

CHAPTER 1

VEIN TO VEIN: A SUMMARY OF THE BLOOD SYSTEM IN CANADA

Sophie Chargé, PhD

Published

2019-01-17

BACKGROUND

As noted in the RAND Corporation's 2016 report, it is internationally recognized that “a robust, sustainable blood system is a crucial component of every health-care system. The availability of safe blood products is a prerequisite for various health-care services — including some surgeries, treatments for cancer and other acute and chronic medical conditions, trauma care, organ transplantation, and childbirths — that extend and improve life for millions of patients annually.”¹

The tainted-blood tragedy² of the 1980s and 1990s left thousands of Canadians infected with human immunodeficiency virus and hepatitis C virus. This tragedy led to the Royal Commission of Inquiry on the Blood System in Canada, led by Justice Horace Krever. In 1997, Justice Krever tabled his report in the House of Commons, putting forward a set of 50 recommendations that, to this day, guide the blood system to ensure safety for all Canadians.³ That same year, federal, provincial and territorial governments enacted a memorandum of understanding that would shape a new, national blood authority. In 1998, an independent national blood service represented by two blood operators, Canadian Blood Services and Héma-Québec, was established; the provincial and territorial governments were identified as primary funders, while the federal government retained regulatory oversight. An extensive framework of advisory and liaison committees was established to ensure communication between parties as well as engagement from the medical community.

This first chapter of the [Clinical Guide to Transfusion](#)⁴ provides an overview of the blood system in Canada, the regulations and standards that are in place and the organizations and professionals that, together, ensure transfusion medicine safety for Canadian patients.

THE FEDERAL GOVERNMENT

The Canadian federal government is responsible for ensuring the quality and safety of blood, blood components and blood products. Following the tainted blood tragedy, recommendations were made to amend the Food and Drugs Act to outline clear requirements for the safety, efficacy, and quality of blood components for transfusion.

Prior to the introduction of the Blood Regulations under the Health Canada Food and Drugs Act, the Canadian Standards Association (CSA) published in 2004 the National Standard of Canada on Blood and Blood Components (CSA Blood Standard). The CSA Blood Standard was published to guide establishments by providing management requirements for facilities that collect, process, store, and use human blood components for transfusion. It addresses issues of safety, efficacy, and quality for recipients, safety of donors, management of blood components,⁵ and safety of facility personnel and others who are exposed to or potentially affected by blood components. The Technical Committee for the CSA Blood Standard includes health professionals as well as representatives from the federal, provincial and territorial governments, user groups, and blood operators. In developing the CSA Blood Standard, the Technical Committee consults equivalent standards in Canada and other jurisdictions, including the AABB Standards for Blood Banks and Transfusion Services and the Canadian Society for Transfusion Medicine's Standards for Hospital Transfusion Services (see details later).

In 2014, Health Canada introduced the Blood Regulations under the Food and Drugs Act.⁶ Administered by the Health Products and Food Branch, the Blood Regulations heavily reference the CSA Blood Standard, and provide specific regulations for blood components intended for transfusion or for further manufacture into drugs for human use. The regulations apply to all persons or establishments that process, label, store, distribute or transform blood for transfusion or for further manufacture, including establishments that import blood for transfusion. Health Canada maintains an arm's-length relationship with Canadian Blood Services and Héma-Québec and does not mandate corporate and operational decisions. However, the blood operators are required to submit operational changes to Health Canada and to demonstrate that the changes would not compromise the safety of the blood.

As part of its surveillance system, the Public Health Agency of Canada has established the Blood Safety Contribution Program ([BSCP](#)), which includes the Transfusion Error Surveillance System (TESS), the Transfusion Transmitted Injuries Surveillance System (TTISS) and the Cells, Tissues and Organs Surveillance System (CTOSS). The information collected through these voluntary surveillance systems is used to identify trends in transfusion-associated errors, adverse reactions and injuries in Canadian hospitals at the national level. They are also used as benchmarks for national and international stakeholders. Overall, these surveillance systems aim to improve transfusion processes and maximize patient safety.

THE PROVINCIAL AND TERRITORIAL GOVERNMENTS

In Canada, the provincial and territorial governments are responsible for the overall direction and operation of their own health-care systems, including the funding for blood operators. Canadian Blood Services' funding is approved annually by all provincial and territorial ministers of health (except Québec). Thus, while hospitals do not pay directly for blood components and products, their respective provincial and territorial ministries of health allocate health-care dollars to pay for blood components and products used by patients. Dollars allocated to Canadian Blood Services by each province or territory are generally based upon the actual distribution of products.

