

Impact Analysis of the National Guidelines for Blood Donor Selection in India: A Single Center Study

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Abstract National Blood Transfusion Council recently released the national guidelines for blood donor selection in India. Some changes in the currently used donor selection criteria have been proposed. However, its effect on future donor availability and deferral has not been studied. To enumerate the changes in current donor selection criteria and analyze its impact on the future blood donor availability vis-à-vis current deferral rate. One year data for both selected and deferred whole blood donors was analyzed retrospectively. Questionnaire forms of the selected donors were screened to analyze the responses given at the time of donation. A total of 4494 donors presented for whole blood donation and 995 (22.1%) were deferred for the various reasons. NBTC has proposed 12 major changes in the currently used donor selection criteria with 11 resulting into increased deferral of the blood donors. These changes would lead to an additional deferral of 32.5% of the currently eligible blood donors mostly due to the change in the blood pressure cut off. National blood donor selection guidelines in the current form would lead to a very high deficit of available blood donors in India. There is an urgent need to reconsider the merit of the changes suggested in these guidelines.

Keywords NBTC guidelines · Whole blood donor selection · Donor deferral

National Blood Transfusion Council (NBTC) is the apex policy formulating body for all the matters concerning the operations of blood centers in India. In a recent circular it announced the national guidelines for the blood donor selection [1]. These guidelines are supposed to be followed by all the blood centers in India. Some changes in the currently used selection criteria [2] are suggested in these guidelines. However, no scientific evidence was quoted for these changes and its possible impact on the future blood availability in India.

We thus planned a study to:

1. Enumerate the exact changes suggested in the existing blood donor selection criteria.
2. Analyze the current whole blood donor deferral pattern at our blood center.
3. Quantify the possible impact on the future blood availability due to the changes suggested in the national guidelines.

Materials and Methods

This study was conducted in a Tertiary care, hospital based, small sized (collecting less than 5000 blood units per annum) accredited blood center situated in a Tier 3 city of Northern India. It was a retrospective observational study conducted over 1 year period (June 2017 to May 2018). Criteria given in the accreditation standards for blood banks/blood centers and transfusion services by the National Accreditation Board for Hospitals and Healthcare

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Providers (NABH) were used for the blood donor selection during the study period [2]. In addition to these criteria, an additional test before the blood donation was done to screen for HBsAg in the whole blood using the Hepa-Scan whole blood rapid test (Bhat Bio-Tech India Pvt Ltd., Bengaluru, India). This was done in view of a high prevalence of hepatitis B in the general population in our region. All the donated units were additionally tested by the chemiluminescence technology for the HBsAg marker in addition to all the other mandatory infectious markers.

The hemoglobin of the donors was tested using an automated cell counter (XP-100, Sysmex Corporation, Kobe, Japan) and the blood pressure (BP) was checked using an automated and calibrated BP monitor (Omron, Omron Healthcare Co Ltd, Kyoto, Japan). If initial BP was higher than the cut off, it was repeated after a rest of 10–15 min using a manual sphygmomanometer. If still found higher, a third measurement after a gap of 10 min was taken. Lower of the two/three values was taken as the correct BP of the donor.

The whole blood donor data from the study duration was analyzed to study the existing donor deferral pattern (deferred donor data) as well as to understand the possible impact of the new national guidelines (selected as well as deferred donor data). The donor questionnaire forms of all the selected donors were scrutinized to look for the answers to the medical questionnaire and remarks by the medical doctor. For e.g. whenever the donor had selected ‘Yes’ as an answer to the antibiotic consumption, the doctor’s remarks for the duration and last consumption date were noted. Similarly, the BP measurement on the donor questionnaire and consent form of the selected donors was compared vis-à-vis the acceptance criteria as per the new national guidelines.

Results

A total of 4494 whole blood donors presented for the donation during the study period. Out of these, 995 were deferred for the various reasons, thus giving a deferral incidence of 22.1% at our center. The demographic profile of the blood donors at our center is given in Table 1. Female and voluntary blood donors constituted only 5.8%

Table 1 Whole Blood donor demographics during the study period

Type of donor (% of total donors)	Gender	Selected	Deferred	Row Total	Category Total
Voluntary (8.1%)	Male	280	43	323	362
	Female	8	31	39	
Replacement (91.9%)	Male	3158	751	3909	4132
	Female	53	170	223	
Grand total		3499	995	4494	

and 8.1% respectively of the total whole blood donors at our center. Not considering the gender or the type of the donor, the low hemoglobin (Hb) was the most common reasons for the donor deferral (Table 2). Along with the low Hb, past or present medical history and a high BP lead to the deferral of majority of the blood donors (Table 2).

The selection criteria where a change is suggested in the national guidelines and its impact on the donor availability is enumerated in Table 3.

