





Blood Donor Deferral Analysis in Relation to the Screening Process: A Single-Center Study from Southern India with Emphasis on High Hemoglobin Prevalence

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Purpose: Donor deferral results in loss of potential, motivated blood donors, and thereby, availability of blood for needy patients. This study analyses the frequency and reasons for donor deferral, including high hemoglobin deferral, which is underreported in India.

Methods: Retrospective analysis of the deferral record of whole blood donors from January 2014 to December 2018 was performed with respect to the pre-donation screening process at our center. Accordingly, the deferrals are categorized as stage 1 – evaluation of Donor History Questionnaire (DHQ), stage 2 – medical examination, stage 3 – hemoglobin (Hb) check using copper sulfate method or a gradually implemented quantitative hemoglobin analyzer, and stage 4 – before phlebotomy. Donor demographic details, donation frequency, and deferral reasons were noted. Descriptive statistical analysis was performed using SPSS version 20 (IBM, USA).

Results: Of 99,680 pre-donation screenings, 10.6% was deferred. The highest deferral (56.02%) was at stage 3 (based on hemoglobin level) contributed by low (52.45%) and high (3.75%) hemoglobin deferrals against cut-off of 12.5 to 18 g/dl. High Hb was noted only in male donors when screened by hemoglobin analyzer. Further, a steady fall in low hemoglobin but a rise in high hemoglobin deferral rate owing to the gradual implementation of hemoglobin analyzer over the study period was noted. The deferrals in stage 1, 2, and 4 were 29.64%, 13.97%, and 0.36%, respectively. Overall, the deferral rate was higher in females (49.88%), and in first-time (13.63%), and 18 to 25 yrs age-group (4.25%) donors for low Hb, underweight, and tattooing/ear piercing.

Conclusion: Insights on donor deferral reasons promote proactive measures towards donor recruitment and retention. Further, donor hemoglobin screening by quantitative method, if followed uniformly by all blood centers across the country, will help identify the true prevalence of high hemoglobin in Indian blood donors and ensures donor safety.

Keywords: deferral reasons, donor return, tattooing, quantitative hemoglobin, high hemoglobin deferral, donor safety

Introduction

Recruitment of voluntary, safe, and healthy blood donors for the provision of quality blood products to needy patients in a timely-manner is a constant challenge faced by blood transfusion services in India. According to the world health organisation (WHO), a minimum need to meet a nation's blood requirement is approximately 1% of its population. In India, annual blood collection during 2016–17 was 11.1 million units against the target of 13 million units with a shortfall of 1.9 million blood units.^{1,2}

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Despite having a huge population of over 1 billion where 50% to 60% are eligible for blood donation, still, a continuous shortage of blood exists.³ Therefore, it is of utmost importance to take necessary measures to increase the blood supply without compromising on the donor's health or safety of transfusion recipients. Besides donor recruitment measures, developing strategies for retention of already motivated and recruited donors is considered as "need of the hour" to meet the rising demand despite shrinking donor pool.⁴⁻⁷ This study intends to address the frequency and reasons for donor deferral including the deferrals due to high hemoglobin which is not commonly reported in Indian studies. Further, in light of the result, to develop strategies to mitigate the donor deferral rate and improve donor re-entry in our center.

Materials and Methods

Study Design and Setting

A retrospective cross-sectional study on analysis of the pre-donation deferral record of whole blood donors from January 2014 to December 2018 over five years was conducted in a blood center in southern Karnataka, India.

Ethical Approval

The institutional ethical clearance was sought from the Kasturba Medical College and Kasturba Hospital Institutional ethics committee (Reference- IEC-419/2019). In view of retrospective study design and no risk of disclosure of donor identity is involved in this study, the requirement to obtain the blood donors' consent to review the donor records were waived off by the institutional ethical committee. Confidentiality of the data was maintained, and the study procedures were performed in compliance with the 1964 Helsinki declaration and its later amendment.

Inclusion and Exclusion Criteria

Voluntary, non-remunerated, whole blood donors recruited at out-door camps and in-house site were included while apheresis donors were excluded from the study.

