OPEN PEER REVIEW

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Hepatitis Monthly
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Peer Review Report for "Efficacy of Blood Donor Selection: Comparing Sero-Prevalence of Transfusion-Transmissible Infections Among Eligible and High-Risk Behavior Deferred Donors in Iran"

Author(s): Sara Riyahi, Sedigheh Amini-Kafiabad, Daryoush Minai Tehrani, Mahtab Maghsudlu, Seyed Moayed Alavian

Review Timeline:

Submit Date: 15 Sep 2020
Revised Date: 13 Dec 2020
Accepted Date: 13 Dec 2020

Revision (0)

Here, you can see the **Reviewers**, **Associate Editors** and **EICs'** comments from the beginning to the end of the revision process.

REFEREE: Reviewer | Revision (0)

23 Sep 2020

Dear AE,
There are some comments which should be addressed by the author:
1- In line 114, Data were analyzed using IBM SPSS version 24. The frequency of characteristics variables
SPSS version 24.0.
2- In the line 175 province of Iran (Ahwaz), the HBV, HCV, and HIV rates in deferred and eligible blood donors.
In the line 175 province of Iran (Khuzestan), the HBV, HCV, and HIV rates in deferred and eligible blood donors.
3- In the line the initial name is not necessary (i.e in line 204 with the results reported by Thelma T. Gonçalez)(12) can be attributed to the sensitivity of.
4- Check grammar in line229 eligible and deferred donors. Most of the participants had a diploma degree, and the higher the
5- The references must be completed and up-date too

Thanks

Mojtaba Sepandi: Reviewer | **Revision** (0) 24 Oct 2020

Dear AE,
There are some comments which should be addressed by the author:
1. In the method section, it is mentioned that the present study was performed on 2,525 high-risk deferred donors, while in the results section, the data related to these people have been compared with eligible blood donors(n=1,315,871), so the actual sample size of the study will be the sum of these two numbers.
2. Secondly, the text of the article states that the sample size was calculated based on a previous study, which means that not all high-risk individuals were included in the study, and sampling was performed. What was the sampling method?
3. If the probability-based sampling method is not used correctly, the resulting estimates will be biased and the "prevalence" term will not be logical.
4. In the results section, It is stated that "The overall prevalence of infections in deferred donors group compared to eligible donors group was 1.78% to 0.07% (a difference equal to 27 times) (table 2)." while : 1.78/0.07= 25.4.
5. How can the mentioned numbers be seen in Table 2?
6. Odd Ratio is a wrong term and Odds Ratio is correct.
7. According to the data in Table 2, the calculated odds ratio values are not accurate. For example, in the case of HIV, if we have 3 positive samples in the high-risk group and 47 positive samples in the normal group, the odds ratio is equal to
33.26 will be calculated, which is mentioned in the text of Article as 33 .
8. Why a Multiple binary logistic regression was not used to evaluate the relationship between TTI and the influencing factors (sex, donor type ,...)?
9. This study is a retrospective in design. Therefore, you were not able to control, or provide information on, a range of factors which may have had a bearing of the results. Another weakness in this study is the use of serological as opposed to nucleic acid-based techniques. Therefore, the results reported in this study may underestimate or overestimate the frequency of infections among donors.
10. Region of residence is a major factor in this study which authors did not pay attention to it.
11. Finally, I would like to know what approach the authors of the article on co-infections have taken in data analysis?
Thanks.

Abdol Majid Cheraghali: Associate Editor | **Revision** (0) 24 Oct 2020

Dear EIC
Please ask the authors to respond to the comments of the referees or revise the manuscript accordingly.
Regards

Seyed Moayed Alavian: EIC | **Revision** (0) 24 Oct 2020

Dear Author,

The reviewers' comments are mentioned. Please correct the details as mentioned above carefully according to reviewers' request.

Thanks.

