Network of Rare Blood Disorder Organizations
Réseau des Associations Vouées aux Troubles Sanguins Rares

Position Statement

PROTECTING AND IMPROVING CANADA'S HEMOVIGILANCE SYSTEMS

May 2025

The Network of Rare Blood Disorder Organizations (NRBDO) calls on the Government of Canada to maintain and enhance, not discontinue, its commitment to national hemovigilance. The decision by the Public Health Agency of Canada (PHAC) to terminate the Blood Safety Contribution Program (BSCP), citing internal evaluations and mandate alignment issues, represents a dangerous step backward for patient safety, public confidence in our blood system, and international reputation. A coordinated national hemovigilance system is essential to ensuring timely and accurate monitoring of blood safety in Canada. Without federal leadership, support, and infrastructure funding, provincial and territorial surveillance efforts become fragmented, reactive, and insufficient. Canada risks falling below the World Health Organization's (WHO) minimum standards for hemovigilance and undermining the safety of patients who depend on blood and plasma-derived products.

BACKGROUND

Hemovigilance, as defined by the WHO, is a system of surveillance procedures that encompasses the entire blood transfusion process, from donor to recipient.[1] It has become a requisite standard of care globally in response to concerns about the potential harms associated with transfusion. Hemovigilance systems play a pivotal role in tandem with blood operators, enabling the proactive detection and mitigation of emerging threats and signals of harm.

In Canada, the BSCP and its supported programs were established in direct response to the findings of the *Royal Commission of Inquiry on the Blood System in Canada* (the Krever Inquiry).[2] This inquiry investigated the catastrophic public health failure of the 1980s, during which thousands of Canadians were infected with HIV and hepatitis C through transfused blood products—an event that proved fatal for many and deeply eroded public trust.

Though its title belies the scope and importance of its function, the BSCP and the programs it supports (the Transfusion Transmitted Injuries Surveillance System (TTISS) and the Transfusion Error Surveillance System (TESS)) have served as the cornerstone of Canada's hemovigilance

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[1] World Health Organization. *Global Consultation on Haemovigilance Systems: Summary Report*. Geneva: WHO, 2012. https://www.who.int/publications/i/item/9789241504726

[2] Krever, H. *Final Report: Commission of Inquiry on the Blood System in Canada*. Ottawa: Government of Canada, 1997. https://publications.gc.ca/site/eng/9.824701/publication.html

infrastructure. All provinces and territories rely on these national programs and their infrastructures (including the Canadian Network for Public Health Intelligence (CNPHI) database), created to standardize and collate data for aggregation and analysis, as well as federal resources to do this work.

In August 2024, the Public Health Agency of Canada (PHAC) issued a brief and unconsulted communication of its intention to end the BSCP. The termination of the BSCP removes not only the funding but also the database, crucial infrastructure that currently allows provinces and territories to collect and transmit hemovigilance data to the federal government. There was no formal engagement with or notice to external stakeholders, including Canada's two blood operators, patient communities, or transfusion clinicians.

Despite strong, immediate, and unanimous concern from these stakeholders, PHAC has maintained that patient safety will not be compromised, asserting that severe adverse events will still be reported directly to Health Canada. This position fails to acknowledge that the BSCP underpins the infrastructure necessary for those reports to happen in the first place. It also reflects a misunderstanding of what effective hemovigilance requires: not just episodic reporting limited to severe adverse events and isolated to blood component/product safety, but ongoing federal/provincial/territorial coordination, federal leadership, and the capacity to analyze and act on signals from across jurisdictions.

The shortcomings identified in PHAC's 2023 evaluation of the BSCP do not support dismantling the program. Rather, they reflect the long-term consequences of inadequate funding and limited federal oversight. The evaluation concluded that the program had become ineffective, and the transfusion community largely concurred, not as evidence of the program's lack of importance but of a lack of resources and federal engagement. Provinces and territories have remained committed, continuing to submit data despite constrained resources. The program's inability to generate timely, meaningful national reports stems from a lack of federal capacity and investment, not from provincial disengagement. For years, the transfusion community has called for modernization and revitalization of the BSCP, not its elimination. To end the program without a plan to replace its core functions is to abandon one of the foundational elements of Canada's blood safety system.

NRBDO's POSITION

The NRBDO unequivocally asserts that:

1. **Canada needs a coordinated and comprehensive national hemovigilance system.** Robust hemovigilance is a recognized international standard for ensuring blood safety. The WHO identifies national hemovigilance as essential for identifying trends, managing

risks, and improving transfusion outcomes. Without a coordinated national system, Canada falls below global standards and places patient safety at risk.

2. **Hemovigilance is a federal responsibility.** PHAC has also stated that the BSCP does not align with its mandate. However, this is a mischaracterization. In fact, PHAC was created in response to the Krever Inquiry's recommendation that surveillance and epidemiology functions be clearly separated from regulatory ones, underscoring the need for a distinct federal body to lead national coordination and surveillance.[2, 3] The BSCP's role in supporting national hemovigilance aligns directly with PHAC's core purpose. That said, the NRBDO maintains that, regardless of where it is housed, hemovigilance must be federally led, funded, and coordinated. Provinces and territories need a shared, standardized database and consistent support to collect and share data. At the same time, Canada requires federal infrastructure to analyze and respond to that data at a national level. In fact, the National Advisory Committee on Blood and Blood Products (NAC) has stated that the impending lack of a national adverse transfusion reaction database threatens not only future data collection and access to historical CNPHI data but also hospital lab accreditation.[4]

3. **The BSCP should be improved, not eliminated.** If PHAC's internal evaluation found underperformance within the BSCP, the appropriate response is to improve it, not to dismantle it. Terminating a program without replacing its essential functions is irresponsible and short-sighted. As health systems face growing complexity and increasing pressure, proactive investment in safety infrastructure is more important than ever.

