



Commentary on: Effectiveness of confidential unit exclusion option in blood transfusion services needs re-evaluation

Abdol Majid Cheraghali ^{1*}

¹ Iran Blood Transfusion Organization Research Center and Department of Pharmacology, University of Baqiyatallah Medical Sciences, Tehran, IR Iran

ARTICLE INFO

Article Type:

Letter to Editor

Article history:

Received: 15 Mar 2011

Revised: 17 Mar 2011

Accepted: 20 Mar 2011

Keywords:

Confidential unit exclusion

Blood safety

► *Implication for health policy/practice/research/medical education:*

Despite current use of CUE in some of the blood transfusion services worldwide, recent reports have questioned its efficacy on improving blood safety profile in these countries. Therefore, it is highly recommended that countries such as Iran should re-evaluate benefits of use of this method versus its disadvantages in their national blood transfusion service.

► *Please cite this paper as:*

Cheraghali AM. Effectiveness of confidential unit exclusion option in blood transfusion services needs re-evaluation. *Hepat Mon.* 2011;11(4):295-8.

© 2011 Kowsar M.P.Co. All rights reserved.

Dear Editor,

In a recent paper, OmidKhoda and colleagues evaluated the efficiency of confidential unit exclusion (CUE) in improving blood safety in Iran's blood-transfusion system (1). This paper reported a significantly higher risk of HBV and HCV markers in donors who use CUE option to prevent their donated blood from being used. Therefore, the authors concluded that CUE is an effective option for identifying donors with increased risk of HBV and HCV infection. Although there is a general consensus that a careful medical history is the most effective way to identify donors with a high risk of viral contamination, since 1990s some blood-transfusion services worldwide have introduced the CUE option as a measure to further reduce the risk of HBV and HCV infection to the recipients. Because many high-risk behaviors that lead to an increased risk of infection with hepatitis or HIV are related to the sexual behavior of donors, providing a confidential option for high-risk donors to discard their do-

nations may improve blood safety. Although CUE option has been initiated by some countries in the developed world, due to lack of efficacy, many have discontinued its use or changed its status from obligatory to optional. In 1986, the FDA recommended the use of CUE in blood banks in the United States. However, later it has changed: its recommendation to an arbitrary option. The American Red Cross, the largest blood supplier in the United States, discontinued the use of CUE in 2005 without any apparent increase in infected donations.

Although early reports regarding the use of CUE showed some degree of efficacy in improving blood safety, recent reports have questioned its net benefits. Specifically, these reports have weighed the benefits of CUE against its main disadvantage, the discarding of a considerable number of donated blood units. In several developed countries that have implemented the CUE option, the donor usage rate of CUE averages 0.5% or less, while this figure in developing countries is above 1%. This might indicate that use of CUE in these countries is somehow tied to misunderstandings by donors regarding CUE's purpose and implications. The usage rates might also indicate an extreme caution from donor side, which forces them to mark "do not use my donation just in case" without fully

*Corresponding author at: Abdol Majid Cheraghali, Iran Blood Transfusion Organization (IBTO), Hemmat Highway, 1449613111, Tehran, IR Iran. Fax: +98-2188601580.

E-mail: Cheraghali@ibto.ir

understanding the implication of the CUE option. CUE has been implemented in Iran's blood-transfusion system since 2003. Currently, more than 1% of blood donors in Iran mark the "do not use my donation" option in the CUE form. A simple calculation indicates that, with an annual donation rate of about 1.8 million, this figure represents discarding about 20,000 units of donated blood per year. By extension, a substantial number of potential blood components (e.g., packed RBC, platelets, and plasma) are discarded in Iran each year as well. Recently Brazilian researchers evaluated the CUE option based on the demographic characteristics and the prevalence of serologic markers among blood donors who use CUE (2). They concluded that due to the modest effect of CUE on blood safety, blood banks should stop discarding blood units from donors who have marked the option on their form. They also concluded that the efficacy and usage rate of CUE very much depend on the demographic characteristics of donors as well as design of the CUE form and method of returning the completed form. Some of the recently published data from countries such as Germany and Canada have also shown that the sensitivity and positive predictive values of CUE are very low and have a minimal impact on transfusion safety (3, 4).

