

Editorial

Repeat voluntary non-remunerated blood donor is the best quality indicator for blood safety

The landmark judgement in 1996 by the Supreme Court of India in the “Common cause versus Union of India”, brought to the fore, the then predominant practice of blood donation by professional donors, the risks associated with transfusion transmitted infections (TTE), and the basic consideration of high haemoglobin level¹. It was this verdict that directed the government to improve the blood transfusion service and resulted in the Government through National AIDS Control Organization (NACO) establishing the National and State Blood Transfusion Councils (NBTC/SBTC) to develop policies and programmes for bringing about improvements in blood banks. In 1997, HIV counselling and testing services were started in India. In 2001, testing of blood for hepatitis C virus (HCV) antibodies was made mandatory². In 2002, the WHO Guidelines on the Clinical Use of Blood was adopted by NACO. In 2003, the Government of India framed and adopted the National Blood Policy (NBP)³. This also brought about a sea change in the activities related to regulation, licensing and operations of blood banks, with the NACO and the office of the Drugs Controller General of India (DCGI) working in tandem to review and amend the Drugs and Cosmetics Act of 1940 to incorporate various provisions that brought blood banking practice under more stringent oversight. The greatest impact of the judgement besides introducing mandatory licensing of all blood banks was the banning of professional donors and the directions to the Government to promote voluntary blood donors in the country⁴.

Replacement donors

The anticipated gap in the blood supply after the change in approach of sourcing blood from voluntary

blood donors was sought to be overcome by coopting replacement donors, comprising relatives and friends of patients. However, the mandate of the authorities was to encourage and motivate these replacement donors to become voluntary blood donors. Although this was a good beginning, the definition leaves a large breach that is still utilized by present day professional donors who donate under the guise of friends or relatives of the patient, a circumstance that cannot be verified by the blood bank staff. Hence the potential for misuse of the system still exists, although the magnitude has significantly reduced. The emphasis has now rightly moved from merely depending on replacement blood donors to voluntary blood donations. Voluntary non-remunerated blood donor (VNRBD) means that a person gives blood, plasma or cellular components with his/her own free will and receives no payment for it, either in the form of cash, or in kind which could be considered a substitute for money. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary non-remunerated donation⁵.

According to blood banks that reported in the computerized Management Information System of NACO in 2012-2013, the percentage of voluntary donors was 73 per cent (34% from voluntary donation in blood banks, 39 % from voluntary donation in camps) and a significant 27 per cent was from replacement donations in blood banks. The NACO supported blood banks recorded a higher proportion of voluntary blood donation. The total blood units collected per 100,000 populations for the country were 587.3 units in 2012-2013⁶. This is the result of the sustained effort by the regulatory and statutory

bodies working with non-governmental organizations to improve the status. The effort requires much more inputs in terms of strategic planning, management framework, trained human resources and funding to realize. The Melbourne Declaration of 2009 stated the fact that “regular VNRBD forms the cornerstone of a safe and sustainable supply of blood and blood products and therefore envisions all national blood systems to be sourcing 100 per cent blood from such donors by the year 2020”⁵. This declaration also encompasses the realization that blood and its components cannot be considered as mere commodities, rather as the result of conscious decisions of healthy and socially committed people⁵.

The National AIDS Control Organization (NACO)

NACO is the primary organization that is responsible for blood safety in the country. Currently 1,137 of a total of 2,760 licensed blood banks in the country are designated NACO supported^{6,7}. The support varies from provision of equipment to ongoing supply of reagents and/or blood bags and in some blood banks, the recruitment of technical staff. Ongoing training of all levels of staff and quality assurance in TTI screening is also ensured by NACO. All blood banks are to submit monthly detailed and summary data via internet based systems to NACO.

The National Blood Policy

Among the eight stated objectives of the National Blood Policy (2003), the fourth one deals exclusively with the issue of blood donors with various strategies suggested towards increasing VNRBD. Objective 4.1.2 specifies the intent to encourage replacement donors into regular voluntary blood donors. The Policy has been followed by an action plan that seeks to provide specific guidance for implementation of the policies. Although significant progress has been made since 1996, there is much to be done especially with regard to VNRBD promotion.

