# Blood donor selection and deferral pattern as an important tool for blood safety in a tertiary care hospital

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#### Abstract:

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**Context:** Blood donor selection criteria based on science and regulatory rules influence donor as well recipient safety and demographics. **Aim:** To evaluate and analyze the blood donor deferral pattern and its causes among blood donors in a tertiary care hospital blood bank and to review its influence on blood safety. **Settings and Design:** Hospital based blood bank, retrospective analysis. **Subjects and Methods:** The data available as donor deferral record over a period of 13 years from 2001 to 2013 was analyzed. **Results:** The blood donor deferral rate was 11.5%, the deferral rate in various categories was 4.8%, 4.7%, 1.6%, and 0.3% in Category 1, Category 2, Category 3, and Category 4, respectively. The majority of deferrals were temporary deferrals (62.8%) of young donors. The maximum number of donors deferred (28.2%) due to a history of jaundice (permanent) followed by 19.4% due to low hemoglobin (temporary). History of malaria, intake of medicines, infections, underweight, last blood donation within 3 months (temporary deferral), and history of heart and lung diseases, diabetes, and with suspicious identity (permanent deferral) were other major causes identified. **Conclusion:** The pattern of donor deferral identified is an important tool for blood safety and also provides key areas to focus on a region or policy formulation nationally for donor selection as well ensure donor safety. The value of determining donor deferral pattern by the categories described is in calling back donors deferred due to temporary reasons and can help retain pool of motivated blood donors.

Key words:

Blood safety, donor deferral, donor selection, permanent deferral, temporary deferral

## Introduction





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Blood safety has received major attention from the point of view of transfusion-transmitted infections, but it has been argued that the most important advancement in this area of medicine has been the collection of blood from nonremunerated repeat voluntary blood donors in the past 50 years instead of paid professional donors.<sup>[1,2]</sup> This process of blood donation involves voluntary and nonremunerated blood donors coming forward to donate blood willingly and the choice when and where to donate is dependent on blood donors' positive action.<sup>[3]</sup> However, the transfusion services have a process of donor selection based on criteria of subjecting donors to a questionnaire, physical examination, and hemoglobin testing before blood donation, and only those who meet the requirements qualify as blood donors. Blood donor suitability criteria are based on science, informed medical opinion and regulatory rules are designed to protect both the blood donors and blood recipients from harm. The criteria are also important for blood safety (microbiological safety of the blood), and there is a need to defer blood donors to protect the recipients from getting transfusion-transmitted infections. The criteria for prospective blood donor selection and deferral in India are provided by the Drugs and Cosmetic Act 1940 (and rules thereunder) supplemented by the Standards for Blood Banks and Blood Transfusion Services.<sup>[4,5]</sup> The process of donor selection before the donation is an important, effective, and economical tool for ensuring blood safety. The process involves legal, ethical, political, and psychological considerations and influences donor demographics and leads to specific deferral patterns. The policies of recruitment and retention of blood donors depend on the deferral pattern in any given area. This study was undertaken to evaluate and analyze the blood donor deferral pattern and causes for deferral of blood donors in

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a tertiary care hospital blood bank and to review its influence on policy for recruitment and retention of blood donors.

## Subjects and Methods

The potential blood donors presenting themselves at the hospital blood bank or the outdoor camps and deferred due to temporary or permanent donor deferral criteria from 2001 to 2013 were included in the study analysis. For collection of whole blood initially, the donor selection standard operating procedure was followed and the donors were subjected to a questionnaire followed by hemoglobin testing, if found suitable, physical examination of donors was performed. The data available as deferral record over a period of the year 2001–2013 was analyzed retrospectively after approval from the Institutional Ethics Committee. The reasons for deferral were analyzed after classification into the following categories, namely, replacement-voluntary blood donors, gender-based (male-female), and various age group categories. Donors were categorized into four categories for analysis based on reasons for deferral. The deferral criteria used for classifying the causes of deferral in Categories 1, 2, 3, and 4 were as follows:

- 1. Donors whose own health might be affected by donating (Category 1)
- 2. Donors with risk of a transmitting transfusion transmissible infections (Category 2)
- 3. Donors with a condition where transmissibility by blood is unknown or donors with diseases or a condition not suitable for blood donation (Category 3)
- 4. Sensitive physical and social considerations making donors nonsuitable for blood donation (Category 4).

