Original Article

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Analysis of Variation in Blood Donor Deferral Statistics as per Drugs and Cosmetics (Second Amendment) Rules, 2020: An Institutional Experience

Transfusion Medicine Section

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ABSTRACT

Introduction: The safety of donated blood is of utmost importance for the well-being of the recipient, which requires proper adherence to donor acceptance criteria. In March 2020, new amendments were introduced in the Drugs and Cosmetics Act, which included several new criteria. It is important to explore these changes and their impact on the donor pool to ensure adequate maintenance of whole blood/component inventory in our blood centre.

Aim: To study the variation in deferral statistics of blood donors after the introduction of new donor criteria as per the Drugs and Cosmetics (Second Amendment) Rules, 2020.

Materials and Methods: The present study was conducted from October 1, 2022, to June 30, 2023, in the Department of Immunohaematology and Blood Transfusion (Blood Centre) of a tertiary care hospital in Punjab, India. Retrospective data for three years was collected from blood donor records and deferral records, divided into two groups: group 1 (October 1, 2018, to March 31, 2020) for the old criteria, and group 2 (April 1, 2020, to September 30, 2021) for the new criteria. Reasons for deferral of donors were categorised into four stages: clinical history, medical examination, investigations (haemoglobin levels), and inadequate collection for both male and female donors. The collected data was entered into a Microsoft Excel sheet. Variables in different categories were represented as frequencies and percentages. Chi-square test was used for comparison between the data of the two groups.

Results: In group I, 332 out of 6,588 donors (5.04%) were deferred, and in group II, 345 out of 6,143 donors (5.61%) were deferred. The deferral rate was comparatively higher in females in both groups, with 17.98% (41/228) in group I and 21.65% (21/97) in group II. The percentage of deferred donors was higher in the age group of 18-30 years in both groups, with 50.60% (168/332) in group I and 47.25% (163/345) in group II. The maximum number of donors were deferred at stage I (clinical history), with 270/332 (81.33%) in group I and 296/345 (85.8%) in group II, followed by stage III (investigations), with 34/332 (10.24%) in group I and 33/345 (9.56%) in group II. COVID-19 related history was the third most common cause of deferral in group II, accounting for 43 (12.46%) of the total deferred cases, which was not present in group I.

Conclusion: The new guidelines, although comprehensive, only minimally increased the deferral rate and did not have a significant impact on the donor pool of our blood centre. Knowledge about the latest deferral guidelines and donor deferral rates is of utmost significance for the maintenance of inventory and to reduce the loss of a significant donor pool.

Keywords: Deferral pattern, Donor guidelines, Donor pool, Temporary

INTRODUCTION

Blood transfusion improves health, well-being, and saves lives, making it a cornerstone of treatment in emergency and trauma cases. The selection of healthy voluntary blood donors is a vital part of blood transfusion services to ensure a safe and adequate supply of blood/components to recipients in times of need. While it is important to have an adequate supply, it is also necessary to ensure that the blood collection process does not harm recipients or donors [1]. Often, blood donors are not selected to donate blood after screening and examination due to various temporary or permanent reasons. These donors who are disqualified from blood donation are referred to as "deferred" donors [2]. Having knowledge of donor deferral criteria is crucial to maintain a precious donor pool for an adequate stock of blood/components [3-5]. However, timely availability of healthy donors poses a challenge in many developing nations. According to World Health Organisation (WHO) data, approximately 13,300 blood centres in 169 countries reported collecting a total of 106 million donations. The median blood donation rate in high-income countries is as high as 31.5 donations per 1000 people, while low-income countries have as low as five donations per 1000 people [6]. The most important aspect of the blood donation process is recruiting voluntary, non-remunerated blood donors who willingly come forward to donate blood with a positive attitude [7].