The National AIDS Control Programme (NACP)

The issue of blood safety has been until now addressed by NACO in the perspective of AIDS control. In that context, the previous National AIDS Control Programme (NACP I – III) formed the major framework under which blood safety was addressed. Each of the three phases of the National AIDS Control Programme in India focused on and emphasized, blood safety in the country⁸. The NACP paved way for revamping the blood collection, processing, and storage

and distribution system in the country. National and State Blood Transfusion Councils were established; relevant policies were formulated, and guidelines were developed covering all aspects of blood donation, testing and storage. Under the NACP initiatives were taken and funds provided to States to modernize existing blood banks and Zonal Blood Testing Centers were set up. Professional blood donation was banned. Component separation units were set up in very large blood banks to address the increasing demand for safe blood. In the current plan, NACP IV (2012- 2017), it is intended that more than 50 per cent of all the blood banks in the country become NACO supported, that 90 per cent of the collected blood be through NACO supported blood banks and that 95 per cent of blood donations in NACO supported blood banks be sourced from VNRBD⁹.

Why VNRBD?

It is believed that repeat VNRBD are a safe group¹⁰. It is also a known fact that positivity rates for viral infections and syphilis were less among VNRBD than replacement donors. From the data reported by all blood banks to NACO in 2012-2013, two thirds were from voluntary blood donors, half of which was from donations at camps⁶. However, among NACO supported blood banks, more than 80 per cent was from voluntary blood donors with two thirds sourced through camps. The positivity rate for HIV in blood sourced from voluntary donors was consistently lower ranging from 0.22-0.17 per cent for the period 2010 to 2013 whereas it ranged from 0.23 to 0.25 per cent among replacement donors over the same time period⁶. A similar pattern was also observed for hepatitis B with 1.06 to 0.95 per cent donations positive among voluntary donors and 1.14 to 1.06 per cent among replacement donations. Similar trends were seen among other markers for hepatitis C and venereal disease testing laboratory (VDRL) for syphilis⁶. There are other imputed benefits that have been reported among regular blood donors including reduced total body iron, improved insulin sensitivity and improved cardiovascular function that have not been uniformly substantiated¹¹.

Responsibility of national programmes and way forward

Based on the 2012 Consensus Declaration of WHO¹² there are 12 recommendations that national health authorities need to act on to ensure self-sufficiency of blood supply based on VNRBD. While India has

gone a long way towards addressing these through the activities of the Blood Safety Division under the National AIDS Control Organization, it is now time to review the current status of VNRBD and streamline the efforts between private and public sectors to move towards achieving targets we have set for ourselves. The responsibility of achieving the desired goal cannot be left to government alone. It is the responsibility of civil society and the health care fraternity as well. It is not legislation or regulatory fiat that will bring about a change in the number of regular VNRBD. Nor is it the sole responsibility of the blood bank. Rather, the need is for a sustained grass roots level movement - with all concerned groups including the healthcare team being involved in a concerted effort, both in exemplary action (by being regular VNRBD themselves) and persevering in making others also see the light. Siromani *et al*¹³ have studied the attitudes of donors and non-donors at a tertiary care hospital in India. The most frequent among the reasons elucidated from persons who have not donated was that they were not asked (67%)¹³.

The Corporate Sector has a crucial role to play in achieving this goal through providing support in terms of manpower and expertise in creating and conducting sustained media campaigns to encourage the public to become regular VNRBD. Most plans and programmes are implemented with numerical targets to be achieved. However, this may be a double edged sword as far as an issue like blood donation/motivation is concerned with social and ethical implications. It might lead to at best, wastage of blood due to overzealous blood drives and at worst, coercion to donate blood leading to serious compromise of safety of the blood donors themselves or recipients.

There are some actionable points that we wish to leave for consideration on the occasion of the World Blood Donor Day:

(i) When a member of the medical team sends a potential replacement donor to a blood bank, the donor should also be informed about the benefits of voluntary donation and encouraged to become one. In our society there is a hierarchical perception of the medical team with the doctor at the apex, nothing will impress the potential donor more than a specific instruction from the treating clinician.

(ii) The responsibility of the blood bank will be to build on this initial step. It begins by making the

donation experience a pleasantly efficient one. While the donor is in the blood bank and undergoing the process of screening and phlebotomy, simple, courteous and respectful interaction by the staff will go a long way towards making this a reality. The follow through with a note of thanks, to show that the act was appreciated is recommended and a gentle reminder when it is time for the next donation.

(iii) It is essential to maintain a local database of consenting donors who need to be reminded about when they are eligible to donate the next time. With technology such as short messaging service (SMS) and email, this should become a less onerous task that it may have been in the past.

(iv) Involvement of social organizations is an important component that needs to be kept in mind.

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