The provincial and territorial ministers of health elect the members of Canadian Blood Services' board of directors, who are responsible for overall direction and oversight of Canadian Blood Services. In addition, representatives from the provincial and territorial governments are members of the Canadian Blood Services/Provincial Territorial Blood Liaison Committee (CBS PTBLC) and the [National Advisory Committee on Blood and Blood Products](#) (NAC),

which have been established for the following purposes:

- The CBS PTBLC facilitates the work between the provincial and territorial governments and Canadian Blood Services to support Canadian Blood Services in the provision of a safe, secure and affordable national blood supply (excluding Québec). The CBS PTBLC membership includes representatives from each provincial and territorial ministry of health and from Canadian Blood Services.
- The NAC provides consultative advice on the utilization management of blood components, plasma protein products and transfusion medicine practice to the provincial and territorial ministries of health and Canadian Blood Services. At the request of the CBS PTBLC, the NAC has developed a series of recommendations and guidelines on relevant topics, including recommendations for the distribution and utilization management of blood products in times of significant blood shortages. The NAC membership includes health professionals appointed by their provincial and territorial governments, Canadian Blood Services representatives, and a ministry of health representative.

Several provincial and territorial governments have established a Provincial Blood Coordinating Program (PBCP) to provide leadership and support to regional health authorities within their province and to Canadian Blood Services. They work together to ensure that blood components and products are managed safely and effectively. The PBCPs also serve as liaisons between the regional health authorities and the provincial governments regarding blood product management. Links to the PBCP websites can be found [here](#).

BLOOD OPERATORS

There are two blood operators in Canada: Héma-Québec, serving hospitals in the province of Québec, and Canadian Blood Services, serving hospitals in all provinces and territories outside of Québec. These organizations are responsible primarily for preparing fresh blood components from volunteer donations and managing their supply to hospitals for patients in need. As part of this responsibility, the blood operators select donors, collect and test donated blood, process donated blood into blood components, and store and transport blood components and products to hospitals. Qualified personnel with a wide range of skills and expertise (e.g. medical, nurses, laboratory technologists, regulatory, legal, finance, IT), supported by an extensive quality system and an appropriate infrastructure, ensure a supply of safe blood components and products of the highest quality.

Canadian Blood Services is incorporated as a not-for-profit organization. It is regulated as a biologics manufacturer by Health Canada and primarily funded by the provincial and territorial ministries of health, except Québec. The ministers of health appoint Canadian Blood Services' board of directors, approve Canadian Blood Services' annual budget and review its corporate plan. With its head office in Ottawa, Canadian Blood Services manages manufacturing sites, testing facilities and collection sites across Canada (except Québec) from both an operations and quality assurance perspective. All sites undergo regular and extensive internal and external audits.

DONOR SELECTION

As stated in the World Health Organization's guidelines on assessing donor suitability for blood donation, "Blood transfusion services have the responsibility to collect blood only from donors who are at low risk for any infection that could be transmitted through transfusion and who are unlikely to jeopardize their own health by blood donation". Guidance on donor selection has been incorporated into standards and blood operators fulfill this responsibility by establishing a rigorous donor selection process, which includes several steps from educating prospective donors to screening potential donors (e.g. donor questionnaire related to acute illness and chronic infections) to obtaining post-donation information. However, donor selection decisions that have a major impact on donor recruitment and retention cannot be taken lightly as there is also a requirement to ensure the sufficient supply of blood components and products for patients in need.

Blood donors play an essential role during the selection process. It is their responsibility to understand the questions asked in the donor questionnaire and to honestly answer these questions. In addition, donors must inform the blood operator of any illness or new diagnosis after donation that might compromise the safety of the blood components made from the donation.

BLOOD COLLECTION AND TESTING

Blood operators have the responsibility to collect whole blood and blood components from selected donors. Annually, Canadian Blood Services relies on blood donors from across the country to collect approximately one million units of blood or blood components at its fixed and mobile donor centres. During the collection process, administrative and nursing staff ensure donor safety by monitoring for potential adverse reactions. Staff also follow a set of policies and procedures to ensure the safety and quality of the donation.

