Original Article

Importance of periodic review of protocols for transfusion transmitted infection sero-reactive blood donor notification- a study in a tertiary care hospital in South India

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Abstract:

Introduction: *Blood donors found reactive for Transfusion Transmitted Infections (TTIs) on screening tests, must be notified and counselled about confirmation of the results, future management and donation. To ensure blood safety, all protocols for the same must be regularly revised and updated in accordance with available resources.* ***Objective:*** *To highlight the importance of reviewing existing protocols periodically, so as to identify, analyse and address challenges faced while notifying TTI reactive donors.* ***Materials and Methods:*** *From records maintained at the blood bank of sero-reactive donors, details of each viral TTI-reactive donor between March 2016 and May 2019 were collected. Initial notification protocol- telephonically contact sero-reactive donors only once. It had been modified on January 2019. New protocol- attempt telephonic communication up to three times until the donor is notified, failing which written information to be sent by post or electronic mail. The same parameters were analysed between January and May 2019 and compared with the pre-modification data (March 2016-December 2018) to note any improvement in donor response.* ***Results:*** *Initial Protocol: Total donors 39,602, 497 donors were sero-reactive: HIV 72, HCV 138 and HBV 287, 213 of them were contacted (HIV 40, HCV 54 and HBV 119) and 57 of them returned for follow-up (HIV 14, HCV 15 and HBV 28). The main reason for inability to contact donors was wrong/ invalid contact information. After modification of the notification protocol: Total donors 5316, 67 were sero-reactive (HIV 9, HCV 26 and HBV 32), 40 of them were successfully informed (HIV 6, HCV 19 and HBV 15) and 16 (HIV 4, HCV 7 and HBV 5) returned for counselling.* ***Conclusion:*** *Regular review of donor notification data and modification of notification protocols help identify and address lacunae. This ensures maximum donor recall, proper follow-up and safety of the donors and that of any potential recipients of their blood components and/or products.*

Keywords : ● *Donor recall* ● *Notification* ● *Sero-reactive* ● *Transfusion-transmitted infection (TTIs)*

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Introduction

In order to supply safe blood to patients, the World Health Organization (WHO) has recommended testing of all donated blood for transfusion transmitted infections (TTIs) like human immunodeficiency virus (HIV- I and II), hepatitis B (HBV), hepatitis C virus (HCV) and syphilis. The Drug and Cosmetics Act, 1945 has additionally recommended testing all donor units for malaria. The National AIDS Control Organization (NACO) suggests the use of 3rd and 4th Generation Enzyme Linked Immunosorbent Assay (ELISA) testing kits with 100% efficiency. While this helps ensure safety for recipients, transfusion services must also concern themselves with donor safety. In India, transfusion services are advocated by the National Blood Policy 2002, to obtain written consent at the time of counselling from donors for screening their blood for TTIs and to communicate sero-positive status, if detected, to donors who consent. These donors are then required to be sent to Voluntary Counseling and Testing Centre for further management.[1] It is also pertinent to have donor follow-up and re-inclusion guidelines. A confirmatory test is an essential part of any "look-back" programme. Donor deferral and follow-up are guided by the results of the confirmatory test.[2] Notification and counselling protocols are usually optimised and implemented by transfusion services as per their available resources. This is essential to ensure early clinical intervention in the donors and reduce the risk to sexual partners and prospective recipients.[3] However, regular review of protocols is a must to identify and address the challenges faced while attempting to notify donors or to introduce modifications at par with availability of resources[4]. Any changes made to an existing protocol should be further evaluated for feasibility and efficacy, and so on. This should be the first step in a continuous process to ensure maximum donor notification, recall and ultimately improve blood safety.

The challenges faced while notifying and counselling sero-reactive donors are specific to every transfusion service and solutions to those issues are usually formulated in accordance with available resources. This study focused on the notification part of the process and highlighted the importance of regularly reviewing donor notification protocols with respect to identifying such challenges. The institutional approach to addressing these problems under the purview and infrastructural setting of the centre has also been highlighted. Besides providing an overview of the measures taken by a moderately resource limited tertiary care facility to ensure blood safety while minimising the risk of donor anxiety, the uniqueness of this study is that it highlights the dynamic nature of the process of donor notification and counselling, by evaluating one cycle of review-improve-evaluate, spanning a period of over 3 years.