## Results

A total number of 53,480 prospective blood donors registered for blood donation and 47,316 blood donors (88.47%) donated blood at the blood center or in outdoor camps during the study period. The deferral rate of 11.5% (6164/53,480) represents prospective whole blood donors deferred under the four categories, and the evaluation is summarized in Table 1. Among the donors deferred 83.3% were males, and 16.7% were females. The rate of donor deferral was 4.8%, 4.7%, 1.6%, and 0.3% in Category 1, Category 2, Category 3, and Category 4, respectively. About 62.8% (3856/6164) of the donors were deferred temporarily while 37.1% (2288/6164) were permanently deferred. Among the deferred donors who could have risked their health (Category 1), 15% were deferred permanently and while 85% were deferred temporarily. In donors at risk of transmitting transfusion transmissible infections (Category 2) 71% were deferred permanently the major causes being a history of jaundice and high-risk behavior. Temporary deferral was done in 29% with main causes being a history of malaria, recent tattooing, and marks of recent cuts in the arms. All the donors (100%) rejected due to other risk conditions were deferred temporarily (Category 3), and the main reasons were upper respiratory tract infection, donors who were on antibiotics or had undergone surgery. Under collection, alcohol intake was the main reasons of deferral of donors (41.5%), and 58% donors were permanently deferred due to suspicious identity (professional donors in disguise) [Table 1].

Figure 1a and b depicts the distribution of age and occupation of the blood donors deferred. Among the donors who came to donate blood 32 were under age, and 2 were overage, as per the regulations and the criteria, they did not qualify to donate blood. Maximum donors deferred were among the age group 18–28 years (54%), next common age group being 29–38 years (27%) followed by the age group 39–48 years with 14% donors getting rejected. The combined analysis of all causes of deferral, permanent and temporary showed are depicted in Figure 2. The maximum number of deferrals, i.e. 28.2% were due to a history of jaundice (1739/6164) followed by 19.4% (1199/6164) donor deferral due to hemoglobin below 12.5 g %. The analysis of causes of temporary donor deferral in all four categories is presented in Table 2. The maximum number of donors rejected was in Category 1 followed by Category 3 and

Table 1: Donor deterral according to four categories of blood donors									
Category of	Total number of	Percentage deferral	Total number of	Percentage	Total number of	Percentage			
donor deferral	donors deferred	out of (53,480)	temporary deferral	temporary deferral	permanent deferral	permanent deferral			
Category 1*	2581	4.8	2192/2581	85	389/2581	15			
Category 2**	2516	4.7	728/2516	29	1788/2516	71			
Category 3***	877	1.6	877/877	100	0/877	0			
Category 4****	190	0.3	79/190	41.5	111/190	58			
Total donors	6164	11.5	3876/6164	62.8	2288/6164	37.1			

\*Donors health at risk on donating blood; \*\*Donors at risk of transmitting transfusion transmitted infections; \*\*\*Donors with other conditions not suitable for blood donation; \*\*\*\*Sensitive physical and social consideration making donors unsuitable



Figure 1: (a and b) Donor deferral according to age and occupation

Category 2, the least being in Category 4. The most common cause of temporary deferral was low hemoglobin (below 12.5 g%) among 19.4% (1199/6164) of the prospective blood donors. 54% of donors deferred were males, and 46% were females due to low hemoglobin. Malaria was the second most common cause and a history of intake of medicine, infection, underweight, allergy, recent marks of razor, history of typhoid, and last blood donation



Figure 2: Common causes of donor deferral. \*Typhoid, lung disease/tuberculosis, epilepsy/psychiatric problem, diabetes, heart disease, cancer, endocrine diseases, and kidney disease. \*\*Menstrual problems, alcohol, underage, high-risk group, over age, H/o previous blood donation reaction, and dog bite/vaccination

