

A study on confidential unit exclusion at Shiraz Blood Transfusion Center, Iran

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Abstract:

Background: Confidential unit exclusion (CUE) system has been designed to enhance transfusion safety as an extra additive approach. **Aims:** This study was designed to survey demographic characteristics, prevalence of serologic markers, and reasons of opting CUE. **Materials and Methods:** The cross-sectional study was performed at Shiraz Blood Transfusion Center (Southern Iran). CUE is used for all individuals who refer for blood donation, and donors can choose their blood not to be used if they have any doubt about their blood suitability for transfusion. The prevalence rate of HIV, hepatitis B virus (HBV), and hepatitis C virus (HCV) was compared between the blood donors who opted into and out of CUE. Then, the donors were contacted to give another blood sample and the reasons of deferral. Researchers also determined whether their reasons were logical or not. Data were analyzed using comparison of proportions in MedCalc software 7. **Results:** Out of all the donors, 2365 ones (2.3%) opted for CUE. CUE was more frequent among men, singles, donors with low education levels, between 18 and 25 years old, and with history of previous donation ($P < 0.05$). The prevalence rate of HCV was higher among the donors who opted for CUE ($P < 0.05$), but it was not the case regarding HBV and HIV ($P > 0.05$). Furthermore, 91.5% of the donors had opted for CUE by mistake and only 8% had chosen CUE logically. **Conclusion:** It is necessary to review the process of CUE, make some changes both in procedure and design, and then survey its effectiveness in blood safety.

Key words:

Blood-borne transmitted infections, blood donor, blood safety, donor exclusion, donor screening, donor selection

Introduction

Blood safety is one of the most important goals of blood transfusion services worldwide.^[1-4] Taking careful medical history and identification and selection of blood donors who are at low risk for any infections which could be transmitted via transfusion is one of the most important steps in blood safety.^[5] Some blood donors may hide their high-risk behavior in their interview with the physician at the donation center. Although these individuals may already know that they are not fit for donation, they still desire to donate their blood because of some gains or hiding their high-risk behaviors for accompanying their family members or friends. Some of them want to donate their blood due to the positive effects of donation on their health status, to do a health check-up, or to get HIV results free of charge and without stigmatization.^[6-9]

Confidential unit exclusion (CUE) system has been designed to enhance blood safety as a tool to detect high-risk donor whose high-risk behaviors can jeopardize the safety of blood. The donors can decide about the suitability of their blood, and if they think their blood may pose a risk to recipients, they can exclude it from use for transfusion by the CUE system. Every donor can withdraw his or her blood

from transfusion without informing of any other accompanying individuals. The CUE system was first launched in the United States in 1984. Since then, it has been used in many countries for improving blood safety.^[10]

After establishment of the CUE system, a lot of studies surveyed its efficacy and came to contradictory results.^[11,12] Some studies indicated that this system had low-cost benefits and led to loss of many blood donors from the donation cycle while some other studies showed that it had favorable results and improved blood safety.^[9,12-14] CUE system was launched at Shiraz Blood Transfusion Organization (Southern Iran) in 2003.

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Aim

This study aims to survey the demographic characteristics of the donors opting for CUE, prevalence of serologic markers, and reasons of opting CUE and determine if the donors properly choose CUE in Shiraz Blood Transfusion Organization (Southern Iran).

Materials and Methods

This cross-sectional study was performed at Shiraz Blood Transfusion Center, one of the main transfusion centers in Iran, from May 21, 2012 to May 21, 2013. Every year, more than 100,000 donors have been referred to Shiraz Blood Transfusion Center for blood donation. Overall, 1.8 million blood donors donate blood in Iran.^[15,16] Before donation, the individuals who had been referred for blood donation read brochures and pamphlets about blood safety and blood donation criteria. After reading these pamphlets, they made a decision whether to donate blood and registered for donation. All the individuals who were referred for blood donation were interviewed by physicians in a private room. Then, the physicians informed the donors about CUE. According to CUE policy by the Iran Blood Transfusion Organization, donors can choose their blood not to be used if they have any doubt about their blood suitability for transfusion. A mailbox for CUE forms was located at the entrance of the donation room after the individuals were interviewed by physicians. If the donors choose CUE, their blood is discarded from the donation cycle. All the screening tests were performed in the blood unit, and the blood samples were examined for HIV (Antigen /Antibody) (bioMerieux, Marcy, France), HCV Ultra (bioMerieux, Marcy, France), hepatitis C virus (HCV) antibody (Biomerieux, Marcy, France), and hepatitis B virus (HBV) antigen (Siemens, Marburg, Germany). Afterward, all the positive results were confirmed by Western blot for HIV (MP Diagnostics, HIVBLOT2.2) (Singapore), recombinant immune blot assay for HCV (BLOT3.0) (MP Diagnostic, Singapore), and HBV confirmatory test (Siemens, Marburg, Germany) for HBV. The prevalence rates of HIV BLOT2.2, HBV confirmatory test, and HCV BLOT3.0 were compared between the blood donors who opted into and out of CUE. An invitation letter was sent to the donors who opted for CUE 3 months after their blood donation asking them to refer to the blood donation center for giving another blood sample and consulting with a physician according to a questionnaire. The questionnaire contained some questions regarding the donors' demographic characteristics, their information regarding CUE, its meaning, if they had received correct information regarding CUE, and their reason for choosing CUE. Then, the physician determined whether their reasons for deferral were logical or not. Afterward, another blood sample was taken from the donors for performing all the screening tests. The donors were reassured about the confidentiality of their information. After all, the data were analyzed using comparison of proportions in MedCalc software. Besides, $P < 0.05$ was considered statistically significant.