The efficacy of the initial protocol that was in place at the blood bank was evaluated over about 3 years, and it was identified that there was scope for modifications in it. The protocol was modified and the efficacy of the modified protocol was studied as well, over a short period of 5 months to detect any improvements in donor response rates.

Materials and Methods

This is a retrospective descriptive study focusing on donor notification only, done over a period of 39 months (March 2016 to May 2019) in the blood bank of a tertiary care centre in South India. The donor questionnaire used at the blood bank requires donors to provide written consent to be informed of the results of their TTI screening, if found reactive. Mandatory viral TTI screening is performed by chemiluminescence assay on all collected donor units. The results of the reactive units are verified by running the chemiluminescence test in duplicate and by another mode of testing- Enzyme Linked Immunosorbent Assay (ELISA). The latter service is provided by the Department of Microbiology of the institution. The concerned sero-reactive units are discarded and the donor is notified accordingly. Separate records are maintained for all donors who have tested reactive for

one or more TTIs. They contain demographic details of donors, type of donor, date of collection and testing, which TTI he or she is reactive for the optical density value as provided by the chemiluminescence test, results of the ELISA test (if done), donor notification status and donor counselling status. The donors are required to sign a designated column in the register after they have been counselled and referred to the suitable authorities for further management.

As per the original protocol, it was attempted to telephonically contact sero-reactive donors only once and documented as informed or not informed and reason, if the attempt was unsuccessful. This was modified in January 2019. All donors were contacted telephonically by the blood bank officer up to three times until they answered. The date and time for all calls were recorded in the aforementioned register. If the donor was unavailable even after 3 calls, it was proposed to send them written communication by post or electronically, depending on the contact information provided by the donor while filling the questionnaire. They were informed of their sero-reactive status and requested to return for counselling and repeat testing. This was a modification of an approach described in previous literature.[3,5]

These records were used to document all the above mentioned parameters over the 39 months as a whole and segregated into "pre" and "post"- modification of protocols. The data was analysed month and year-wise according to number of donors notified, reason for non-notification and whether the donor returned for counselling, for all the viral TTIs. All data were compiled and analysed in Microsoft Excel 2010.

Results

A total of 44,918 donors donated and were screened over these 39 months as part of routine pre-transfusion screening. All of them had consented to being informed of the results of TTI screening and hence it was attempted to contact sero-reactive donors telephonically. Five hundred and sixty four donors were found to be sero-reactive for the viral TTIs- HIV 81 (0.18%), HCV 164 (0.36%) and HBV 319 (0.71%). Two hundred and fifty three of them were contacted (44.8% of all seroreactives)- HIV 46, HCV 73 and HBV 134 (56.7%, 44.5% and 42% of respective individual sero-reactives). Seventy three donors returned for further follow-up; HIV 18, HCV 22 and HBV 33 (22.2%, 13.4% and 10.3% of respective individual sero-reactives). The three hundred and eleven donors who could not be contacted had provided wrong and/or invalid contact information.

Since modifying the protocol in January 2019, 67 out of the 5,316 donors who donated were found to be sero-reactive up to 31st May 2019 (HIV 9, HCV 26 and HBV 32). Forty of them were successfully notified (HIV 6, HCV 19 and HBV 15) and 16 of them (HIV 4, HCV 7 and HBV 5) availed counselling. The 27 donors who could not be notified telephonically had not provided their e-mail IDs and the postal addresses provided were also incompleted. Of the 40 donors that were successfully contacted, 24 responded on the first call while the other 10 and 6 responded to the 2nd and 3rd calls, respectively.

The data has been tabulated in Table 1, divided according to before and after modification of notification protocol.

