

A study of the noncompliance of blood banks on safety and quality parameters in blood donation camps in Bengaluru

Rajat Kumar Agarwal, Rakesh Dhanya, Lalith G. Parmar, Arpit Vaish, Amit Sedai¹, Sundar Periyavan²

Project Rakta Kranti,
Sankalp India
Foundation, Bengaluru,
India, ¹Technology
Team, Sankalp India
Foundation, Bengaluru,
India and ²Department
of Neuropathology,
Transfusion
Medicine Center,
National Institute
of Mental Health
and Neurosciences,
Bengaluru, India

Abstract:

Aims: The compliance of safety and quality parameters laid out by national and international guidelines in outdoor blood donation camps has not been studied in India. Our study aimed at identifying, monitoring, analyzing, and developing preventive strategies for several key parameters associated with the quality and safety of outdoor voluntary blood donation camps (VBDC). **Settings:** The study covered a total of 424 VBDCs at various locations in Bengaluru, Karnataka (South India) from 2009 to 2013. Seven government hospitals based blood banks, three private hospitals based blood banks and two voluntary standalone blood banks participated in the VBDCs included in the study. **Materials and Methods:** At the onset, the quality and safety standards to be followed were discussed and agreed upon. During the study, noncompliance (NC) to the agreed upon standards were recorded and shared. Periodic trainings were also organized to help minimize NC. **Results:** One or more instances of NC in 73% of the VBDCs. Highest NC were observed associated with punctuality (34%), wearing gloves (16%), hemoglobin (Hb) estimation (11%) and donor screening and selection other than Hb check (8-9%). **Conclusion:** For all 16 parameters under study, significant NC was observed. As a whole private hospital based blood banks were more noncompliant. The high degree of NC to matters relating to quality and safety in VBDCs is high and warrants for urgent attention and further study. Our study also shows that regular monitoring and systematic and strategic intervention can decrease the rate of NC.

Key words:

Blood donation camp, hemovigilance, noncompliance, quality, voluntary blood donation

Introduction

Voluntary blood donors are the cornerstone of a safe and sufficient supply of blood products. The safest blood donors are voluntary, non-remunerated blood donors from low-risk populations.^[1]

In India, the collection of most of the blood from voluntary, non-remunerated blood donors from low-risk population happens in voluntary blood donation camps (VBDC). Any compromise on the quality and safety of the blood collection procedure has the potential impact on the safety and well-being of the donor and the recipient. In addition, failure to maintain quality and safety negatively impacts donor retention and in more serious situations it could deter the organizers from conducting more VBDCs.

Unlike countries where structured and robust vigilance and surveillance systems exist as part of national entities, at VBDCs in India no such system is in place to assess the adherence to the laid out guidelines for blood collection. The understanding

of quality and safety issues associated with blood donation camps is subjective. The compliance of the blood bank to the safety and quality parameters in outdoor blood donation camps have not been studied in India.

This study aimed at identifying, monitoring, and analyzing several key parameters associated with the quality and safety of outdoor blood donation camps.

Aim

Our study was aimed at assessing the quality and safety aspects of VBDC. Consequently, we aimed at helping improve quality and safety.

Materials and Methods

The study was conducted on VBDCs over a period of 4 years 10 months that is, from 1st January 2009 to 31st October 2013. The study covered a total of 424 blood donation camps at various locations in Bengaluru, Karnataka (South India).

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Correspondence to:
Rajat Kumar Agarwal,
#304 D, Chamundi
Emerald, 1st Main, 7th
Cross, N. S. Palya,
B.T.M. II Stage,
Bengaluru - 560 076,
Karnataka, India.
E-mail: sankalp.admin@gmail.com

Sankalp India Foundation (SIF), a voluntary youth organization, initiated this study with the intent to improve the quality and safety in the VBDCs. At the onset of the study the minimum basic standards required by the blood bank to follow during a VBDC, according to the National AIDS Control Organization (NACO, India) and Central Drugs Standard Control Organization, India^[1-3] guidelines were drafted. The blood banks which were expected to attend the VBDCs participated in drafting these guidelines. Each blood bank agreed to adhere to the same in every VBDCs.