Study Methods

Analysis of donor deferral reasons was performed in relation to the donor screening process, which includes evaluation of Donor History Questionnaire (DHQ), brief physical examination by medical officer followed by hemoglobin (Hb) estimation. According to regulatory

guidelines, blood donors with a hemoglobin level of 12.5g/dl and above, detected by either a qualitative copper sulfate method or a quantitative method like portable hemoglobin analyzer (CompoLab TS – Fresenius Kabi India Pvt Limited) are qualified for blood donation.⁸⁻¹⁰ Both the methods were quality checked before being used for donor screening. In copper sulfate method, a drop of donor's capillary blood obtained from a finger prick is allowed to fall from a height of 1 cm into Coplin's jar containing copper sulfate solution of specific gravity 1.053, which corresponds to Hb level > 12.5g/dl. Blood drop of Hb >12.5g/dl will sink, and those of <12.5g/dl tend to float for some time. The hemoglobin analyzer using reagent free microcuvette measures the absorbance of capillary whole blood photometrically at a broad-spectrum wavelength to estimate total hemoglobin concentration.¹¹ During the study period, there was a gradual implementation of a portable hemoglobin analyzer substituting the traditional copper sulfate method. The decision on acceptance or deferral of blood donors is made by the medical officer considering the overall health status of blood donors at the time of donation, including if he/she fulfills the standard operating procedure (SOP) for donor selection. This SOP is based on Drugs and Cosmetics Act (the rules thereunder) and supplemented by the Directorate General of Health Services and National AIDS Control Organisation (NACO) guidelines, including their amendments.^{9,10}

Data Collection

The total number of whole blood donors enrolled, accepted, and deferred during the study period were noted. In addition to demographic details of deferred donors and the reason/s for deferral, whether temporary or permanent, the deferral reasons corresponding to the stage of deferral in the donation process (Figure 1) were also accounted for the study. The data required for the study were retrieved from departmental software (Easy software solutions, Ahmedabad). The data obtained were analyzed using SPSS version 20 (IBM, USA).

Statistical Analysis

Descriptive statistical analysis, like mean and percentage, were used. Chi-square χ^2 test with Yate's correction was used to assess the categorical variables. p-value <0.05 was considered as statistically significant.