Discussion

It is of prime importance to address sero-reactivity of TTIs in a cautious and systematic manner, not only to ensure blood safety for the recipients, but also for the sake of the donor's health and that of any sexual partners and future blood component recipients. However, the process of notifying donors who have been labelled sero-reactive is always precarious. On one hand, protocols and testing platforms should be chosen so as to ensure identification of all sero-reactive samples to ensure blood safety. On the other hand, if donors are notified on the basis of false positive results, it can lead to unnecessary emotional anxiety[6], and cause them to be discouraged to donate in the future and increase wastage of units. Therefore, protocols for donor notification, confirmation,

Table 1 Viral TTI sero-reactivity, notification and counselling status in whole blood donors

		March 2016-December 2018 (Initial protocol)	January 2019- May 2019 (After modification of protocol)
Total donors screened		39,602	5,316
Percentage of TTI reactive donors	HIV	0.18	0.16
	HCV	0.34	0.48
	HBV	0.72	0.6
Donors notified as percentage of donors reactive for specific TTI	HIV	55.5	66.6
	HCV	39	73
	HBV	41.4	42.8
Counselled donors as percentage of donors reactive for specific TTI	HIV	19.4	44.4
	HCV	10.8	26.9
	HBV	9.7	15.6

The cumulative data has been divided into before and after modification of notification protocol

deferral and possible re-inclusion as a donor are usually carefully standardised by transfusion services under the purview of guidelines provided by sources like WHO, NACO, and National Blood Policy, etc.

For blood safety, the NACO recommendation is to perform only one test of high sensitivity. If the donor is to be notified, the recommended strategy is to use one more test (ELISA or rapid) on samples testing positive by the first modality and report the donor to be sero-reactive / non-reactive if the 2nd test is positive or negative, respectively.[7]

In this tertiary care institution, mandatory viral TTI screening is performed on all collected donor units by chemiluminescence. All those units found to be reactive are further tested in duplicate and by another mode of testing (ELISA) as provided by the Department of Microbiology of the institution. This helps provide an additional layer of safety to rule out false positives and errors due to technical reasons. Two-step serological assays have been recommended in literature previously, as a means to reducing discard rates and donor anxiety due to false positives.[8] But while this approach also helps reduce false negative rates, especially in early stages of infection, a risk of higher rates of false positives, has been reported with the use of serial rapid diagnostic kits.[9]

Once a scientifically sound protocol is in place, it is vital to put it through a continuous process of assessment. The sequence of such an assessment usually is evaluation, analysis, problem identification, modification to address the problem and re-evaluation of the modification made. This cycle is to be repeated to ensure optimum utilisation of institutional facilities towards ensuring blood safety, while keeping abreast of factors that also have a bearing on blood safety, such as donors' awareness of TTIs.

In this present cycle of assessment, those stages were as follows:

Evaluation and analysis of the existing protocol showed

- A donor notification percentage of 44.8%, and only about one-fifth of all sero-reactive donors had actually availed counselling.

- A few donors who could not be notified, unfortunately did not provide e-mail addresses or complete postal addresses.

Identification of the lacunae

- The most common reason for not being able to notify the donors was wrong or unreachable contact numbers, especially in case of out-of-state donors.

Addressing the lacunae

- The protocol was modified to include attempting telephonic communication up to three times. The reasoning was that by increasing the number of attempts, the probability of actually reaching the donors increases.[10] This was inspired by an approach mentioned in previous literature.[3,5,11]

- The staff involved in donor counselling were trained to stress on the importance of availing counselling if found sero-reactive and to ensure the donors provided complete postal addresses and/or email addresses during screening.

Reanalysis

- The effects of the modification were assessed over the next 5 months. While the detected rate of seroreactivity of viral TTIs among donors was found to be comparable, the percentage of donors notified and subsequently that of donors returning for counselling were found to have improved after modification of the protocol as shown in Figure 1.

It was also interesting to note that out of the 40 donors notified after modifying the protocol, 16 donors responded after > 1 attempts. It would not be possible to notify them if the attempt to contact them had been made only once. Under the modified protocol, there was also a means of notifying donors in writing by post or e-mail, which would be particularly helpful for out-of-town donors with unreachable phone numbers.

It is important to re-iterate that the modifications would not be implemented if a review of efficacy of the existing protocol would not have been done first. Also, since the modified protocol has shown a rise in notification and counselling rates, as reflected in the re-evaluation, it was concluded that this approach can continue to be implemented under regular review, at least for the time being.

