ABSTRACT: BACKGROUND: Pre-donation donor screening is must for the safety of the blood donor and recipient. Deferrals lead to loss of precious whole blood donors and blood units available for transfusion purposes. AIM: To record and document the current rate and reasons for donor deferral in our tertiary care hospital based blood bank to modify recruitment strategy for blood donors. MATERIAL AND METHODS: Study was conducted by retrospective data analysis of whole blood donors (Voluntary/Replacement), arrived for donating blood at blood bank and in outdoor camps, during the period 1st July 2010 to 30th June 2014. The donor selection was done by pre-donation screening tests like questionnaire followed by physical examination and haemoglobin estimation. National guidelines were used for selection and deferral of donors. The deferred donor's data was analyzed statistically. RESULT: Out of 34380 blood donors who came to donate blood, 31049 (89.63%, out of which 97.51% voluntary donors) were eligible for donation and 3331 (10.37%) blood donors were deferred. The deferral rate among male population 7.47% and female population 42.09% were observed. Odds ratio for deferral in female donors was 8.99, implying thereby that chance of deferral in females is nearly 9 times higher as compared to males. The five leading causes for male donor deferral were low haemoglobin, hypertension, medication, and malaria & alcohol intake in last 48 hours & for the female donor deferral were low haemoglobin, menstruation, medication, low weight & hypotension. CONCLUSIONS: Studying the frequency and the different causes of donor deferral will help to identify sections of the population which could be targeted for increasing and retaining of the existing pool of voluntary blood donors and also to guide and provide the necessary essential database for the policy design and programme implementation at local, regional, and national level. KEYWORDS: Blood donor deferral, deferral criteria, donor rejection, low haemoglobin, hypertension. MESH TERMS: Blood donors, haemoglobins, hypertension, blood banks and blood donations.

INTRODUCTION: In many medical and surgical diseases of human beings, a blood transfusion is a vital as well as life-saving intervention. However, it requires an adequate supply and timely access of safe blood. The blood requirement can be fulfilled by voluntary or replacement blood donation. According to World Health Organization (WHO) figures, of the 108 million blood donations collected globally; approximately half of these are collected in the high-income countries, home to 18% of the world's population. Blood donation rate in high-income countries is 36.8 donations per 1000 population; 11.7 donations in middle-income and 3.9 donations in low-income countries.[1] It is estimated that donation by 1% of the population (10 per 1000 population) is generally the minimum needed to meet a nation's most basic requirements for blood; the requirements are higher in countries with more advanced health-care systems.[2] National AIDS Control Organization's
(NACO) statistics show that during 2012-13, 67.56 lakh blood units were collected across the country till December 2012, against the targeted requirement of 80 lakh units.\[3\]

Most of the efforts at government, community and individual level are focused at recruiting more and more new donors while less attention is given to the retention and re-entry of those donors who deferred due to various causes after suitable time interval for temporary deferral reasons. Deferral is a painful and sad experience for blood donor as well as the transfusion centre and it necessitates additional efforts towards new recruitments. Moreover, deferring prospective donors often leaves them with negative feelings about themselves as well as the blood donation process additionally these donors are less likely to return for blood donation in future.\[4\]-\[5\] Various causes of the pre-blood donation deferral need to be studied systematically to improve the donation rate. Nonetheless, criteria for these deferrals and their implementation strongly influence the quality of blood supply in a population.

There are few studies on whole blood donor deferrals in India. Lack of "sensitization" to these deferral criteria seems to be both cause and effect of this "scarcity of literature" on the topic. Primary objective of this study was to record and document the current rate and reasons for donor deferral in our tertiary care hospital based blood bank so that the centre can modified its policy if required.

**MATERIALS & METHODS:** A retrospective data analysis was conducted on whole blood donors, arrived for donating blood at outdoor camp & at blood bank, during 1st July 2010 to 30th June 2014. The donor selection was done by pre-donation screening tests like questionnaire followed by physical examination and haemoglobin estimation. The criteria for prospective blood donor selection and deferral in India are provided by the Drugs and Cosmetic Act 1940 (and rules there under) supplemented by the Technical Manual 2003 (Directorate General of Health Services, MOH and FW, Govt. of India). Deferred donors data was analysed with respect to different categories like age group, gender based (Male-female, type of donor and causes for deferral which were also categorised into permanent and temporary causes based on the curability of the condition.

