## Comments on confidential unit exclusion at the Regional Blood bank in Montes Claros – Fundação Hemominas

Ingridt Hildegard Vogler

Laboratory of Clinical Analysis, Universidade Estadual de Londrina – UEL, Londrina, PR, Brazil

Conflict-of-interest disclosure: The author declares no competing financial interest

Submitted: 12/23/2011 Accepted: 12/24/2011

## Corresponding author:

Ingridt Hildegard Vogler Laboratory of Clinical Analysis Universidade Estadual de Londrina Avenida Robert Koch, 60 – Vila Operária 86038-350 – Londrina, PR, Brazil Phone: 55 43 3371-2670 vogler@uel.br

www.rbhh.org or www.scielo.br/rbhh

DOI: 10.5581/1516-8484.20120004

In the 1980s, HIV infection became a serious problem for transfusion services and the first screening serological tests developed were not very sensitive to detect the presence of anti-HIV antibodies in infected blood because of a large window period. An alternative way to reduce the risk of infected blood being transfused was proposed by the United States Food and Drug Administration (FDA) and widely used around the world. A strategy, usually known as confidential unit exclusion (CUE), was created so that donors could confidentially exclude their own blood after the donation process in cases in which donors were uncertain about the safety of transfusing their blood or when donations were made for reasons other than humanitarian purposes such as for HIV testing. So, the blood bag would be discarded and not used for transfusion every time a CUE was answered positively.

Published data show that CUE does not improve safety and is often misunderstood and incorrectly used by donors leading to the unnecessary discard of safe donations. (1,2) For this reason, most US blood banks discontinued the use of CUE; in other countries, such as in the United Kingdom, Switzerland, Iran and Germany, it is still recommended. (3)

In Brazil, CUE was mandatory from 2002 until December 2010 when a new resolution by the National Health Surveillance Agency (ANVISA) made the use of CUE in Brazilian blood banks optional.<sup>(4)</sup> During the last few years, several studies have been performed in an attempt to analyze the epidemiologic profile of self-excluding donors in Brazil as in the case of the article of the Regional Blood bank in Montes Claros, Minas Gerais State, Southeast Brazil published in this issue.<sup>(5)</sup>

The authors analyzed data on age, marital status, gender, ethnical background, blood group, Rh factor, number of donations, type of donation and serologic results of 34,778 donors in a period from 2008 until 2010. They found that 0.62% of the donors self-excluded their donations. The profile of those who self-excluded donations was male, unmarried, young mulattos. They were also blood group O and Rh positive in most cases. Interestingly, 43.7% of the self-excluding donors had donated blood on 2 to 5 occasions in the blood bank. In a total of 69.3% of the 215 self-excluded donations, thus a positive CUE was given in a return donation, but there was no statistical association between this variable and marital status, age or gender. It is supposed that the profile of self-excluding donors found in this blood bank is very similar to the whole blood donor population in the institution.

The frequency of reactivity (Chagas' disease, syphilis and hepatitis B) in serological tests of donors who self-excluded their donations was 5.6%. It was expected to find an association between CUE and sexual transmitted diseases such as HIV, syphilis and hepatitis B. However, the authors did not find any self-excluding donor positive for the anti-HIV antibodies test; three donors (1.4%) had antibodies to Chagas' disease which is an infection that is not sexually transmitted. These data suggest that the use of CUE in blood donation is not very effective in preventing blood-borne infections. It is well known that, among donors that self-exclude themselves, the frequency of reactivity to serological markers is higher than in the group that did not. However, the CUE has a low power as a diagnostic test because of its low sensitivity and positive predictive value. So, the process is almost unable to prevent new seroconversion cases by the use of laboratorial screening tests.<sup>(6)</sup>

In the Regional Blood bank of Montes Claros, the CUE option is offered to all donors but a large proportion of donors do not use it correctly. The authors report that 31.9% of donors return the questionnaire incorrectly completed (blank, null, or noncompliant). No information on the use or the disposal of these blood bags is given by the authors. In our blood bank reality, incorrectly completed questionnaires should be considered as positive and the blood bag should be discarded. Anyway, it is well known that donors commonly misunderstand the self-exclusion process and its importance and thus undermine its effectiveness.

In conclusion, the current study shows that the rate of self-exclusion in the Regional Blood bank of Montes Claros is low compared to other institutions in Brazil. The authors verified the profile of the blood donors who self-excluded their donations and situations about the correct use of the instrument. The cost-benefit of CUE is an important point to be reviewed because of the unnecessary waste of safe blood.

There is much evidence that the self-exclusion process should be discontinued or replaced by alternative strategies to increase the donor's understanding of safe donation.

## References

 Petersen LR, Lackritz E, Lewis WF, Smith DS, Herrera G, Raimondi V, et al. The effectiveness of the confidential unit exclusion option. Transfusion. 1994;34(10):865-9. Comment in: Transfusion. 1994; 34(10):840-1.

- Zou S, Notari EP 4th, Musavi F, Dodd RY, ARCNET Study Group. Current impact of the confidential unit exclusion option. Transfusion. 2004;44(5):651-7.
- 3. Gonçalez TT. Confidential donation confirmation as a alternative exclusion. Rev Bras Hematol Hemoter. 2011;33(4):251-2
- 4. Agência Nacional de Vigilância Sanitária [Internet]. Resolução -RDC n. 57, de 16 de dezembro de 2010. Determina o regulamento sanitário para serviços que desenvolvem atividades relacionadas ao ciclo produtivo do sangue humano e componentes e procedimentos transfusionais. Brasilia (DF): ANVISA; 2010. [cited 2011 Jan 8]. Available from: http://www.brasilsus.com.br/legislacoes/rdc/ 106696-57.html
- Maia CN, Oliveira Ruas MO, Urias EV. Confidential unit exclusion at the Regional Blood Bank in Montes Claros – Fundação HEMO-MINAS. Rev Bras Hematol Hemoter. 2012;34(1):17-20.
- 6. Vogler IH, Saito M, Spinosa AA, da Silva MC, Munhoz E, Reiche EM. Effectiveness of confidential unit exclusion in screening of blood donors of regional blood bank of Londrina, Parana State. Rev Bras Hematol Hemoter. 2011;33(5):347-52. Comment in: Rev Bras Hematol Hemoter. 2011;33(5):330-1.