Research Unit

Modeling risk to ensure safety when considering changes to blood testing

Collected in January 2019

What is this research about?

At Canadian Blood Services, blood safety is paramount. At every step along the path from donor to recipient, measures are taken to protect recipients from receiving blood that contains infectious disease agents such as viruses or bacteria. Donors are screened for risk factors, blood donations are tested for infectious disease agents, and production processes and storage conditions that limit the risk are use.

In brief…

This modeling study suggests that moving from testing all donations for the virus HTLV, to testing only first-time donors, would have a negligible impact on risk to recipients.

Human T-cell lymphotropic viruses (HTLV, of which there are two sub-types) are infectious agents that can be transmitted through sexual contact or blood transfusion with an infected unit of platelets or red blood cells. HTLV can also be transmitted from mother to child. Once you have HTLV, you remain infected for life. Although there are diseases associated with HTLV, they rarely develop, so most people who have HTLV do not know that they are infected.

Since 1990, all blood donations in Canada have been tested for HTLV. Since then, there have been no identified cases of HTLV transmission by transfusion. The rate of HTLV in Canadian blood donors is about 1 in 100,000 donations. In over 20 years of monitoring, this rate has not changed, and most donations that test positive for HTLV are from first-time donors.

In 1999, universal leukoreduction – a process which greatly reduces the number of white blood cells (which are also called leukocytes) in blood transfusion products – was introduced in Canada. HTLV infects white blood cells, so leukoreduction should reduce the risk of HTLV in blood products. Due to this, the benefit of testing all donations for HTLV when blood products are leukoreduced has been questioned. Some European countries who use leukoreduction do not test for HTLV. Others (England and Ireland) recently changed from testing all donors for HTLV to testing only first-time donors. To understand the potential impact of making a similar change to HTLV testing in Canada, the researchers developed a simulation model. This model was designed to estimate the risk of an infectious unit of red blood cells or platelets being released into inventory (*i.e*. being available for transfusion to a recipient) if changes were made to the current HTLV testing algorithm.

What did the researchers do?

A random probability simulation was used to model the risk of a HTLV-positive donation being released into inventory under three scenarios:

- the current approach in which all donations are tested for HTLV;
- an alternative approach in which only first-time donors are tested for HTLV;
- another alternative approach in which testing for HTLV is stopped altogether.

Separate simulations were carried out for red blood cells, whole blood-derived platelets, and apheresis platelets, each comprising 10 billion prospective donors. Real-world data was used to produce the model. For example, residual white blood cell counts in blood products after leukoreduction were based on quality control data from Canadian Blood Services and Héma-Québec. The infectious dose of HTLV was based on data from a Japanese study.

What did the researchers find?

With universal leukoreduction in place:

- When all donations are tested for HTLV, the residual risk of releasing a unit potentially infectious with HTLV was estimated to be **1 in 1.2 billion units**;
- When only first-time donors are tested for HTLV, the residual risk of releasing a unit potentially infectious with HTLV was estimated to be **1 in 7.1 million**;
- When no testing for HTLV is conducted, the residual risk of releasing a unit potentially infectious with HTLV was estimated to be **1 in 1.0 million**.

How can you use this research?

The results show that moving from testing all donations for HTLV to testing only first-time donors would lead to a small change in risk. To put the calculated risk estimates in context, Canadian Blood Services produces approximately 0.8 million RBC units and less than 0.2 million platelet units for transfusion every year. The model used in this study estimated the risk of potentially infectious units being released into inventory. The risk of transfusion transmission to a recipient would be even lower, and if HTLV does transmit, it rarely leads to disease. This study indicated that even if the rate of HTLV-positive donations increased substantially, the risk would remain low when testing only first-time donors. However, stopping testing altogether may lead to an unacceptable risk.

While zero risk with blood products is unattainable, blood operators strive for the lowest, tolerable risk. The risk associated with testing only first-time donors for HTLV is sufficiently low to be considered a tolerable risk, and the results of this study suggest considering a change in HTLV testing policy is merited. Further information would need to be considered to determine the risk-benefit ratio of a change to HTLV testing. For example, economic analyses in other countries (*e.g.* England) have suggesting that switching from testing all donations for HTLV to testing just first-time donors could lead to potential cost-savings. There are economic considerations specific to Canada that would need to be assessed before deciding if a change in testing would also result in cost-savings in Canada.

About the research team: This research was conducted by **Sheila O'Brien**, **Qi-Long Yi**, and **Mindy Goldman** from Canadian Blood Services' Centre for Innovation, and **Yves Grégoire** and **Gilles Delage** from Héma Québec. **Dr. O'Brien** is the associate director of epidemiology and surveillance at Canadian Blood Services, and an adjunct professor in the school of epidemiology & public health at the University of Ottawa. **Dr. Yi** is a senior biostatistician at Canadian Blood Services and an adjunct professor in the school of epidemiology & public health at the University of Ottawa. **Dr. Goldman** is a Canadian Blood Services medical director and an adjunct professor in the department of pathology and laboratory medicine at the University of Ottawa.

This ResearchUnit is derived from the following publication:

[1] O'Brien SF, Yi Q-L, Goldman M, Gregoire Y, Delage G. Human T-cell lymphotropic virus: A simulation model to estimate residual risk with universal leukoreduction and testing strategies in Canada. *Vox Sang* 2018: 113; 750-759.

Acknowledgements: This research received financial support from Canadian Blood Services, funded by the federal government (Health Canada) and the provincial and territorial ministries of health. The views herein do not reflect the views of the federal government of Canada, or provincial or territorial governments. Canadian Blood Services is grateful to blood donors for making this research possible.

Keywords: Safety, human T-cell lymphotropic virus, testing, infectious disease, simulation.

Want to know more? Contact Dr. Sheila O'Brien at sheila.obrien@blood.ca