Donations are tested for the presence of known transfusion-transmissible infectious agents using multiple screening tests that are performed in-house. Tests are either performed on all donations (e.g. HIV 1/2, hepatitis B and C) or on a subset of the donations based on risk information obtained via the donor questionnaire (e.g. *Trypanosoma cruzi*, the pathogen which causes Chagas Disease). More detailed information about donor screening and testing is presented in Chapter 6 of this [guide](#).

Every blood donation is also tested for ABO blood group, RhD blood group, and the presence of irregular red blood cell antibodies. These tests are necessary to reduce the risk of premature destruction of the transfused donated red blood cells in a recipient's circulation due to immunological incompatibility. In addition to testing blood donors, Canadian Blood Services and Héma-Québec laboratories support transfusion practice by assisting hospitals with testing of patients with complex transfusion needs. Canadian Blood Services also provides antibody testing and consultation for pregnant women in Canada with antibodies that may impact pregnancy management.

With the emergence of new pathogens and the development of new or improved tests (e.g. nucleic acid testing, next-generation sequencing) and blood manufacturing technologies (e.g. leukoreduction, pathogen reduction), blood operators must continuously reassess their donor selection and testing processes to ensure the safety of the blood supply while being as inclusive as possible of all prospective donors. Health Canada must approve changes made to donor screening and testing processes prior to the implementation of major changes. In recent years, the Alliance of Blood Operators (ABO) has developed a [risk-based decision-making framework](#) for blood safety to support blood operators in their decision-making process and facilitate proportional responses to risk. This framework has been used by Canadian Blood Services in the context of donor screening and testing, for

example to assess the risk posed by *Babesia microti* and Zika virus.

BLOOD COMPONENTS AND BLOOD PRODUCTS MANUFACTURING AND DISTRIBUTION TO HOSPITALS

Fresh blood components are prepared in the blood operators' facilities.¹³ More detailed information about blood components manufacturing is presented in Chapter 2 of this [guide](#).

Plasma protein products and recombinant therapeutic products are not manufactured by blood operators but by pharmaceutical companies currently located outside of Canada. Canadian Blood Services collects plasma which it provides to pharmaceutical companies to fractionate into plasma protein products. In addition, Canadian Blood Services negotiates contracts with pharmaceutical companies to provide appropriate fractionated and recombinant products to meet the needs of Canadian patients (see Chapter 5 of this [guide](#) for details).¹⁴

Fresh blood components and plasma protein products are stored at Canadian Blood Services' facilities and shipped to approximately 600 health-care facilities according to a pre-arranged schedule of supply and upon request for additional products.

RETRIEVAL/LOOKBACK AND TRACEBACK PROCEDURES

Any information arising after the time of donation that may affect the safety of a transfusion recipient must be reported to the blood operator. Such information can be received from many sources, including the blood operator (testing/medical/regulatory), donors, hospitals, and physicians. Canadian Blood Services receives information from hospitals that report an adverse reaction to a blood component as well as post-donation information from donors who become unwell following a blood donation. All reports are fully investigated by Canadian Blood Services' medical team, and depending on the nature of the information the following procedures may be initiated:

- **Product inventory retrieval** is a procedure established by the blood operator on a voluntary basis or mandated by the regulatory agency, Health Canada. The procedure involves identifying fresh blood components that could compromise the integrity and safety of the blood supply and removing them from the blood operator's inventory. If the blood components have already been transfused, the blood operator medical director, the hospital blood bank director (or hospital unit) and recipient's attending physician will determine if recipient notification is required.¹⁵ Examples of inventory retrievals would be the retrieval and destruction of a platelet unit from the blood operator's storage when the unit tested positive for bacterial contamination, or the retrieval of blood components stored in the hospital blood bank when a blood donor reports a fever within a few days following the donation.
- **Traceback investigation** is the process of investigating a report of a potential transfusion-transmitted infection (e.g. HIV, HBV, HCV, WNV, Chagas) in a blood recipient. The purpose of the traceback investigation is to investigate any associated donors, obtain either negative ('clearing') test results (from a subsequent donation) or identify a donor who subsequently has tested positive for that marker. When Canadian Blood Services learns that a blood recipient has tested positive for a transfusion-transmitted infection (without another known cause), the implicated donor (or donors) associated with the blood components transfused

are identified and located, and arrangements are made to retest the donors for the appropriate transmissible disease.