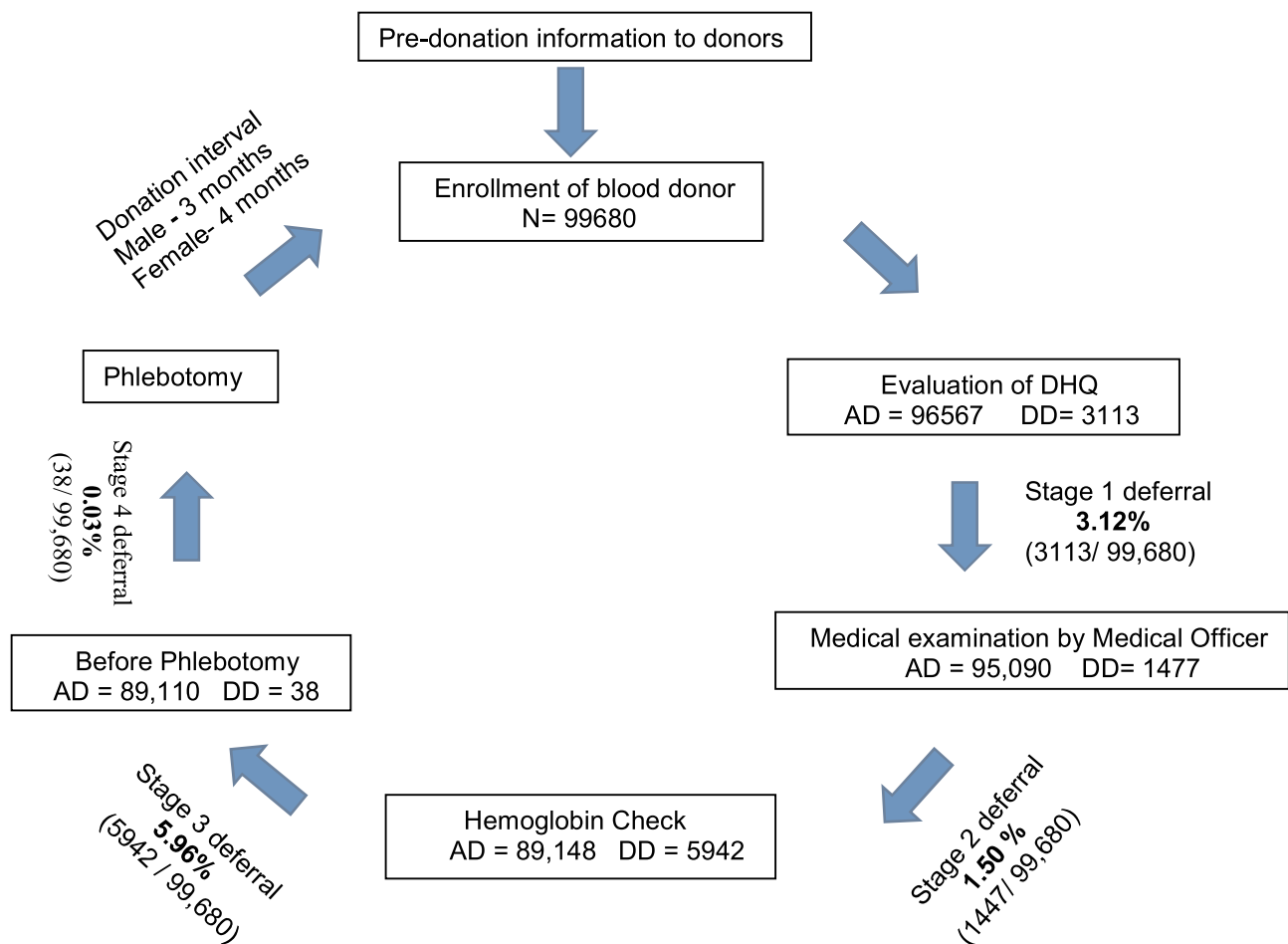


Figure 1 Pre-donation screening process and stages of donor deferral. Bolded numerals - Deferral percentage following each stage of screening process. **Abbreviations:** DHQ, Donor History Questionnaire; AD, accepted donors; DD, deferred donors.

Results

A total of 99,680 voluntary blood donors, including 6.5% (n= 6479), of family/friend donors, were registered during the study period, of which 91.20% (n=90,911) were male, and 8.8% (n=8769) were female donors. Donors recruited from out-door camp and in-house site were 69.85% (n=69,631) and 30.15% (n= 30,049) respectively. Likewise, first time donors were 53.7% (n=53,528) and repeat donors were 46.30% (n=46,152). Following the pre-donation screening process, 89,110 blood donors were accepted, and 10,570 donors were deferred resulting in a mean deferral rate of 10.6%. The characteristics of deferred donors are shown in Table 1. The deferral rate was higher in in-house donors [11.67% (3507/30049) compared to 10.14% (7063/69631) of out-door camp donors, $p<0.05$] and in first-time donors [13.63% (7297/53528) compared to 7.09% (3273/46152) of repeat donors, $p<0.05$]. On a gender basis, the deferral rate was higher in female donors (49.88% compared to

6.76% of male donors, $p<0.05$). Common deferral reasons among female donors include low Hb (70.08%), underweight (8.14%), medicine intake (3.68%), and others. Similarly, the proportion of deferral was higher (40.16%) in the age group of 18 to 25 yrs (Table 2) due to low Hb (61.56%), underweight (12.76%), tattooing/ear piercing (4.02%) followed by alcohol consumption (3.41%) and others. Low Hb was the common reason for deferral in all age groups except 56 to 65 years, where high blood pressure (36.6%) accounts for common deferral reason.