4. **The loss of BSCP funding undermines patient safety.** Adverse event reporting depends on dedicated personnel, systems, and coordination, all of which require sustained investment. Without federal funding and database infrastructure, provinces will lack the capacity to maintain timely, high-quality reporting. The claim that patient safety will not be affected ignores the foundational role that BSCP support plays in enabling surveillance at all.

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[3] Public Health Agency of Canada. *Learning from SARS: Renewal of Public Health in Canada – A Report of the National Advisory Committee on SARS and Public Health.* Ottawa: Health Canada, 2003. https://www.canada.ca/en/public-health/services/reports-publications/learning-sars-renewal-public-health-canada.html

[4] NAC. *Letter to CBS-PTBLC - Urgent Need to Transform the Canadian Hemovigilance System: A Call to Action*. 2025. https://nacblood.ca/en/resource/nac-letter-cbs-ptblc-urgent-need-transform-canadian-hemovigilance-system-call-action

RECOMMENDATIONS

The NRBDO urges the federal government to:

- Reverse the decision to withdraw funding and infrastructure support from national hemovigilance monitoring;
- Commit to long-term, stable funding for a national hemovigilance program that supports provincial and territorial participation;
- Clarify which federal agency will be accountable for this essential responsibility, and ensure that the agency has the mandate, resources, and authority to lead national blood safety surveillance, including timely national reporting;
- Work in collaboration with clinicians, blood operators, patient organizations, and provinces to co-design a modernized and strengthened national hemovigilance system.

CONCLUSION

For people living with rare blood disorders, and for all Canadians who rely on a safe and secure blood supply, national hemovigilance is not optional. It is an essential safeguard. The NRBDO joins our clinical, operational, and patient partners in urgently calling for the preservation and strengthening of Canada's national hemovigilance system, and we offer our full collaboration to help achieve this goal.

SUPPORTING CASE STUDIES

Case Study 1: Development of Guidelines for Investigating Suspected Transfusion-Transmitted Bacterial Contamination

The BSCP facilitated the creation of national recommendations for categorizing different types of adverse transfusion events, including investigations of suspected transfusion-transmitted bacterial contamination. This ensures national harmonization for data aggregation and, consequently, actions that have an impact on the safety of the blood supply.

For example, the PHAC criteria for identifying patients at high risk of a septic transfusion reaction due to bacterial contamination of transfused components or products allow for immediate actions such as quarantining products from the same source and assessing or treating other recipients of those components or products. This proactive approach has been instrumental in both donor and recipient notification, their management, and preventing further adverse events by ensuring the safety of the blood supply.

Case Study 2: Elucidation and Mitigation of Risk due to Transfusion-Related Acute Lung Injury (TRALI), which was Highly Associated with Transfusion-Related Patient Mortality

Through data collected by the Transfusion Transmitted Injuries Surveillance System (TTISS), supported by the BSCP and other hemovigilance systems worldwide, TRALI was identified as the most frequent transfusion-related adverse event among transfusion-attributed fatalities.

Importantly, Health Canada's Canada Vigilance Program also receives reports of TRALI in accordance with the Blood Regulations, as TRALI is a serious complication that can be life-threatening. Still, annual reports on the number of TRALI events have never been released by Health Canada. It was the analysis of national TRALI rates via the TTISS Program that helped blood operator investigations identify the association with plasma from female donors who had been pregnant, which led to targeted mitigations. Thus, the TRALI incidence rate has fallen from 1:1,200-5,000 to 1:10,000 blood component recipients nationally.

Case Study 3: Highlighting Risks Due To Hospital Transfusion Practice, with Transfusion-Associated Circulatory Overload and Immune Incompatibility (Error-Related or Idiosyncratic) Events Currently Most Associated with Recipient Mortality

Given the focus on mitigating infectious risks of the blood supply, including donor screening and pathogen-inactivation technologies, the primary risks of blood transfusion now reside in hospital practice and in immune personalization.

Two relevant examples include a) transfusion associated circulatory overload (TACO) where a patient's respiratory status is compromised by the inability to handle the extra fluid from a blood transfusion; and b) red cell incompatibility from human error (wrong blood given) or catastrophic rejection events (hyperhemolysis) despite suitable crossmatching practices.

Conservative estimates place the risk of TACO at 1:100, where TACO is now the adverse transfusion event associated with the highest mortality (up to a third of deaths related to transfusion adverse events). Wrong blood given is almost always due to an error at the hospital level, where one of the main factors, incorrect patient identification at sample collection, occurs in approximately 1 in 3,000 patients. Hyperhemolysis, in turn, is a rare complication of transfusion that occurs disproportionately in people with sickle cell disease despite high-fidelity matching practices. Its occurrence is a call for better reporting to achieve a better understanding of the phenomenon.

Hemovigilance systems outside of the BSCP do not capture all TACO events, and Canada captures data only from a limited number of hospitals for transfusion chain error, unlike other hemovigilance systems. In other hemovigilance systems internationally, TACO and sample collection errors have directly led to hospital accreditation standards and policies aimed at reducing risk to patients.