#### Table 2: Causes of temporary donor deferral

	Total number	Percentage	Percentage
	of donors	(out of 2192)	on total
	deferred		(3876)
Causes in Category 1			
Anemia	1199	54.70	30.93
Under weight	254	11.59	6.55
Allergy	220	10.04	5.68
Typhoid	194	8.85	5.01
Last blood donation <3 months ago	179	8.17	4.62
Weakness/dizziness	90	4.11	2.32
Menstrual problems	30	1.37	0.77
Under age Total	26 2192	1.19	0.67
		Percentage	
		(out of 728)	
Causes in Category 2			
Malaria	494	67.86	12.75
Razar mark	226	31.04	5.83
High risk group	8	1.10	0.21
Total	728		
		Percentage	
		(out of 877)	
Causes in Category 3			
Medicine (antibiotics)	386	44.01	9.96
Infection	367	41.85	9.47
Surgery	75	8.55	1.93
Phlebotomy site not clear	48	5.47	1.24
Dog bite/vaccination	1	0.11	0.03
Total	877	-	
		Percentage	
		(out of 79)	
Causes in Category 4			
Under collection	50	63.29	1.29
Alcohol	29	36.71	0.75
Total	79		

within 3 months were major causes of temporary donor deferral. Among the causes of permanent donor deferral history of jaundice was the most common reason followed by high blood pressure and suspicious identity [Table 3].

## Discussion

Donor counseling and screening through questionnaire before donation is an important process not only to ensure blood safety but also to recruit and retain regular voluntary nonremunerated donors. The deferred donors are informed about the reason of deferral and counseled accordingly. In a study from South India, the deferral rate was found to be 5.04% and low hemoglobin the most common cause of deferral in females. The rate of deferral was highest in age group of 18-25 years similar to our study. Unlike our study where the most common cause of deferral was a history of jaundice, the study showed the reason as low hemoglobin followed by hypertension and cardiac causes.<sup>[6]</sup> Another study by Agnihotri et al. reported a similar deferral rate as our study. However, unlike our study, deferral percentage increased significantly (P < 0.05) as the age of the donor increased to >40 years and more donors were deferred due to abnormal blood pressure readings with increasing age. The most common reason (55.8%) for deferral was low hemoglobin followed by an abnormal blood pressure recording (either high or low) and ongoing medications (11.1% and 6.9%, respectively) in the study. The study laid emphasis on determination of rate and causes of deferral of donors to work as strategy making effort for recruitment and retention of blood donors both regionally and nationally.<sup>[7]</sup> Another study from Delhi region showed low hemoglobin as the most common cause of deferral (32.9%). However, second and third most common reasons in their study were low weight (26.6%) and history of jaundice/hepatitis (8.1%).[8]

#### Table 3: Causes of permanent donor deferral

	Total number	Percentage	Percentage
	of donor	(out of 389)	on total
	deferred		(2288)
Causes in Category 1			
Blood pressure (high)	169	43.44	7.39
Lung disease/	52	13.37	2.27
tuberculosis			
Epilepsy/psychiatric	50	12.85	2.19
Diabetes	49	12.60	2.14
Heart disease	45	11.57	1.97
Cancer	7	1.80	0.31
Endocrine diseases	5	1.29	0.22
Kidney disease	4	1.03	0.17
Over age	4	1.03	0.17
History of previous	4	1.03	0.17
blood donation reaction			
Total	389		
		Percentage	
		(out of 1788)	
Causes in Category 2			
Jaundice	1739	97.26	
Tattoo	49	2.74	
Total	1788		
		Percentage	
		(out of 111)	
Causes in Category 3			
Suspicious identity	111	100.00	4.85
Total	111		

In a study from New Delhi, a total donor deferral rate was 5.1%. The deferral rate was significantly (P < 0.001) higher for females (32.7%) than for males (3.92%). Similarly, rates of deferral among voluntary donors (2%) was lower than the replacement donors (13.5%) with statistical significance (P < 0.001).<sup>[9]</sup> In contrast, Agnihotri found that the related donors had a significantly low deferral rate as compared with voluntary donors, and deferral rate increased as age increased (P < 0.001).<sup>[7]</sup> The most common cause of deferral was low hemoglobin in 49.7% donors, and other common causes were ongoing medication (s) (11.8%), intake of alcohol within 24 h (8.6%), and fever and/or infection (5.5%). The majority of donors were among younger age group ranging 26–35 years.<sup>[9]</sup>