Results

Out of all the donors (101,245), 2365 (2.33%) opted for CUE. Comparison of the demographic characteristics (sex, age, gender, marital status, education level, and donation status) of the blood donors who chose or did not choose CUE is summarized in Table 1. Accordingly, CUE was more frequent among males, singles, less educated donors, those between 18 and 25 years old, and the donors

Table 1: Comparison of demographic characteristics of blood donors who chose confidential unit exclusion or not

Variable	CUE			
	Yes	No	OR	P
Educational level				
Below diploma	857	28,371	0.58-1.03	<0.0001
Diploma or higher	1508	70,509		
Age				<0.0001
18-25	327	2187		
26-45	1441	72,868		
>46	597	23,825		
Marital status				
Married	1835	82,691	0.58-1.02	<0.0001
Single	530	16,189		
Number of donations				
Donors with the history of previous donation	1987	79,044	0.39-0.81	<0.0001
First-time donors	378	19,836		<0.0001
Sex				
Male	2299	94,966	0.3-1.1	0.0035
Female	66	3914		

CUE: Confidential unit exclusion, OR: Odds ratio

Table 2: The prevalence of hepatitis B virus, hepatitis C virus, and HIV in the blood donors who chose confidential unit exclusion and those who did not

Blood test	CUE	Number of donors	Number of positive cases	Disease prevalence (%)	P	CI
HIV	No	98,880	3	0.003	0.09	0.004-0.006
	Yes	2365	0	0		
HBV	No	98,880	65	0.06	0.09	-0.06-0.1
	Yes	2365	1	0.04		
HCV	No	98,880	47	0.04	0.007	0.01-0.3
	Yes	2365	5	0.21		

HBV: Hepatitis B virus, HCV: Hepatitis C virus, CI: Confidence interval, CUE: Confidential unit exclusion

with the history of the previous donation ($P < 0.05$). Moreover, the prevalence rates of HBV, HCV, and HIV in the blood donors who opted for CUE were 0.04%, 0.21%, and 0%, respectively. In addition, these measures were, respectively, 0.06%, 0.04%, and 0.003% in the blood donors who had not opted for CUE [Table 2]. The prevalence rate of HCV was higher among the donors who had opted for CUE ($P < 0.05$), but it was not the case regarding HBV and HIV ($P > 0.05$). Then, invitation letters were mailed to the 2365 donors who had opted for CUE, but only 1720 donors (72.72%) agreed to take part in the study. The results of all the screening tests were negative (1720 out of 1720). Among these 1720 participants, 1675 (97.3%) were male, 1298 (75.4%) had a high level of education, and 589 (34.3%) were donors with the history of the previous donation. The mean age of the participants was 36.9 ± 10.34 years (range: 18–63 years), and the mean number of blood donations was 3.7 ± 3.6 (range: 0–25). Moreover, only 18.4% of the participants had read the brochures that contained information regarding CUE option. In addition, 48.6% of the participants believed that they had received enough information regarding CUE option from physicians regarding donor selection process and 35.8% thought that they knew the meaning of CUE option, but only 21.2% of them had correctly answered the questions regarding the meaning of CUE. Overall, 91.5% of the donors had opted for CUE by mistake. Yet, choosing CUE by mistake was not related to sex and the place of donation ($P > 0.05$). Opting CUE by mistake was more frequent among the donors who had the history of donation and those with a

lower educational level ($P < 0.05$). Also, as the donors' age increased, CUE option by mistake increased too ($P < 0.05$).