The distribution of deferral rate in decreasing order of frequency concerning the pre-donation screening process includes 5.96% (5942/99680) in stage 3 (Based on hemoglobin check), 3.14% (3133/99680) in stage 1 (Evaluation of DHQ) followed by 1.50% (1477/99680) in stage 2 (medical examination) and 0.03% (35/99680) in stage 4 (Before phlebotomy) respectively (Table 2). Of 99680 registered donors, after stage 1 and stage 2 deferral,

Table 1 Characteristics of Deferred Blood Donors

	2014	2015	2016	2017	2018	Total N=10,570
Visit						
First	968	1641	1667	1359	1662	7297 (69.04%)
Repeat	724	656	542	690	661	3273 (30.96%)
Gender						
Male	943	1181	1314	1320	1439	6197 (58.63%)
Female	749	1106	905	719	894	4373 (41.37%)
Age						
18–25	735	941	842	721	1006	4245 (40.16%)
26–35	398	403	446	496	550	2293 (21.63%)
36–45	315	342	384	440	481	1962 (18.56%)
46–55	147	140	160	182	184	813 (7.69%)
56–65	23	35	28	44	35	165 (1.56%)
Type of deferral						
Temporary	1645	2372	2047	2035	2280	10,379 (98.19%)
Permanent	37	38	29	44	43	191 (1.81%)

95,050 donors underwent stage 3 hemoglobin estimation. The proportion of donors screened and deferred by copper sulfate and portable hemoglobin analyzer are shown in (Table 3). Common reasons for deferral in stage 3 include low Hb (n=5545) followed by high hemoglobin (n=397) against Hb cut-off of 12.5 to 18 g/dl. The proportion of low Hb deferral against the total donor population was high in female donors (3667/8767) as compared to male donors (1858/90911) [41.83% vs 2.04% with p-value <0.05], while 100% of High Hb deferrals were male donors detected only by hemoglobin analyzer. High Hb levels ranged between 18.1 and 21.5g/dl. Further analysis of stage 3 deferral demonstrated a steady fall in low Hb but a rise in high Hb deferral rates, respectively, over the study period (Figure 2). Common reasons for deferral in Stage 1 based on DHQ includes underweight (8.14%), alcohol consumption (6.99%), medicine intake (4.68%), age below 18 or above 60 yrs (2.63%) followed by vaccination (1.27%), and others (Table 2). Stage 2 deferral

based on medical examination comprises 12.31% (n=1301) of high blood pressure (BP), 0.89% of low BP followed by 0.59% of poor venous access, and 0.19% of open wound or skin rash in phlebotomy site. Stage 4 deferral before phlebotomy includes 0.27% of pre-donation adverse reaction and 0.08% of apprehensive behavior. Overall, the proportion of temporary and permanent deferrals were 98.13% (n= 10,372) and 1.87% (n= 198) respectively. The common reasons for temporary deferral include low hemoglobin, high BP, underweight, alcohol consumption, medicine intake, age-related, and tattooing. In contrast, common reasons for permanent deferral include at-risk donors capable of spreading trans-fusion-transmitted infection, endocrine, and systemic disorders.

Discussion

Blood donor selection and deferral criteria play a vital role in blood transfusion safety and are designed to ensure the donor as well as the recipient's health. It is a challenge for blood transfusion service to balance between donor acceptability and management of adequate blood inventory by conforming to regulatory rules and guidelines, including their amendments. It is a well-known fact that donor deferral has a negative impact on donor return of both first and repeat donors.^{6,12} Hence, it is essential to understand donor deferral reasons and develop effective strategies to retain these already motivated but deferred donors.

The donor deferral rate of 10.6% in this study is comparable to other reports in the literature, ranging from 5% to 35.6%.^{13–17} However, unlike other studies, the categorization of donor deferral in line with the donation process flow (Table 2) provides a better understanding of deferral reasons including high hemoglobin and tattooing, which are often overlooked but have significant implication on deferral rate.