Donors were categorized into six age group categories for the sake of convenience and analysis. Qualitative data were summarized as number of cases and percentage while quantitative data were presented as number of cases, mean, median, range, standard deviation, and 95% confidence interval for the difference. The significance limit was set at 0.05 and chi-square test was used to determine statistical significance. Odds ratio was calculated to determine the probability of deferral among male and female donors. The collected data was analysed using Epiinfo™ version 7.1.4.0. All the deferral data was collected from the deferral records maintained in the blood bank documentation, hence ethical committee clearance is not necessary.

**RESULTS:** Out of 34380 blood donors who came to donate blood, 31049 (89.63%, out of which 97.51% voluntary donors) were eligible for donation and 3331 (10.37%) blood donors were deferred. The deferral rate among male population (2405/32180 cases, 7.47%) and female population (926/2200 cases, 42.09%) were observed. Significantly more female donors were deferred as compared to male donors (42.09% vs. 7.47%; P=0.000, Figure 1). Odds ratio for deferral in female donors was 8.99, implying thereby that chance of deferral in females is nearly 9 times higher as compared to males.
Deferred donor age group ranged from 18 to 65 years with a mean age 31.11 years. Average age of the deferred female donors (30.30 years) was nearly same as the average age for deferred male donors (31.43 years). The deferred donors were divided according to the age group as shown in the (Figure 2). Deferral rate was highest among 21-30 years age group (1224, 36.75%) followed by 31-40 years (832, 24.98%), 18-20 years (589, 17.68%), 41-50 years (536, 16.09%), 51-60 years (140, 4.20%) & >60 years (10, 0.30%).

Highest deferral rate among male (902/2405, 37.50%) and females (322/926, 34.77%) were seen in 21-30 years age group. Most common cause of deferral in our study was low haemoglobin (1163, 34.91%), followed by hypertension (550, 16.51%), medication (322, 9.67%), malaria (173, 5.19%), alcohol intake in last 48 hours (139, 4.17%), infectious diseases (130, 3.90%), jaundice (125, 3.75%), hypotension (123, 3.69%), menstruation (99, 2.97%), weight < 45 kg (91, 2.73%) and other causes (416, 12.49%) including uncontrolled diabetes & other endocrine disorders, tuberculosis, fasting, epilepsy, generalised weakness, heart disease, allergy, previous donation, previous surgery, breast feeding, immunisation, unfit due to age, tattooing, abnormal bleeding, pregnancy or abortion, breast feeding, self-deferral & high risk behaviour. The five leading causes for male donor deferral were low haemoglobin, hypertension, medication, and malaria and alcohol intake in last 48 hours & for the female donor deferral were low haemoglobin, menstruation, medication, low weight & hypotension. Although the most common reason for deferral in both the genders was a low haemoglobin, significantly higher number of females were deferred due to this reason alone (62.10% in females vs 24.45% in males; \( P=0.000 \), odds ratio = 5) (Table 1).

While comparing deferral factors among sex, statistically significant association was observed with the almost all factors except for jaundice & hypotension (\( P \) value of 0.14 & 0.95, odds ratio 0.71 & 1.03 at 95% confidence level). Except for alcohol intake in last 48 hrs, almost all other deferral causes showed significant association with age. (\( P \) value <0.05, table 2).

Out of the total 3331 deferrals, 682 cases (20.47%) were due to permanent causes and 2649 (79.52%) were due to temporary causes. Common deferral causes in younger population (age between 18-30 years) were low haemoglobin, infectious disease and jaundice. Common deferral causes in older population 31-60 years age group were hypertension. (Table 2).

**DISCUSSION:** During blood donor selection procedure, donor may get rejected or deferred for blood donation depending on criteria laid down by regulatory authorities. This may hurt feelings of enthusiastic and especially 1st time donors and there are chances that such donors may not be return to the Nobel cause of blood donation to serve required patients in future.

Donor deferral rates in blood centres vary from 5 to 24% which may lead to specific deferral patterns.\(^{[6-7]}\) The Blood banks should study deferral pattern belonging to their regions so that donor motivators and the government can take educative and motivating steps so that more and more differed donors can be prevented from dropping out for future possible and valuable blood donation. Thus deferral data need to be calculated for various regions and the entire country to guide the recruitment efforts of blood collection services.

