Canadian

Recipient Hemovigilance System Renewal Process

RECOMMENDATIONS PAPER

Process facilitated by

RSI RISK SCIENCES INTERNATIONAL

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Executive summary

Background

Hemovigilance, defined by the World Health Organization[1] as a system of surveillance procedures that encompasses the entire vein-to-vein process of blood transfusion, has become a requisite standard of care worldwide given concerns regarding the potential harms of transfusion.

The Canadian Recipient Hemovigilance System Renewal Process was undertaken to develop recommendations for the structure, elements and functions of a future renewed national recipient hemovigilance system for Canada, following the announcement by the Public Health Agency of Canada (PHAC) that the Blood Safety Contribution Program (BSCP) would sunset as a funding mechanism as of March 31, 2026. Recommendations were developed during a major Consensus Conference that took place on March 23-24, 2026, and included more than 100 participants from the Canadian transfusion medicine community, patient organizations, Canada's two blood system operators, and representatives of the federal, provincial and territorial governments.

Hemovigilance encompasses surveillance activities across the blood system, including donor safety, product safety, and recipient outcomes associated with blood transfusion. Recipient hemovigilance represents a specific component of this broader system and focuses on monitoring adverse transfusion reactions and patient outcomes following transfusion. This renewal process and the Consensus Conference were focused on recipient hemovigilance.

The Blood Safety Contribution Program was implemented on the recommendation of the Krever Commission of Inquiry into the contamination of the blood supply in the late 1970s and 1980s. It supported the development of three provincial and territorial surveillance systems. This process draws on experience with two of these three systems to inform recommendations for a renewed national recipient hemovigilance system: these are the Transfusion-Transmitted Injury Surveillance System (TTISS), established in 2001 for monitoring adverse transfusion reactions (ATRs), and the Transfusion Error Surveillance System (TESS), initiated as a pilot in 2005 to monitor transfusion errors.

The BSCP was a contribution-funded mechanism operated by the federal government through the PHAC. It provided national coordination and support, including funding, data collection, analysis and reporting, in support of the provincial-territorial (PT) recipient hemovigilance programs. At the operational level, hospitals detected, investigated, and reported ATRs and errors to their respective PT blood coordinating offices or directly through the Canadian Network for Public Health Intelligence (CNPHI) database. These data were then submitted to and integrated into the national hemovigilance databases. The national BSCP system, managed through the PHAC, harmonized reporting practices and definitions across PTs, analyzed surveillance data, produced national reports and provided PTs with funding for BSCP functions.

The sunsetting of the BSCP removed the national coordination, data analysis, and reporting functions of the recipient hemovigilance systems, as well as federal funding that supported BSCP activities, but the broader hemovigilance activities conducted by PTs continue. Hemovigilance in Canada extends beyond the BSCP and includes PT surveillance systems, Health

1 WHO (2016) *A guide to establishing a national haemovigilance system.* Geneva. Available at https://iris.who.int/server/api/core/bitstreams/1a491336-afb2-4e27-a960-38982209f5ac/content

Canada's regulatory oversight, and operational blood safety systems managed by Canadian Blood Services and Héma-Québec.

With the closure of the BSCP, PHAC no longer has program authority and does not hold a regulatory mandate for blood safety. However, Canadian Blood Services (CBS) and Héma-Québec (HQ) continue to manage and protect the Canadian blood supply. Health Canada also continues to focus on regulatory oversight for blood and blood products for transfusion, and cells, tissues and organs for transplantation, and mandatory requirements continue to be in place for safety surveillance of these products of human origin. Regulatory reporting of adverse reactions, errors and accidents that could affect the safety of blood, cells, tissues and organs remains in place.

A schematic of recipient hemovigilance functions and the impacts of the sunsetting of the BSCP are shown in Figure 1 below.