Donation Site-Based Deferral

The majority of our center's donor population were recruited from the out-door campsite, which includes a pool of committed repeat donors who are well aware of donor selection and deferral process by experience. Hence, the deferral rate was higher among in-house donors (11.67%). A study by Spekman et al¹⁸ on return of deferred whole blood donors, has also highlighted that experienced donors are most likely to return, even after deferral. Further, as our center is attached to

Table 2 Blood donor deferral reasons in relation to the screening process

Deferral stage	Screening process	2014	2015	2016	2017	2018	Total N=10570	% in deferred donors	% in donors enrolled (N=99680)
Stage 1	Evaluation of DHQ								3.12
1	Age related (< 18 yrs / >60yrs)	60	51	64	58	61	294	2.78	(3113/99680)
2	Underweight	97	206	198	197	212	910	8.60	
3	Blood donation within last 3 months	2	14	16	16	18	66	0.62	
4	Alcohol consumption	66	217	112	169	155	719	6.80	
5	Acute/chronic Medical illness	26	22	20	28	26	122	1.15	
6	Ear piercing/tattooing	25	47	22	45	35	174	1.64	
7	Jaundice	27	15	11	34	40	127	1.20	
8	On medication	66	102	59	128	140	495	4.68	
9	Minor/ Major Surgery	10	10	20	15	16	71	0.67	
10	Vaccination	27	17	31	22	38	135	1.27	
	Total						3113	29.46	
Stage 2	Medical Examination								1.50
1	High BP	254	212	248	270	317	1301	12.31	(1477/99680)
2	Low BP	43	8	5	12	27	95	0.90	
3	Poor venous access	5	12	2	18	23	60	0.56	
4	Open wound/Skin rash in phlebotomy site	5	3	4	6	3	21	0.19	
	Total						1477	13.97	
Stage 3	Hemoglobin check								5.96
1	Low Hb (<12.5g/dl)	926	1447	1223	991	958	5545	52.46	(5942/99680)
2	High Hb (>18g/dl)	37	15	32	64	249	397	3.75	
	Total						5942	56.21	
Stage 4	Prior to Phlebotomy								0.03
1	Donor apprehension	2	3	2	0	2	9	0.08	(38/99680)
2	Donor reaction pre-donation	4	9	7	6	3	29	0.27	
	Total						38	0.35	

Table 3 Categorization of Hemoglobin Deferral Based on the Screening Methods Used

Hemoglobin Check	Donors Enrolled						Hb Deferral (%)
	2014 N=20,021	2015 N=20,906	2016 N=21,017	2017 N=19,160	2018 N=18,574	Total N=99,680	
A) Screened by Copper sulfate	15,766	16,845	16,225	11,353	3013	63,202	
i) Low Hb	801	1289	1014	644	170	3908	3.92
B) Screened by Hemoglobin analyzer	3542	3125	3980	6789	14,452	31,888	
i) Low Hb	125	158	219	347	788	1637	1.64
ii) High Hb	37	15	32	64	249	397	0.39
						Total	5.56%

