December 18, 2024

CBS-PTBLC Co-Chairs:
Antje Helmuth, Senior Director, National Blood Portfolio, BC Ministry of Health
Lindy McIntyre, Director, Health Policy and Governmental Affairs, Canadian Blood Services
Via email

RE: Urgent Need to Transform the Canadian Hemovigilance System: A Call to Action

Dear CBS-PTBLC Colleagues,

The National Advisory Committee on Blood and Blood Products (NAC) wishes to express, to and through the CBS-PTBLC, extreme distress with the Public Health Agency of Canada's (PHAC) decision to sunset the Blood Safety Contribution Program (BSCP), including the Transfusion Transmitted Injuries Surveillance System (TTISS) and the Transfusion Errors Surveillance System (TESS), as of March 31, 2026. This unilateral decision was communicated on August 28, 2024, without any external consultation or warning to the transfusion community. Only a small, selected number of recipients who directly contribute data to the TTISS and TESS programs received the PHAC announcement directly.

The BSCP and its supported programs were initially established in response to the published report of the Krever Inquiry, following the catastrophic public health failure of the 1980s in which thousands of Canadians were infected with often fatal transfusion transmitted illness. Hemovigilance, defined by the World Health Organization as a system of surveillance procedures that covers the entire process of blood transfusion, became a requisite standard of care worldwide given concerns regarding harms of transfusion. Justice Krever included in his findings explicit recommendations for a Canadian hemovigilance system:

40: ***It is recommended that there be an active program of post-market surveillance for blood components and blood products.***

43: ***It is recommended that the Bureau of Biologics and Radiopharmaceuticals be given sufficient resources to carry out the functions properly.***

48: ***It is recommended that the governing bodies of physicians and surgeons in the provinces and territories make it a standard of practice that physicians report adverse reactions from the transfusion of blood components to the national blood service, and adverse reactions from the infusion of blood products to the national blood service and the manufacturers of blood products.***

Justice Krever recommended a system in which the federal government has clear and ultimate responsibility for maintaining a national hemovigilance system. The establishment of the renewed Blood System in Canada, under the leadership of the then Federal Minister of Health, Alan Rock, in the late 1990s was predicated on this premise. The BSCP and its activities are the cornerstone of Canada's hemovigilance system, in which the goal is to improve the safety of blood transfusions by identifying and preventing adverse events when they occur in recipients, **complementary** to activities of our national blood suppliers. The decision to end Canada's

hemovigilance system would relegate Canada's protection of blood recipients below that of countries with comparable health systems and render it vulnerable to repeating tragedies of the past. **It is essential that the Federal Government reverse its decision to end national blood safety surveillance system program funding, as the lack of this post-marketing surveillance will undermine patient safety, public confidence and international reputation. We see an opportunity for the government to partner with the transfusion community in strengthening the Canadian system to both provide the best patient care for the best return on investment.**

The BSCP was established following a federal approval of funding in 1998 and recognized as a federal responsibility. According to the original agreement, the BSCP was allocated an annual $4 million budget to salaries, operations and program maintenance. The TTISS program was created in 2001 to improve on the base program, as a supported and voluntary nationwide surveillance system to monitor serious, moderate, and selected minor transfusion-related adverse events occurring in Canadian healthcare settings. Given the importance of transfusion-related errors and near-misses in harming patients, the TESS program was implemented as a pilot through a national working group and PHAC funding in 2005.

Regrettably the federal contribution to the BSCP has dwindled, with recent funding amounting to only $2.19 million annually, leading to ineffective hemovigilance. TTISS and TESS have functioned ineffectively as determined by the Evaluation of the PHAC BSCP report published in February 2023 by the Office of Audit and Evaluation. This opinion is shared by Canada's transfusion community which has long sought to contribute suggestions for the necessary enhancement of the program, and which is shocked and outraged by the decision to eliminate it, rather than enhance it.

Despite lacking resources, the dedication of hospitals to hemovigilance has been steadfast, with provinces and territories leveraging limited funding to support data entry into the Canadian National Public Health Information (CNPHI) database for both TTISS and TESS. Data from over 98% of transfusing facilities in Canada is available in TTISS, though the TESS program has only been funded and therefore implemented at 30% of transfusing facilities. Although each province and territory submits data annually to ensure ongoing federal program funding commitments, resource limitations within the federal PHAC TTISS office have precluded meaningful data review and the provision of timely national reports back to provinces.

At an informational meeting on September 10, 2024, held by PHAC and Health Canada – Canada Vigilance, PHAC outlined their rationale for sunsetting the BSCP, stating that:

1) The objectives of the BSCP do not align with PHAC's mandate and priorities,
2) The BSCP sunsetting was not significant in terms of hemovigilance as provinces and territories have adequate resources in place within their jurisdictions to continue to collect information on transfusion adverse reactions,
3) PHAC was not collecting and synthesizing data in a timely fashion to inform decision-making, and
4) Ongoing monitoring of severe reactions through Health Canada – Canada Vigilance was putatively sufficient to meet the recommendations made within the Krever report.