A traceback investigation may lead into a lookback investigation, if the donor tests positive for the infectious agent and has previously donated blood.

- **Lookback investigation** is the process of identifying and contacting recipients of blood components from a donor who, on a subsequent donation or testing, is confirmed to have tested positive for the presence of a transmissible infectious agent (e.g. HIV, HBV, HCV, WNV, Chagas). When Canadian Blood Services learns that a blood donor has tested positive for a transmissible disease, a lookback procedure is initiated on that donor's previous relevant donations. A recall procedure is initiated for blood products manufactured from these donations. A communication with hospitals that received blood products manufactured from these donations is initiated to identify and notify recipients. Recipients are tested for the infectious agent found in the donor and Canadian Blood Services may be informed of the results.

For both lookback and traceback investigations, identifying individuals with positive tests for transfusion-associated infections is important for the safety of the blood supply. It is also essential for the donors and recipients so that they can receive appropriate testing and follow up. Donors may be indefinitely deferred following a lookback investigation, depending on the nature of the infectious agent. Canadian Blood Services provides a final report on all lookback and traceback investigations to Health Canada and shares investigations' results in its annual [Surveillance Report](#)¹⁶ published online.

STAKEHOLDER ENGAGEMENT

Through the activities of its National Liaison Committee and its Regional Liaison Committees, Canadian Blood Services receives input from relevant stakeholder groups, such as consumer groups, patient/recipient groups, health professionals, and hospitals; as well as from the Canadian youth community and members representing diverse communities.

HOSPITALS

Hospitals play a primary role in ensuring the safe transfusion of blood products to Canadian patients. Depending on the size of the hospital, various frameworks may be in place; however, three main structures are generally considered:

- **Transfusion laboratory staff and medical directors** request blood products from the blood operator, as needed, and ensure their safe storage and distribution to clinical staff. This group is involved in blood products compatibility testing to ensure an appropriate match between a blood product and a patient. They respond to blood operators' requests to identify recipients of previously transfused units with possible infectious risks based on subsequent information as part of a lookback investigation or other correspondence. They may also be involved in informing the physician who ordered the suspect unit, and/or

the recipient, depending on hospital policies, of the possible risk and need for testing. Through reporting, they are informed of adverse transfusion reactions and transfusion-related errors occurring within their hospital. In turn, they report to blood operators any adverse transfusion events thought to be caused by a deficiency of the blood product. Similarly, they report to manufacturers of plasma protein products any adverse transfusion reactions thought to be related to the quality of a plasma protein product. They also report adverse transfusion events either voluntarily through the Public Health Agency of Canada TTISS program or Québec Hemovigilance System (in Québec), or as required by Health Canada. See Chapter 10 of this [guide](#) for more information on Adverse Reactions. The transfusion medicine laboratory director oversees clinical transfusion and blood utilization policies.

- **Transfusion clinical staff**, in hospital units where blood is transfused, are responsible for developing and implementing transfusion policies approved by the hospital or regional transfusion committee.
- **Transfusion recipients' physicians** order blood products for their patients in need. They are responsible for optimal utilization of blood products and appropriate transfusion practices.

Following the Krever Inquiry,³ Transfusion Safety Officer (TSO) positions were created within most major hospital centres across Canada. These transfusion-dedicated medical lab technologists or registered nurses are responsible for the quality and safety of transfusion within their respective institutions, particularly in the transfusion service and in the transfusing units, wards or clinics.

Hospital transfusion committees or regional transfusion committees were also established to oversee the transfusion activities of usually more than one hospital in a region. These committees provide consultation and support related to safe transfusion practice. Their multidisciplinary membership includes physicians, nurses, transfusion service staff, and executive management.^{5 17}

In most jurisdictions, the applicable College of Physicians and Surgeons and/or the ministry of health also play an essential role in setting standards for patient testing laboratories, including hospital transfusion medicine laboratories. Laboratories performing transfusion medicine testing in these jurisdictions must be licensed and/or accredited and must abide by relevant provincial standards.

Under the new Blood Regulations enacted in 2014,⁶ Health Canada is exercising increased oversight on hospitals for activities that impact the quality and safety of blood products. Hospitals who transform blood (e.g. washing red blood cells and irradiating blood products) must be registered with Health Canada and are subject to regular Health Canada audits. Hospitals that distribute and transport blood products must also comply with certain provisions in the Blood Regulations, although there is no registration requirement for carrying out these activities.