The selection of blood donors requires an extensive screening process, including an elaborate questionnaire, consent, medical examination, and haemoglobin estimation. Various governing bodies have developed uniform blood donor selection criteria and deferral policies [Table/Fig-1] [4,5,8-11]. Regulatory acts such as the Drugs and Cosmetics Act, 1940 (23 of 1940) by the Government of India in the Ministry of Health and Family Welfare (MoHFW) have been created and amended over time to ensure blood safety and the selection of safe donors [5]. Blood banking services in India are mandatory in following these regulations. The latest guidelines, called the Drugs and Cosmetics (Second Amendment) Rules, 2020, were issued by the MoHFW, New Delhi (India) on March 11, 2020, resulting in changes in donor selection criteria and deferral rates [Table/Fig-1] [8]. Furthermore, the Coronavirus Disease 2019 (COVID-19) pandemic and the subsequent introduction of COVID-19 vaccination have had a significant impact on donor deferral patterns [9,10]. The present study aims to analyse the variation in deferral statistics of blood donors after the introduction of new donor criteria as per the Drugs and Cosmetics (Second Amendment) Rules, 2020

[8]. It is important to explore these changes and their impact on donor pools to adequately maintain the inventory of whole blood/components in our blood centre and provide proper counseling and guidance to temporarily deferred voluntary donors regarding the causes and patterns of deferral.

MATERIALS AND METHODS

This retrospective cross-sectional study was conducted from 1st October 2022 to 30th June 2023 in the Department of Immunohaematology and Blood Transfusion (Blood Centre) of a tertiary care hospital in Punjab, India. Ethical clearance was obtained from the institutional ethical committee (Reference No: AU/EC/PH/2K21/54, dated 7/12/21). As the study design was retrospective and donor identity was not disclosed, the requirement to obtain donor's consent for the study was waived by the ethical committee. Retrospective data for three years was collected from blood donor records and deferral records, divided into two groups: Group 1 (1st October 2018 to 31st March 2020) for the old criteria

Criteria	Old guidelines [4,5]	New guidelines [8-11]
Whole blood volume collected and weight of donor	350 mL- 45 kg 450 mL- more than 60 kg	350 mL- 45 kg 450 mL- more than 55 kg Apheresis- 50 kg
Donation interval for whole blood	Once in 3 months Apheresis platelet donor shall not be accepted for whole blood donation before 72 hours from the last platelet donation	Once in 3 months (90 days) for males Once in 4 months (120 days) for females Apheresis platelet donor shall not be accepted for whole blood donation before 28 days from the last platelet donation
Pulse (beats per minute)	80-100	60-100
Occupation: Air crew member, long distance vehicle driver, either above sea level or below sea level or in emergency services or where strenuous work is required	Shall not donate blood at least 12 hours prior to their next duty shift	Shall not donate blood at least 24 hours prior to their next duty shift
Pregnancy or recently delivered	Defer for 6 months after delivery	Defer for 12 months after delivery
Major surgery	Defer for 6 months after recovery	Defer for 12 months after recovery
Minor surgery	Defer for 3 months after recovery	Defer for 6 months after recovery
Tooth extraction	Defer for 3 days	Defer for 6 months
Dental surgery under anaesthesia	Defer for 1 month	Defer for 6 months after recovery
Convulsions and epilepsy	Defer, if not taking medicine for >2 years can be accepted after evaluation	Permanently defer
Thyroid disorders	Permanently defer	Accept donations from individuals with benign thyroid disorders if euthyroid. Others permanently defer
At risk for hepatitis by tattoos, acupuncture or body piercing, scarification and any other invasive cosmetic procedure by self or spouse/partner	Defer for 6 months	Defer for 12 months
Spouse/partner of individual receiving transfusion of blood/components	Not mentioned	Defer for 12 months
Dengue/Chikungunya	Not mentioned	History of Dengue/Chikungunya: Defer for 6 months following full recovery. Following visit to Dengue/Chikungunya endemic area: 4 weeks following return
Zika virus/West Nile virus	Not mentioned	In case of Zika infection: Defer for 4 months following recovery. In case of history of travel to West Nile Virus endemic area or Zika virus outbreak zone: Defer for 4 months
Syphilis	Defer for 12 months after rashes disappear and completion of therapy	Permanently defer
Tuberculosis	Defer for 5 years after cessation of symptoms and treatment	Defer for 2 years following confirmation of cure
Diarrhoea	Not mentioned	Defer for 2 weeks after complete recovery and last dose of medication
Gastrointestinal (GI) endoscopy	Not mentioned	Defer for 12 months
Non live vaccines and Toxoid: Typhoid, Cholera, Papillomavirus, Influenza, Meningococcal, Pertussis, Pneumococcal, Polio injectable, Diphtheria, Tetanus, Plague	No waiting period	Defer for 14 days
Live attenuated vaccines: Polio oral, Measles(rubella) Mumps, Yellow fever, Japanese encephalitis, Influenza, Typhoid, Cholera, Hepatitis A	Defer for 14 days	Defer for 28 days
Swine flu vaccination	Not mentioned	Defer for 15 days
Antibiotics	Defer for 3 days and till symptom free	Defer for 2 weeks after last dose if donor is well
Ticlopidine, clopidogrel, piroxicam, dipyridamole	Not mentioned	Defer for 2 weeks after last dose
Radioactive contrast material	Not mentioned	8 weeks deferral
Dutasteride	Not mentioned	Defer for 6 months after the last dose
Recipients of organ, stem cell and tissue transplants	Not mentioned	Permanently defer
Residents of other countries	Not mentioned	Accept only after stay in India for three continuous years
Corona (SARS-CoV-2)	Not applicable	Donor should be deferred for 28 days till there is complete recovery from the COVID-19 including radiological and virological clearance
COVID-19 vaccine	Not applicable	14 days after receiving each/any dose of COVID-19 vaccine currently available in India

