June 16, 2025

Karen Hogan
Auditor General of Canada, Office of the Auditor General of Canada (OAG)

RE: Blood Safety Crisis, Prompted by the Inappropriate Sunsetting of the Public Health Agency of Canada Blood Safety Contribution Program, against Audit Recommendations

Greetings,

On behalf of the Ontario Regional Blood Coordinating Network (ORBCoN), we wanted to take this opportunity to formally express our disappointment and concerns with the plan by the Public Health Agency of Canada (PHAC) to discontinue funding of the cornerstone hemovigilance programs in Canada, the Transfusion Transmitted Injury Surveillance System (TTISS) and the Transfusion Errors Surveillance System (TESS), through their Blood Safety Contribution Program (BSCP) as of March 31, 2026. This was done without consultation with the blood system and against the recommendations of two independent audits.

Hemovigilance is critical for continuous quality improvement of the blood system through corrective and preventative actions to improve donor and patient safety as well as reduce wastage, and recommended by the World Health Organization, to be implemented into national blood and health systems. The creation of TTISS and TESS, as having a primary role in hemovigilance, arose as recommendations from learnt experiences from the tainted blood scandal as findings from the 1997 Royal Commission of Inquiry on the Blood System in Canada (led by Justice Horace Krever). The loss of these two systems in Canada will threaten the health and safety of Canadians and adversely impact the mitigation of future risks in the transfusion of blood and blood products.

Despite the participation by hospitals in provinces and territories, two independent evaluations found that TTISS and TESS nationally functioned ineffectively, namely:

- In 2020, the Value-for-Money Audit Blood Management and Safety report from the Office of the Auditor General of Ontario recommendations, which emphasized the need for raising awareness for the requirement for all hospitals to report serious transfusion-related

incident data, improved tracking, increased and regular reporting, and annual collating of transfusion data (recommendations #5, 11).

- In 2023, the Evaluation of the PHAC BSCP report from the Office of Audit and Evaluation recommendations are primarily to clarify PHAC's roles and responsibilities to financially support and establish a surveillance system and activities in relation to transfusion injury and error, with an emphasis on timely reporting (recommendations #1, 2).

Instead of complying with these recommendations, which are fully supported by Canada's transfusion community, PHAC's decision to sunset the BSCP destroys the existence of the hemovigilance program in Canada relevant to hospitals. The rationale provided for sunsetting included that data provided by the national TTISS program was not timely and that federal regulations and Health Canada would be sufficient. However, the lack of timely summary reports are a responsibility of PHAC and not the reporting hospitals. We feel that not providing timely data is a disservice to Canadians and should be a rationale to reprioritize the importance of hemovigilance and its resourcing from PHAC.

Furthermore, without a provincial or federal authority to provide surveillance, hospitals will not be able to comply with accreditation and Health Canada requirements. Standards and regulations for transfusion safety require a means to collect, collate, and analyze appropriately comprehensive data. In the absence of TTISS and TESS, these data are not fully collected by Health Canada nor blood operators, who narrow focus on unexpected and/or severe outcomes solely associated with blood quality. TTISS and TESS provide surveillance on inappropriate hospital transfusion practices, an example being transfusion-associated circulatory overload, now the leading cause of transfusion-related fatality. Data from Health Canada is also not provided to provinces and territories to assess and interpret. Removal of TTISS/TESS and thus hemovigilance, leads to hospital blood banks' licensure being put at risk, and reducing patient care and requirements to an inferior standard of care that puts patients at risk.

Finally, the negative impact to public trust and safety is incalculable without support for surveillance. Blood transfusion is ubiquitous and lifesaving. During the tainted blood crisis, trust was eroded as transfusion recipients died or had lifelong anguish because of adverse events. These hemovigilance programs are considered standard of care worldwide for these reasons. The identification of emerging risks and reaction trends will no longer be available without support for these programs, and we cannot rely on other nations to do this work in our stead.

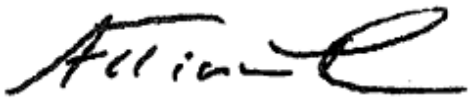
Given this, I urge the OAG in its role to ensure accountability to Parliament, to have the federal government rescind the decision to withdraw funding from hemovigilance counter to the recommendations of two independent audits. Instead, Canada's federal hemovigilance system must be reformed to ensure a timely and accountable structure, with engagement and representation from provincial and territorial governments and transfusion medicine community stakeholders.

Sincerely,

Andrew Shih, MD, FRCPC, DRCPSC, MSc
Associate Professor, Department of Pathology and Molecular Medicine, McMaster University
Project Sponsor, Ontario Regional Blood Coordinating Network – Southwest

Yulia Lin, MD, FRCPC
Division Head, Transfusion Medicine & Tissue Bank
Precision Diagnostics and Therapeutics Program (Laboratory Medicine), Sunnybrook Health Sciences Centre
Professor, Dept of LMP, University of Toronto
Affiliate Scientist, Sunnybrook Research Institute
Project Sponsor, Ontario Regional Blood Coordinating Network – Central

Antonio Giulivi MD FRCPC
Associate Professor and Vice Chair, Dir. of Research, Dept. of Pathology & Lab. Medicine, University of Ottawa
Medical Director, OHRI Biotherapeutics Manufacturing Centre, Ottawa Hospital Research Institute
Clinician Investigator, Regenerative Medicine Program, Ottawa Hospital Research Institute
Medical Scientific Lead, Innovation and Research, EORLA
Clinical Hematopathologist, Transfusion Medicine, Division of Hematopathology & Transfusion Medicine, The Ottawa Hospital
Program & Project Sponsor, Ontario Regional Blood Coordinating Network – Northeast



Alan Tinmouth, MD FRCPC
Associate Professor, Department of Medicine, University of Ottawa
Director, Ottawa Hospital Hemoglobinopathy Program, Department of Hematology
Director, Ottawa Hospital Centre for Transfusion Research
Ottawa Hospital and Ottawa Health Research Institute
Program & Project Sponsor, Ontario Regional Blood Coordinating Network – Northeast