OPEN PEER REVIEW

Revision (1)

Reply to Reviewers

Ideally, the reviewing process can significantly improve the submitted manuscripts by allowing the authors to take into account the advice of reviewers. Author(s) must reply to all reviewers' comments in a separate Word file, point by point. A "**Reply to Reviewers**" document is submitted along with revised manuscript during submission of revised files, summarizing the changes that the authors made in response to the reviewers' comments. The responses to reviewers' comments specifies how the authors addressed each comment the reviewers made.

You can read the authors' responses to the reviewers' comments in the next page.

Dear Dr. Seyed Moayed Alavian

Thank you for your email dated Oct 24, 2020 enclosing the reviewer comments. We have carefully reviewed the comments and have revised the manuscript (ID: 109451), which entitle, “Efficacy of blood donor selection: comparing sero-prevalence of transfusion-transmissible infections among eligible and high-risk behavior deferred donors in Iran,” accordingly. Our responses are given in a point - by- point manner below. Changes to the manuscript are shown with highlighted parts. We hope the revised version is now suitable for publication and look forward to hearing from you in due course.
Sincerely,

Sedigheh Amini-Kafiabad

Blood Transfusion Research Center, High Institute for Research and Education in Transfusion Medicine, Tehran, Iran.

Response to reviewer1:

Thank you for review of our paper. We have answered each of your points below.

Q: *[1-In line 114, Data were analyzed using IBM SPSS version 24. The frequency of characteristics variables SPSS version 24.0.]*
R: Thank you for your comment. Following yours comment, the manuscript is revised.
Data were analyzed using SPSS version 24.0.

Q: [*2-In the line 175 province of Iran (Ahwaz), the HBV, HCV, and HIV rates in deferred and eligible blood donors. In the line 175 province of Iran (Khuzestan), the HBV, HCV, and HIV rates in deferred and eligible blood donors.]*
R: Thank you for this direction. We checked the mentioned paper and the study was performed in Ahwaz city, so the manuscript is revised as below.
According to another study in a city of Iran (Ahwaz), the HBV, HCV, and HIV rates in deferred and eligible blood donors.

Q: [*3-In the line the initial name is not necessary (i.e in line 204 with the results reported by Thelma T. Gonçalez)(12) can be attributed to the sensitivity of.]*
R: As you suggested, all of the text is revised and the initial names is removed.
an American study by Gonçalez showed the prevalence of HIV.
the regular donors constituted the majority of eligible donors (58.1%) (consistent with the results reported by Gonçalez)(13)
The results suggested that in the deferred group the deferration rate was decreasing and the maximum deferration was under 34 years (similar to the results reported by Gonçalez) (13).

In contrast, Zou in an American Red Cross study showed that donors deferred for bloodborne pathogen risk (BBPR).

Q: [*4-Check grammar in line229 eligible and deferred donors. Most of the participants had a diploma degree, and the higher the]*
R: Thank you so much for your good comment. this sentence is revised.
Diploma are the most likel participants in the donation and the prevalence of infection is reduced by university degree in both groups.

Q: [*5-The references must be completed and up-date too/*]
R: Thank you for this suggestion. Three new references are mentioned.
1-Goldman M. Donor selection for recipient safety. ISBT Science Series. 2013;8(1):54-7.
2-Hatami H, Maghsulu M, Balali M, Seyfi Targhi M. The Efficacy impact of donor temporary deferal on the safety of blood donations in Iran during the years 2012-2014. Scientific Journal of Iran Blood Transfus Organ. 2020;16(1):17-23.
3- Kafando E, Nébié Y, SS KK, Dahourou H, Simpore J. Risk behavior among ineligible blood donors in a blood transfusion center (Burkina Faso). J Hematol Blood Transfus Disord. 2017;4:015.

Response to reviewer2:

Q: [*1. In the method section, it is mentioned that the present study was performed on 2,525 high-risk deferred donors, while in the results section, the data related to these people have been compared with eligible blood donors(n=1,315,871), so the actual sample size of the study will be the sum of these two numbers*.]
R: Thank you for your comment. The actual sample size of the study is explained in method. So the actual sample size of the study is including eligible and differed blood donor is 1,318,396.