[Table/Fig-1]: Major changes in donor selection criteria as per old and new guidelines [4,5,8-11].

[4,5], and Group 2 (1st April 2020 to 30th September 2021) for the new criteria as per the Drugs and Cosmetics (Second Amendment) 2020 Rules [Table/Fig-1] [8].

Inclusion criteria: All blood donors who visited the blood centre or voluntary blood donation camps for blood donation but were deferred according to any deferral criteria were included, with total blood donation as the denominator.

Exclusion criteria: Apheresis donors were excluded from the study.

Study Procedure

All donors underwent a thorough screening process, which included a detailed donor screening questionnaire and a medical examination conducted by a medical officer. The medical examination included measurements of weight, pulse, temperature (using a clinical thermometer), blood pressure (using a mercury sphygmomanometer), venous access, and haemoglobin estimation (using the Diaspect Tm Haemoglobin analyser). Donor selection was done according to the Standard Operating Procedure (SOP) of our blood centre, which was based on the latest standard guidelines during that period.

Group I (for the old criteria): The SOP for donor selection and deferral was based on the guidelines in the Technical Manual by the Directorate General of Health Services (DGHS), Ministry of Health and Family Welfare (MoHFW), Government of India, and the Drugs and Cosmetics Act, 1940 (23 of 1940), 2015 [4,5].

Group II (for the new criteria): The SOP was based on the Drugs and Cosmetics (Second Amendment) 2020 Rules, which were notified in the Gazette notification 2020.18.03_Final GSR 166(E) by the Central Drugs Standard Control Organisation, DGHS, MoHFW, Government of India [8].

Additionally, after the COVID-19 pandemic, new guidelines were introduced by the National Blood Transfusion Council of India (NBTC) regarding COVID-19 positive donors, history of contact, travel, and COVID-19 vaccination [9,10]. On 5th May 2021, the deferral period for COVID-19 vaccinated individuals was reduced from 28 days to 14 days by the NBTC [10,11].

The data was collected from the database and archives of the blood centre. Donor deferral criteria were categorised into four stages:

1. **Stage I** (Clinical history): This stage was further divided into criteria such as alcohol consumption, medical and surgical causes, high-risk history, drug addiction, medication intake, vaccination, COVID-19 related history, menstrual and lactation history in females, and a shorter duration interval.
2. **Stage II** (Medical examination): This stage included criteria such as being underweight (<45 kg), hypertension (>140 mm Hg systolic and 90 mm Hg diastolic), hypotension (<100 mm Hg systolic and <60 mm Hg diastolic), and poor venous access.
3. **Stage III** (Investigations): This stage involved criteria related to high (>16.5 g/dL in males and >16 g/dL in females) or low haemoglobin levels (<12.5 g/dL) [4,5,8].
4. **Stage IV** (Inadequate collection).

STATISTICAL ANALYSIS

The data collected was entered into a Microsoft Excel sheet. Variables from different categories were represented as frequencies and percentages. For the comparison between the data of two groups, a Chi-square test was used, and the p-value was calculated. A p-value <0.05 was considered significant at a Confidence Interval (CI) of 95%.

