

Peer Review File

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Reviewer comments

Reviewer A

The current manuscript describes a study about determinants of donor re-activation after false positive test results. This is a very interesting topic as false positive test results can occur regularly and everywhere and both blood centers and donors need to learn how to deal with this.

Most importantly however, such a study aim would require a focus on knowledge, motivation and attitudes by (deferred) donors and communication procedures by blood centers and donor physicians in bringing over information about the meaning of false positive tests results for donor and patient health, so far completely lacking from the study and analysis.

Comment 1: The abstract in its current form is not so informative. It should state the exact aim more clearly and shortly mention the study population. The results are partly very vague and partly too detailed. Try to give main results, such that e.g., occupation played a role as did difference between first and repeat donor. Try to end with a more general concluding remark.

Reply 1: Detailed revisions have been made to the abstract. The exact aim of this study is to enable more deferred blood donors to participate in blood donation again and explicitly state that purpose in the BACKGROUND. The study population is re-entered blood donors and covered in the method. The results are sorted out again.

Changes in the text: We have modified our text as advised (see Page 2, line 24-42).

Comment 2: Introduction: The study mainly describes testing strategies and testing results of reactive and non-reactive donations. However, the main goal is to better understand and predict return behaviour of deferred donors, due to false positive test results.

For such a study embedding in behavioral theories and literature is important. Donors are human beings that have to understand and process complex medical and biological information, together with worry and anxiety about their own infectious status. In addition, as identified by the authors, occupation and education, together with other demographic background characteristics and time to return may play a very important role in the re-entry decision making process. However, it remains completely illusive how and why this might be the case.

If the authors wish to shed more light on the re-recruitment of previously deferred donors and offer implication for successful reactivation, they also need to provide information about procedures, communication strategies by the blood center.

Reply 2: The information about procedures, communication strategies by the blood center will be provided in Materials and methods.

Changes in the text: We have modified our text as advised (see Page 5, line 121-125).

Comment 3: The structure of the introduction could be improved by first making clearer what the background and main aim are of the study are. Then describe empirical studies on similar topics, including information about donor motivation after deferral, return behaviour and knowledge about donor and patient safety. Make one paragraph about the Chinese situation and describe why it is similar or different to other study settings. This paragraph should also mention what the guidelines and standard procedures are for donors who were deferred for a reactive test that later appeared to be false positive. Also, very important, describe how the communication with and counseling of these donors happens. This might be among the most important factors determining successful re-entry. To my opinion, it is not possible to properly embed this study and interpret the results without knowing how this process goes.

Reply 3: The structure of the introduction has been adjusted according to the opinion of the reviewer. The first paragraph clarifies the research background. The empirical studies on similar topics are described in lines 76-81. The guidelines and standard procedures are for donors who were deferred for a reactive test are described in lines 64-69. The Chinese situation and details why it is similar or different to other study settings are described in lines 69-76. The details about how the communication with and counseling of these donors happens are described in the method.

Changes in the text: We have modified our text as advised (see Page 3, line 50-88).

Comment 4: Was the study cleared by an ethics or institutional review board?

Reply 4: This study was reviewed by Ethics Committee of Chongqing Blood Center in April 2016. Informed consent was provided by all patients participating in this study. And its described in the Ethics statement.

Changes in the text: We have modified our text as advised (see Page 4, line 106-107).

Comment 5: The methods section is unbalanced in my view in the sense that it gives ample information about the testing strategies and results, the validation tests and the procedure of possible return of deferred donors after a certain time period. Yet, the most important information here, namely about donors' donation history, donor communication, donor attitudes and knowledge is lacking.

Reply 5: This paper only studied the factors affecting the re-entry and donation again for deferred blood donors, but did not study the factors that affected whether blood donors participated in the re-entry programme. Therefore, donors' donation history, donor communication, attitudes and knowledge are lacking in the text. On the other hand, all the relevant factors in this paper were obtained from the information system without questionnaire survey, so these information could not be known.

Comment 6: What is the total number of eligible donors and how come that 844 participated of how many in total? This is a selection bias and it would be informative to know how many former donors did not participate and what their characteristics are.

Also, how exactly were these donors approached and what (new) information was shared with them.

Reply 6: The deferred blood donors from January 2017 to December 2019 who met the Guideline for reentry of reactive blood donors in blood screening test are 4643. Only 844 of the donors contacted the blood center after receiving the text message and volunteered to participate in the re-entry programme and then became study subjects. The paper mainly studies the factors that affect the success of blood donors' re-enter, so it does not analyze the characteristics of blood donors who did not participate in re-entry programme.

Changes in the text: We have modified our text as advised (see Page 5, line 126-128).