Q: [*2. Secondly, the text of the article states that the sample size was calculated based on a previous study, which means that not all high-risk individuals were included in the study and sampling was performed. What was the sampling method?]*
R: Thank you for your assessment. In this study, we used a simple census method. we select individuals based on exemption due to risky behavior and then if they signed the informed consent, they were included in the study and sampling was performed. can be found - Study population and data collection.
The participants signed the informed consent.

Q: [*3. If probability-based sampling method is not used correctly, the resulting estimates will be biased and the "prevalence" term will not be logical.]*
R: Thank you for this great attention. Since population with the specific characteristics (exemption due to high-risk behavior) were included in the study within a certain period of time after signing the consent form, the term prevalence seems appropriate.

Q: [**4.** *In the results section, it is stated that "The overall prevalence of infections in deferred donors group compared to eligible donors group was 1.78% to 0.07% (a difference equal to 27 times) (table 2)." while: 1.78/0.07= 25.4.***]**
R: Thank you for this excellent. In this case, we did the calculations based on three decimal places (1.782 /0.066), which was exactly 27, but because the whole text uses two decimal places, and as you mentioned, we changed the result to 25.4.
this ratio is about 25.4 –times.
a difference equal to 25.4 times.

Q: ***[****5. How can the mentioned numbers be seen in Table 2?]*
R: As your comment, we revised manuscript.
For assessing frequency of characteristics variables the prevalence of variables per 100 000 donations and 95% confidential intervals (95% CIs) was calculated.

Q: [6. *Odd Ratio is a wrong term and Odds Ratio is correct.*]
R: Thank you for pointing this out. We have, accordingly, changed the whole manuscript.
HBV Odds Ratio= 26.30.
HCV Odds Ratio = 28.02

Q: [*7. According to the data in Table 2, the calculated odds ratio values are not accurate. For example, in the case of HIV, if we have 3 positive samples in the high-risk group and 47 positive samples in the normal group, the odds ratio is equal to 33.26 will be calculated, which is mentioned in the text of Article as 33.]*
R: We agree with this comment and so we have calculated all manuscript odds ratio based on your comment with two decimal places.
HBV Odds Ratio= 26.30 (95% CI: 18.1-38.3), HCV Odds Ratio = 28.02 (95% CI: 16-49), and HIV Odds Ratio = 33.30

Q: [*8. Why a Multiple binary logistic regression was not used to evaluate the relationship between TTI and the influencing factors (sex, donor type ,...)?*]
R: Thank you once again for your valuable comments and suggestions. We agree that use multiple logistic regression when we have one nominal variable and two or more measurement variables is helpful to know how the measurement variables affect the nominal variable. But, we extracted data of eligible donors from database of IBTO and unfortunately, data of eligible
donors on the SPSS software with details that we need is not available.
1,315,871 eligible donors in the indicated period obtained from the national database on blood
donors.

Q: [*9. This study is a retrospective in design. Therefore, you were not able to control, or provide information on, a range of factors which may have had a bearing of the results. Another weakness in this study is use of serological as opposed to nucleic acid based*

techniques. Therefore, the results reported in this study may underestimate or overestimate the frequency of infections among donors.]

R: We obtained detailed description of the donors' demographics and TTI marker rates of 1,315,871 eligible donors in the indicated period of this prospective study obtained from the national database on blood donors and we collected the same accurate information about 2,525 differed donors by using a designed questionnaire.

The current research was performed on 2,525 high-risk deferred donors who were presented for blood donation from March 1, 2018, to September 30, 2019, at the twenty participating blood transfusion centers in IBTO.

To make a better prospect of the results, a detailed description of the donors' demographics and TTI marker rates of 1,315,871 eligible donors in the indicated period obtained from the national database on blood donors.

Because we agreed with you in this regard, at the end of the article, we have mentioned this issue as a limitation of the research and a suggestion to continue the research.

It is recommended to use nucleic acid test (NAT) in deferred donors due to their high-risk behaviors in parallel with serology screening, (10, 23).