OTHER ORGANIZATIONS CONTRIBUTING TO THE BLOOD SYSTEM

Other organizations support a safe blood system in Canada by developing standards and guidelines as well as by supporting research and education.

The [Canadian Society for Transfusion Medicine \(CSTM\)](#) is an inter-professional, not-for-profit organization founded in 1979 (originally known as the Canadian Association of Immunohematologists) that promotes excellence in transfusion medicine in Canada. CSTM facilitates opportunities for education in transfusion medicine. Its flagship education program is the CSTM Annual Conference, organized by experts from the transfusion community in partnership with Canadian Blood Services and Héma-Québec. CSTM also plays a leadership role in the continuing development of standards by publishing the Standards for Hospital Transfusion Services which reflects evidence-based best practice in Canada. Compliant with both the CSA Blood Standard and the Health Canada Blood Regulations, this publication supports safe transfusion practice in hospitals and assists in meeting accreditation requirements in some jurisdictions.

The [AABB](#), formerly known as the American Association of Blood Banks, is an international, not-for-profit association representing individuals and institutions involved in the fields of transfusion medicine and cellular therapies. The AABB develops standards for blood banks and transfusion services that provide additional guidance for Canadian institutions. In addition, the AABB has an extensive suite of educational resources that are relevant to the Canadian system.

As per one of Krever's recommendations, advancing research is an essential element to a continued safe transfusion system. In Canada, Health Canada provides financial support to Canadian Blood Services for implementing a research and development program to improve the safety and supply of the Canadian blood system.¹⁸ Internationally, the [International Society of Blood Transfusion \(ISBT\)](#) founded in 1935 is a scientific society which promotes research and knowledge mobilization through the organization of regional and international Congresses. The ISBT also advocates standardization and harmonization in the field of blood transfusion. For example, it played a significant role in the development of the global standard for the identification, labelling, and information transfer of medical products of human¹⁹ origin (including blood components) known as the ISBT 128 labelling standard which has been adopted in Canada. The other major impact of the ISBT on the transfusion community is the classification of various human blood group systems under a common nomenclature. There is also the [Biomedical Excellence for Safer Transfusion \(BEST\) collaborative](#), an international research organization, that explores ways to improve transfusion-related services through standardization of analytic techniques, development of new procedures, systematic review of evidence, and execution of clinical and laboratory studies. Currently, the BEST brings together 42 scientific members, 13 manufacturing sponsors, and 17 blood service sponsors from 22 countries.

Health advocacy groups relevant to the field of transfusion also play an important role in ensuring the safety of the blood system. Through their activities in knowledge mobilization and research, as well as their engagements with blood operators, they ensure the best transfusion practice for Canadian patients.

COLLABORATIVE ENVIRONMENT

The interrelationships between the protagonists of a safe Canadian blood system are illustrated in Figure 1. The system works as well as it does because a framework is in place to facilitate these relationships, and competent, caring, and committed professionals contribute at all levels. Despite advances in ensuring the safety of the blood system, potential risks from transfusion remain and blood transfusion should never be considered completely safe.

Decisions about blood utilization remain primarily a medical responsibility within Canadian hospitals. The safe collection and testing of recipient samples, and the careful transfusion and monitoring of those receiving blood components and products, rely on health professionals. Continuing education for all involved, including recipients, as to risks and benefits of transfusion remains a constant challenge. It is hoped that the information in this [guide](#) will help optimize the utilization and the safety of blood components and products.