Deferral incidence in present study was 10.37% while others studies had like Agnihotriet al (11.6%), Zouet al (12.8%), Chaudharyet al (16.4%), Bahadur and colleagues (9%) and Custer et al (13.6%).\(^{[8-12]}\) However, studies by Rabeya et al & Kwa et al have cited low incidence (5.6-7.1%) to very high incidence by studies done by Charles et al, Di Lorenzo Oliveira et al and Madan et al (20-35).
The deferral incidence in their donor populations, which probably reflects the regional diversity and marked variation in whole blood donor eligibility criteria internationally.\textsuperscript{[18-19]}

The share of female donor was very small in the present study (6.39\%) which was might be due to fear, lack of awareness and motivation among females. The study performed by Bahadur et al, Sundar et al & Unnikrishnan et al also showed same findings.\textsuperscript{[11,20-21]} The present study also highlighted that significantly more female donors were deferred as compared to male donors (42.09\% vs 7.47\%; $P=0.000$) & odds ratio for deferral in female donors was 8.99, implying thereby that chance of deferral in females is nearly 9 times higher as compared to males. This finding had reflected that there is a need for improvement in female health status especially their blood iron status as prime cause of deferral was low haemoglobin.

One of the major tool for optimizing donor re-recruitment and retention in the long run is to categorize deferred donors into temporary and permanent groups. In present study, out of the total 3331 deferrals, 20.47\% were due to permanent causes and 79.52\% were due to temporary causes. The major temporary deferral causes were anaemia, medication and malaria in present study which reflected that these donors were most appropriate candidates for donating blood in future and so they were counselled for the same.

In the younger age group (18-30 years), 11.92\% of total differed donors were rejected due to permanent deferral causes while in older age group (41-65 years), 41.25\% of total differed donors were with permanent causes. This increase of permanent deferral causes in older age groups were correlated with the findings of study done by Girish et al.\textsuperscript{[22]}

The most common reason for deferral in present study was low haemoglobin (34.91\% of differed donors) like other studies done in past.\textsuperscript{[9,11-14,18-19]} The odds ratio indicated very high probability of deferral in females as compared to males due mainly to low haemoglobin. As this is major temporary deferral reason in almost all centres in India, the blood banks should give attention to such differed donors in the form of providing post deferral counselling and IEC materials leaflet distribution & physician reference if required, so that these donors will return to blood donation in future once they will achieve haemoglobin level above cut off.

The second most common reason for deferral in our study was high blood pressure (16.51\%). This finding correlated with the findings of Indian study done by Agnihotriet al (11.1\% including donors with lower blood pressure also), Unnikrishnan et al (13.18\%) and Rathod et al (14.74\%).\textsuperscript{[8,21,23]} Hypertension was the main cause for deferral in older age group (41-60 years) while third common cause in younger donor (18-30 years). The fear of first time donation, blood sight fear, vein puncture fear or white coat hypertension could be justifiable explanations for younger donor high blood pressure rather than medical essential hypertension.

The third most common reason was donor on medication (9.67\%, antibiotics were the major medication type) which needs deferral. The same finding was present in study done by Agnihotri et al (6.9\%).\textsuperscript{[8]}

Donor self-deferral is valid for reducing the risk of HIV transmission through blood transfusions and its implementation should be encouraged, when recruiting blood donors.\textsuperscript{[24]} In our set-up, self-deferral rate was 0.27\%. Similarly high risk behavior is also considered as one of the way to reduce the HIV transmission through blood transfusion & the rate for the same was 0.06\%. The isolated space for confidential pre donation counselling is essential for the implementation of the
both reasons and lack of adequate arrangements for the same in most of the voluntary blood donation camps is big hurdle.

The lack of uniformity for the donor deferral criteria at local level was again one practical problem faced in the blood donation & collection process. This led to the situation in which the donor was differed at one blood bank & was selected for blood donation by other blood banks. In a long run, such type of lack of uniformity for donor selection & rejection may lead to decrease in society trust for blood donor selection procedure. Domen et al, indicate that shared donor deferral registries may be valuable at the local or regional level to prevent deferred blood donors from donating at other blood collection facilities.[25] In India, blood centres are not well connected for sharing of deferral registry as well as absence of any policy for the same.

CONCLUSION: The process of donor deferral & recalling of deferred donors has got less attention by blood banks & donor motivators in comparison to other costlier procedures for recruiting new donors. The deferral data is not widely recorded and reported till date. If collected and studied in a systematic way it will definitely improve the collection of blood from prospective blood donors. The blood banks should modify recruitment strategy according to locally and regionally prevalent donor demographics.