Discussion

Blood donor selection criteria is an important parameter to safeguard the health of both the recipient and the donor of a blood unit. NBTC, the apex policy formulating body for the blood centers in India, has recently circulated a donor selection guideline [1]. The intention is to have a uniform donor selection criteria throughout India. It is for the first time, that an attempt has been made to have a uniform blood donor selection criteria (BDSC) throughout the country and is thus laudable. However, many changes have been suggested in the currently used selection criteria without analyzing its possible future impact on the donor availability. Internationally, high quality evidence for the selection of prospective donors for blood donation is limited or even lacking in relation to many medical conditions and risk behaviors [3]. Therefore, most of the times a highly defensive approach is taken while preparing these guidelines.

Through this study we made an attempt to evaluate the probable impact of these new guidelines and shall discuss them under three orthodox categories of—the good, the bad and the ugly.

Probable Impact: The Good!

Unlike the most commonly used guidelines [2, 4] the new guidelines [1] are clearer on most of the selection and deferral criteria.

NBTC has clarified on some of the currently used ambiguous selection criteria for the blood donors. Important amongst these are the donation interval after a

Table 2 Deferral reasons in the whole blood donors

Sr. no.	Reason	N (% of deferred)	Primary reason
1	Low Hb	341 (34.3%)	–
2	Acute infection ± medicines	140 (14.1%)	Antibiotics, open wound, active cough
3	Past ds/surgery ± medicines (except heart and liver disease)	126 (12.7%)	Typhoid (n = 40;4%), animal bite (n = 40;4%), epilepsy, DM on insulin
4	High BP	101 (10.2%)	> 160 and 100 for sys and dia respectively
5	Pre-donation HBsAg	70 (7.0%)	Initiative to increase counseling
6	Miscellaneous	35 (3.5%)	Alcohol, fasting, high Hb, low BP, BT
7	Donation within last 3 months	30 (3.0%)	–
8	Inventory related	27 (2.7%)	Overstock of particular blood group
9	H/o jaundice (1 year), hepatitis B/C	24 (2.4%)	
10	Under/Over age	24 (2.4%)	Mostly under age
11	Unwilling	21 (2.1%)	Peer pressure to donate but not willing
12	Heart disease history	16 (1.6%)	Past or ongoing
13	Under weight	15 (1.5%)	< 45 kg
14	High risk and menstrual bleeding	25 (2.55)	High risk (n = 12;1.2%); Menstrual bleed (n = 13;1.3%)
Grand total		995 (100%)	

Table 3 Change in the blood donor selection criteria suggested in the NBTC guidelines

Donor selection criteria	Current cut off	Change suggested	Deferral Impact ↑↓*	No of new deferrals (% of currently acceptable donors, i.e. 3499)
Systolic blood pressure (mm Hg)-upper limit	160	140	↑	806 (23.0%) [#]
Diastolic blood pressure (mm Hg)-upper limit	100	90	↑	303 (8.7%)
Pulse (beats per minute) lower range	≤ 50	≥ 60	↑	17 (0.5%)
Antibiotics-after last dose (days)	3–4	14	↑	9 (0.3%)
Delivery/pregnancy (months)	6	12	↑	Nil found
Breast feeding (months)	12	24 (Total period of lactation)	↑	Nil found
Minor surgery (months)	3	6	↑	Nil found
Dental manipulation or surgery (months)	1–3	6	↑	2 (0.1%)
Asthmatic attack (weeks)	1	Permanently defer	↑	Nil found
Syphilis and Gonorrhoea (months)	12	Permanently defer	↑	Nil found
Vaccines-Oral Polio, Measles, Mumps, Yellow fever (days)	14	28	↑	1 (0.01%)
Tuberculosis (years)	5	2	↓	Nil found
Total new deferrals (% of currently acceptable blood donors)				1138 (32.5%)

*↑ = Increased deferral; ↓ = decreased deferral

[#] Out of the 806 donors, 412 (11.8%) had only systolic > 140 mm Hg and 394 (11.3%) had both systolic as well as diastolic above the cut off, i.e. > 140 and > 90 mm Hg respectively

component donation (and vice versa), high risk behavior, endocrine disorders, jaundice history, some infectious diseases and medications used by the prospective blood

donors. Clarity on these selection criteria has the potential to optimize the donor deferral and enhance the blood safety.