The initial response rate of donors in this study was found to be low, as has been seen widely in literature. This can be attributed to poor knowledge of TTI spread and transmission.[12,13] While the improved

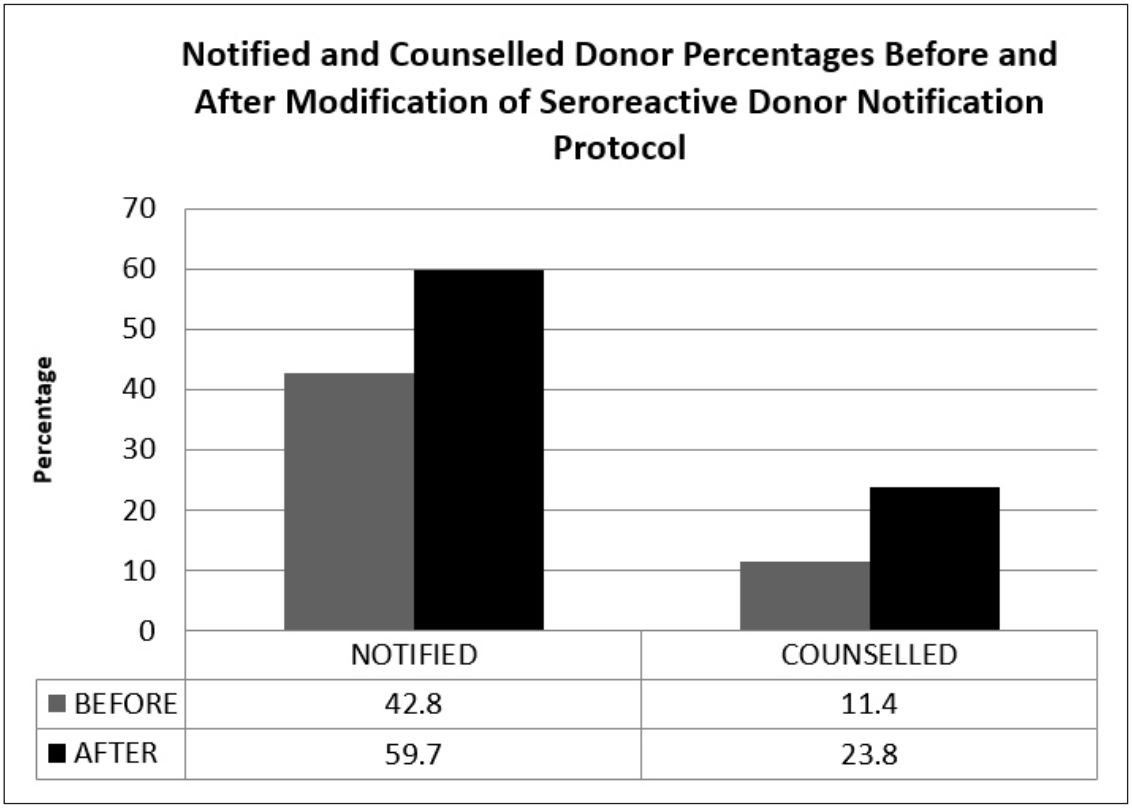

Figure 1 Donor notification and counselling percentages before (March 2016-December 2018) and after modification of notification protocol (January 2019-May 2019) showing improvement in both parameters

approach of attempting communication with the donors may have been responsible for the increased notification rates, the increase in the number of donors returning for counselling can be attributed to the staff training. Special training sessions were conducted for the staff highlighting the basics of the TTIs, their mode of spread, detection at the blood centres and the role of donor history and counselling in ensuring blood safety. They had been instructed and trained to interview donors carefully about any suggestive history and to stress to the donors that it is important to provide correct history and contact information and to avail counselling if found sero-reactive. Proper donor interview during screening has also been found to be of immense help in increasing general donor awareness about the spread and implication of TTIs to donors themselves and any potential recipients.[11,14,15] Therefore, proper staff training and subsequent proper pre-donation interview are of prime importance in reducing the gap between donors being notified and those actually availing counselling.

Since the prevalence of sero-reactivity in donors as per this study has remained steady at a mere 1.2% during the study period, continued monitoring of the revised protocol will be required to conclusively determine the efficacy of the modified protocol in terms of time and sample size. More studies are also required to provide a more focused approach in determining factors affecting donor response (eg. literacy rate, ignorance about spread of TTIs).[16] Studies pertaining to donor counselling are also advisable to assess donor reaction, perception and attitude towards the information provided and the way it was communicated.[17] They can also provide valuable feedbacks about the notification and counselling system. This, in turn, will provide important information about how to ensure maximum donor notification and response.