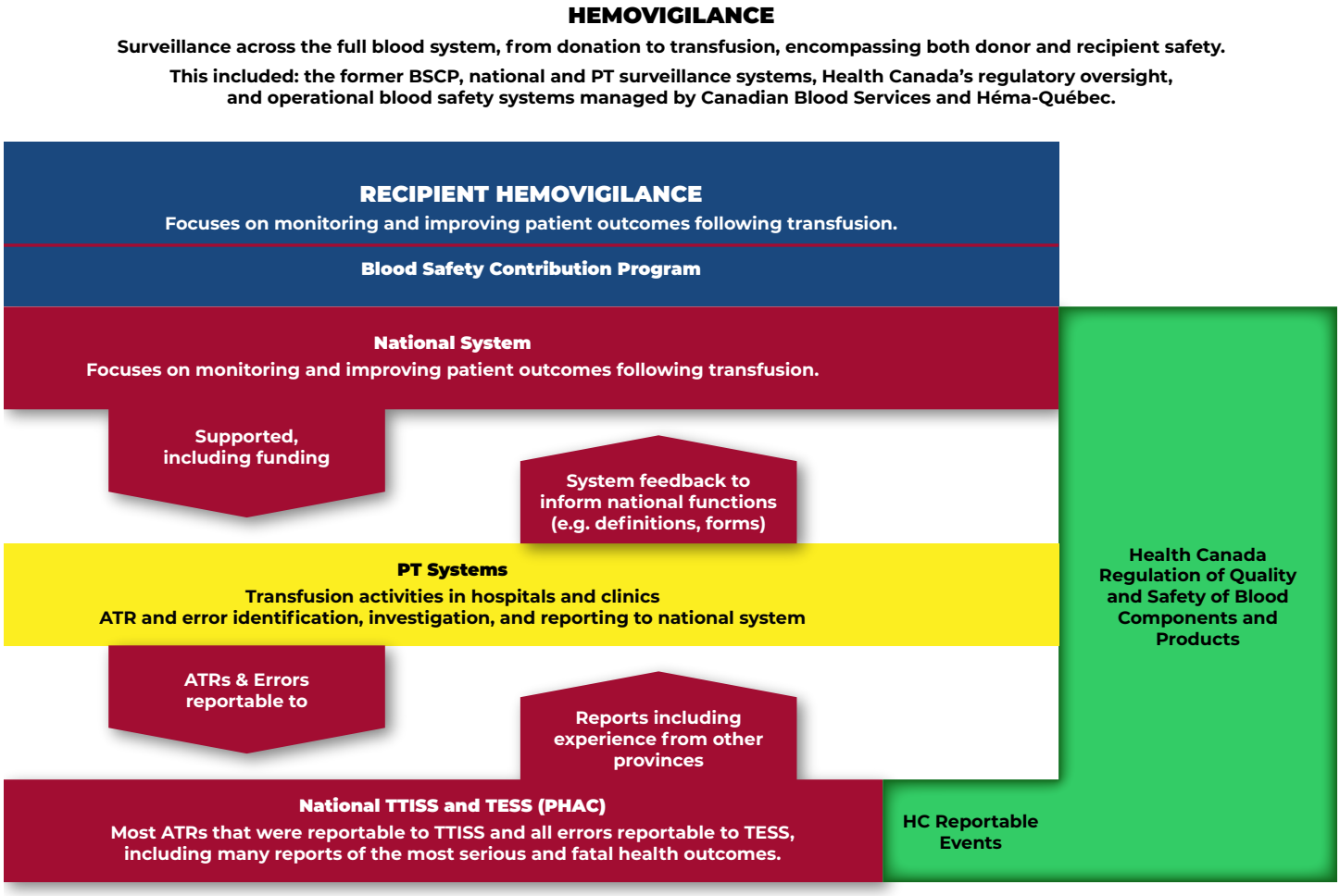

Figure 1. The structure of and changes to recipient hemovigilance functions within the overall hemovigilance program in Canada. The sunsetting of the BSCP results in the elimination of some recipient hemovigilance functions (red), the loss of support for others (yellow), while some functions remain the same (green).

There is widespread concern with the sunsetting of the BSCP, as the PTs had relied on national BSCP funding to carry out many essential recipient hemovigilance activities; in addition, the national and PT systems need to interact and be coordinated on many functions. Reasons for concern with the loss of essential recipient hemovigilance functions include:

1. The inability to capture the most severe transfusion reactions that are not captured by other organizations responsible for hemovigilance, which are primarily concerned with blood quality;
2. The need for national collation and coordination to effectively monitor and detect emerging trends, for which individual PTs would not have the capability;
3. The need to provide medical and scientific community reporting to identify emerging threats from trends and mitigation strategies at the national scale.

The Canadian Recipient Hemovigilance System Renewal Process

In response to the concern regarding the loss of national blood safety surveillance, the Canadian Recipient Hemovigilance System Renewal Process was initiated in late 2025 with the intent of involving blood system stakeholders to develop recommendations for a renewed hemovigilance system for Canada. The recommendations would be presented to federal and PT governments for a decision on the way forward, based on the expertise and experience of stakeholders in the transfusion community.

The Canadian Recipient Hemovigilance System Renewal Process was guided by a multi-stakeholder Stewardship Working Group; it was supported by Risk Sciences International, a consultancy engaged by Canadian Blood Services and funded by PHAC, to conduct a consultation and prepare a White Discussion Paper and this Recommendations Paper, as well as to design, manage and facilitate the Consensus Conference.

The foundation of the renewal process was a major consultation that involved interviews with 47 representatives of the transfusion medicine community, patient groups, Canada's two blood system operators, and federal and PT governments. The interviews focussed on participants' evaluations of the existing surveillance systems, and their suggestions and preferences for the structure and functions of a renewed system. There was significant convergence in interviewees' experience that national reporting was ineffective as reports were not timely, data were outdated and analysis was cursory. There was near unanimity that a national recipient hemovigilance system is essential in Canada to coordinate ("White Discussion Paper") that formed the substance of the discussions at the Consensus Conference, where they were refined into recommendations for a renewed system. The White Discussion Paper was circulated to attendees in advance of the conference to enable preparation for the Consensus Conference. The process is summarized in Figure 2 on page iv.