A group of volunteers was given training about the guidelines associated with VBDCs. They were specifically trained to help prevent, identify and report any events of NC. Each VBDC under study was attended by one such volunteer from beginning through till the end of the camp. The volunteers were provided refresher training and skill building workshops periodically. A web portal was built systematically to capture the feedback for each VBDC and NC.

Licensed blood banks with permission to organize outdoor VBDCs, and keen to participate and comply with the minimum basic standard were invited to attend the camps. A total of seven government hospital-based blood banks, three private hospital based blood banks, and two voluntary standalone blood banks participated in the VBDCs included in the study.

Based upon the feedback from the past VBDCs and mutually agreed upon minimum basic standards of quality and safety, the parameters for NC were identified. One parameter each was identified to track whether sufficient number of bedding (pillow, cots, mattress, and sheets), refreshments and donor certificates on the equipments/consumables front. A parameter was identified to capture whether sufficient technicians came to attend the blood donation camps.^[3] For the starting and closing time of the camp, two timing and punctuality related parameters were identified to track deviation by half an hour or more. Four parameters were identified to track adherence to the donor selection criteria, one to track whether any donor was allowed to donate blood without hemoglobin (Hb) estimation, one to track whether the procedure used to determine Hb had a problem, one to track any mistakes which were identified for donor selection (apart from Hb estimation) and one to track whether Bombay blood group was excluded using H-antigen or not. Whether the donors were given 5 min rest post phlebotomy, whether the donors were shifted to resting beds immediately following their donation and whether the post donation reactions were promptly attended to or not were tracked on the post donation care front. Compliance related to safety and hygiene was tracked for wearing gloves and handling of biomedical waste.

Blood donation camps in which the volunteer captured insufficient data due to paucity of time to decide upon NC were to be excluded from the study. Out of the 424 camps, there were 10 such instances of exclusion.

For each camp, blood bank was sent an e-mail containing the details of the camp including the timings, and the number of beds to bring in advance. In response, the lists of staff members attending the camp and the materials to be brought by the blood bank were communicated by the blood banks. On the day of each

camp the performance of the blood bank was observed, recorded and shared through the feedback form. Any blood bank that refused to initiate corrective action in subsequent VBDCs was not invited for future camps.

Periodically the SIF and the blood bank met and reviewed the noncompliance (NC). Support to enhance compliance was offered to the blood banks by means of organizing training sessions, sharing of best practices between institutions and providing suggestions on corrective actions.

The data collected through the web application were analyzed using Microsoft Excel software.

Results

Out of the 414 VBDCs conducted between 1st January 2009 and 31st October 2013, NC was observed on one or more parameters in 301 (73%) camps. Table 1 shows the parameter wise NC. It was reported that 138 (33%) camps had 1 NC and 163 (40%) camps had 2 or more NCs as shown in Figure 1.

On studying the NC based upon blood bank type, voluntary standalone blood banks showed 62% NC versus 79% NC for government blood banks and 92.5% NC for private hospital based blood banks. The voluntary standalone blood banks were the most non compliant when it came to “fewer technicians” with NC of 8.5% versus 4.6% for government blood bank and 2.5% for private hospital based blood bank. They also showed remarkably higher NC of 10.2% for using “resting beds” (vs. 2-3% for others). Voluntary blood banks had low NC in Hb estimation (2.3%), and Hb estimation process error (1.7%) compared with other blood banks (6-10%). The government blood banks were more NC when it came to “time of closing camp” and “time of arrival/camp start”. They arrived late 43% of the time versus 22-26% for other blood banks. They also left early 4% of the time versus 2.5% for private blood banks and 0.6% for voluntary blood banks. The government blood banks were most NC for “pillows, cots, mattress, and sheets” with 12.8% NC versus 1% for voluntary blood banks and 5% for private blood banks. On other parameters (that included staff training) 15% NC was observed. The private hospital based blood banks were most noncompliant on all other parameters. They performed high NC associated with certificates (25%), gloves (22%), H-antigen screening (27.5%), time of arrival/camp start (22.5%), and others (25%).