Conclusion

To ensure safe blood components, transfusion services must have proper protocols in place for confirming, notifying, counselling and deferring donors deemed sero-reactive for TTIs. It is also important to regularly review the efficacy of such protocols to address the challenges faced and modify them in accordance with available resources. Proper staff training to conduct effective pre-donation interviews is also key in ensuring blood safety.

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References

1. *Kaur G, Kaur P, Basu S, Kaur R, Sharma S. Donor notification and counseling- experience and challenges. Transfus Apher Sci. 2013;49:291-4.*
2. *World Health Organization. Screening donated blood for transfusion-transmissible infections. Recommendations. Geneva: World Health Organization; 2009. p. 50-54. Available from: https://www.who.int/bloodsafety/ScreeningTTI.pdf*
3. *Kotwal U, Doda V, Arora S, Bhardwaj S. Blood donor notification and counselling- our experience from a tertiary care hospital in India. Asian J Transfus Sci. 2015;9:18-22.*
4. *Miller D, Kalibala S, Anderson S, Emmanuel J, Petitgirard A. Blood donor counselling for HIV: results of a multi-country feasibility study. Public Health. 1994;108:219-26.*
5. *Kaur D, Pahuja S, Jain M, Khaspuria R. Donor notification: Streamlining the existing enigmatic process: an experience from a tertiary care hospital in Central Delhi, India. Transfus Apher Sci. 2015;53:173-5.*
6. *Delage G, Myhal G, Grégoire Y, Simmons-Coley GM. Donors' psychological reactions to deferral following false-positive screening test results. Vox Sang. 2014;107:132-9.*
7. *National AIDS Control Organization. National guidelines for HIV testing. New Delhi: National AIDS Control Organization; 2015. Available from : naco.gov.in/sites/default/files/National_Guidelines_for_HIV_Testing_21Apr2016.pdf*
8. *Stoyanov E, Gozlan Y, Wax M, Levin E, Shvatz L, Shinar E, et al. HIV-1/2 screening in blood centers: implementing a two-step serological screening assay approach to reduce donor deferral. Transfusion. 2019;59:2054-60.*
9. *Baveewo S, Kamya MR, Mayanja-Kizza H, Fatch R, Bangsberg DR, Coates T, et al. Potential for false positive HIV test results with the serial rapid HIV testing algorithm. BMC Res Notes. 2012;5:154.*
10. *Porto-Ferreira FA, de Almeida-Neto C, Murphy EL, Montebello SC, Nogueira FA, Koga da Silva EM, MacFarland W, Custer B. A randomized trial to evaluate the use of text messaging, letter, and telephone call reminders to improve return of blood donors with reactive serologic tests. Transfusion. 2017;57:102-7.*

11. *Kleinman S, Wang B, Wu Y, Glynn SA, Williams A, Nass C, et al. The Donor Notification process from the donor's perspective. Transfusion. 2004;44:658-66.*
12. *Roshan TM, Rosline H, Ahmed SA, Rapiaah M, Khattak MN. Response rate of Malaysian blood donors with reactive screening test to transfusion medicine unit calls. Southeast Asian J Trop Med Public Health. 2009;40:1315-21.*
13. *Agarwal N. Response rate of blood donors in the Uttarakhand region of India after notification of reactive test results on their blood samples. Blood Transfus. 2014;12(Suppl 1):s51-3.*
14. *Chaurasia R, Zaman S, Das B, Chatterjee K. Screening donated blood for transfusion transmitted infections by serology along with NAT and response rate to notification of reactive results: an Indian experience. J Blood Transfus. 2014;2014:412105. doi: 10.1155/2014/412105.*
15. *Sachdev S, Mittal K, Patidar G, Marwaha N, Sharma RR, Duseja AK, et al. Risk factors for transfusion transmissible infections elicited on post donation counselling in blood donors: need to strengthen pre-donation counselling. Indian J Hematol Blood Transfus. 2015;31:378-84.*
16. *Raza N, Qureshi H, Qureshi A. Reactive donor notification; their responses and perceptions: experience from Southern Pakistan. J Ayub Med Coll Abbottabad. 2018;30:351-55.*
17. *Reynolds CA, Brailsford SR, Hewitt PE. Notifying blood donors of infection: results of a donor satisfaction survey. Transfus Med. 2015;25:358-65.*