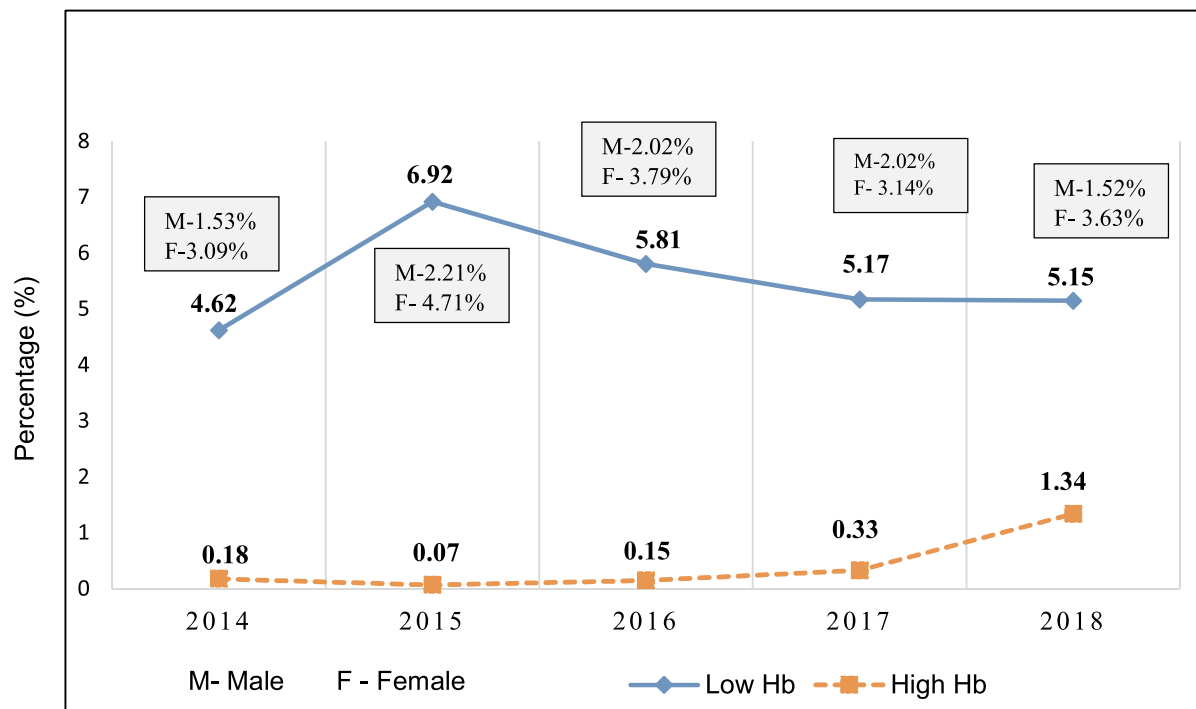


Figure 2 Trend of low and high hemoglobin deferral rates in % against total donors enrolled during the study period.
Abbreviations: M, % of male donors with low Hb; F, % of female donors with low Hb.

a teaching hospital, the majority of the in-house donations were made by the migrating student population and thus a higher deferral rate in first-time donors (13.63%).

Age and Gender-Based Deferral

The deferral rate against total donation events was high among females than male donors, primarily due to low hemoglobin (70.08%), followed by underweight (8.14%), medicine intake (3.68%), and others. Further, most deferred donors belonged to the age group of 18 to 25 years, while in an Indian study, a high deferral rate was reported in donors aged 25 to 39 years.¹⁴ Underweight and tattooing/ear-piercing were reported as common deferral reasons next to low Hb among young adolescent donors, specifically female donors. In regions with the rise in tattooing culture, especially among the teenagers, it is essential to educate these donors at the time of recruitment about the deferral period and risks involved with needle sharing or usage of unsterilized needles. This helps at-risk donors to self-defer for 12 months from the time of tattooing. Low Hb remains the common deferral reason in all age groups except in 56 to 65 years, where high blood pressure was more prevalent.

Hemoglobin-Based Deferral

Deferral performed on hemoglobin basis had the highest deferral rate of 56.21% contributed by low hemoglobin (52.46%) and high hemoglobin (3.75%). The prevalence of low Hb in adolescent donors, particularly among female donors, was noted in earlier studies and this study.^{3,19} Dietary advice on intake of iron-rich foods, iron tablets, and regular follow-up of anemic donors improves their health status. Also, it increases their chances of re-entry to the donor pool.

Although data on high hemoglobin deferrals are available in international studies, it is not commonly reported in India as most blood banks follow the traditional copper sulfate method for various reasons.^{11,20,21} This method is capable of detecting Hb >12.5 g/dl, which is mandatory for blood donation but lacks the competency to differentiate between normal and high Hb levels.¹¹ Lack of both precise upper limit cut-off for Hb in donor selection criteria and uniform hemoglobin screening method across the country, the high Hb deferral rate is likely to differ from one center to another.^{3,21}

Our study's mean high Hb deferral rate was 3.75%, with a wide range of 0.62% to 10.71% (Figure 2). On the other hand, it was reported as 6% in an Indian study by Bobati et al.³ Likewise, high hemoglobin levels among blood donors in our study ranged from 18.1 to 21.5g/dl, while other studies in the literature had a range of 17 to 23g/dl.^{3,20} Of concern, donors

with high hemoglobin, are primarily deferred for the underlying risk of polycythemia vera (PV). However, factors such as smoking, high altitude, dehydration that might influence hemoglobin levels should also be considered before disqualifying these potential blood donors.^{22–24} In a cohort study on 1.4 million donors by Edgren et al,²² there was no evidence of excess risk of PV among blood donors or association between donation frequency and PV risk. More indigenous studies on donor hemoglobin level and the inherent risks involved to both donor and recipient are required to have scientific reasoning and evidence-based approach towards the deferral decision of these healthy blood donors.