Discussion

In this study, 2.3% of the donors opted for CUE. However, this measure was obtained as 0.7% in a previous study conducted in this center.^[8] In the previous studies, 1.3% and 3.2% of the donors excluded their blood.^[17] The higher frequency of using CUE option may be related to opting CUE by mistake, donors' misunderstanding about the criteria for choosing this option, physicians' insufficient explanation regarding the correct use of CUE, and donors' lower socioeconomic status.^[18,19] In this study, 91.5% of the donors opted for CUE by mistake. Furthermore, only 21.5% of the donors understood the meaning of CUE. Only one previous study surveyed donors' understanding of CUE and showed that donors with greater rate of CUE did not understand the meaning of CUE compared to those without CUE.^[9]

In this study, the correct use of CUE was related to the donors' level of education, which is similar to the results of the previous studies.^[20] This emphasizes the importance of donors' knowledge regarding the correct use of CUE, and that CUE option may be more helpful for the educated donors.

In the present study, the use of CUE option was more frequent among men, singles, less educated donors, those between 18 and 25 years old, and the donors with the history of the previous donation. In other study also, CUE was more frequent among males, first-time donors, and those below 30 years old.^[14]

There are already several studies surveying the effects of CUE. Most of these have not focused on the quality of CUE processes and only compared the donors opting for CUE and those without CUE regarding the serological markers.^[9,13,21,22] Nevertheless, comparison of HIV prevalence between CUE and non-CUE donors is difficult due to the very low prevalence rate of HIV among blood donors.^[9,13,21,22] A previous study showed that the prevalence of HBV, HCV, and HIV was higher among the CUE donors.^[23] In another previous study, the prevalence of HIV antibody was 21 folds higher among the blood donors who had opted for CUE compared to those who had not.^[9] Another study showed that the use of CUE option could prevent the collection of 0.2–1.3% windows period units every year. It was mentioned that the prevalence of HIV, HBV, and HCV was, respectively, 13, 7, and 5 times higher among the CUE donors in comparison to the others.^[23] Another study which was conducted in Tehran, Iran, in 2006 also indicated that the prevalence of HBV and HCV was higher among the CUE donors.^[21] Similarly, a study performed in Tehran in 2009 demonstrated a higher prevalence of HBV and HCV among the CUE donors.^[24] Another study which was carried out in this center in 2006 and 2007 also revealed that the prevalence of HBV, HCV, and HIV was higher among the CUE donors.^[8] In the present study, the prevalence rate of HCV was higher among the donors who had opted for CUE ($P < 0.05$). This might be because some HCV patients intended to donate blood due to some beliefs. For instance, some of them believed that blood donation could eradicate virus from their blood while they already knew that they must not donate blood; therefore, they opted for CUE. However, the prevalence rates of HBV and HIV were not higher among the CUE donors ($P > 0.05$). However, it was not the case

regarding HBV and HIV ($P > 0.05$). This may be due to strict donor selection, existence of the reasons and period of deferral in the software during donor registry, decrease in the prevalence of HBV, HCV, and HIV in blood donors population, good communication between physicians and donors for explaining high-risk behaviors during their selection process, donors' better understanding of the donation criteria, insufficient explanation regarding CUE correct use, lower perception of donors, and opting for CUE by mistake. Moreover, the donors who previously opted for CUE did not have permission to donate unless the consultant physician distinguished that they could enter the donation cycle. Thus, probably these donors never choose this option again in spite of their unsuitability for donation to prevent their exclusion from the donation cycle.

In the current study, 91.5% of the donors had opted for CUE by mistake. This might be due to the incorrect explanation of this option, lower perception of the donors regarding its correct use, and the criteria for CUE option. In our center, physicians informed donors regarding CUE option. Due to lack of time, large number of donors, or different educational backgrounds, physicians might not have been able to provide donors with clear explanations using simple words. Thus, designing some pamphlets with simple, understandable words and in appropriate size may be helpful for donors' better understanding.^[9,13] Without enough explanation, this option can lead to misinterpretation, loss of eligible donors, discard a lot of blood units from the donation cycle, and waste of time.

In our study, 2365 individuals who had been referred to Shiraz Blood Transfusion Center chose CUE. Out of these individuals, 1720 returned to blood center for giving new sample and filling up the designed questionnaire. All of them showed negative results for transfusion transmitted infection. This might be because the subjects with positive results in the first screening tests did not show up at the blood centers again due to fear from getting positive results.

One of the limitations of this study was not surveying the meaning of CUE among the non-CUE donors. Therefore, some donors might not have opted for CUE in spite of unsuitability of their blood for transfusion or misunderstanding of CUE meaning. Moreover, comparison of the results of the present study to other ones regarding the effectiveness of CUE option may be difficult because of differences in the exact process of CUE, the way it is performed, physicians' explanations regarding the correct use of this option, and donors' demographic characteristics and perceptions and confidential process of CUE system.

Conclusion

Overall, it is highly essential to review the process of CUE option, make some changes to perform it more efficiently, more involvement of physicians in CUE process, educate physicians regarding how to inform donors with simple and understanding words according to donors knowledge, design some pamphlets for improving the donors' understanding regarding its correct use, and then survey its effectiveness in blood safety.

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Conflicts of interest

There are no conflicts of interest.

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