Q: [*10. Region of residence is a major factor in this study which authors did not pay attention to it.*

R: Thank you for this suggestion. It would have been interesting to explore this aspect. However, in the case of our study, our aspect was throughout the country.

Q: [*11. Finally, I would like to know what approach the authors of the article on co-infections have taken in data analysis?]*

R: We find this an interesting query. In this study, we did not encounter co-infections.

OPEN PEER REVIEW

Revision (1)

Here, you can see the **Reviewers**, **Associate Editors** and **EICs'** comments from the beginning to the end of the revision process.

Mojtaba Sepandi: Reviewer | **Revision** (1) 17 Nov 2020

Dear AE,
1. In response to my second comment on the sampling method, the authors stated that the study was conducted by the census method. This is while the text of the article states that the sample size has been calculated. If the sample size is calculated, it is necessary to mention the sampling method.
2. My third comment on the sampling method was about sampling method , not the study period. Therefore, I was not satisfied with the authors' answer.
3. Also, the answer to comment number 8 regarding the reason for not using multiple logistic regression is not convincing.
Thanks.

REFEREE: Reviewer | **Revision** (1) 18 Nov 2020

Dear AE,
There are some comments which should be addressed by the author:
1- For a sentence "Using national standards, international guidelines, and safety concerns, the Iranian blood transfusion organization (IBTO) has established donor suitability criteria and deferral policies to ensure the effectiveness of donor selection (4-9). using 6 references is unusual it is better to reduce it to 1-2 references only.
2- The article must be edited carefully too. (i.e diploma in English term is a higher degree but in Iran is obtained after high school graduation (pls check and so on).
3- Recheck the data in Tables too.
4- Use more up-date references like ref 11 in both the introduction and discussion sections too.
Thanks.

REFEREE: Associate Editor | **Revision** (1) 22 Nov 2020

Dear EIC,
Please ask the authors to revise the manuscript according to the referee's new comments and return for a final decision.
Thanks.

Seyed Moayed Alavian: EIC | **Revision** (**1**) 23 Nov 2020

Dear Author,

The reviewers' comments are mentioned. Please correct the details as mentioned above carefully according to reviewers' request.

Thanks.

OPEN PEER REVIEW

Revision (2)

Reply to Reviewers

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You can read the authors' responses to the reviewers' comments in the next page.

Dear Dr. Seyed Moayed Alavian

Thank you for your email dated Nov 23, 2020, enclosing the reviewer comments. We have carefully reviewed the comments and have revised the manuscript (ID: 109451), which entitle, “Efficacy of blood donor selection: comparing sero-prevalence of transfusion-transmissible infections among eligible and high-risk behavior deferred donors in Iran,” accordingly. Our responses are given in a point - by- point manner below. Changes to the manuscript are shown with highlighted parts. We hope the revised version is now suitable for publication and look forward to hearing from you in due course.
Sincerely,

Sedigheh Amini-Kafiabad

Blood Transfusion Research Center, High Institute for Research and Education in Transfusion Medicine, Tehran, Iran.

Response to reviewer1:

Thank you for review of our paper. We have answered each of your points below.

Q: *1. In response to my second comment on the sampling method, the authors stated that the study was conducted by census method. This is while the text of the article states that the sample size has been calculated. If the sample size is calculated, it is necessary to mention the sampling method.*
R: We agree with your assessment. As it is in the text and you mentioned correctly, the sample size in this research has been calculated based on the previous study in this field. The process of enrolling participants (individuals deferred from donation due to high risk behavior and of course signing the informed consent to participate in the study) was a convenience sampling method.

Apart from collecting characteristics of deferral donors (such as age, sex, occupation, marital status, education, and history of donation (first-time, repeat, and regular)), the method of sampling was convenience as if the volunteers were interviewed by a physician and differed from donation if they don’t meet any blood donor selection criteria including: History of current or past viral infection, injecting or non-injected drugs use, blood transfusions, unsafe current sexual, and household contact of individuals with an active infection, cosmetic treatments, and rituals (tattoo, Hijama, Acupuncture), history of detention in jail for more than 72 hours, and a history of medical and surgical interventions by using a uniform questionnaire and the participants signed the informed consent.