Comment 7: What are the guidelines for re-entry? Describe the program not only in terms testing strategy and deferral periods but more so in how donors are informed, whether they understand what has happened, what this means for their own health and donor status etc. Also, I wonder whether donors are confused about the first positive later negative test and really fully understand. As they have been deferred permanently first, how are they then approached, reached and informed and recruited again. This is quite complex information for them to process.

Reply 7: In the participants and sample collection, we added the content how donors are informed, whether they understand what has happened, what this means for their own health and donor status etc. If these deferred donors are confused about the first positive, they will call or go to the blood donation site for consultation, and the staff will inform their own health and donor status and provide professional explanation and medical advice to the them, and finally inform them whether and how they can participate in the re-entry programme.

Changes in the text: We have modified our text as advised (see Page 5, line 166-169).

Comment 8: All the variables that are entered in analyses need to be described in the method section, together with the answer categories. Especially, the following variables might not be familiar to all readers: times of blood donations after returning to the team, interval of participation in the returning team since the unqualified test. Hence, these concepts need explanation, maybe they are not the right translation/terminology, or they need a proper definition. It also remains unclear whether the study data was retrieved from a donor registry, from the participants themselves (survey, interview) and how it was processed.

Reply 8: Interval of participation in the returning team since the unqualified test means the time between the first test failure and participation in the re-entry programme. The study data are from blood donor registration in the blood center information system.

Changes in the text: We have modified our text as advised (see Page 6, line 177-181).

Comment 9: Results: The empirical part seems not sound as it is hard to follow what exactly has been done. I wondered why the authors do not want to share the data and code? This would be very helpful as the exact way of how the analyses have been

conducted is not totally clear to me.

Reply 9: I am very sorry that the research data involves the privacy of blood donors. According to the relevant regulations of Chongqing Blood Center on the privacy of blood donors, the original data should not be disclosed. If possible, I can provide evidence of the whole analysis.

Comment 10: Language editing if possible, by native speaker would improve the readability of the paper.

Reply 10: We have asked native speakers to help fix the language problems to improve the readability of the article.

Changes in the text: We have revised the language of the full text.

Comment 11: Also, I would be curious whether donors who have reactive tests, even though they appear false positive, have higher likelihood of reactive tests again. They then would need to be clearly informed about their health status as non-infected but the inability to donate because of reoccurring false positive results.

Reply 11: The donors who have reactive tests, even though they appear false positive, have higher likelihood of reactive tests again. According to Chinese regulations, if a blood donor has two false positives, the donor will be clearly informed about their health status as non-infected but the inability to donate because of reoccurring false positive results.

Reviewer B

General: This is a blood center based study looking at the policy to allow donor re-entry for donors that have tested positive during a previous donation attempt in China. Overall, this is an interesting paper and provides country level description of the success of the reentry program by assessing the demographics of those donors that re-entered successfully and those that did not. The authors need to improve on English grammar. There are several areas in the paper where it's not clear which part of the testing and re-qualification process they are describing and other specific items that need revision. The paper needs additional English language polishing for syntax. See specific comments.

Comment 1: Line 20: "Certain errors in detection..." This would more accurately be described as false positives, which can occur due to the low prevalence of disease in the population.

Reply 1: According to the opinion of A reviewer, the content of the abstract was sorted out and the word was deleted.

Changes in the text: "Certain errors in detection..." has been deleted.

Comment 2: Line 24 and throughout: This reviewer is not used to the term "on the team" or "donation team" although I do understand what the authors mean, and it is an endearing term to describe donors. I am ok with it, but other reviewers may find it too

colloquial.

Reply 2: We have corrected the “on the team” and “donation team” in the text.

Changes in the text: We have corrected the “on the team” and “donation team” in Line 24 and throughout.

Comment 3: Line 27: should “returning” donors be “re-entered donors”? This is important sometimes the description of the process (what happens first, then next, then after that) is not super clear in the paper. I would use precise language throughout. In the USA, we refer to it as “re-entry” to describe the process of trying to bring a donor who has tested positive to attempt to be re-tested. This is noted again on line 32.

Reply 3: We have changed the word "returning blood donors" to "re-entered donors" in the paper.

Changes in the text: We have changed all "returning blood donors" to "re-entered donors".

Comment 4: Line 32 – 34: The first few lines of the results focus on occupation, maybe overly so. Consider going back to the age and more general demographics, and discuss occupation on briefly (not all of the results need to go into the abstract).

Reply 4: We have simplified the results in the abstract. The results show that the factors affecting the success of deferred donors returning to the team include occupation, the intervals between the first reactive result and the qualification tests for re-entry, reactive items and donor status.

Changes in the text: We have modified our text as advised (see Page 2, line 36-39).

Comment 5: Line 35: Add “The” before “Factors”

Reply 5: We have added “The” before “Factors”.