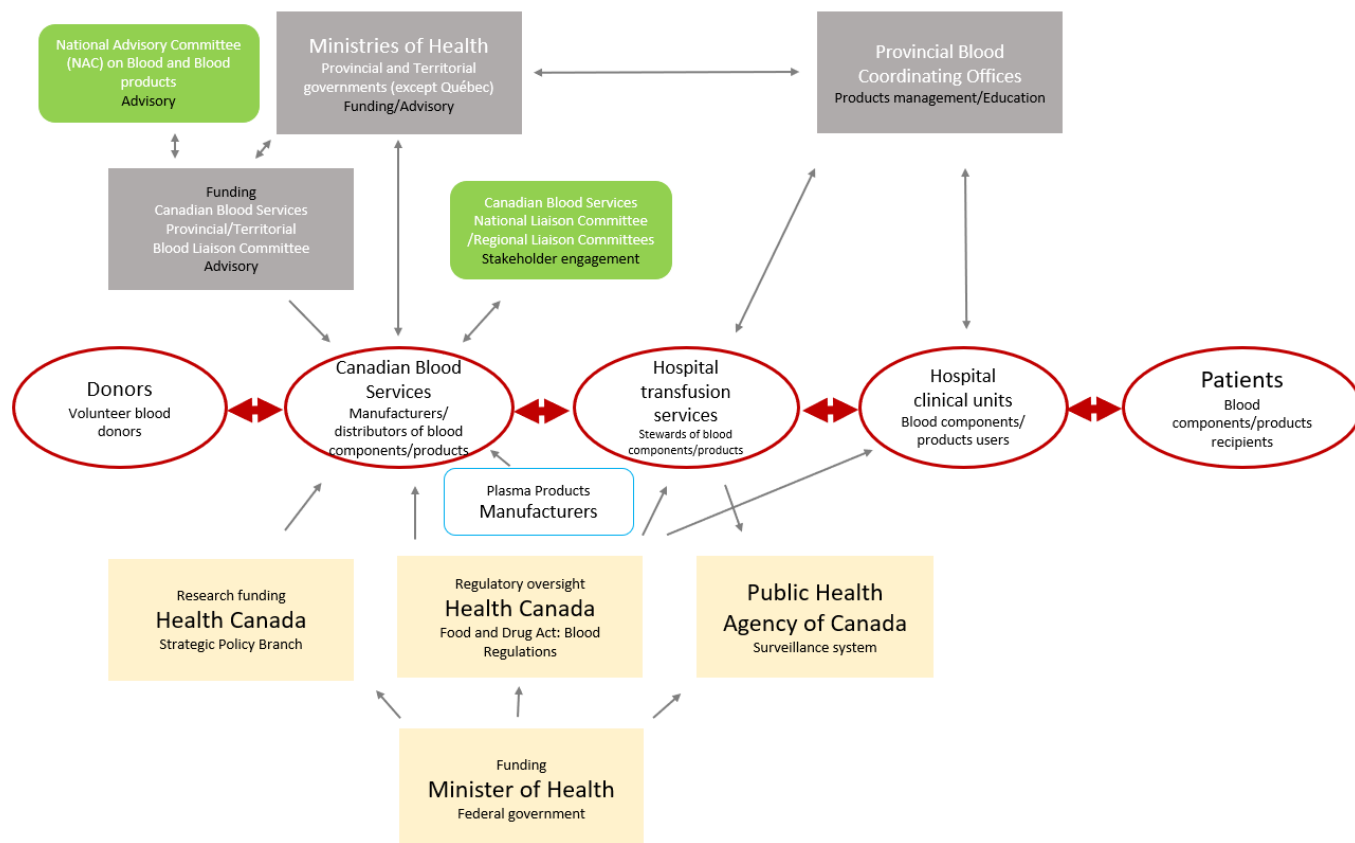


Figure 1: Interrelationships between the protagonists of a safe blood system in Canada. For simplicity, the Province of Québec is not represented in this schematic.

CONTINUING PROFESSIONAL DEVELOPMENT CREDITS

Fellows and health-care professionals who participate in the Canadian Royal College's Maintenance of Certification (MOC) program can claim the reading of the [Clinical Guide to Transfusion](#) as a continuing professional development (CPD) activity under [Section 2: Self-learning credit](#). The reading of one chapter is equivalent to **two credits**.

Medical laboratory technologists who participate in the Canadian Society for Medical Laboratory Science's [Professional Enhancement Program](#) (PEP) can claim the reading of the [Clinical Guide to Transfusion](#) as a non-verified activity.

ACKNOWLEDGEMENTS

The author acknowledges Robert Barr and Ted Alport who wrote the previous version of this chapter, and Amanda Cullen, Jennifer Biemans, Rosanne Dawson, Margaret Fearon, Oksana Prokopchuk-Gauk, Robert Romans and Kathryn Webert who reviewed the current version.

If you have questions about the *Clinical Guide to Transfusion* or suggestions for improvement, please contact us through the [Feedback form](#).

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