We also observed a steady fall in low Hb but a rise in high Hb deferral rates over the study period (Figure 2). This change is likely to be attributable to the gradual implementation of a quantitative hemoglobin analyzer to replace the traditional qualitative copper sulfate method during the study period (Table 3). The possibility of false deferral of normal hemoglobin blood donors as low hemoglobin owing to technical reasons like the incorporation of air bubbles, use of an inadequate height for dropping the blood into Coplin's jar and inability to differentiate normal Hb level above 12.5g/dl from actual high hemoglobin (>18g/dl) are the major drawbacks associated with copper sulfate method.¹¹ Elimination of these pitfalls by Compolab quantitative hemoglobin analyzer, which is also claimed to give erroneous high hemoglobin results with the bias of -0.53 ± 0.81 ,¹¹ together could have led to a decrease in low Hb deferral rate but an increase in high Hb detection rate. Irrespective of the methodology used, blood transfusion services shall take efforts to mitigate hemoglobin-based deferral rate, especially in repeat donors who are at risk for the depletion of iron stores. In a pilot study conducted earlier in our center on the impact of blood donation on body iron stores, 11.2% of regular blood donors were found to have iron deficiency erythropoiesis, which is considered as an at-risk group for iron deficiency anemia with their further donations.²⁵ Mitigation effort to manage at-risk donors of anemia or polycythemia vera, in a blood center shall be sought by effective communication of the same to regular blood donors besides prompt referral and follow-up.

Donor History Questionnaire-Based Deferral

Amongst stage 1 deferrals, underweight (8.14%) was the most frequent reason with high prevalence in student donors, while other Indian studies in literature ranged from 4.72% to 32.3%.^{16,26} This shows that a significant proportion of donor pool in India comprises of motivated young donors. The other common reasons for deferral in

this stage was alcohol consumption before blood donation (6.99%), medicine intake (4.68%) which includes short-term antibiotic or analgesic followed by age factor (2.14%) and tattooing or ear-piercing (1.64%), a growing trend among young population. Of concern, 1.20% of deferrals in this stage were permanent for a history of hepatitis B infection. However, the majority of the reasons accounted for temporary deferral. Effective communication of donor eligibility criteria and optimal deferral period to the general population may help them opt for self-deferral and return later for blood donation.

Medical Examination-Based Deferral

Of 13.94% stage 2 deferral, the common reason was hypertension (12.30%) with a higher proportion in the age group of 56 to 65 years in contrary to 36 to 55 yrs as reported by other studies in the literature.^{3,16} Further, in a randomized controlled study by Ou-Yang J et al, 30.6% of self-reported deferral reasons accounted for medical reason.²⁷ In our center, hypertension happened to be an incidental finding for a few first-time donors, and was referred to a physician for further management. Earlier intervention in these donors can prevent complications and increase their likelihood of returning to the donor pool in the future.

Deferral Before Phlebotomy

The deferral reasons in stage 4, like donor reaction pre-donation and donor apprehension, although rare, are usually seen in first-time donors. Prompt pre-donation counseling and individual psychological support help in avoiding these deferrals besides the effective retention of first-time donors.²⁸ On the whole, most of the deferral reasons noted in our study account for temporary deferrals, and this emphasizes the fact that these donors if adequately followed up, can be retrieved for future donations.

Conclusion

Insights on donor deferral reasons help us to identify the lacunae and promote proactive measures towards donor retention and increase the return of temporarily deferred donors. Further, this study also highlights the need to determine the true prevalence of high hemoglobin among Indian blood donors by utilizing a quantitative hemoglobin estimation method to ensure donor safety. However, extensive multicentric research is required to reach a consensus on high hemoglobin deferral criteria based on the rationale and scientific evidence obtained.

Disclosure

All the authors report no conflicts of interest in this work.

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