In this study, we analysed donor deferral patterns of our region in an attempt to provide insight into the reasons for donor deferral. In present study, the incidence of donor deferral was 10.37 % with low haemoglobin level, hypertension and medication as top three causes. The female donors were rejected nine times the male donors. Among temporary causes for deferral, anaemia especially in female can be easily alleviated by proper nutritious supplement.

STUDY LIMITATIONS: In this study, deferred donor segregation was not done in terms of “first time and repeat donors” and “voluntary & replacement donor”. Recalling of temporarily differed donors did not get much success in present study as major part of blood collection was from blood donation camps.

REFERENCES:
1. Blood safety and availability [Internet]. [cited 2015 May 12]. Available from: http://www.who.int/mediacentre/factsheets/fs279/en/
2. GDBS Summary Report 2009 [Internet]. p. 5. Available from: http://www.who.int/bloodsafety/global_database/GDBS_Summary_Report_2009.Pdf.
3. Lov Verma (Department of AIDS Control M of H& FW. Annual Report 2012-13, Department of AIDS Control, Ministry of Health & Family Welfare [Internet]. Annual Report NACO. 2013. Available from: http://www.naco.gov.in/upload/Publication/Annual Report/Annual report 2012-13_English. Pdf.
4. Technical Manual. 15th ed. AABB; 2005.
5. Custer B, Chinn A, Hirschler NV, Busch MP, Murphy EL. The consequences of temporary deferral on future whole blood donation. Transfusion. 2007; 47 (8): 1514-23.
6. Tomasulo PA; Anderson AJ; Paluso MB; Gutschenritter MA; Aster RH. A study of criteria for blood donor deferral. Transfusion 2003; 20 (5): 511-18.
1. Newman B. Blood donor suitability and allogenic whole blood donation. Transfusion Med Rev 2001; 15 (3): 234-44.
2. Agnihotri N. Whole blood donor deferral analysis at a center in Western India. Asian J Transfus Sci 2010; 4: 116-22.
3. Zou S, Musavi F, Notari EP, Rios JA, Trouern-Trend J, Fang CT. Donor deferral and resulting donor loss at the American Red Cross Blood Services, 2001 through 2006. Transfusion. 2008; 48 (12): 2484-6.
4. Chaudhary RK, Gupta D, Gupta RK. Analysis of donor-deferral pattern in a voluntary blood donor population. Transfusion Med 1995; 5 (3): 209-12.
5. Bahadur S, Jain S, Goel RK, Pahuja S, Jain M. Analysis of blood donor deferral characteristics in Delhi, India. Southeast Asian J Trop Med Public Health. 2009; 40 (5): 1087-91.
6. Custer B, Johnson ES, Sullivan SD, Hazlet TK, Ramsey SD, Hirschler NV, Murphy EL, Busch MP. Quantifying losses to the donated blood supply due to donor deferral and miscollection. Transfusion. 2004; 44 (10): 1417-26.
7. Rabeya Y, Rapiaah M, Rosline H, Ahmed SA, Zaidah WA, Roshan TM. Blood pre-donation deferrals-a teaching hospital experience. Southeast Asian J Trop Med Public Health. 2008; 39 (3): 571-4.
8. Kwa SB, Ong YW, Gaw YN. Blood donor rejects - a study of the causes and rejection rates. Singapore Medical Journal 1966; 7 (1): 61-8.
9. Charles KS, Hughes P, Gadd R, Bodkyn CJ, Rodriguez M. Evaluation of blood donor deferral causes in the Trinidad and Tobago National Blood Transfusion Service. Transfusion Med 2010; 20 (1): 11-14.
10. Di Lorenzo Oliveira C, Loureiro F, de Bastos MR, Proietti FA, Carneiro-Proietti AB. Blood donor deferral in Minas Gerais State, Brazil: blood centers as sentinels of urban population health. Transfusion 2009; 49 (5): 851-7.
11. Madan N, Qadiri J, Akhtar F. Study of Blood Donor Profile at a Tertiary Care Teaching Hospital. Journal of the Academy of Hospital Administration. 2005; 17 (2): 31-4.
12. Karp JK, King KE. International variation in volunteer whole blood donor eligibility criteria. Transfusion 2010; 50 (2): 507-13.
13. Halperin D, Baetens J, Newman B. The effect of short-term, temporary deferral on future blood donation. Transfusion 1998; 38 (2): 181-3.
14. Sundar P, Sangeetha SK, Seema DM, Marimuthu P, Shivanna N. Pre-donation deferral of blood donors in South Indian set-up: An analysis. Asian J Transfusion Sc. 2010; 4 (2): 112-15.
15. Unnikrishnan B, Rao P, Kumar N, Ganti S, Prasad R, Amarnath A, et al., Profile of blood donors and reasons for deferral in coastal South India. AMJ 2011; 4 (7): 379-85.
16. Girish C. J., Chandrashekhar T. N., Ramesh B. K., Kantikar S. M. Pre-Donation Deferral of Whole Blood Donors in district transfusion centre. Journal of Clinical and Diagnostic Research. 2012 February, Vol-6 (1): 47-50.
17. Rathod K, Gupta M, Shah M. Analysis of blood donor deferral characteristics in a Blood Bank at A Tertiary Care Hospital attached to Medical College in Gujarat. Pathology & laboratory Medicine. July - December 2012; 4 (2): 85-8.
24. Urwijitarron Y, Barusrux S, Romphruk A, Puapairoj C, Pakote L. Reducing the risk of HIV transmission through blood transfusion by donor self-deferral. Southeast Asian J Trop Med Public Health 1996; 27: 452-6.