We hold that each of these statements is either untrue or disingenuous:

- PHAC's posted mandate on their own website currently denotes their role in preventing and controlling chronic diseases, injuries, and infectious diseases, and strengthening public health collaboration between governments.
- The BSCP sunsetting is absolutely significant, as few provinces and territories actually have a database infrastructure in place to collect adverse transfusion reaction data independent of the CNPHI database. In fact, every jurisdiction currently relies on federal resources and the CNPHI database for information entry, storage, and subsequent report generation to tabulate adverse reaction data. This activity has continued despite limited resourcing as Canadian hospital lab accreditation standards require regular reporting to a hemovigilance program. The impending lack of a national adverse transfusion reaction database threatens future data collection and hospital lab accreditation, as well as the accessibility and use of historical CNPHI data.
- The most recent full publication of TTISS data was a 2016-2020 summary report. In June 2024, only a standalone 2022 data infographic was published. This must be seen as evidence of a lack of resources and engagement within the national TTISS office, not of a lack of importance of hemovigilance. Decision-making and policy instead have relied on provincial and territorial efforts leveraging their data because the national analysis was untimely and lacked granularity.
- From a public health perspective, hemovigilance relies on the comprehensive collation of data across Canada to inform signals of harm from blood. This is currently facilitated by the CNPHI database which standardizes and collates data for aggregation and analysis, to be discontinued with the sunsetting of the BSCP. Health Canada – Canada Vigilance acts as a unilateral repository only capturing serious transfusion reactions associated with blood quality, missing much of what TTISS and TESS captures.

What does this mean for patients and the public if the BSCP is sunset? Blood transfusion is one of the most ubiquitous and life-saving therapies for patients with unique risk considerations due to its human donor origin, unlike other pharmaceutical therapies. Canada would not have the infrastructure nor organizations needed to sustain hemovigilance without a suitable replacement. While the blood supply has become safer through detailed donor screening and testing for known transfusion transmitted diseases, complacency would be an unfortunate and dangerous result. Hemovigilance systems work in concert with blood operator efforts to detect and mitigate emerging threats and signals of harm. We have been fortunate that emergent infectious agents in recent years, such as the SARS-CoV-2 and Zika viruses, have not greatly affected the blood system, in part because global surveillance information enabled the initiation of rapid action. However, emerging disease threats remain, notably for example related to climate change and consequent changes in patterns of arthropod and tick-borne diseases.

The function of Health Canada – Canada Vigilance as a unilateral repository for "post-marketing surveillance" for blood components and products is incomplete and ineffective. Summary reports are not generated for review by hospital facilities and therefore cannot be used as a resource for system improvement. To provide a concrete example, Health Canada – Canada Vigilance receives reports of transfusion associated lung injury (TRALI) events in accordance with the Blood Regulations, as TRALI is considered to be related to blood quality. Annual summary reports defining the number of national TRALI events have never been released by Health Canada –

Canada Vigilance. However, analysis of national TRALI rates via the TTISS Program aided blood operator investigations, which led to the identified need to exclude multiparous female donors to mitigate the risk of TRALI in blood component recipients. Thus, the TRALI incidence rate has fallen from 1:5,000 to 1:10,000 blood component recipients nationally. Without these data, it would be impossible to understand adverse reaction rates and to identify and develop interventions to protect patient transfusion recipients.

Further, transfusion reactions not related to blood quality are not captured by Health Canada – Canada Vigilance. Monitoring the frequency of these events is essential to ensure identification of product lot related cluster reactions or trends which may be related to the presentation of an emerging pathogen or hospital practice (such as transfusion associated circulatory overload, which is now the most common adverse reaction leading to patient death), to enable intervention and mitigation of the risk of additional transfusion recipient events. Present and emerging harms can only be detected through all adverse events and systems gaps across Canada being integrated with proactive analysis and connections to public health.

Without the continuation of federal funding, important hospital-based resources in transfusion safety are now at risk. The discontinuation of annual BSCP funding will mean the termination of personnel within provinces and territories who are currently contributing to transfusion safety and data entry, along with the potential forced closure of provincial databases and educational programs. Further, this lack of personnel and reporting databases will put hospital operations and lab accreditation at risk, placing significant unanticipated pressures on provincial budgets to fund resources required to perform required transfusion reaction monitoring activities within hospitals.

We call on the Federal Government to ensure that public trust and confidence in Canada's blood system is not eroded. The risk of negative impact to the federal public health reputation by sunsetting blood safety monitoring programming is immeasurable. Collecting adverse reaction data and its surveillance are standard of care worldwide to create policy and practices that bolster transfusion safety. Any resulting adverse patient harm from the sunsetting of BSCP and the dissolution of hemovigilance in Canada will a burden to patients and costs will fall to the individual provinces and territories. Canada must align with modern and effective hemovigilance programs worldwide, including the UK Serious Hazards of Transfusion (SHOT) System, the US Centre for Disease Control's National Healthcare Safety Network, and organizations represented within the International Hemovigilance Network; all have **increased** focus on the role of hospital practice and error in harming patients while maintaining their robust activities.

To ensure Public Health surveillance and transfusion safety, it is imperative that a robust, sustainable hemovigilance system is implemented in Canada.

As the country's medical and technical advisory body for the CBS-PTBLC, the NAC is recommending that the following two actions are put forth to PHAC:

1) **Rescind its decision to withdraw funding away from national hemovigilance monitoring, and**
2) **Reform Canada's federal hemovigilance system to ensure a timely and accountable structure, which functions with engagement and representation from provincial and territorial governments and transfusion medicine community stakeholders.**

We, the NAC Membership, are ready to participate in consultative conversations with federal and provincial and territorial governments, as well as with our colleagues within the health system, to establish a new hemovigilance system which is appropriately funded as an essential and sustainable national program. We request that you bring these concerns to the attention of officials in government with urgency.

Although Québec is an observer on this committee, it shares the concerns expressed in the letter.

Thank you very much for your attention.

Dr. Andrew Shih
NAC Chair

Dr. Oksana Prokopchuk-Gauk
NAC Adverse Transfusion Reaction Subcommittee Chair

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