The NC associated with various blood banks varies from 50% to 100%. The mean NC was 73%.

The number of blood units collected in each one of these camps was known for 391 camps. The mean collection was 77.3 units with a standard deviation of 42.5. Figure 2 shows the variation of NC with number of units collected, which shows that there is no trend associated.

The average number of NC incidence/camp is shown in Table 2. In the year 2009, 1.14 NC were recorded per camp. From the year 2010 to 2013, the rate of NC has steadily declined from 1.64 NC/camp to 1.36 NC/camp.

Table 1: Category wise NC report

Category	Parameter	Overall NC		Blood bank type wise NC			Details
		Instance of NC	NC %	Voluntary (177) %	Government (195) %	Private (40) %	
Equipment/ consumables	Pillows, cots, mattress and sheets	29	7	1	13	5	
Equipment/ consumables	Certificates	27	7	6	4	8	No donor certificates: 9 times No organiser certificates: 9 times Missed giving certificates to all donors/insufficient certificates: 9
Equipment/ consumables	Refreshment	21	5	1	8	25	Forgot refreshment: 2 times Insufficient refreshment: 19 times
Personnel	Less technicians	25	6	8	5	3	
Timing/ punctuality	Time of arrival/ camp start	139	34	26	43	23	
Timing/ punctuality	Time of closing camp	10	2	1	4	3	
Donor selection	Hb estimation	24	6	2	9	8	Skipped Hb estimation for no apparent reasons: 18 times Inadequate supplies to do Hb test: 4 times
Donor selection	Hb estimation process error	19	5	2	6	10	Wrong calibration: 5 times Squeezed finger to get blood drop: 7 times First drop used for Hb estimation: 8 times
Donor selection	Donor screening	34	8	3	11	28	Medical officer approved donors falling under deferral criteria (donation for pregnant woman, person <18 or >65 years of age, lactating mother, individual on active treatment for asthma, had surgery in last 4 months, had ear piercing in last 10 days, taken aspirin on day prior, had got tattoo in last 1-month, taken antibiotic in last 72 h, tooth extraction in last 1-month): 12 times Discriminated in donor selection (based upon gender): 2 times Postgraduate students having no prior experience at blood donation camps were sent as medical officers: 11 times Blood banks invited practicing doctors with no relation to blood banking: 4 times
Donor selection	H antigen screening	38	9	6	10	10	
Postdonation care	Rest	25	6	5	7	10	Insufficient rest given
Postdonation care	Resting beds	23	6	10	2	3	Asked donors to move immediately after donation
Postdonation care	Attending to postdonation reaction	18	4	6	3	8	Failed to attend to postdonation reaction
Safety and hygiene	Gloves	67	16	10	21	23	Did not wear gloves in spite of 1 reminder. Behavioral reasons not associated with shortage of supplies
Safety and hygiene	Hygiene issues	28	7	4	7	18	Spillage of blood on floor/working surface not cleaned: 11 times Stained cotton swabs disposed all over the floor: 8 times Stained bed sheets: 3 camps Left biomedical waste at camp site: 3 times Juice box full of cockroaches: 1 time
Others	Others	58	14	10	15	25	Staff skipped processes: 6 times Staff was inexperienced and inadequately trained: 15 times Unruly behaviour: 2 times Casual/careless attitude including prolonged usage of mobile phones: 11 times Inability to communicate with donor: 6 times Avoidable time wastage: 4 times Missing supplies other than those covered in other parameters: 8 times
	Total number of NC	585		62	79	93	