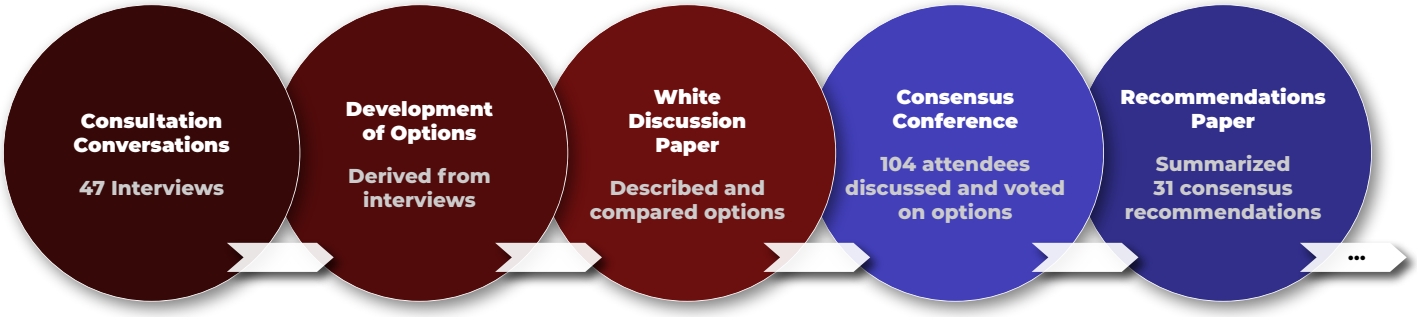

Figure 2. The Canadian Recipient Hemovigilance Renewal Process.

The Consensus Conference

The Consensus Conference was attended by 43 individuals in person, and an additional 61 individuals participating virtually through an MS Teams meeting that allowed them to contribute to the discussions. Facilitated discussions followed the content of the White Discussion Paper, which included options related to elements and functions needed in a renewed hemovigilance under a set of seven categories, addressed in order of importance. Participants addressed options only as they were presented within the White Discussion Paper, and were not given further parameters including feasibility regarding operations and policy.

The Consensus Conference was opened with remarks from representatives of the key stakeholder groups: Canadian Blood Services and Héma-Québec; the Canadian Hemophilia Society (Bleeding Disorders Canada), representing patient groups; the PHAC and Health Canada – Canada Vigilance representing the federal government; the Provincial Blood File Lead, representing provincial governments; and the transfusion medicine community. The issues were addressed in the Consensus Conference over two days, under the following seven main categories:

Day 1

- Program leadership and governance, including expert capacity and funding.
- National recipient hemovigilance system components, including ATR and error reporting systems, and transfusion safety officers in hospitals.
- ATR and error reporting, including mandatory or voluntary reporting, the key types of data to collect on adverse reactions, and standardization of definitions.

Day 2

- National data system reporting, which included four issues: ATR reporting frequency, ATR and error report presentation, ATR and error report data analysis, and ATR and error report data access and sharing.

- Ancillary national functions, including feedback and communication; education and training; and collaboration and coordination.
- Data infrastructure, including integrated databases, reporting processes and tools, and national database functions.
- Cluster definition and identification.

Conference participants had the opportunity to offer their opinions on each option, modifying or removing some, and adding new options; after each discussion, participants participated in an anonymous vote through the *Mentimeter*™ app (both in-person and on-line) accessed on their phones, laptops or tablets. Participants were permitted to abstain from voting at their discretion. The options that received the strongest support are reflected in the recommendations that are presented in this paper. The issues, arguments given in consideration of each option, and the options that received the greatest support, are summarized in sections "2.3 Conference Proceedings - Day 1" on page 12 and "2.4 Conference Proceedings - Day 2" on page 26

In addition to the specific issues that were discussed and resulted in a recommendation, there were several matters that received significant attention, either as important considerations related to an issue or recommendation, or as concerns that ran through many discussions. In summary, these are (addressed in section "2.5 Special topics" on page 38):

Québec's hemovigilance system

- A member of the transfusion medicine community working in the Québec hemovigilance system described Québec's system, as it has been noted as a successful model funded by the provincial Québec public health construct.

International recipient hemovigilance systems

- National recipient hemovigilance programs of six developed countries were reviewed or referred to throughout the course of discussions (United Kingdom, France, Germany, the Netherlands, Norway, and Australia).
- All countries have a national recipient hemovigilance system led by a national government agency that is responsible for monitoring and publishing national ATR data on an annual basis. Australia is very similar to Canada, as it has a federated system in which hemovigilance activities are carried out by states and territories, and a national authority that has coordinating, monitoring and reporting responsibilities.