RESULTS

A total of 12,731 donors were screened over three years in both groups, out of which 677 (5.31%) were deferred. The deferral rate was higher after the introduction of new criteria, specifically 5.04% (332/6,588) in group I and 5.60% (345/6,143) in group II. However, the change was not statistically significant (odds ratio 0.91, p-value=0.2334). Most of the donors visiting the blood centre were males in both groups, with 96.53% (6,360/6,588) in group I and 98.4% (6,046/6,143) in group II. The deferral trends based on gender and age were similar in both groups, with a comparatively higher deferral rate among female donors in both groups, specifically 17.98% (41/228) in group I and 21.65% (21/97) in group II. The percentage of deferred donors was higher in the younger age group of 18-30 years in both groups, with 50.60% (168/332) in group I and 47.25% (163/345) in group II. Furthermore, a greater number of deferred donors were males in both groups, specifically 87.6% (291/332) in group I and 93.9% (324/345) in group II, which was statistically significant (odds ratio=0.46, p-value=0.0047) [Table/Fig-2,3].

		Group 1 (n) (%)	Group 2 (n) (%)	Odd's ratio (CI)	p-value (difference between total of 2 categories (χ^2)
Total donors screened		6588 (100)	6143 (100)		
Gender Wise donors screened	Male	6360 (96.53)	6046 (98.42)		
	Female	228 (3.46)	97 (1.58)		
Total units collected		6256 (94.96)	5798 (94.38)		
Total donors deferred		332 (5.04)	345 (5.6)		
Age of deferred donors	18-30 years	168 (50.60)	163 (47.25)	**1.1212 (0.96-1.30)**	**0.147331 (2.0997)**
	31-45 years	134 (40.36)	147 (42.61)		
	46-60 years	30 (9.04)	35 (10.14)		
Gender of deferred donors	Male	291 (87.6)	324 (93.9)	**0.46 (0.27-0.79)**	**0.0047 (7.975)**
	Female	41 (12.4)	21 (6.1)		

[Table/Fig-2]: Number of donors screened and deferred according to age and gender.
A p-value <0.05 was considered significant at a Confidence Interval (CI) of 95%

Stage	Group 1 (n) (%)	Group 2 (n) (%)	Odd's ratio (CI)	p-value (stage wise difference between total of 2 categories (χ^2)
I (Clinical history)	270 (81.33)	296 (85.8)	0.083 (0.73-1.02)	0.0826 (3.0123)
II (Medical examination)	26 (7.83)	15 (4.35)	1.65 (0.87-3.11)	0.119 (2.43)
III (Investigations)	34 (10.24)	33 (9.56)	0.98 (0.61-1.58)	0.93 (0.007)
IV (Inadequate collection)	2 (0.60)	1 (0.29)	1.90 (0.17-20.98)	0.593 (0.284)
Total deferred	332 (100)	345 (100)	0.91 (0.78-1.06)	0.2334 (1.419)

[Table/Fig-3]: Number of donors deferred according to stage.
A p-value <0.05 was considered significant at a Confidence Interval (CI) of 95%

The highest number of donors were deferred during stage I (clinical history), specifically 81.33% (270/332) in group I and 85.8% (296/345) in group II, followed by stage III (investigations), with 10.24% (34/332) in group I and 9.56% (33/345) in group II [Table/Fig-3]. In group I, 31.02% (103/332) of donors were deferred due to alcohol intake within the last 48 hours, followed by 21.38% (71/332) due to medicine intake, 16.58% (55/332) due to medical causes, and 9.64% (32/332) due to low haemoglobin. In group II, alcohol intake/signs of alcohol intoxication were again the most common cause, specifically 21.74% (75/345), although less than in group I, followed by medical causes at 19.71% (68/345). COVID-19 history was the third most common cause of deferral, accounting for 12.46% (43/345) of total deferred cases, which was not present in group I. Another significant change was observed in the number

of donors deferred due to high-risk history, which increased from 1.51% (5/332) to 4.06% (14/345) of total deferrals in the respective periods [Table/Fig-4].

