A study of whole blood donor deferrals in the blood bank of a rural medical college in India

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Abstract

Introduction: To provide safe blood to the recipients, proper donor selection and deferral is as important as screening of blood bags for various transfusion transmissible infections (TTI).

Aims and Objectives: To study and analyse various causes & rate of pre-donation deferral of blood donors and to take proper follow up actions to decrease the temporary deferral rate without compromising blood quality and recipient's safety, thus retaining prospective blood donors and preventing loss of precious blood.

Materials and Method: A retrospective study of various causes of pre-donation deferral of whole blood donors in the blood bank of our institute was done. Records of all deferrals of Financial Year 2012 to 2016 (4 years) were reviewed and analysed.

Results: A total of 6633 potential blood donors were registered during the study period which includes 6474 males (97.6%) and 159 females (2.4%) with 5840 Voluntary and 793 Replacement donations. Out of which, a total of 273 donors (4.11%) were deferred due to various reasons. Among these, 235 were Temporary (86.08%) and 38 were Permanent deferrals (13.92%). The main reason for temporary deferral is Low Haemoglobin; while for permanent deferral is Hepatitis B Positivity.

Conclusion: The donor deferral rate obtained in our study is 4.11% which is quite good as compared to higher deferral rates of some other studies. Majority of the donors were males, so encouragement and motivation of female donors is equally important to increase the overall donor pool. Temporary deferrals were more as compared to permanent deferrals. So by counselling and educating the temporary deferred donors regarding some common causes of temporary deferrals and deferral period, they can be brought back for future donations. The Leading causes of permanent deferrals were Transfusion Transmissible Infections (HBV, HIV, HCV). So proper counselling is also necessary to prevent them from donating blood for the safety of the recipient. In this ways, a pool of healthy blood donors can be increased without compromising quality of blood and safety of the recipients as well as donors.

Keywords: Whole blood donor, Blood bank, Deferral, Temporary, Permanent.

Received: 23rd May, 2017

Accepted: 9th June, 2017

Introduction

Human blood is very precious but unfortunately it can't be manufactured in factories just like drugs. So the only way to maintain inventory in any blood bank is blood donation by healthy donors. They may be voluntary or replacement donors. Voluntary donors are those who donate blood in good faith for the patient without expecting anything in return. While, replacement donors are mostly the family members or friends of the patient who donate blood to compensate the stored blood used for their patient. All voluntary and replacement blood donors have to pass through predefined health screening before donation to determine their eligibility and suitability of donating blood. This screening is mandatory for quality of blood and safety of both, the recipient as well as the donor. Besides, collection of blood from non-remunerated repeat voluntary blood donors instead of paid professional donors is equally important.^(1,2) For the safety of the donor, it is necessary to check whether he is fit enough to tolerate the procedure. While for the safety of recipient, it is must to ensure that the donor is not suffering from any Transfusion Transmissible Infection. Based on this screening, many donors are

rejected temporarily or permanently, as the case may be, from donating blood. They are called 'deferred donors'. Among these, many temporary deferred donors usually left with a negative impression assuming they have been rejected for lifetime and are less likely to return for future blood donation.^(3,4) According to National AIDS Control Organization (NACO) in India, during FY 2016-17, annual blood collection was 7.05 million units against the requirement of 12.8 million units (1% of total population).⁽⁵⁾ So the shortfall is approximately 45%. In this scenario of blood shortage, a uniform donor selection and deferral policy is developed by various agencies to decrease this shortfall.^(6,7,8) So for preventing unnecessary deferral of healthy donors and re-recruiting and motivating temporary deferrals for future blood donations, adequate knowledge of deferral causes and rates is of prime importance.^(9,10) The main aims and objectives of this study is to analyse various causes & rates of predonation deferral of blood donors and to take proper follow up actions to decrease the temporary deferral rate without compromising blood quality and recipient's safety. Thus helps in maintaining a sufficient inventory of whole blood in rural medical institutes by

increasing availability of prospective healthy blood donors through their proper counselling and guidance.

