Effectiveness of confidential unit exclusion for screening blood donors

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The confidential unit exclusion (CUE) option in the process to screen blood donors was conceived in the 1980s as a possible means to reduce the risk of transfusion transmission of HIV before sensitive tests became available.[1] The use of CUE allows blood donors at increased risk for HIV or other sexually-transmitted diseases who may feel pressured to complete the donation, or who are inappropriately donating blood in order to be tested, a chance to confidentially indicate that their blood should not be used for allogeneic transfusion. CUE has been abandoned by blood centers in many countries but is still voluntarily used or mandated in other jurisdictions. The centers that have eliminated CUE largely based their decisions on published evidence that the process did not improve safety and was more often misunderstood and incorrectly used by donors, leading to the unnecessary waste of many safe donations.[2,3] The effectiveness of CUE, however, could still differ among blood centers because of the various methods to administer the CUE option, variability in the criteria to select blood donors, the performance characteristics of laboratory tests, or disparate demographics among donor populations. Consequently, blood centers that continue to use CUE, either as a voluntary or compulsory measure, should evaluate its effectiveness in their donor population.

To that end, Volger and colleagues report on the effectiveness of CUE in the screening of blood donors of a regional blood bank of Londrina, Parana State.[4] The authors evaluated the donors' use of CUE in 51,104 successful donations during the period of January 2004 to December 2008. Their CUE instrument consists of 4 questions related to intravenous drug use, sexual activity with a partner of the same gender, "professional of sex" and occasional sexual partner. The frequency of positive serology was 5.3% in the group that used CUE and 3.5% in the group that did not use CUE (χ^2 =15.66; p-value < 0.0001). Eighty-nine of 1672 donors who used the CUE option had at least one reactive serological test result. Follow-up testing for 8 donors who had reactive serological tests after a positive CUE donation failed to identify seroconversion after self-exclusion: 4 of the 8 were falsely-reactive for *T cruzi* antibodies (2 donors) or anti-HCV (2 donors) and were readmitted for future donations, one had inconclusive results for Chagas' disease, two were reactive for VDRL and one failed to return to be tested for HIV1/2.

The results are consistent with other studies that found CUE associated with a higher prevalence of reactive markers for HIV, HBV, HCV and syphilis, but having only minimal ability to prevent the collection of window period units.[2,3] For example, Zou et al. evaluated the self-exclusion of over 14,000 donors among the 6.5 million donations to the American Red Cross in 2001, after the implementation of NAT testing for HIV1/2. The CUE process asked donors to confidentially select one of two indistinguishable bar-coded stickers to attach to their blood donation record indicating either to use or discard the donation for any reason. This study reported a prevalence of 0.77% for confirmed infectious disease markers for HIV, HBsAg, HCV, syphilis or HTLV among blood donors who self-excluded their donation compared to 0.15% among those who did not use CUE (p-value < 0.001). With the exception of HTLV, a reactive infectious test result was 4 to 13-fold more likely among donors who selected the CUE option compared to donors who did not exclude their donation. Likewise, Volger and colleagues report a 1.5 to 3-fold higher risk of reactive serologic markers associated with the use of CUE.

Prevalence data on CUE donations, however, only reveal the likelihood of detectable infection at the current donation. More informative is the analysis of donors who use the CUE option when their test results are negative and would not have been excluded from donation by other means, but who later demonstrate confirmed, laboratory evidence of infection. Seroconversion after use of CUE provides an estimate of the possible benefit of CUE use in reducing the residual risk of window-period donations. Volger and colleagues found little evidence to suggest that CUE intercepted potentially infectious units based on follow-up information on 8 donors who showed reactive serological screening tests after using the self-exclusion option during a prior donation. Although one donor did not return for follow-up testing to investigate an indeterminate HIV1/2 serologic result, he had used CUE on 2 different occasions. Donors who use CUE on more than one occasion deserve

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special consideration, as discussed further below. In the American Red Cross study, seroconversion and the use of CUE at the prior donation was evaluated for more than 5,000 donors revealing a low sensitivity (0.0175) and positive predictive value (0.0009) for detecting a window period donation. CUE may have prevented only an estimated 0.2 to 1.3 window period units within the entire American Red Cross system which collects more than 6.5 million donations each year.

The low positive-predictive value likely reflects errors in the selection of CUE option by donors, either from misunderstanding or poor explanation by staff about the instrument. The cost and waste associated with the use of the CUE instrument is not trivial. With the accumulated evidence that the CUE option has only minimal effectiveness in further reducing the transmission of infectious diseases through window-period units – even prior to the introduction of NAT[2] – CUE can safely be eliminated during the routine donor screening process. Blood centers, however, should still instruct all donors to report after the donation if they realize for any reason that their blood should not be used for transfusion, so that their components can be discarded. While not "confidential" because the donors must identify themselves to the blood center staff, they do not have to give the reason why they feel their blood is not safe. The management of post-donation information in this way has not been subjected to the same scrutiny as the use of CUE, but it may achieve the same purpose, possibly not with any more sensitivity but with much less waste of acceptable donations.

Whether blood centers continue to use a CUE process or similarly manage post-donation information from donors who exclude their donation for confidential reasons, special consideration should be given to donors who report on two or more occasions that their blood should not be used for transfusion. Interestingly, Volger and colleagues revealed that most of their donors (1269) used the CUE option just once, but 158 selected the CUE option twice, 30 donors on 3 occasions and 21 donors on 4 or more donations. One donor who presented with both HIV and syphilis co-infection had self-excluded on five prior occasions. Repeated use of CUE likely reflects test seeking by donors who are at ongoing risk of parenteral infection but may be inappropriately using regular blood donation for reassurance. The unexpected observation that the prevalence of *T cruzi* antibody was higher among donors that used CUE remains unexplained but also raises the specter of test-seeking among blood donors. Blood centers should explain the risks of transfusion-transmitted infectious diseases to blood donors who repeatedly use the CUE option or report post-donation information to exclude their donation for confidential reasons on more than 2 occasions. Blood centers should also consider whether repeated self-exclusion after donation is grounds for indefinite deferral of the individual as it likely suggests ongoing high risk activity or test-seeking behavior.

In conclusion, the current study from the regional blood bank of Londrina, Parana state provides some new insights, and reinforces the available published experience with the CUE option in other countries, thus providing ample support for the conclusion of Vogler and colleagues to eliminate CUE after the introduction of nucleic acid tests in Brazil. In the opinion of this author, they do not have to wait for nucleic acid tests.

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