The history of alcohol consumption was the most common cause of deferral in males in both groups, specifically 35.39% (103/291) in group I males and 23.15% (75/324) in group II males. The maximum number of males were deferred in the age group of 18-30 years in both groups, accounting for 50.51% (147/291) in group I and 46.91% (152/324) in group II. In females, the most common cause of deferral was low haemoglobin, with 48.78% (20/41) in group I females and 42.86% (9/21) in Group II females. The most common age group deferred in females was 18-30 years in both groups, with 51.21% (21/41) in Group I and 52.38% (11/21) in Group II [Table/Fig-4].

The majority of donors were temporarily deferred in both groups, specifically 98.19% (325/332) in group I and 97.10% (334/345) in Group II, with alcohol intake as the most common reason. Endocrinological disorders were the most common reason for permanent deferral.

The rate of detection of Transfusion Transmissible Infections (TTIs) increased to 4.38% (254/5,798) in group II compared to 3.18% (199/6,256) in group I, with Hepatitis C being the most common TTI, accounting for 1.36% (85/6,256) in group I and 2.33% (135/5,798) in group II [Table/Fig-5].

DISCUSSION

The blood donor screening and selection, based on scientifically proven medical opinions and criteria approved by regulatory bodies, form the baseline for the blood collection procedure at any blood centre. The donor selection criteria used in the current study were in accordance with our Standard Operating Procedures (SOP), which are based on the criteria set by the National Regulatory Authority mentioned earlier. The aim of the authors was to study and compare the rates of donor deferrals and the reasons for deferral

Stage	Cause		Group 1							Group 2						
	Gender		Female (n)			Male (n)			Total (n) (%)	Female (n)			Male (n)			Total (n) (%)
	Age (in years)		18-30	31-45	>45	18-30	31-45	>45		18-30	31-45	>45	18-30	31-45	>45	
Stage I (Clinical history)	Alcohol		0	0	0	41	52	10	103 (31.02)	0	0	0	20	39	16	75 (21.74)
	Medical causes		3	1	1	29	17	4	55 (16.58)	0	2	0	34	20	12	68 (19.71)
	Surgical causes		0	2	0	6	4	0	12 (3.62)	0	0	0	9	1	1	11 (3.19)
	Drug addiction		0	0	0	7	3	0	10 (3.01)	0	0	0	5	5	0	10 (2.90)
	Medicine intake		1	1	1	38	24	6	71 (21.38)	0	2	0	28	24	4	58 (16.81)
	High risk history (tattoo embossing, multiple sex partners)		0	0	0	5	0	0	5 (1.51)	0	0	0	12	2	0	14 (4.06)
	COVID-19	Positive (last 28 days)	NA							0	0	0	0	0	0	0 (0)
		Travel history (last 28 days)	NA							0	0	0	1	2	0	3 (0.87)
		Contact history (last 28 days)	NA							0	0	0	1	3	0	4 (1.16)
		COVID vaccination (last 14 days)	NA							0	1	0	14	15	0	30 (8.69)
		Flu like symptoms (last 28 days)	NA							0	0	0	1	5	0	6 (1.74)
	Other vaccines (Non live vaccines, live vaccines-measles, mumps, chicken pox, rubella, anti-rabies vaccine, swine flu vaccine)		0	0	0	1	1	0	2 (0.60)	0	0	0	1	1	0	02 (0.58)
	Menstruation/Breast feeding		2	0	0	NA	NA	NA	02 (0.60)	3	1	0	NA	NA	NA	04 (1.16)
	Less donation interval		0	0	0	7	3	0	10 (3.01)	0	0	0	10	1	0	11 (3.19)
Stage II (Examination)	Underweight		4	0	0	4	1	0	9 (2.71)	2	0	0	3	1	0	06 (1.74)
	Hypertension		0	0	1	1	5	5	12 (3.62)	0	0	0	2	3	1	06 (1.74)
	Hypotension		2	1	0	1	0	0	4 (1.20)	0	0	0	2	0	0	02 (0.58)
	Poor venous access		1	0	0	0	0	0	1 (0.30)	0	0	0	0	1	0	01 (0.29)
Stage III (Investigations)	Low Hb (<12.5 gm/dL)		8	10	2	6	6	0	32 (9.64)	6	3	0	9	12	1	31 (8.98)
	High Hb (>18 gm/dL)		0	0	0	0	2	0	2 (0.60)	0	0	0	0	2	0	02 (0.58)
Stage IV (Collection)	Inadequate collection		0	0	0	1	1	0	2 (0.60)	0	1	0	0	0	0	01 (0.29)
	Total		21 (6.32)	15 (4.52)	5 (1.51)	147 (44.28)	119 (35.84)	25 (7.53)		11 (3.19)	10 (2.90)	0 (0)	152 (44.06)	137 (39.71)	35 (10.14)	
	Total		41 (12.35%)			291 (87.65%)			332 (100)	21 (6.09%)			324 (93.91%)			345 (100)

