RESEARCH IMPACT CASE STUDY

Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

Introducing a new blood product to better meet the transfusion needs of the Canadian Armed Forces

What was achieved?

In November 2022, Canadian Blood Services began manufacturing whole blood for the Canadian Armed Forces.

> Whole blood is used to treat severely injured trauma patients and others who experience clinically significant bleeding (Mack, 2022). The use of whole blood simplifies the transfusion process in the challenging environments in which the Canadian Armed Forces operates.

Transfusing whole blood requires just a single bag and one storage temperature compared to separately transfusing three blood components (red blood cells, platelets, and plasma), each with different storage specifications. There is also growing evidence that whole blood is a more effective initial resuscitation fluid for trauma patients than individual blood components (see Geneen et al., 2022; Malkin et al., 2021). Today, Canadian Blood Services is helping to better meet the needs of military trauma patients by providing whole blood to the Canadian Armed Forces. Work is underway to extend the benefits of this new blood product to non-military trauma patients in Canada.

How was this achieved?

In Canada, all blood components for transfusion undergo a process called leukoreduction. Leukoreduction removes white blood cells (leukocytes) that could transmit infectious diseases or cause an unwanted immune response. A key part of Canadian Blood Services' development work was to design a leukoreduction process that removes white blood cells but maintains the concentration of platelets — small cell fragments that help blood clot — in the final whole blood product. The research team showed that the blood clotted normally after filtration, suggesting the preservation of functional platelets. Their findings also showed the whole blood could be held for up to 24 hours before being leukoreduced without affecting the quality or safety of the product (Schubert et al., 2021; Schubert et al., 2022; Ramirez-Arcos et al., 2022). This storage time is three times longer than the eight hours recommended by the filter manufacturer. Extending the storage time before filtration was crucial to ensuring Canadian Blood Services could introduce a safe and effective product that fit our operational needs.

Related development work established the storage time, temperature and conditions for leukocyte-reduced whole blood (LrWB) — up to 21 days at 1 to 6°C without agitation — to ensure product quality until transfusion. The team also collaborated with the Canadian Armed Forces to test the quality of the LrWB once it was delivered to military sites where it would be transfused. The LrWB was transported to a site in Africa and stored following the Canadian Armed Forces' regular processes. The product was shown to clot normally, demonstrating that LrWB is logistically feasible and effective for treating military trauma patients.

This development work supported Canadian Blood Services in integrating the LrWB production process within our existing operations (Canadian Blood Services, 2022b; Walsh, 2022). It also supported our submission to Health Canada requesting regulatory approval to manufacture LrWB.

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A circular of information was developed to provide detailed product information to clinicians on this new blood product (Canadian Blood Services, 2022a). Our knowledge mobilization team also developed an educational resource to support the Canadian Armed Forces in using LrWB (Mack, 2022). This resource was shared with members of the transfusion community in Canada to help them understand why we are manufacturing whole blood for military use.

What was the impact and outcome?

The availability of LrWB gives members of the Canadian Armed Forces better access to transfusions in challenging environments. LrWB is manufactured primarily from male donors who have type O blood with low levels of antibodies to group A and B red cell antigens. These characteristics help ensure transfused blood is safe for all recipients, regardless of blood type (with rare exceptions). When Canadian Blood Services introduced this product, we also introduced automated antibody testing on all whole blood donations.

In October 2022, Canadian Blood Services received regulatory approval to manufacture and distribute LrWB. We have been making and providing this product to the Canadian Armed Forces on demand since November 2022. Within the first six months, we provided 47 units to the Canadian Armed Forces. Our experience manufacturing and distributing LrWB for the Canadian Armed Forces will help guide future decisions about the use of LrWB outside the military. The National Advisory Committee on Blood and Blood Products, in partnership with Canadian Blood Services and our research team, is surveying Canadian non-military health-care providers to evaluate and plan for the use of LrWB outside the military in Canada.

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