Materials and Method

This retrospective study was conducted in the hospital based blood bank of our rural Medical College. Four year's records of all whole blood donors including voluntary and replacement blood donations in the blood bank as well as in outdoor camps from April-2012 to March-2016 (FY 2012 to 2016) were reviewed and the data was analysed. The criteria for prospective blood donor selection and deferral in India are provided by the Drugs and Cosmetic Act 1940 & Rules 1945 supplemented by the Standards for Blood Banks and Blood Transfusion Services by National AIDS Control Organisation (NACO) and Transfusion Medicine Technical Manual by Ministry of Health and Family Welfare (MoHFW), Government of India (GOI). These agencies laid down a questionnaire for screening of all blood donors (Annexure I), in which every prospective donor is required to give their demographic data as well as answer all questions related to their status of health. After taking proper 'health history', a limited General Physical Examination was done measuring Pulse, Blood Pressure, Temperature, Weight and Haemoglobin (Hb). Screening for haemoglobin was done by Specific Gravity method by Copper Sulphate solution. It was re-checked by Sahli's Method or by Abacus 3 part Cell Counter in case of query in any donor. Some basic cut-off provided by NACO for blood donor selection are; Age: 18-65 years, Weight: \geq 45 Kg, Pulse: 60-100 beats/minutes, Blood Pressure (BP): Systolic: 100-180 mmHg, Diastolic: 50-100 mmHg, Temperature: ≤ 37.5 °C and Hb: ≥ 12.5 gm%. So all the prospective blood donors were accepted or deferred (temporarily or permanently) according to Standard Operating Procedure (SOP) prepared on the bases of various criteria laid down by above agencies. Temporarily deferred donors were deferred for a specific time period according to diseases or conditions they had which were curable or last for temporary period and after which they again become eligible for blood donation. While permanently deferred donors were deferred or rejected for lifetime because the diseases or conditions were not curable or tends to remain for lifetime. Records of all donors were reviewed and analysed according to age, sex and type of donor (voluntary or replacement) and reasons for deferral were categorised into temporary and permanent with their absolute and relative proportions.

Annexure I: Blood Donor Questionnaire

	Blood Donor Registration & Consent Form	
		8. Is there any history of surgery or blood transfusion
-	Name and address of the Blood	in the past 6 months?
	Bank	Major Surgery Minor Surgery Blood Transfusion
-	License No Blood Unit	9. For women donors,
	No	- Are you pregnant?: Yes / No
-	() Tick wherever applicable.	- Have you had an abortion in the last 3 months?:
-	Pl. answers the following questions correctly.	Yes /No
	This will help to protect you & the patient who	- Do you have a child less than one year old?: Yes/
	receives your blood.	No
-	Name:	- Is the child still breast-feeding?: Yes/ No
	Male/Female,	- Are you having your periods today?: Yes/ No
-	Date of Birth Age	10. Would you like to be informed about any abnormal
-	Occupation	test result at the address furnished by you?: Yes/
	Address	No
	Mobile No	11. Have you read and understood all the information
-	Have you donated previously: Yes /No	presented and answered all the questions
-	If yes, on how many occasions: When	truthfully?, as any incorrect statement or
	last:	concealment may affect your health or may harm
-	Your blood group: Time of last	the recipient.: Yes/ No
	meal:	
-	Did you have any discomfort during/after	I understand that
	donation? Yes /No	a. Blood donation is a totally voluntary act and no
		inducement or remuneration has been offered.
1.	Do you feel well today?: Yes /No	b. Donation of blood/components is a medical
2.	Did you have something to eat in the last 4	procedure and that by donating voluntarily, I accept
	hours?: Yes/ No	the risk associated with this procedure.
3.	Did you sleep well last night?: Yes /No	c. My blood will be tested for Hepatitis B, Hepatitis C,
4.	Have you any reason to believe that you may be	Malarial parasite, HIV/AIDs and venereal diseases
	infected: by either Hepatitis, Malaria,	in addition to any other screening tests required to