25. Domen RE, Grewal ID, Hirschler NV, Hoeltge GA. An evaluation of the need for shared blood donor deferral registries. Int J Qual Health Care 1997; 9: 35-41.

| Sex                  | Male | Female | odds ratio | P value |
|----------------------|------|--------|------------|---------|
| Low haemoglobin      | 588  | 575    | 5.06       | 0.000   |
| Hypertension         | 517  | 33     | 0.14       | 0.000   |
| Medication           | 279  | 43     | 0.37       | 0.000   |
| Malaria              | 154  | 19     | 0.31       | 0.000   |
| Alcohol intake in last 48 hrs | 138 | 1     | 0.02       | 0.000   |
| Infectious disease   | 116  | 14     | 0.30       | 0.000   |
| Jaundice             | 98   | 27     | 0.71       | 0.140   |
| Hypotension          | 88   | 35     | 1.03       | 0.950   |
| Menstruation         | NA   | 99     | NA         | NA      |
| Weight <45kgs.       | 51   | 40     | 2.08       | 0.000   |
| Other                | 376  | 40     | -          | -       |
| **Total**            | **2405** | **926** |            |         |

Table 1: Gender distribution of deferred blood donors.

| Age group (years) | 18-20 | 21-30 | 31-40 | 41-50 | 51-60 | >60 | Total (%) | P value |
|-------------------|-------|-------|-------|-------|-------|-----|-----------|---------|
| Low haemoglobin   | 239   | 428   | 290   | 179   | 27    | 0   | 1163 (34.91) | 0.000   |
| Hypertension      | 22    | 116   | 153   | 183   | 69    | 7   | 550 (16.51)  | 0.000   |
| Medication        | 44    | 126   | 98    | 35    | 16    | 3   | 322 (9.67)   | 0.000   |
| Malaria           | 32    | 66    | 55    | 18    | 2     | 0   | 173 (5.19)   | 0.011   |
| Alcohol intake in last 48 hrs | 10 | 56   | 49    | 21    | 3     | 0   | 139 (4.17)   | 0.123   |
| Infectious disease| 31    | 62    | 27    | 9     | 1     | 0   | 130 (3.9)    | 0.000   |
| Jaundice          | 37    | 56    | 23    | 9     | 0     | 0   | 125 (3.75)   | 0.000   |
| Hypotension       | 35    | 41    | 30    | 10    | 7     | 0   | 123 (3.69)   | 0.000   |
| Menstruation      | 21    | 42    | 24    | 12    | 0     | 0   | 99 (2.97)    | 0.013   |
| Weight <45kgs.    | 32    | 46    | 9     | 4     | 0     | 0   | 91 (2.73)    | 0.000   |
| Other             | 86    | 185   | 74    | 56    | 15    | 0   | 416 (12.49)  | Not done|
| **Total**         | **589** | **1224** | **832** | **536** | **140** | **10** | **3331** |         |

Table 2: Age distribution of deferred blood donors.
Fig. 1

Accepted & deferred blood donor distribution

Fig. 2

Deferred donor distribution: Gender & temporary/permanent

Fig. 1

Fig. 2
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