Having had come from the NBTC, there is high likelihood that these guidelines would be adopted by the licensing authorities as well as the accrediting bodies in India. Such an adoption and uniform implementation can be presumed to do a lot of good [5] to the subjective interpretation of BDSC currently used in India. This subjectivity in BDSC can be adjudged from the high variability in the most common deferral reasons [6–11] reported in studies done across India. The donor deferral rate also has varied hugely from 5.1 to 16.4% [6–11] in these studies reported across India. However, it is prudent to admit it here that the regional variation in donor demographic profile may also explain the different deferral rate as well as the common reasons for deferral. For e.g. 8% deferral only due to typhoid and animal bite leading to a cumulative deferral rate of 22.1% in our study, supports this notion of regional variability (Table 2). The uniform guidelines and thus resulting donor questionnaire, nonetheless, can still be predicted to iron out the subjective variations in the BDSC across India.

Although female donors constitute a very small fraction of our blood supply [6–11], an increased deferral duration after pregnancy and for the feeding mothers is a welcome clarity in the new guidelines. Permanent deferral for gonorrhoea has the potential to further curb the high risk donors joining the eligible donor pool. Although we could not find any impact of the decreased deferral for tuberculosis (from current 5 years to the suggested 2 years post treatment) in our study, it may add some more donors in the high prevalence areas for the tuberculosis.

Having glimpsed at the probable good effects, we can expect other ‘not so desirable’ effects also, as explained in the paragraphs below.

Probable Impact: The Bad!

Donor deferred at our center, due to the antibiotic intake and/or a history of past minor surgery/dental manipulation/asthmatic attack constituted 8.1% of the total deferred donors and nearly 2% of the total donors ($n = 81$). The revised donor selection criteria proposes to greatly increase the deferral duration for these conditions (Table 3). This increase can severely impact not just the immediate donor deferral but also the future return of these deferred donors [12]. Overt misuse and self-medication for antibiotics is already a major public health issue in India [13, 14]. Additionally, with increasing government support (like Ayushman Bharat Scheme), minor surgical procedures/day care procedures and dental procedures can be presumed to increase further in India. So in addition to having the immediate impact on the donor availability, a known poor return behavior of such temporarily deferred donors [12]

would greatly impact the future blood supply also. Therefore, when effectiveness of even the current deferral durations is unknown and without any concrete evidence [3], further increasing the deferral duration can hardly be justified and seems unwarranted.

Although, our study could find an additional deferral of only 0.4% for the above mentioned conditions, it can easily be explained as a gross under-estimate. This is because the prospective donor does not discuss/report a condition if it is beyond the duration mentioned on the questionnaire form. So, it is prudent to first conduct studies with revised/proposed deferral periods mentioned on the blood donor questionnaire form and then analyze the deferral impact.

Probable Impact: The Ugly

WHO recommends that the national donor selection guidelines and criteria should be based on the epidemiological and/or scientific evidence or, where evidence is limited or lacking, on best practices [3]. These recommendations are at the best, contradicted when NBTC revised the acceptable blood pressure limit in blood donors in India. In just one stroke, NBTC has wiped off nearly 32% of the currently eligible blood donors from the available donor pool (Table 3). It is not clear how such an acute and huge deficit of blood units would be compensated in the current scenario of big and chronic shortage of blood units in India.

An increasing population with asymptomatic hypertension and chronic blood shortage in India, would make it difficult to implement the new BP guidelines effectively.

It is now well known that a raised baseline blood pressure, treated hypertension or low blood pressure are not predictive of an increased adverse reaction in the blood donors [15]. On the contrary, high systolic BP has shown to protect the donors against the syncope [15]. Stainsby and colleagues in their systematic review could not find any evidence of increased risk to homologous or autologous donors with treated hypertension or with systolic blood pressure up to 200 mmHg [16]. Probably, for the same reasons mature blood transfusion services like in United Kingdom [17] and Unites States of America either do not recommend blood pressure measurements or allow up to 180 mm Hg systolic and 100 mm Hg diastolic BP respectively [18]. Even WHO has labeled the limits of 100–140 mm Hg systolic and 60–90 mm Hg diastolic for blood donors as being an arbitrary acceptable limit [3]. Therefore there is an urgent and serious need to drop the change in the acceptable BP limit set forth by the NBTC in the new guidelines.

Conclusion

The guidelines released by the NBTC for blood donor selection in India, is a welcome move however, its impact on the future blood donor availability has not been studied. Our single center study showed that the proposed guidelines will severely impact the already short blood supply in India. More studies on the impact of the guidelines are needed before a uniform roll out in India is pursued.

Author's Contributions Naveen Agnihotri planned the study, analyzed the data and designed the manuscript. Ajju Agnihotri & Yatendra Mohan conducted the research, prepared the data and assisted in the manuscript.

Compliance with Ethical Standards

Conflict of interest No conflict of interest by any of the authors.

Research Involving Human Participants and/or Animals This article does not contain any studies with human participants or animals performed by any of the authors.

Informed consent Informed consent was obtained from all individual participants included in the study.

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