HIV/AIDS, and/or venereal disease? Yes/ No	ensure blood safety.			
5. In the last 6 months have you had any history				
of the following:	I hereby voluntarily consent to donate my blood/blood			
Unexplained weight loss	components to be used as directed by the Blood Bank			
Repeated Diarrhoea	as per policy of the Govt. for the blood safety.			
Swollen glands				
Continuous low-grade fever	Date:Time:Donor's			
6. In the last 6 months have you had any:-	Signature:			
Tattooing				
Ear Piercing				
Dental Extraction	General Physical Examination: (To be filled by			
7. Do you suffer from or have suffered from any	<u>Blood bank staff)</u>			
of the following diseases?				
Heart Disease Lung disease Kidney Disease	Weight:Kg. Pulse:Beats/Min.			
Cancer/Malignant Disease Epilepsy	BP:mmHg Temperature:°C			
Diabetes Tuberculosis	Hb:gm%			
Abnormal bleeding tendency Hepatitis B/C				
Allergic Disease Jaundice	Accept / Defer Reason:			
Sexually Trans. Diseases Malaria				
Typhoid (last 1 yr.) Fainting spells	Tapping done by: Blood Group:			
- Are you taking or have taken any of these in				
the past 72 hours?	Signature of Medical			
Antibiotics Aspirin Alcohol	Officer:			
Steroids Vaccinations				
Dog Bite/Rabies vaccine (1 yr.)	@ Blood safety begins with a Healthy Donor @			

Results

A total of 6633 prospective blood donors were registered in the blood bank of our rural medical college during four year time period. Among which 6474 (97.6%) were males and 159 (2.4%) were females. Out of 6633 blood donors, 5840 were voluntary donors (88%) while 793 were replacement donors (12%). Total in-house (in blood bank) blood donation was 4073 (61.4%) which includes all replacement donors (793) and some part of voluntary donors (3280). Total outdoor camp donors (voluntary only) were 2560 (38.6%). All this demographic data is shown in Table 1.

Financial	Total	Male	Female	Voluntary		Replacement Deferred		Repeat		
Year	Donors			Donors		Donors	Donors		Donors	
	Registered			In	In	In Blood Bank	Male	Female	Male	Female
				Blood	Camp	only				
				Bank	_	-				
2012-13	734	713	21	302	215	217	27	12	24	3
2013-14	1350	1283	67	606	641	103	54	14	68	9
2014-15	1973	1923	50	870	830	273	83	15	114	5
2015-16	2576	2555	21	1502	874	200	64	4	111	4
Total	6633	6474	159	3280	2560	793	228	45	317	21
				(49.4%)	(38.6%)	(12%)				
Grand	6633	6474	159	5840		793		273		338
Total	(100%)	(97.6%)	(2.4%)	(88%)		(12%)	(4	1.1%)	(.	5%)

Table 1: Whole Blood Donor's Data for FY 2012 to 2016

Out of 6633, total 273 (4.11%) donors were deferred due various reasons including 228 males (3.43%) and 45 females (0.68%) along with their gender specific deferral proportions as depicted in Table 2.

Table 2: Gender Specific Blood Donor Deferral Distribution								
Gender Total Donors Deferred % Deferrals of Gender specific								
	Registered	Donors	total donors	% deferrals				
Male	6474	228	3.43	3.52				
Female	159	45	0.68	28.30				
Total	6633	273	4.11					

These 273 deferrals were further divided into 235 temporary deferrals (86.08%) and 38 permanent deferrals (13.92%) along with their relative proportions to total registrations as shown in Table 3.

Type of Deferral	No. of Deferrals	% of Total Deferrals	% Deferrals of Total Donors Registered
Temporary	235	86.08	3.54
Permanent	38	13.92	0.57
Total	273	100	4.11

 Table 3: Temporary and Permanent Deferral Distribution

Table 4 shows demographic distribution of various reasons for temporary deferrals. Out of 235 temporary deferrals, 197 were male and 38 were females. Low Haemoglobin (34.05%) was the commonest reason among temporary deferrals followed by Under Weight (16.18%), High BP (13.19%) and some others. Whereas out of 38 permanent deferred donors (31 males & 7 females), the top most reason was Hepatitis B Positivity constituting (26.31%) followed by HIV (18.42%), Hepatitis C (15.79%) and some others (Table 5).