The efficiency of CUE has been evaluated recently in an Ontario (Canada) blood bank over a 4-year period. Although there were a total of 1,030 positive donations over this period, 99.3% of these donations were from donors who indicated that their blood was safe for transfusion, and only 0.7% from donors who marked the "unsafe" option on the CUE form. The researchers found an extremely low sensitivity and positive predictive value for CUE on blood safety in this center (3). Unfortunately, reports from Iran regarding the use of CUE have focused only on the higher prevalence of viral markers in blood donations marked as the "do not use" option in CUE form, and none have reported sensitivity or positive predictive values for their data. Therefore, it is very difficult to evaluate the real impact of the CUE option on blood safety in Iran. Reports from other countries have provided very low figures for these values, indicating a very modest effect of CUE use on blood safety (3, 4).

Although OmidKhoda *et al.* reported a significantly higher prevalence of HBsAg in blood donations marked with CUE (odds ratio 3.9), even in their data, 94% of HBsAg-positive donations came from donors who did not mark the CUE option. This figure emphasizes the importance of suitable donor screening instead of relying on the use of CUE by high-risk donors. CUE should be designed carefully to exclude blood samples from high-risk donors who seek safety tests in transfusion services. In countries

with a high rate of CUE use, such as Iran, it is important that both the procedures and donors' motivations for use of CUE be investigated thoroughly. A recent study reported that modifying the procedure for donors' use of CUE and, more important, providing clear and self-explanatory CUE forms have a significant effect on the CUE usage rate. Specifically, such modifications have reduced the use of CUE in Germany by more than 30% (4).

CUE in Iran should focus on high-risk behaviors of donors who are not willing to disclose their risky behavior during the interview with the physician. Sexual behavior is the most important type of risky behavior. Therefore, CUE should be designed in a format that would exclude donations of such donors from the national blood service. It seems that ambiguity in both the design and procedures for using CUE in Iran have caused a high usage rate of CUE, which in turn has resulted in a high discarding rate of donated blood. This of course might outweigh CUE's modest impact on blood safety in Iran. The procedure should clearly explain to the donors why and under what circumstances they should use CUE and its "do not use" option. Surely a clear and self-explanatory form will contribute greatly to the appropriate use of the CUE option. Recent reports from developed countries indicate that the CUE option has a minimal effect on high-risk donors, test seekers, or donors who feel pressured to donate and feel they can not reveal their risk factors. This approach has shown a modest effect on blood safety in a blood-transfusion service that has implemented effective predonation screening and blood testing. There is a growing sentiment in these countries that CUE might have outlived its usefulness. However, because the efficacy of this method is highly dependent on both the procedure and donors' demographic backgrounds and perceptions, it is highly recommended that countries such as Iran design studies to evaluate the exact contribution of CUE on national blood safety. Furthermore, the effectiveness of CUE should be weighed against the discarding of a substantial number of donations and the loss of donors. However, it should be kept in mind that in contrast to countries such as Germany and Canada, HIV incidence is on the rise in the general population in Iran, and sexual behaviors have changed dramatically in recent years.

In conclusion, although CUE may modestly enhance blood safety in some blood-transfusion services, this occurs at the cost of discarding a substantial number of blood units and in turn their potential blood components. Therefore, the CUE option should be re-evaluated in the broader national spectrum of blood-transfusion services.

Authors' Reply: Effectiveness of confidential unit exclusion option in blood transfusion services needs re-evaluation

Ahmad Gharebaghian ^{1*}

¹ Research Center of Iranian Blood Transfusion Organization, Tehran, IR Iran

ARTICLE INFO

Article Type:

Letter to Editor

Article history:

Received: 17 Mar 2011

Revised: 28 Mar 2011

Accepted: 30 Mar 2011

Keywords:

Blood Donors

Risk factors

Iran

► Please cite this paper as:

Gharebaghian A. Authors' Reply: Effectiveness of confidential unit exclusion option in blood transfusion services needs re-evaluation. *Hepat Mon.* 2011;11(4):295-8.

© 2011 Kowsar M.P.Co. All rights reserved.