[Table/Fig-4]: Stage, age and gender wise distribution of old and new deferral criteria.

Transfusion transmissible infections	Group 1 (n) (%)	Group 2 (n) (%)
Total blood collected	6256	5798
HIV	06 (0.095)	10 (0.17)
Hepatitis B	30 (0.48)	26 (0.45)
Hepatitis C	85 (1.36)	135 (2.33)
Syphilis	78 (1.25)	83 (1.43)
Malaria	00	00
Total	199 (3.18)	254 (4.38)

[Table/Fig-5]: Frequency distribution of Transfusion Transmissible Infections (TTI) in collected blood units.
HIV: Human immunodefeciency virus

in our region, based on both the old and new deferral guidelines [4,8,9,12]. This study will further assist in developing strategies for recruiting regular voluntary donors and creating donor directories based on the reasons for donor deferrals [7].

Our study observed that the majority of donors coming for donation were males, while the deferral rates were higher in females. Similar findings have been observed in studies from other parts of the world, where the number of male donors outnumbered female donors, with a higher rate of deferrals among females [13-15]. This significant difference in male and female donors may be attributed to social stigma among females. Additionally, low haemoglobin levels in Indian females are a major contributing factor, as observed in various other Indian studies [7,16,17].

The total deferral rate in the present study over three years was 5.31%, with 5.04% in group I using the old criteria and 5.61% in group II using the new criteria. The mean deferral rate was found to vary, ranging from 4.27% to 11.5% in different studies conducted in India and other parts of the world [2,7,16-19]. This change in the deferral rate may be attributed to differences in donor screening procedures and donor awareness, where detailed clinical history of the donor was not properly obtained. Additionally, variations in TTI screening protocols may also contribute to these differences. In a study from Nigeria, predonation screening using rapid cards was performed, while in others, screening was conducted after donation, and thus not considered in the deferral criteria [18].

The maximum number of deferrals was observed in stage I (clinical history) during both study periods. In group II, the number of deferrals increased by 85.8% from 81.33% of the total deferrals in the respective periods. This highlights the importance of clinical history in the recruitment of voluntary blood donors. The most common cause of deferral in both periods was a history of alcohol intake, although it decreased from 31.02% in group I to 21.74% in group II. This change may be attributed to the COVID-19 phase, which led to a reduction in social gatherings.

In group I, the second most common cause of deferral was medicine intake (21.38%), whereas in group II, it was medical illnesses (19.71%). Another significant change in the deferral pattern was observed in high-risk patients, which increased from 1.51% in group I to 4.06% in group II. All of these deferrals occurred in males, mostly in the age group of 18-30 years. This increase may be due to changes in the deferral guidelines concerning high-risk history. One major change was that spouses and partners of individuals who had received a transfusion in the last 12 months were also deferred. Additionally, better and stricter donor screening regarding high-risk behaviors may account for the higher rate of deferrals in group II.

For group II, a criterion related to the history of COVID-19 was added, which accounted for 12.46% of the total deferral cases. This included 8.69% deferrals due to COVID-19 vaccination intake in the last 14 days, 1.74% due to flu-like symptoms, 1.16% due to a history of contact with COVID-19 patients in the last 28 days, and 0.87% due to a history of travel in the last 28 days. These deferrals were most prevalent in the age group of 31-45 years, with all except one being males. This aligns with another study where the COVID-19 related deferral rate was 12.6%, primarily due to a larger donor pool in the age group of 25-44 years [20].