Table 4: Reasons for	· Temporary	Deferrals wit	th Demographic	Distribution &	Proportion

Reasons for Temporary Deferral	Male	Female	Total	% of	% of Total
				Temporary	Deferral
				Deferral	
Low Haemoglobin	67	13	80	34.05	29.3
Under Weight	31	7	38	16.18	13.92
High Blood Pressure	27	4	31	13.19	11.36
Jaundice	16	2	18	7.66	6.6
Under Age	13	2	15	6.39	5.5
Medication	12	1	13	5.54	4.8
Surgical Procedure	8	1	9	3.82	3.3
Alcohol	8	0	8	3.4	2.9
Skin Disease	7	1	8	3.4	2.9
Low Blood Pressure	5	3	8	3.4	2.9
Menstruation	0	4	4	1.7	1.5
Previous Donation <3months	3	0	3	1.27	1.1
Total	197	38	235	100	86.08

Table 5: Reasons for Permanent Deferrals with Demographic Distribution & Proportion

Reasons for Permanent Deferral	Male	Female	Total	% of Permanent	% of Total
				Deferral	Deferral
Hepatitis B	8	2	10	26.31	3.67
HIV	6	1	7	18.42	2.56
Hepatitis C	4	2	6	15.79	2.2
Cardiac Disease	4	1	5	13.16	1.83
Asthma	3	1	4	10.53	1.47
Chronic Renal Disease	3	0	3	7.9	1.1
Diabetes	2	0	2	5.26	0.73
Malignancy	1	0	1	2.63	0.36
Total	31	7	38	100	13.92

Discussion

The donor deferral rate ranged from 5.1% - 19.2% across the world in various international and national studies.^(10-17, 19,20) however in present study, out of 6633 registered blood donors, total 273 donors were deferred due to various reasons constituting 4.11% deferral rate, which is quite comparable to some studies by other researchers of South Asian Countries who have reported a nearby lower deferral rates; 5.1% by John et al⁽¹¹⁾ (India), 5.6% by Rabeya et al⁽¹²⁾ (Malaysia) and

7.2% by Patil et al⁽¹³⁾ (India). While some studies from West Asian, European and Western Countries showed a quite higher deferral rates; 19.2 % by Bashawri et al⁽¹⁴⁾ (Saudi Arabia), 14.6% by Arslan et al⁽¹⁵⁾ (Turkey), 13.6% by Custer et al⁽¹⁶⁾ (USA) and 10.8% by Lawson et al⁽¹⁷⁾ (France). Few studies from India and Pakistan also showed higher deferrals rates. Deferral rate comparison of various studies is shown in Table 6. The deferral rate may vary from country to country and region to region. These could be due to different donor

selection criteria in different countries like Age, Weight, Haemoglobin levels, Blood donation interval, Endemicity of transmittable diseases, High risk behaviour, religious restriction on blood donation etc.

In our study 97.6% of the donors were males while only 2.4% were females. Similar rate has been reported by Pandey et al & Rehman et al.^(9,10) These lower rates of female donations were might be because of prevalence of anaemia among rural female population, socio-cultural & socio-economic factors, ignorance, lack of awareness & motivation for blood donation. In present study, the deferred donors were divided into temporary (86.08%) and permanent (13.92%) deferrals. Ouite similar rates were reported by Arslan et al⁽¹⁵⁾ constituting 90% temporary and 10% permanent deferrals, while comparatively lower rate of 62.8% for temporary & higher rate of 37.2% for permanent deferrals were mentioned by Srivastava et al.⁽¹⁸⁾ The leading reason of temporary deferral in our study was Low Haemoglobin level comprising of 34.05% of temporary deferrals which was comparable to study done by Khurram et al⁽¹⁹⁾ (33.7%). On the contrary, comparatively higher deferral rates of 45.31% for haemoglobin were reported by Annam et al⁽²⁰⁾ while Rehman et al and John et al reported lower rates of 17.9% and 15.6% respectively. The main reason for low haemoglobin in rural population could be poor nutrition due to lower socio-economic status. Second common reason for temporary deferral was Underweight (16.1%), almost similar with findings of Bashawri et al⁽¹⁴⁾ (14.6%). In contrast, some other studies showed comparatively lower deferral rate of around 5% for Underweight.^(10,11,13,19) Improper diet and poor nutrition could be the reason for underweight in rural area. We reported High BP (13.1%) as the third main cause of temporary deferral in contrast to lower rate (average 4%) reported by other studies.^(10.14,19) It was also noted that some authors have counted High BP as a reason for Permanent Deferral^(11,13,18,20) which is a point of debate. Among donors deferred due to High

BP, not all were true hypertensive. Some could be due to stress, exercise or apprehension of needle and doctor. Other causes of temporary deferrals in descending order were History of Jaundice within last 1 year, Under Age (less than 18 years), consumption of aspirin or antibiotic or medication in last 3days, Surgical Procedure in last 6 months, Alcohol within last 72 hours, Skin Disease, Low Blood Pressure, Menstruation, Previous Donation within 3months etc. which were also reported in various studies. In rural area, Low BP could be due to increased starvation, excessive fluid loss or heat stroke during labour work.