The federally-coordinated collaborative FPT model of governance

- The preferred governance model is a pan-Canadian governance structure: this is an independent body that has a mandate and structure for interoperability with PT governments, and a dedicated operational unit enabled by federal or mixed federal and PT funding.

Jurisdictional responsibilities and constraints

- There was a lack of clarity on the data that PTs are permitted to share with a national office for inclusion in a national report. Factors that determine the ability to share data include jurisdictional privacy legislation and data-sharing agreements between PTs and the federal government.

Federal and PT government engagement

- Participants wished for guidance from government representatives on the resources that would be available for a renewed system. However, representatives of the federal and PT governments did not take part in voting on options for the issues: this was due to the understanding that governments would be the recipients of the conference's recommendations, and that the purpose of voting was to allow for the recommendations to come from and directly reflect the recommendations of system users and experts. In addition, government wanted to hear directly from stakeholders and without swaying discussions. It should be noted that key federal and provincial government representatives did provide feedback and overarching guidance during the conference's proceedings.
- Some participants at the conference raised concerns that this would preclude any feedback on the feasibility of an option that would enable participants to select an option that is realistic.

Concerns with the transition to a renewed hemovigilance system

- The cessation of federal funding for BSCP hemovigilance activities through the transition to a renewed system raised concerns related to hospital staff who were funded through the BSCP. Not all PTs have a mechanism to collect and analyze data without the federal infrastructure from PHAC. In addition, it was seen as important that PTs should be able to continue to retain and pull information from the BSCP systems beyond March 31, 2027, the date to which the PHAC has agreed to extend access to the national database.

Recommendations

The Consensus Conference resulted in 30 recommendations for the design and implementation of a renewed national recipient hemovigilance system. These recommendations pertain to the categories of the issues that were addressed during the Consensus Conference.

The recommendations reflect stakeholder consensus on the need for a coordinated national approach to hemovigilance. Their implementation will require alignment with federal, provincial, and territorial roles and responsibilities, as well as agreement on governance, funding, and data-sharing arrangements. They are meant to help guide decision-makers on the future of a national recipient hemovigilance system.

Program leadership and governance

Governance

Recommendation 1: The national recipient hemovigilance governance structure should apply a federally-coordinated collaborative FPT model.

This governance structure is effective as it involves both federal and PT governments, to ensure representation and coordination of all jurisdictions, and leadership that is independent of governments, blood operators and industry. The governance body provides the national mandate for hemovigilance and accountability for its performance.

It is similar to pan-Canadian structures, which have been adopted for other systems in Canada and should be applicable to hemovigilance. The development of this model will require federal operational participation and secure federal or FPT cost-shared funding. A diagram depicting this governance structure is found in section 2.4.2. on page 38.

Expert Capacity

Recommendation 2: **An external advisory group should be provided for a national organization that has internal expertise.**

The national structure should include relevant expertise, including medical, nursing, technical, and patient representation, and should also be supported and advised by an expert steering committee with dedicated experts in transfusion medicine, data and research, and other areas. Expertise must be appropriately compensated. An independent expert steering committee was identified as a characteristic of other internationally recognized hemovigilance systems.

Funding

Recommendation 3: **Funding should be a mix of federal and provincial/territorial contributions.**

The essential requirements for funding are that it be adequate to support necessary functions and activities in the hemovigilance system, and that it be sustainable with equitable distribution. Adequate funding is particularly necessary for expert advisors and Transfusion Safety Officers (TSOs) to ensure capacity for surveillance functions.

National Recipient Hemovigilance System Components

ATR and error reporting systems

Recommendation 4: **Error reporting should be retained as part of hemovigilance, merged and/ or expanded as part of hemovigilance to include data from all transfusing facilities.**

Recommendation 5: **The ATR and error reporting systems should be merged.**

Error reporting should be merged and expanded within the hemovigilance system, as opposed to the current limited implementation of error reporting, to ensure that all relevant information on adverse reactions and root causes is collected across Canada.

Transfusion safety officers in hospitals

Recommendation 6: **All hospitals should have access to a TSO. Large hospitals have TSOs; smaller hospitals' access is determined by their network or region.**

Transfusion safety officers are essential for the investigation, education, and reporting of ATRs; neither ATR nor error reporting can operate without a TSO. A unified definition of the TSO role and identification of an appropriate resourcing rubric are needed.

Adverse reaction and error reporting

Mandatory or voluntary reporting

Recommendation 7: **Reporting of all ATRs should be mandatory, regardless of severity.**

Full reporting is necessary to get information on all reactions. Less severe reactions are important, as they can indicate effects of a change in the constitution of some blood components and products or be a marker for insidious dangers to recipients. This is necessary for blood operators to know, for informing physicians' prescribing practice, and for informed patient consent.