Deferral rates due to other criteria in the clinical history stage were similar in both groups for males, females, and all age groups.

Different studies from various regions demonstrate variability in the reasons for donor deferrals, which may be attributed to differences in demographic profiles, screening processes, medical and endemic conditions. However, the stage of clinical history remains the most significant cause in most of these studies. Routray SS et al., also concluded that clinical history was the most common cause for deferral [20]. In another study from India, the most common causes for deferral were low haemoglobin (49.7%), followed by medication (11.8%), and alcohol intake within 24 hours (8.6%) [7].

The number of deferrals decreased from 2.71% in group I to 1.74% in group II in the criteria of underweight, as the weight guideline changed from 60 kg to 55 kg for 450 mL donations [8]. Similar deferral patterns were observed in both groups regarding age groups, types of deferrals (temporary and permanent), stages of medical examination (Stage II), investigations (Stage III), and collection (Stage IV), as there were no major changes in the guidelines for these stages.

A significant difference was observed in the deferral pattern between males and females. Low haemoglobin levels were the most common cause of deferral in both group I and group II, accounting for 48.78% and 42.86% of total female donors, respectively, compared to 4.12% and 6.79% of total male donors. However, low haemoglobin accounted for only 9.64% and 8.98% of total deferral cases. This number is considerably lower compared to other studies available in the literature. Chauhan DN et al., reported anemia as the main cause of deferral in 15.45% of cases. This difference may be attributed to demographic and dietary variations in populations across different regions [1]. High levels of haemoglobin (18 gm/dL) were observed in 0.60% and 0.58% of cases in both groups, respectively. Two of these cases had a history of high-altitude travel, and two had a history of smoking, but none had signs of polycythemia vera. In two other studies, 3.75% and 6% of cases were deferred due to high haemoglobin, respectively [17,21].

In terms of temporary and permanent deferrals, 98.19% of deferred cases in group I and 97.10% of deferred cases in group II were temporarily deferred. The most common causes of permanent deferrals were high-risk history, cardiac illness, and endocrine disorders. It is crucial to study the causes and guidelines for temporary deferrals as these donors need proper counseling for future donations since they represent a significant portion of the donor pool. Regular updating and analysis of the Donor Health Questionnaire and deferral rates related to temporary and permanent criteria can serve as important quality indicators for donor selection, rejection, and counseling. However, these forms must be regularly reviewed and analysed to ensure they are easily understandable [22].

Contrary to our expectations, the rate of TTIs increased in group II compared to group I, from 3.18% to 4.38%. This may be due to some laxity in donor screening within group II, possibly influenced by the COVID-19 pandemic. Additionally, donors may be unwilling to provide specific details regarding high-risk history. It is of paramount importance to conduct more thorough and guided history taking to decrease the rate of TTIs among blood donors and prevent wastage of precious resources. The public should be educated about Hepatitis B vaccination and the routes of transmission for various TTIs through counseling sessions and information brochures, aiming to reduce the rate of TTIs and permanent deferrals.

Only a few studies have been reported in the literature regarding donor deferral patterns after the introduction of the new Drugs and Cosmetics (Second Amendment) Rules, 2020, through the GSR (166) E notification dated March 11, 2020, by the Ministry of Health

and Family Welfare (MohFW), New Delhi, India [8]. The present study was conducted over a three-year period and included more than 12,000 donors, making it comprehensive, informative, and contributing to the recruitment, retention, and retrieval of temporarily deferred donors.

Limitation(s)

Due to the lack of awareness among the staff, there was a paradoxical increase in the rate of TTIs in group II of this study, despite the criteria being more comprehensive. Donor non-compliance with all questions, especially those regarding high-risk history, was an important limiting factor.

CONCLUSION(S)

The new guidelines, although comprehensive, only resulted in a minimal increase in the deferral rate and did not have a significant impact on the donor pool of our blood centre. As donor screening and recruitment are subjective, deferral rates can vary from region to region. Having knowledge about the latest deferral guidelines helps to control the rate of TTIs. Awareness and understanding of deferral criteria aid in identifying deficiencies in the donation and retention process of donors and encourage the return of donors who were temporarily deferred. Additionally, these donors should be motivated through proper counseling and effective communication skills to encourage regular blood donation.

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