Transfusion Transmissible Infections (HBV, HIV & HCV) accounted for the commonest cause of permanent deferral in our study. They together constituted 60.5% of permanent deferrals which was comparable to studies done by John et al & Khurram et al.^(11,19) Among which, Hepatitis B is the topper followed by HIV and Hepatitis C. Transfusion of blood withdrawn from these donors carries highest risk to the recipients. So we should remain more stringent while screening them, particularly eliciting history of tattooing, piercing, high risk behaviour etc. Other causes of permanent deferrals were Cardiac Disease, Asthmatic on steroid, Chronic Renal Disease, Diabetics on insulin, Malignancy etc. which were also documented by other studies.

The major problem with temporary deferred donors was a negative psychological impression on the assumption of being rejected for lifetime and they are less likely to return for future blood donation. Therefore all temporarily deferred donors must be properly counselled about the cause and deferral period so that they can get the cause rectified and return for future donations. Donors deferred due to Low Haemoglobin should be referred of further evaluation and treatment. Studies have shown that by lowering haemoglobin standard levels and offering iron treatment for premenopausal woman could increase female eligibility.⁽²¹⁾

Studies Year of		Country	Total	Deferred	% of Deferred	
	Publication		Donors	Donors	Donors	
Lawson et al ⁽¹⁷⁾	1999	France	64092	6921	10.8	
Custer et al ⁽¹⁶⁾	2004	USA	116165	15798	13.6	
Bashawri et al ⁽¹⁴⁾	2005	Saudi Arabia	33900	6508	19.2	
Arslan et al ⁽¹⁵⁾	2007	Turkey	95317	13916	14.6	
Rabeya et al ⁽¹²⁾	2008	Malaysia	4138	231	5.6	
Rehman et al ⁽¹⁰⁾	2012	India	53950	6690	12.4	
Annam et al ⁽²⁰⁾	2014	India	933	85	9.1	
John et al ⁽¹¹⁾	2015	India	16805	858	5.1	
Khurram et al ⁽¹⁹⁾	2016	Pakistan	25901	3156	12.2	
Patil et al ⁽¹³⁾	2017	India	1267	92	7.2	
Present Study		India	6633	273	4.1	

Table 6: Comparison of Deferrals of Present Study to Other Studies^(10-17, 19,20)

Conclusion

The donor deferral rate obtained in our study is 4.11% which is comparable to some studies. However some have reported much higher rates which could be due to different donor selection criteria in different countries. Major chunk of the donors were males while females constituted only 2.4% of the total blood donation. So female participation should be increased by decreasing social, economic & cultural hurdles which prevent them from donating. Temporary deferrals occupy major portion of total deferrals as compared to permanent deferrals. The main reasons for temporary deferrals were Low Haemoglobin. Underweight, High BP and some others. So efforts should be made to clearly inform the donors regarding their deferral reasons and period. It should also be emphasized to counsel and ensure them that the deferral is temporary and encourage them to safely return for donation in future after rectification of the cause without worrying about their deferral status. Educating the community people regarding some common causes of temporary deferrals like abstaining from smoking and alcohol, age limit, menstruation, breastfeeding women, drugs consumption before donation etc. may help pre-screen themselves and avoid unnecessary deferrals. The Leading causes of permanent deferrals were Transfusion Transmissible Infections (TTI) (HBV, HIV, HCV) and some major systemic illnesses. Proper counselling is also necessary for permanently deferred donors about their disease. They should be strictly advised not to donate blood to protect safety of the recipient and to some extent their own safety. In this ways, a pool of healthy donors can be increased without compromising quality of blood and safety of the recipients as well as donors.

Acknowledgement

Nil

Funding

None

Conflict of Interest

None declared

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