In a study from Western India an effort to study the retrieval of temporarily deferred donors to the main pool was analyzed. The deferred donors were called back after completion of deferral period based on the cause for deferral. A total of 33% donors were deferred either temporarily or permanently which is higher than reported in our study. In the repeat donors (5.32%), the deferral rate was significantly higher than in 1st time (1.32%) donors and a significant female preponderance in deferrals was observed (15.05% vs. 2.51%). The majority of temporarily deferred donors were <40 years of age (80.80%), graduate (82.90%), from low-income groups (62.90%), and profession was service (48.10%). 31.20% of deferred blood donors returned to donate blood again out of which 27% donors qualified to donate.<sup>[10]</sup> Thus, temporary deferral should not be a reason not to donate blood in future, and such donors should be followed up and if found safe then recruited back into the donor pool. In a retrospective study from sub-Saharan Africa, 77.4% donors were repeat donors and the deferral rate still 10.8%. Most donors (42.5%) were deferred due to low hemoglobin and were females followed by males with multiple sexual partners (34.3%). Although the rates for permanent and temporary deferral rates were similar between the Ivory Coast and high-middle income countries, the causes and demographics differed. The reasons for exclusion of blood donors were preventable through awareness and education of prospective blood donors.<sup>[11]</sup> In a recent study of donor deferral among students in Northern Japan, 23% donors were deferred. The main reasons for temporary deferral were reported as low hemoglobin, questionnaire-based interview decisions, and medication. The study concluded that focus on deferred donors and the causes are important in planning recruitment strategies and returning of deferred donors due to temporary reasons so as to reduce the loss of blood donors.<sup>[12]</sup> In a study from Huelva (South Western Spain), the role of women was determined in altruistic blood donations. The study described the willingness of women to donate blood to be higher than men. However, the deferral was higher in women due to low hemoglobin levels, poor venous access, and higher frequency of vasovagal reactions. The study concluded a donor fidelity of 48.6% for women and 58.6% for men and emphasized on the need to adapt measures to ensure reduction in deferrals of women as blood donors and bring in more women in the pool of regular blood donors.<sup>[13]</sup> In a retrospective analysis of blood donor deferral according to demographic characteristics from Iran, a deferral rate as high as 30.9% (4.5% permanent deferral) was reported unlike 11.5% in our study. The deferral rate was significantly higher among women, single individuals and 1st time donors, compared with men, married individuals and those with a history of the previous donation (P < 0.0001). Similar to our study, the deferral rate was significantly higher in the 17-30 year-old group (P < 0.05). The reasons for deferral were divided into five categories: risk factors possibly related to HIV or hepatitis (43.6%), underlying diseases (31.9%), noneligible conditions (13.5%), medications that interfere with blood donation (7.8%), and risk factors that may relate to bacterial or viral infections except HIV and hepatitis infections (3.2%).<sup>[14]</sup> The study emphasized the need to document, monitor, and check effectiveness of donor deferral and its impact on blood safety.

It is important to analyze the donor deferral criteria in specific demographic areas in the categories described unique to the area so as to develop a safe pool of blood donors as well to bring back donors deferred due to temporary causes and minimize loss of blood donors and keep them motivated. Regular blood donors make the best group of blood donors, and low hemoglobin levels were the most important reasons for temporary deferral in most studies and in this study too. Thus, combining anemia prevention and treatment in donor recruitment strategies could help regain the donors and develop a healthy blood donor pool. Efforts to increase the hemoglobin in the repeat donors has the potential to improve the donor retention and increase overall blood safety.<sup>[15,16]</sup> Donor selection through structured questionnaires is an important prerequisite for safe donor recruitment and if carried out as a uniform policy may even affect the prevalence data as donors with transfusion-transmitted infections would be excluded even before donating a unit of blood. There is a need to assess the deferral pattern in different regions for recommending revisions in donor selection criteria as well planning strategies for re-entry of donors deferred temporarily to be brought back to regular donor pool. Deferral is a form of rejection and also could be a representation of loss of time for both blood donors and blood bank and the importance of explaining the status of deferral cannot be ignored.<sup>[17]</sup> Different rates and reasons of donor deferral may be attributed to different donor selection criterion in different regions and centers. Donor recruitment strategies with more liberal criterion without affecting blood safety may reduce the number of deferrals. Efforts must be taken to increase awareness among deferred donors and to encourage them for future donations to reduce the loss of useful units of blood. Raising general awareness for blood donation and encouraging related donors to become regular donors may help increase the number of voluntary donations. The analysis of the pattern of deferral and interventions to bring back deferred donors when possible could be a strategy for long-term retention of motivated blood donors.

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#### **Conflicts of interest**

There are no conflicts of interest.

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