Data to collect on adverse reactions

Recommendation 8: **Information collection and definitions should be optimized.**

The value of data elements should be examined and a list prepared of those that should be added or changed. A key consideration is the utility of data to inform clinical practice, research, and identifying patient safety threats.

Standardization of definitions

Recommendation 9: **The adverse event definitions need to be updated.**

Recommendation 10: **The best mechanism to achieve harmonized definitions is that the national structure described in Recommendation 1 convenes a standing expert committee to revise and publish updated definitions.**

The current Canadian ATR case definitions have not been updated since 2007. A standing expert committee is necessary to provide stable and representative membership and ensure the credibility and authority to propose updates to ATR and error case definitions. Many such definitions can be derived from internationally well-recognized organizations and peer-reviewed publications.

National data system reporting

ATR reporting frequency

Recommendation 11: **Regular reporting should be on an annual basis.**

Recommendation 12: **Ad hoc reports should be required when an issue is identified.**

Regular reporting has been sought by health care practitioners but was not reflected previously in the PHAC BSCP. A functional national structure ensures that when an issue is identified, there is pan-Canadian reach and action.

ATR and error report presentation

Recommendation 13: **Report data should include provincial and territorial comparisons.**

Recommendation 14: **The following features should be included in reports: (1) Additional ATR data entry fields (2) Infographics focusing on key outcomes (3) More of the data that PTs submit.**

The reporting of PT data will depend on data-sharing agreements that PTs make with the federal government, and on the granularity of the information that is to be shared. Current data reported to the national system does not include patient identifiers, and published reporting is in aggregate.

ATR and error data analysis

Recommendation 15: **All adverse reactions should be tracked.**

Recommendation 16: **Patient data should be analyzed in relation to interventions or products.**

Recommendation 17: **The impacts of changes in products, processes or practices on outcomes should be analyzed.**

Minor reactions have been demonstrated to be a signal for significant harms to recipients, as observed during the tainted blood scandal. Root cause and risk-based analyses are necessary for intervention and mitigation of recipient risk.

ATR and error reporting data access and sharing

Recommendation 18: **Access to historical and future data should be ensured for PTs and other approved users.**

It is essential that the historical data in the national system be preserved through the entire period of transition from the BSCP systems to the renewed hemovigilance system, to enable comparison of current adverse transfusion reaction and error rates to historical rates.

Ancillary national functions

Feedback and communication

Recommendation 19: **Targeted safety alerts should be communicated when an issue arises.**

Recommendation 20: **Monthly or quarterly newsletters should be prepared.**

Electronic newsletter-style communications should report adverse transfusion reaction rates or safety concerns to the transfusion community, including hospitals that submit data into the hemovigilance system. Safety alerts require two-way interaction to allow stakeholders to engage with the hemovigilance system on the issue of concern to mitigate recipient risk.

Education and training

Recommendation 21: **The national organization should provide guidelines and case reviews.**

Recommendation 22: **National education sessions should be presented.**

Education should be delivered in different formats for different groups; it should include both evidence-based and patient-centred management of adverse transfusion reactions and of potential adverse events.

Collaboration and coordination

Recommendation 23: **The national office should collaborate with existing groups in the transfusion community, foster a national community of practice, and create networks for sharing experiences and harmonizing practices.**

Many collaborations were facilitated in the past by the national organization. Existing professional groups in the transfusion community require a national coordinating function to be more effective.

Data infrastructure

Integrated databases, reporting processes and tools

Recommendation 24: **The national hemovigilance database should be configured as a single standardized data collection system.**

Recommendation 25: **If error and ATR reporting systems are merged, the reporting forms should be integrated.**

Recommendation 26: **Reporting forms should be automated and streamlined.**

Recommendation 27: **The use of digital tools for reaction detection should be explored.**

Each of these functions is partly the responsibility of the PTs but requires a harmonized national mandate and approach on data collection. Hospitals and healthcare systems vary in their expertise to report and in information technology resources, and not all are currently in a position to adopt automated data entry and analysis.

National database functions

Recommendation 28: **The national database should have the following four capabilities, in order of importance: (1) Enable the detection of rare patterns (2) Have customizable data fields to add specific diagnoses (3) Have a dashboard interface that allows real-time data entry by PTs (4) Enable correction of past entries when revision is needed.**

Cluster identification

Recommendation 29: **Health Canada's Canada Vigilance Program should clarify the definition of a cluster for reporting purposes.**

Recommendation 30: **A national coordination contact centre should be created for communication of clusters within the transfusion community.**

Recommendation 31: **A dashboard that allows real-time data entry by PTs should be created.**

Cluster identification remains a challenge given the lack of clarity, for both communication within the transfusion community and for reporting a significant cluster to the CVP. An electronic system should be developed to identify reports related to identical lot numbers of product to contribute to cluster detection.

