Portugal, Spain, Sweden, and Switzerland) for a cumulative period of 5 years or more between 1st January 1980 until now.

in Malaysia who practices a voluntary non-remunerated donation system. Before blood donation, each potential donor is subjected to a direct finger stick haemoglobin level examination and pre-donation counselling, which includes a health questionnaire to determine their eligibility for donation, as well as assessments of blood pressure and body weight.

The findings of this study reveal that the overall deferral rate among blood donors in NBC was 22.9%, exceeding the median deferral rate of 12% by the World Health Organization (WHO) (12). Moreover, this rate surpasses those reported in other studies, where deferral prevalence ranged from 8.7% to 19.4% (13,14). This discrepancy may be attributed to variations in whole blood donor deferral criteria, which differ across regions and are influenced by the overall health status of the donor community (15).

In the present study, most deferrals were temporary (1,053, 95.5%), compared to permanent deferrals (50, 4.6%). This contrasts with a previous study conducted by Valerian et al. in northern Tanzania, which reported nearly equal rates of temporary and permanent deferrals (50.7% and 49.3%, respectively). These differences could be due to infections such as Hepatitis B and human immunodeficiency virus (HIV), which were the primary causes of deferral in their study. Furthermore, replacement donation, which was also practised in Tanzania, was associated with a higher deferral rate compared to voluntary non-remunerated blood donors (15.8% and 12.3%, respectively) (16). However, other studies have shown that most deferrals were temporary, ranging from 90.9% to 99.2% (17,18).

**Table IV:** Factors associated with donor deferral, (N = 1103)

Variables	Simple logistic regression		Multiple logistic regression	
	Crude OR (95% CI)	p-value	Adjusted OR (95% CI) <sup>a</sup>	p-value
<b>Age</b> (years)	1.017 (0.990 - 1.044)	0.232*	1.024 (0.997 - 1.052)	0.079
<b>Gender</b>				
Male	1		1	
Female	6.226 (3.213 - 12.06)	<0.001*	5.220 (2.657 - 10.25)	<0.001**
<b>Ethnicity</b>				
Malay	1		1	
Chinese	0.291 (0.063 - 1.344)	0.114*	1.514 (0.775 - 2.958)	0.225
Indian	0.402 (0.084 - 1.913)	0.252*	1.056 (0.340 - 3.279)	0.925
Others	0.301 (0.050 - 1.800)	0.188*	3.276 (0.615 - 17.46)	0.164
<b>Donor Type</b>				
New	1		1	
Regular	5.561 (1.703 - 18.16)	0.004*	6.470 (1.929 - 21.70)	0.002**
Lapsed	0.340 (0.068 - 1.700)	0.189*	0.406 (0.080 - 2.050)	0.275
<b>Donation Place</b>				
Mobile sites	1		1	
Blood Centre	0.568 (0.222 - 1.456)	0.239*	1.057 (0.384 - 2.911)	0.914
Donation suites	0.394 (0.094 - 1.652)	0.203*	0.767 (0.159 - 3.688)	0.740

\* p-value <0.25 were included for multivariable analysis

\*\*significant p-value <0.05

<sup>a</sup>Variable selection using backward (LR) method

Multicollinearity and interaction terms were checked and not found. Hosmer-Lemeshow test (p-value > 0.05), classification table (overall correctly classified percentage = 95.3%), and area under the ROC curve (86%) were applied to check model fitness.

Our study also found that female donors had a deferral rate of 64.4% and were 5.2 times more likely to be deferred compared to male donors. This contrasts with previous studies by Elsafi et al. in Saudi Arabia and Lamba et al. in India, which reported deferral rates among their female donors of only 2.2% and 11.5%, respectively, since less than 2% of their total blood donations were from female donors (6,19). Our study also revealed that regular blood donors were 6.5 times more likely to be deferred than first-time blood

