



NAC Statement on the Introduction of Leukocyte Reduced Whole Blood in Canada

Prepared by:	Alan Tinmouth, MD, NAC Chair Chantale Pambrun, MD, Subcommittee Chair Johnathan Mack, MD
Provincial Ministry Representative:	Thomas Smith (Ontario)
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Prior to 1999, whole blood was available as a licensed blood product in Canada. It has not been available since the introduction of universal leukoreduction because the filters used to remove white blood cells also significantly reduced the platelet concentration. Since that time, only component therapy (packed red blood cells, platelet concentrates, frozen plasma) has been available from Canadian Blood Services. However, platelet-preserving leukoreduction filters for whole blood have been developed that now make it possible for Canadian Blood Services to produce a leukocyte-reduced whole blood product.

There has been renewed interest in the use of whole blood, particularly for the treatment acutely bleeding trauma patients. This increased interest in whole blood (either leukoreduced or non-leukoreduced) as a resuscitation product for acutely bleeding trauma patients followed on observational studies that found an association between improved hemostasis and fixed ratio transfusion of red cells, plasma and platelets in trauma patients. Most of the recent use of whole blood has been in the military trauma setting but it has also been adopted by some civilian trauma centres, and the use of whole blood has also begun to expand to the management of bleeding patients in non-trauma settings.

Despite the significant enthusiasm for whole blood in trauma and bleeding patients, the evidence regarding clinical effectiveness is limited. Four recent systematic reviews, which identified a total of 21 controlled studies (in which 1951 patients received whole blood), did not demonstrate a benefit for whole blood as compared to standard component therapy²⁻⁵. Importantly, there were no safety issues identified in the published studies of whole blood. International studies to assess efficacy and safety in settings where component therapy is not readily available are ongoing (e.g. the pre-hospital setting).

In October 2022, Health Canada approved **Whole Blood, Leukocytes Reduced** to be manufactured and distributed by Canadian Blood Services. The use of **Whole Blood Leukocytes, Reduced** is indicated for treatment of patients with clinically significant bleeding, and will have low anti-A and anti-B titres (less than a manual equivalent of 1:128)¹. The shelf life of **Whole Blood, Leukocytes Reduced** is 21 days and the product should be stored at 1-6°C¹. **Whole Blood, Leukocytes Reduced** will be collected primarily from group O (Rh positive and/or negative) male donors given the expected use for this product¹.

The introduction of **Whole Blood, Leukocytes Reduced** by Canadian Blood Services presents a unique situation with specific challenges. Donor and product requirements for **Whole Blood, Leukocytes Reduced** will increase pressure on the blood supply, particularly products from Group O donors. Group



O-negative donors are already in high demand; Group O-negative units represent 15% of all RBC units transfused in Canada, but only 3-4% of the potential donor population. The need for low anti-A and Anti-B titres will limit the number of potential donors for **Whole Blood, Leukocytes Reduced**. Additionally, potential recipients of **Whole Blood, Leukocytes Reduced** are relatively few in number and spread across the country, which will present challenges for maintaining inventory and avoiding outdated given the high acuity needs of these patients.

Initially, **Whole Blood, Leukocytes Reduced** will only be available for military use. Introduction of **Whole Blood, Leukocytes Reduced** for non-military use requires additional careful planning. A subcommittee of the National Advisory Committee on Blood and Blood Products is currently undertaking an assessment to determine the initial non-military use of **Whole Blood, Leukocytes Reduced** in Canada. Following ethics and stakeholder input, and taking into account pragmatic considerations regarding supply, the NAC subcommittee will provide specific recommendations for the introduction of **Whole Blood, Leukocytes Reduced** including clinical versus research use, patient groups (pediatric, trauma, surgical, and pre-hospital) and monitoring of outcomes (utilization, wastage, safety, effectiveness, impact on utilization of other blood products).

The National Advisory Committee on Blood and Blood Products is interested in the perspective of Canadian healthcare providers on the non-military use of **Whole Blood, Leukocytes Reduced** in Canada. A website is underdevelopment to capture the input from the broader community and will be available by February 2023.



References

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