Changes in the text: We have modified our text as advised (see Page 2, line 38)

Comment 6: Lines 48 – 59: First paragraph – describe if any of this testing is molecular? Does the center the authors are from doing MORE testing than is mandated by the government? If so, make this clearer.

Reply 6: We test in accordance with national government regulations. We do not more testing than is mandated by the government. And it has been made clear in the article.

Changes in the text: We have modified our text as advised (see Page 5, line 110)

Comment 7: Line 94: Not sure what MDAR is, I think its journal specific.

Reply 7: The MDAR is journal specific.

Changes in the text: MDAR has been deleted.

Comment 8: Fix sentence describing the setting. “Chongqing is located...”

Reply 8: We revise the sentence according to the opinions of reviewers. Chongqing is located in the southwest of China and is a city with a population of 32 million.

Changes in the text: We have modified our text as advised (see Page 4, line 92)

Comment 9: Line 99 served not serverd

Reply 9: We revise the sentence according to the opinions of reviewers. The population served by Chongqing Blood Center is about 10,612,600.

Changes in the text: We have modified our text as advised (see Page 4, line 110)

Comment 10: Line 100: “during community sessions”

Reply 10: We revise the sentence according to the opinions of reviewers. The Chongqing Blood Center collects about 240000 blood units per year across the city during community sessions.

Changes in the text: We have modified our text as advised (see Page 4, line 103)

Comment 11: Lines 104 - 115: Please explain in chronological order how donor testing is done. Are all donors tested for all of the serologies AND all of the NAT tests? It is not clear.

Reply 11: We have explained how donor testing is done in Screening of blood donations. All donors are tested for all of the serologies and all of the NAT tests.

Changes in the text: We have modified our text as advised (see Page 4, line 110-116)

Comment 12: Line 121: What is “T/CSBT 002”

Reply 12: The T/CSBT 002 is guideline for reentry of reactive blood donors in blood screening test in China.

Changes in the text: We have modified our text as advised (see Page 5, line 130-131)

Comment 13: Line 205: Can you explain in the “false positive” terminology how many donors were deemed to have false positive serology results and if any were “false positive” NAT results? The Results paragraph should include numerical summary of the main finding(s) and then refer to the tables for more details.

Reply 13: 726 donors were deemed to have false positive serology results and 118 were deemed to have false positive NAT results.

Changes in the text: We have modified our text as advised (see Page 9, line 229-231)

Comment 14: Line 211: “So the logistic regression....” This sounds colloquial. Also, on line 208 “donor status” is too general – what are you referring to? The Results paragraph should include numerical summary of the main finding(s) and then refer to the tables for more details.

Reply 14: “So the logistic regression....” is modified to “Therefore the logistic regression...” The donor status referred that the donor is new donor or repeat donor. The “donor status” is explained in the Data collection.

Changes in the text: We have modified our text as advised (see Page 9, line 240 and Page 7, line 178).

Comment 15: Line 220 – 224: The Results paragraph should include numerical summary of the main finding(s) and then refer to the tables for more details. Right now, this tells the reader to see the table.

Reply 15: Numerical summary of the main finding(s) is described in the paper: 726 donors were deemed to have false positive serology results and 118 were deemed to have false positive NAT results. The results in Table 3 showed there was no significant difference in qualification failure rate based on donor sex and age. The returning outcomes of deferred donors were influenced by blood type, donor status, occupation, education, reactive items, time interval which were $P < 0.1$

Changes in the text: We have modified our text as advised (see Page 9, line 227-233).

Comment 16: Line 229: When you say “permanently” do you mean these are not eligible for reentry or they are?

Reply 16: These permanently deferred blood donors here include all those who failed the test for infectious diseases. Some of these permanently deferred blood donors are eligible for reentry and some are not eligible for reentry.

Changes in the text: We have modified our text as advised (see Page 10, line 258-260).

Comment 17: Line 244: Consider (also for results) stating “donor status X was associated with X times more likelihood of being able to re-enter” or something like this. The general way these are described makes it hard to keep the study’s findings in focus. (Same comment as I described in Results.)

Reply 17: We very much agree with your point of view, but the result description of multivariable logistic regression analysis is basically described in this way.

Comment 18: Line 252: I do not agree that the job of a person leads to disappearance of a false positive result. Often false positive serology results are due to cross reactive antibodies to other pathogens or allergens in the environment. A donor who was recently very sick with an upper respiratory infection may have positive serology results as cross reactive antibodies in the weeks following their convalescence.

Reply 18: We very much agree with your point of view, but the statistical results are true, the possible reasons are that these people paid more attention to their health and were more willing to participate in the re-entry programme.

Changes in the text: We have modified our text as advised (see Page 9, line 251-253).