Canadian

Recipient Hemovigilance System

Renewal Process

Recommendations Paper

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1. Introduction

1.1 Background of recipient hemovigilance system renewal process

The Canadian Recipient Hemovigilance System Renewal Process was undertaken to develop recommendations for the structure, elements and functions of a future renewed national recipient hemovigilance system for Canada, following the announcement by the Public Health Agency of Canada (PHAC) that the Blood Safety Contribution Program (BSCP) would sunset as of March 31, 2026. The BSCP functioned as a federally funded mechanism which provided national coordination, surveillance, and reporting for recipient hemovigilance, in addition to funding for related provincial and territorial (PT) surveillance activities. The recommendations developed through a Consensus Conference (see Section 2) are intended for consideration by federal and provincial and territorial governments in determining a path forward for a renewed system.

Hemovigilance encompasses surveillance activities across the blood system, including donor safety, product safety, and recipient outcomes related to blood transfusion. Recipient hemovigilance represents a specific component of this broader system and focuses on monitoring adverse transfusion reactions (ATRs) and patient outcomes following transfusion. This Renewal process and the Consensus Conference focused specifically on recipient hemovigilance.

The Blood Safety Contribution Program was implemented on the recommendation of the Krever Commission of Inquiry into the contamination of the blood supply in the late 1970s and 1980s. It was a national contribution-funded program intended to support provincial and territorial surveillance activities, and to enable national coordination, surveillance, and reporting related to recipient hemovigilance. Under the BSCP three surveillance systems were supported: the Transfusion-Transmitted Injury Surveillance System (TTISS), the Transfusion Error Surveillance System (TESS) and the Cells, Tissues and Organs Surveillance System (CTOSS).

This process draws on experience with two BSCP-supported systems—TTISS, established in 2001, and TESS, initiated as a pilot in 2005—which monitor adverse transfusion reactions (ATRs) and errors associated with blood transfusions and blood products respectively. The third system supported under the BSCP, CTOSS, is not within the scope of the Hemovigilance System Renewal Process.

In keeping with Canada's federalist government system, in which the federal and provincial and territorial (PT) governments have distinct but complementary roles in health care, TTISS and TESS operated through two interacting components:

- National systems, managed by the federal government through the PHAC, which received data on ATRs and errors from the PTs, aggregated and analyzed those data, and produced national reports. The data was submitted by PTs on a national reporting form (the Canadian Transfusion Adverse Event Reporting Form, or CTAERF), and uploaded to the Canadian National Public Health Information (CNPHI) database;

- The PTs developed and operated their own jurisdictional hemovigilance surveillance programs, in which hospitals detected and investigated ATRs, and reported them to their respective blood coordinating office or ministry using the CTAERF and the CNHPI. PT offices submitted their data to the national system. Transfusion errors were similarly collected in participating jurisdictions.

The closure of the BSCP resulted in the conclusion of the federally supported national coordination, aggregation, and reporting functions, as well as the associated contribution funding to PT programs, prompting the initiation of the Recipient Hemovigilance System Renewal Process. Provincial and territorial surveillance systems may continue to operate, alongside regulatory oversight by Health Canada, including mandatory reporting of serious and unexpected adverse reactions under the Blood Regulations through the Canada Vigilance Program. Operational safety systems managed by Canadian Blood Services and Héma-Québec also continue to support blood safety.

A schematic of recipient hemovigilance functions and the impacts of the sunsetting of the BSCP is shown in Figure 3 below.