Q: *2. My third comment on the sampling method was about sampling method, not the study period. Therefore, I was not satisfied with the authors' answer.*

R: Thank you for your comment. Because our research sampling method is convenience, this is a type of non-probability sampling, as you mentioned, it can sometimes have potential bias. But what is remarkable is that limited number of people eligible to participate in the project (defer due to high-risk behaviors) and their unwillingness to cooperate and participate in research, extends the sample collection time to 18 months (if sampling method was of a probable type, it would have taken a long time and this was not possible because the study was PhD thesis). Given that the sample collection period lasted 18 months we think that it can be generalized to all individuals deferred from donation due to high-risk behavior, and the term prevalence seems appropriate for it. Thank you for your consideration.

Q: *3. Also, the answer to comment number 8 regarding the reason for not using multiple logistic regression is not convincing.*

R: Thank you for your comment. definitely not clearly explained last time. We obtained the number and percentage of donors' demographics characteristics (such as age, sex, occupation, marital status, education, and history of donation (first-time, repeat, and regular)), and TTI marker rates of 1,315,871 eligible donors used as a control group for comparison from the IBTO database totally. While the logistic regression method required details of each donor (donor` s records) which unfortunately was not available.

To make a better prospect of the results, number and percentage donors' demographics description and TTI marker rates of 1,315,871 eligible donors in the indicated period obtained from the national database on blood donors totally.

Response to reviewer2:

Q: *1-For a sentence "Using national standards, international guidelines, and safety concerns, the Iranian blood transfusion organization (IBTO) has established donor suitability criteria and deferral policies to ensure the effectiveness of donor selection (4-9). using 6 references is unusual it is better to reduce it to 1-2 references only.*
R: Thank you for your comment. We changed as your comment.
Using national standards, international guidelines, and safety concerns, the Iranian blood transfusion organization (IBTO) has established donor suitability criteria and deferral policies to ensure the effectiveness of donor selection(4, 5).

Q: *2-the article must be edited carefully too. (i.e diploma in English term is a higher degree but in Iran is obtained after high school graduation (pls check and so on).*
Q: *3-recheck the data in Tables too.*
R: R: Thank you for your comment. This classification was used based on the conventional term used in the articles of Iranian colleagues in reputable journals, however, in the manuscript and at the end of the tables, we added the meaning of the word diploma in Iran.

****Diploma= A certificate awarded by Iranian education system to show that someone has successfully completed high school.

Q: *4-use more up-date references like ref 11 in both introduction and discussion sections too*
R: Thank you for your comment. We added update references.

Zezai D, Chinnakali P, Dlodlo RA, Mugauri HD, Owiti P, Mutenherwa M, et al. Safety of Blood Maintained in Zimbabwe: Low Transfusion Transmissible Infections among Blood Donors. Journal of Biosciences and Medicines. 2020;8(7):35-43.

Mahapatra S, Palai S, Parida P, Das PK. Screening of blood donors by ELISA & Nucleic acid amplification testing along with notification to TTI reactive cases–A comprehensive measure for blood safety. International Journal. 2019;2(2):501.

Stokx J, Gillet P, De Weggheleire A, Casas EC, Maendaenda R, Beulane AJ, et al. Seroprevalence of transfusion-transmissible infections and evaluation of the pre-donation screening performance at the Provincial Hospital of Tete, Mozambique. BMC infectious diseases. 2011;11(1):1-8.

OPEN PEER REVIEW

Revision (2)

Here, you can see the **Reviewers**, **Associate Editors** and **EICs'** comments from the beginning to the end of the revision process.

Seyed Moayed Alavian: EIC | **Revision** (2) 13 Dec 2020

Dear Author,
The document is reviewed carefully by the reviewers. According to their comments and your revisions as requested, this manuscript is accepted.
Thanks.