NC: Noncompliance, Hb: Hemoglobin

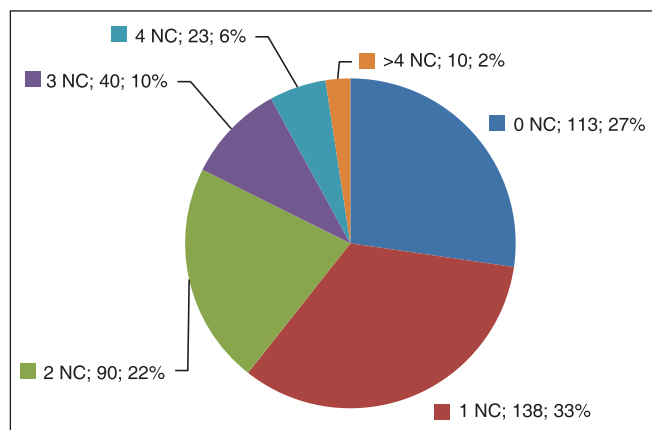


Figure 1: Frequency of noncompliance

Table 2: Change in NC over time

Year	Number of NC	Number of camps	NC/camp
2009	79	69	1.14
2010	105	64	1.64
2011	137	86	1.59
2012	110	78	1.41
2013	159	117	1.36

NC: Noncompliance

Discussion

Primum nonnocere (first, do no harm) is one of the principal precepts of medical ethics. The NC associated with donor selection, post donation care, safety and hygiene issue has direct implications on the donors and the patient's safety. Since the blood banking system of today relies upon the selfless and philanthropic act of the voluntary non-remunerative blood donors, it is a moral and social responsibility of the blood banks to strive to reduce any kind of discomfort or problem that the donor may be subjected to.^[4-7] Significant focus of WHO, NACO, AABB and Central Drugs Standard Control Organization has been to design and implement a stringent donor selection criteria both to ensure donor's and recipient's safety. Several studies have shown the anemia as the single largest cause of donor deferral with quantum of deferral ranging from 12.4% to 26%^[8-11] in India. NC associated with Hb estimation might lead to the person who is already anemic to donate blood and in effect increasing the severity of anemia. Our findings suggest gaps in the application of the quality and safety criteria in VBDCs. If the standards and protocols are not applied stringently, the intent and purpose of putting them in place is defeated, and it could have a serious impact on the safety and well-being of both the donor and the recipient.

Recruiting and retaining voluntary non-remunerative blood donors is cornerstone of a safe and adequate supply of blood in modern blood transfusion medicine. With the recent advances in information technology, internet and social networking and the success of the voluntary blood donor information, education, and communication programs, donors are becoming more aware of the rights and procedures. Any suspected lapses on the part of the blood banks are open to scrutiny by the donors who have knowledge and access to the guidelines and rules expected to be followed. It has been shown that 75% of the general population will advise friends and family when they have a bad experience