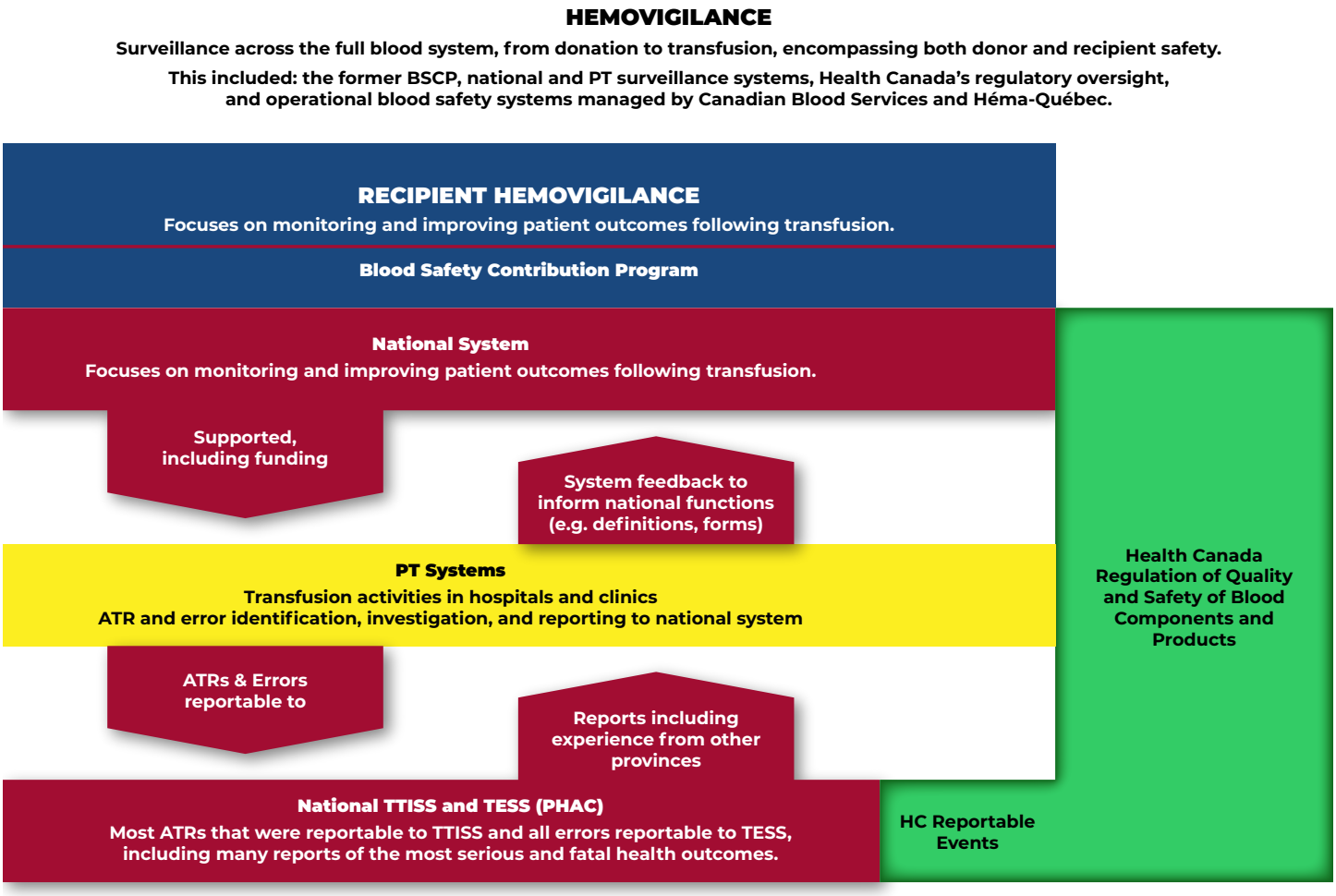

Figure 3. The structure of and changes to recipient hemovigilance functions within the overall hemovigilance program in Canada. The sunsetting of the BSCP results in the elimination of some recipient hemovigilance functions (red), the loss of support for others (yellow), while some functions remain the same (green).

There is widespread concern with the sunsetting of the BSCP, as the PTs had relied on national BSCP funding to carry out many essential recipient hemovigilance activities; in addition, the national and PT systems need to interact and be coordinated on many functions. Reasons for concern with the loss of essential recipient hemovigilance functions include:

1. The inability to capture the most severe transfusion reactions that are not captured by other organizations responsible for hemovigilance, which are primarily concerned with blood quality;
2. The need for national collation and coordination to effectively monitor and detect emerging trends, for which individual PTs would not have the capability;
3. The need to provide medical and scientific community reporting to identify emerging threats from trends and mitigation strategies at the national scale.

1.2 The consultations: system evaluations and option development

The major work of this process focused on the development of recommendations for the design and function of a renewed recipient hemovigilance system for Canada, which took place in a Consensus Conference on March 23-24, 2026.

The Consensus Conference was the final phase of a longer process that led to the development of options outlining a renewed hemovigilance system. The process was overseen by a Stewardship Working Group (SWG) that provided strategic direction and advice: it consisted of 24 members, representing the federal government, provincial ministries of health, subject matter leaders and clinical experts, blood system operators, and patient organizations. Project support was provided by Risk Sciences International (RSI), an independent consultancy that was contracted by Canadian Blood Services, funded by the PHAC, to conduct a consultation process, prepare a White Discussion Paper reporting on the findings of the consultations, facilitate discussions at the Consensus Conference, and prepare a final Recommendations Paper. RSI was also responsible for conference facilities and logistics.

The first phase of the process began in November 2025, with an extensive stakeholder consultation process that involved outreach to approximately 140 individuals, and interviews with 47 representatives of the transfusion medicine community, federal and PT governments, and patient groups. The consultation process focussed on participants' evaluations of the existing programs, and their suggestions and preferences for the structure and functions of a renewed system.

In the consultation process, interviewees were asked for their opinions on several aspects of hemovigilance in general, and the effectiveness of TTISS and TESS systems. The main themes of comments received from interviewees are summarized below:

- The value of a national hemovigilance system
    - A national system is necessary to maintain patient safety and trust in a safe blood supply, and ensure that contamination of the Canadian blood supply, which occurred in the late 1970s and 1980s, can never happen again.