Dear Editor,

We highly appreciate the valuable comments provided by Dr. Cheraghali. He has truly raised some valuable points that we have somehow tried to deal with in our new research (unpublished data). However, I take this opportunity to clarify a few things. Transfusion-transmitted diseases (TTDs) are considered major challenges for blood services in the world(5). The FDA (1986) recommended using confidential unit exclusion (CUE) process to reduce TTD risk in donors who are in window period (6). One of the goals of CUE process is the exclusion of blood units, which are potentially positive for one of the transmissible diseases and it was mainly designed for HIV (7). This process provides an extra-opportunity for high risk donors to exclude their given blood units confidentially; however, it greatly relies on how well-designed CUE is to detect high risk blood donors whose high risk behaviors jeopardizing blood safety were not revealed during pre-donation interview (5, 6).

Korelitz, *et al.* (1994), performed a study on CUE and its efficacy. They found that infectious markers like HBsAg, anti-HCV, anti-HIV and syphilis in CUE-positive units are 8-41 times more frequent than CUE-negative units(8). On the other hand, Zou, *et al.* (2004), showed that CUE option has a low sensitivity (3.7%) which results in discarding of 7000 blood units in 2001 in the US (9). Iran is one of the countries where CUE has been used since 2003. The main goal of our study was to assess the usefulness

of CUE process rather than its efficacy by comparing the prevalence rates of TTD markers in CUE-positive and CUE-negative donations. The findings showed a higher significant prevalence rate of HBV and HCV in blood donors who used CUE option compared to blood donors who did not(9). I agree with the critic's statement that CUE needs serious revision in Iran, both in design and procedure, so that it would be more efficient. We hope the results of our almost completed study would shed light over different aspects of CUE efficacy.

References

1. Omidkhoda A, Gharebaghian A, Jamali M, Ahmad Beigi N, Hashemi SM, Rahimi A, et al. Comparison of the prevalence of major transfusion-transmitted infections among Iranian blood donors using confidential unit exclusion in an Iranian population. *Hepat Mon.* 2011;11(1):1-3.
2. de Almeida-Neto C, Liu J, Wright DJ, Mendrone-Junior A, Takecian PL, Sun Y, et al. Demographic characteristics and prevalence of serologic markers among blood donors who use confidential unit exclusion (CUE) in São Paulo, Brazil: implications for modification of CUE policies in Brazil. *Transfusion.* 2011;51(1):191-7.
3. O'Brien SF, Fan W, Xi G, Yi QL, Goldman M. Evaluation of the confidential unit exclusion form: the Canadian Blood Services experience. *Vox Sang.* 2010;98(2):138-44.
4. Sunnig A, Konerding U, Kohlmann T, Greinacher A. Factors influencing confidential unit exclusions in blood donors. *Vox Sang.* 2010;98(3 Pt 1):e231-40.
5. Rezvan H, Abolghassemi H, Kafiabadi SA. Transfusion-transmitted infections among multitransfused patients in Iran: a review. *Transfus Med.* 2007;17(6):425-33.
6. FDA. Memorandum to blood establishments. Additional recommendations for reducing further the number of units of blood and plasma donated for transfusion or for further manufacture by persons at increased risk of HTLV-III/LAV infection. Washington, DC: Office of Biologics Research and Review, National Center for Drugs and Biologics; 1986; Available from: <http://www.fda.gov/AboutFDA/CentersOffices/CBER/default.htm>.
7. Rudmann SV. *Text book of blood banking and transfusion medicine.*

* Corresponding author at: Ahmad Gharebaghian, Research Center of Iranian Blood Transfusion Organization, Next to Milad Tower, Hemmat Exp. Way, Tehran, IR Iran. Tel: +98-2188601573.

E-mail: Gharebaghian@ibto.ir

© 2011 Kowsar M.P.Co. All rights reserved.

2nd ed. Philadelphia, Pennsylvania: Elsevier Saunders; 2007.

8. Korelitz JJ, Williams AE, Busch MP, Zuck TF, Ownby HE, Matijas LJ, et al. Demographic characteristics and prevalence of serologic markers among donors who use the confidential unit exclusion process: the Retrovirus Epidemiology Donor Study. *Transfusion*. 1994;34(10):870-6.
9. Zou S, Notari EPt, Musavi F, Dodd RY. Current impact of the confidential unit exclusion option. *Transfusion*. 2004;44(5):651-7.