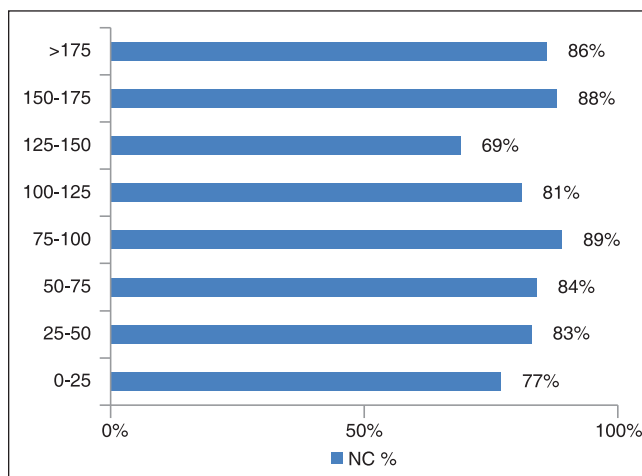


Figure 2: Relationship of noncompliance with total blood collection in camps

with a product or service.^[12] Poor commitment to punctuality, lack of adequate materials and equipment in blood donation camps and shortage of staff contribute towards making the blood donation experience less fulfilling. Blood donation being an altruistic, selfless act without any substantial benefits to the donor, any news of the threat to donor's safety or well-being could have severely damaging impact on the non-remunerative voluntary blood donation. When asked the reasons for not donating blood, 10% responded saying they were afraid of getting sick, and 6% indicated fear of getting infected^[13] highlighting the need for better safety, care and hygiene. Poor adherence to wearing gloves as stressed by WHO Guidelines on Hand Hygiene in Health Care^[14] and NACO guidelines for laboratory manual for technicians^[15] and lack of hygiene in the blood donation camp is un-acceptable to donors. Studies have shown the rate of adverse events/reactions to varying from 0.59% to 33%.^[16-19] Our study shows wide gaps in the post donation care being given to the donor. The high degree of NC could contribute to unpleasant experiences and has the potential of strengthening the misconceptions, increasing skepticism towards blood donation and deterring people from coming forward to donate blood voluntarily thereby derailing the blood donation movement as a whole. A direct consequence of NC was seen in with 4 (3.5%) out of 115 organizations refusing to conduct blood donation drives in the future because of several serious NCs/lapses on the part of the blood banks.

Our study shows that the private hospital-based blood banks to be most non compliant. They relied heavily upon in-house replacement blood donors for their blood-stocks and participated in VBDCs when they faced occasional shortages. They were found to be least responsive to any feedback. Their punctuality was comparable to that of standalone voluntary blood banks, and they did not make much use of resting beds. On all other parameters, they were on the higher side of NC when comparing the three type of blood banks.

While some government institutions were found to be receptive to feedback, there were others who were persistently non compliant. We observed vast difference between the NC for various government blood banks. Government blood banks had persistent NC when it came to timings, bedding and consumables, training needs of the staff and donor screening.

Voluntary standalone blood banks showed an overall NC of 62% while the government blood banks are showing an NC of 79% and private hospital-based blood banks showed an NC of 93%. We found voluntary standalone blood banks to be most receptive to feedback, and they initiated timely corrective action. These blood banks were most keen on attending blood donation camps, and they were most sensitive towards keeping the organizers satisfied with the quality and safety of drive execution. The voluntary blood banks had a greater focus on maximizing the blood collection with minimum manpower, and this reflected in them being most NC when it comes to bringing less technicians for the camps and the use of resting beds after donation.

The 1st year of the study shows NC reported to be 1.14/camp. This is the least in 5 years. The lower rate of NC in the 1st year could be attributed to the fact that the volunteers who were reporting NC were getting introduced to the process of effectively monitoring drives and not all methods to detect effectively NCs were well-understood by them. From 2nd year, more NC was observed with better understanding and reporting. Since the 3rd year, the NC has steadily declined from 1.64 NC/camp to 1.36 NC/camp. This shows that the program was effective in reducing instances of NC.

It should also be noted that H-antigen screening, Hb process errors and staff experience related issues were reported in the later 3 years. Yet the decline in the overall NC is seen.

Conclusion

Our study has done an assessment of NC in VBDCs. The extent and nature of NC are high and warrants for urgent attention. As seen by our study, this rate of NC can be decreased by regular monitoring and systematic and strategic intervention.

Blood policy states “rigid adherence to donor screening guidelines shall be enforced”. However, there is a complete absence of a mechanism to enforce and evaluate adherence. It is being assumed that the blood banks follow the right standards and practices in these camps. Our study shows that there is an urgent need to focus upon the quality and safety issues in VBDCs and set up structured and robust vigilance and surveillance systems.

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