donors. These significant findings could be attributed to potential low haemoglobin levels, which were the most common cause for temporary donor deferral in our study. It is estimated that approximately 250 mg of iron is lost in each blood donation, leading to a high incidence of iron deficiency in frequent donors, particularly women (20). A study by Vinkenog et al. showed that 25% of female first-time donors and 1.6% of male first-time donors had ferritin levels below 30 ng/mL, compared to 53% of female repeat donors and 42% of male repeat donors with ferritin levels below 30 ng/mL (21). Furthermore, donors who had donated 21 times or more, had a mean serum ferritin level of 56.69 ng/mL, compared to 101.57 ng/mL serum ferritin level in donors who donated between 1 to 10 times (22). However, there is no standard deferral period following a low haemoglobin deferral in the guideline (11). Following deferral due to low haemoglobin, a previous report showed that only 21% of first-time donors and 64% of repeat donors returned within three years for blood donation, contributing to further blood donor loss (20). Consequently, strategies to prevent iron depletion among blood donors may include regular monitoring of ferritin levels, implementation of iron conservation programmes such as oral iron supplementation for regular donors, and education about iron-rich foods. Additionally, potential blood donors, particularly females, who are repeatedly deferred due to low haemoglobin levels should be investigated for potential iron deficiency anaemia.

In terms of permanent deferral, the most common cause was attributed to medical illnesses such as uncontrolled hypertension, diabetes mellitus with complications, history of stroke, and cardiovascular diseases. These findings align with the National Health and Morbidity Survey conducted in 2019, which reported a high prevalence of hypertension (30%) and diabetes (18.3%) in the adult population (23). Therefore, routine medical check-ups would be beneficial for the health maintenance of blood donors and could be considered as one of the privileges of blood donation.

The subsequent most common cause for permanent deferral was high-risk behaviour. Previous studies had reported rates of high-risk behaviours among deferred donors between 2.2% to 6.2% (17,24). A systematic review and meta-analysis by Remoortel et al. concluded that sexual risk behaviour is associated with transfusion-transmissible infections such as

Hepatitis B or C and HIV infection (25). Another study found that 20.4% of first-time donors and 14.5% of repeat donors, who were infected with HIV, Hepatitis C, Hepatitis B, or human T-lymphotropic virus but had denied risk factors during the donor health questionnaire, claimed that test-seeking was their motivation for blood donation (26). Therefore, strategies to improve high-risk behaviours deferral could include enhancing pre-donation educational materials regarding transfusion-transmitted infection across all media, conducting attentive pre-donation interviews to foster a more trusting and confidential donor screening experience to encourage potential donors to report high-risk behaviours, and implementing confidential unit exclusion where donors confidentially indicate whether they believe their donated blood is not safe for transfusion to others (27).

Donor deferral, particularly temporary deferral, leads to the loss of potential blood donors. Due to the negative emotional impact, such as feelings of anger, frustration, and rejection, these potential donors who were temporarily deferred are hesitant to return for subsequent donation attempts, thus affecting the availability of blood (28). For instance, a study in the Netherlands demonstrated the return rate in non-deferred donors was higher compared to deferred donors (87% and 76% respectively). Among those non-returned donors, 50% were first-time donors and 8% were reactivated or lapsed donors (29). Therefore, temporarily deferred donors should be informed about the cause of their deferral, the length of their deferral, and the strategies to avoid future deferrals. Additionally, some deferral reasons may need to be communicated earlier to the blood donors. For example, donors who are on medication should be advised to bring along their medication or hospital discharge notes so that their medication and the seriousness of their disease can be evaluated by medical personnel during pre-donation counselling. Furthermore, the blood centre should also play an active role in recruiting the deferred donors once their deferral period has ended by calling, sending text messages or reminder email to these donors.

This study was conducted retrospectively, using the pre-established information system, BBISv2. Consequently, the potential for incomplete data entry or missing data, a common occurrence in retrospective studies, cannot be disregarded. This study also did not analyse the return rate of deferred blood donors within the study timeframe. As a result, it is suggested that future research

should be prospective in nature, incorporating a comprehensive socio-demographic analysis of deferral causes across multiple blood centres. Additionally, an examination of the return rate among deferred donors could provide valuable insights. Such an approach would contribute significantly to refining donor eligibility criteria and enhancing recruitment efforts.

## 5 CONCLUSION

Our study showed that female and regular blood donors were among the significant factors associated with donor deferrals. Although donor deferral rates may be similar across populations, the reasons for deferral may differ, reflecting differences in socioeconomic status as well as cultural and environmental factors. Therefore, a more targeted approach such as donor educational programmes is important to prevent the loss of valuable blood donors.

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