Building a Better Blood System for Canadians

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Each year, donated blood saves or improves the lives of thousands of Canadians. Yet blood is also the potential carrier of both viral and bacterial infections. This possibility was fully realized in the 1980s when blood supplies around the globe were infected with Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV).

It is the mission of Canadian Blood Services (CBS) to provide the safest possible blood components to blood transfusion recipients in nine provinces and three territories across the country. Our mission statement commits us to provide a safe, secure, reliable, cost-effective, affordable and accessible supply of blood, blood products and their alternatives and to manage the blood supply system in a manner that nurtures the trust, commitment and confidence of Canadians.

Lines of defense

At CBS our operating assumption is that there will always be threats to the blood supply. As a result, we are instituting changes to enable the organization to remain at the height of vigilance to guard against any potential threat to the blood system and to respond quickly and effectively if and when a problem arises.

Our first line of defense against potential threats to the blood system involves recruiting only volunteer blood donors. This is perfectly within the Canadian tradition; but its most significant value may be that the safest blood donor is one whose only incentive is to save someone’s life.

CBS screening procedures rely heavily on the honesty of prospective donors. Safety demands that they respond truthfully to pointed questions on their health and risk activities; a donor motivated by money, time off work or other incentives may be less likely to be completely honest. The exclusive use of volunteer donors, whose only motivation is altruism, remains a fitting safety feature of our system.

While CBS is in the process of becoming a totally new organization, we nevertheless have a unique opportunity to build on an existing tradition of community service as we design a new framework for Canada’s blood supply. The fact is that, in Canada, blood donors are arguably the most important link in the blood system.

Our second line of defense is the screening of prospective blood donors. Strict screening ensures that each donor presents the least possible risk of transmitting diseases.

Potential donors whose tests or answers indicate that they are at higher risk for certain diseases or medical conditions are deferred from giving blood. Applicants may be deferred for their own safety, or to protect the safety of the blood supply.

The criteria CBS uses to determine the eligibility of blood donors are based on scientific knowledge of risk factors. All screening measures must meet stringent regulatory requirements and keep pace with the accepted standards of blood services worldwide.

Deferral periods range from as short as a few days for cold symptoms, to a few years for the risk of malaria. In some cases, applicants are permanently deferred, such as for individuals who have engaged in high-risk behaviours or have lived in certain higher risk areas of the world.

Our third line of defense involves the testing of each and every unit of donated blood. Every time someone makes a donation, CBS takes a sample of this blood for testing by trained laboratory technicians using sophisticated, reliable procedures.

For example, CBS routinely tests for the following transmissible diseases:
- Hepatitis B and Hepatitis C
- Human immunodeficiency viruses (HIV-1 and HIV-2)
- Human T-Cell lymphotropic virus HTLV-I and II
- Syphilis

As innovations to improve safety or efficiency are developed, CBS has a clear process for evaluating their potential benefits and risks, as well as their costs relative to other alternatives or technologies. With major advances being made in testing for transmissible diseases, new tests are being added to the roster of testing requirements as we continue to meet accepted and improved international standards.

Testing for HCV

As a case in point, in the fall of 1999, Canada joined Europe and the United States with the introduction of a new, more sensitive test for Hepatitis C (HCV), called Nucleic Acid Amplification Testing, or NAT.

CBS filed an Application for Investigational Testing with Health Canada to use the AmpliScreen 2.0 HCV PCR assay, manufactured by Roche Molecular Systems, to screen blood donations for HCV nucleic acid. NAT is being introduced on an investigational basis in order to demonstrate its efficacy in detecting HCV. The Canadian regulator, the Bureau of Biologics and Radiopharmaceuticals (BBR), does not require CBS to conduct NAT at this time. However, it does expect

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CBS to investigate NAT’s efficacy. The data collected from the investigation will be used to support the manufacturer’s application for licensing of the testing kit as a blood donor screening test in Canada.

NAT works by detecting low levels of viral genetic material present when an infection occurs but before the body begins producing antibodies in response to a virus. As a result, NAT significantly reduces the “window period” or the time between initial infection and when the virus is first detectable. Studies have shown that NAT can detect HCV within 14 to 28 days as compared to about 70 days using previous tests.

For purposes of organizational efficiency, NAT testing at CBS begins with a number of blood samples being “pooled” together in the laboratory. If the pool is positive, then the samples are tested in smaller pools and then individually until the actual positive sample is identified. CBS will then notify the donor, provide appropriate counselling to that individual, and discard all the products made from that donation.

The CBS NAT sites across Canada are located in Vancouver, Toronto, Ottawa and Halifax. The blood centres in these cities have undergone extensive renovations to accommodate the special requirements of NAT and 28 new technical positions have been created to conduct testing.

HCV is an often debilitating and sometimes fatal disease. With the addition of the HCV PCR assay to HCV antibody testing, it is anticipated that a greater number of HCV infectious units will be detected. The exact degree to which transfusion safety will be improved is not known at this time. It is thought that the risk factor, formerly estimated at 1 in 120,000 units, will be reduced to 1 in 500,000 units or less. Mathematical models indicate that NAT will detect an additional four to six cases of HCV each year in Canada and since each blood donation may result in two or more blood components for transfusion, NAT has the potential to prevent up to 13 HCV infections annually.

Managing risk

At CBS, risk management is integral to our business planning. Blood is a precious resource, and we take very seriously our responsibility for its efficient and safe use. NAT is becoming the standard of practice in the blood and plasma industry in Europe and the United States; since blood products cross international borders, it is important to have consistent standards.

Canada was not alone in facing a tragedy over tainted blood in the 1980s and 90s. It was in fact a global crisis and a direct reflection, albeit a negative one, of the overall globalization trend of our era. The business of blood banking is becoming truly global; we are increasingly interdependent and CBS must plan accordingly.

When it comes to risk, however, there can be no guarantees. There may never be a time when blood will be absolutely 100% safe. There must be vigilance and systems in place to minimize the risk. We are in the process of building a better blood system to be able to tackle the challenges that will inevitably come our way in the future.

Perhaps most importantly, a creed of safety now permeates the CBS organization. We ensure that CBS meets or exceeds all relevant national and international standards for safety in blood management and operations and we are fostering a corporate culture within CBS whereby employees understand their individual and collective responsibility for safety.

Bloodborne disease diagnosis and testing is a rapidly evolving field and CBS intends to remain at the forefront of change both through our responses to new challenges and changing technology as well as through instigating innovations via significant research and development activities.

In fact, we are committed to setting aside up to 10% of our operating budget for research directed at improving blood safety and reducing our dependence on blood. This represents a significant pool of ongoing funding that can be used in the development of innovations in both products and systems for:

- Maintaining the safety of the blood supply;
- Enhancing our utilization of blood products;
- Developing alternatives to human blood.

Today, CBS is concentrating on shaping a very different future for the blood system than its recent past. We are building a better blood system for this country that is, and will be, much better prepared for the changed realities of our times.