

# Confidential donation confirmation as a alternative exclusion

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In this issue of the *Revista Brasileira de Hematologia e Hemoterapia*, Loureiro et al. present their evaluation of the use of confidential donation confirmation (CDC), i.e., release of blood units from donors who have confirmed that their blood may be used for transfusion by choosing the "yes" option.<sup>(1)</sup>

The conclusion of this case-control study is that CDC did not reduce the residual risk of transfusion-transmitted infections (TTIs) nor did it deter at-risk donors from donation. In brief, no real benefit was associated with the use of CDC.

The safety of the blood supply has been improved over the years by the progressive implementation of measures aimed at reducing the risk of TTIs. The use of voluntary non-remunerated donors, the implementation of donor education programs, the careful selection of donors interviewed before their donation using donor questionnaires and the development of sensitive laboratory screening assays have all contributed tremendously to the improvement in blood safety. Over the last decade, the use of nucleic acid amplification technology (NAT) has improved blood safety by reducing the window period and the residual risk of human immunodeficiency virus (HIV) transmission around the world.<sup>(2,3)</sup> Nowadays, a lower prevalence of infectious diseases is observed among blood donors and the immunological window periods for these infections have been shortened remarkably.<sup>(3)</sup> However, global and regional differences persist due to higher or lower incidences of diseases and, because of the window period, there will always be a residual risk for TTIs. The improvement in blood safety therefore requires ongoing effort within a wide range of contexts.

In 1986, the U.S. FDA recommended the use of confidential unit exclusion (CUE).<sup>(4)</sup> This approach allows at-risk donors to confidentially exclude their blood from being used for transfusion. However, the use of CUE is controversial as many authors have reported that CUE has low sensitivity, a low positive predictive value<sup>(5-7)</sup> and no proven benefit in terms of improving blood safety. Furthermore, CUE has even been associated with a small but constant loss of apparently safe donations.<sup>(7)</sup> For this reason, the CUE is no longer in use in most U.S. blood banks<sup>(8)</sup> However, CUE is still used or recommended in other countries, such as in the United Kingdom,<sup>(9)</sup> Switzerland,<sup>(9)</sup> Iran,<sup>(10)</sup> Brazil<sup>(11,12)</sup> and Germany.<sup>(9)</sup>

The use of CUE has been evaluated in countries where NAT screening is performed and where the residual risk of HIV transfusion-transmission is lower, such as in Germany and Canada and results have shown that the sensitivity and positive predictive values of CUE are very low and it has minimal impact on transfusion safety.<sup>(9,13)</sup> Also, the researchers concluded that the efficacy and usage rate of CUE depend very much on the demographic characteristics of donors as well as the design of the CUE form and procedures.

In Brazil, NAT screening for HIV is not performed routinely by most blood banks. This results in a longer infectious window period and substantially greater residual risk of transfusion-associated transmission of HIV than in the U.S.<sup>(2,3)</sup> and Europe.<sup>(14,15)</sup> In Brazil, estimates of HIV incidence are approximately 10-fold higher in first-time donors than in the U.S.<sup>(3)</sup> and Europe.<sup>(15)</sup> A recent study by Dr. Sabino et al.<sup>(16)</sup> showed that even with the implementation of NAT, the risk of residual HIV in Brazil will remain higher than it was in the U.S. prior to NAT screening.<sup>(3,17)</sup> In this case, the use of CUE could potentially help exclusion of units donated during the HIV window period.<sup>(18)</sup>

The CUE or CDC approaches have been used in several Brazilian blood banks in compliance with local regulations or recommendation.<sup>(12)</sup> Mendrone et al.<sup>(19)</sup> found that, in

the absence of better methods to reduce the HIV window period, the CUE option would potentially prevent only a few cases of transfusion-transmitted HIV infection. Almeida-Neto et al.<sup>(18)</sup> demonstrated that the use of the CUE option, although resulting in a high number of discarded units, was predictive of marker-positive donation and thus appeared to contribute modestly to blood safety.

As long as no consensus has been reached on the use of CUE or CDC to prevent high risk blood donors from donating blood, the rights of the recipients to receive the safest possible blood supply should prevail. Meanwhile, blood bankers are investigating ways to improve blood safety for the community and further studies, in each locale, will be important for informed decision making about CUE, CDC or other measures. In the interest of recipients, high risk blood donors should be excluded from donating blood. Thus, the use of CUE might contribute to an improvement in the safety of blood. CUE might be even more relevant in middle- and low-income countries with high prevalence and incidence rates of HIV, in countries with high rates of prejudice and stigma against HIV positive persons, in countries where infections are not concentrated in specific at-risk populations (i.e., where donor deferral questions are not as efficient) such as sub-Saharan African countries, or in countries where costly measures to reduce the risk of TTIs (e.g., NAT testing) are not feasible and where access to alternative testing is limited. In Brazil, as NAT screening will be implemented in the entire country in the near future, larger scale studies would be useful to balance the benefit of using CUE or CDC in addition to NAT screening to reduce the number of units from risky but test-negative donors with the loss of blood units from safe donors.

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