- National leadership and governance
  - A national, potentially federal, presence is required to provide strategic direction, coordinate PT activities, and ensure equitable access to safe transfusion services across Canada.
  - The TTISS national organization lacked the necessary expertise to evaluate and analyze data.
- Data collection requirements
  - Mandatory reporting may be optimal, but it is unclear if it is realistic for all ATRs.
  - The data on adverse reactions was thought by some to be incomplete, and the definitions of ATRs in the national reporting form defined in the 2007 TTISS Manual are outdated. Some PTs have accordingly adopted more recent definitions from a variety of international sources, leading to inconsistencies in the understanding of ATRs.
- PT reporting to the national TTISS
  - Reporting of ATRs by hospitals and PTs is variable, with many PTs developing their own reporting forms and processes that may not align well with the national system to which the data will be submitted.
  - The current structure of reporting is time-consuming, contributing to the under-reporting of minor reactions and some types of reactions.
  - There was a desire for data from PT jurisdictions to be shared to enable comparison and benchmarking. However, there were constraints based on agreements between PTs and the PHAC, which limit the ability for the PHAC to share PT data reports alongside national aggregate data.
- Effectiveness of data reporting and other functions by the national system
  - The reporting mechanism was considered to be inadequate, as published analyses were not timely, presented outdated information, and had only cursory information with little useful detail or comprehensive analysis.
  - National collaboration, coordination and communication functions were inadequate; early activities had been very useful for supporting the transfusion community, but these had been discontinued.

Interviewees were also asked for their suggestions for necessary and desirable features and functions of a renewed Canadian hemovigilance system; those that were mentioned by a majority of interviewees were developed into a set of options for consideration for a renewed system, and were described in a Canadian Recipient Hemovigilance Renewal Process White Discussion Paper ("White Discussion Paper"), which was circulated to stakeholders in several rounds of review and revisions.

The process is summarized in "Figure 4. The Canadian Recipient Hemovigilance Renewal Process." on page 6.

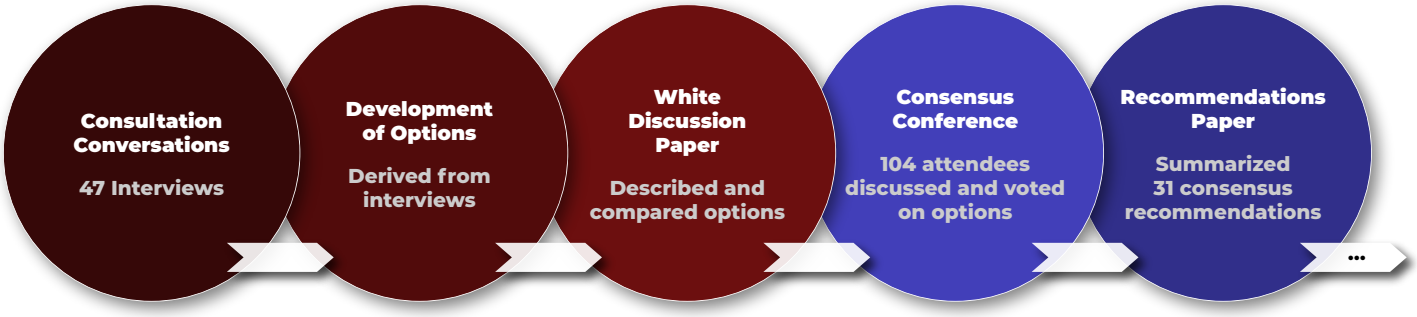

Figure 4. The Canadian Recipient Hemovigilance Renewal Process.

In order to ensure that conference participants shared a full understanding of the context of the options they would be discussing, the White Discussion Paper reviewed essential background information on the context of hemovigilance activities in Canada, and on expectations and best practices that could serve as models for a renewed Canadian system. This background information consisted of the following:

- An overview of federal, PT and physicians' responsibilities in the Canadian health care system, and in the blood safety and transfusion safety system, including roles and responsibilities for reporting to hemovigilance systems, and regulatory oversight and requirements.
- Necessary and desirable elements in an effective hemovigilance system, from several sources:
  - The report *Evaluation of the Public Health Agency of Canada's Blood Safety Contribution Program 2017-18 to 2021-22*[1] conducted by the Office of Audit and Evaluation of Health Canada and the Public Health Agency of Canada. This audit evaluated the effectiveness of the three BSCP systems, including the TTISS and the TESS, and made several recommendations for future actions for those national systems.
  - International guidance on the structure and function of a successful national hemovigilance system, from the World Health Organization[2].
  - A brief review of the structure and functions of the national hemovigilance systems of the United Kingdom (UK), France, Germany, The Netherlands, Norway, and Australia, indicating the functions that are included in most of the systems, and the alignment of a hemovigilance system with its national government system. The UK Serious Hazards of Transfusion (SHOT) program was described in more detail, as it was frequently cited by interviewees as an effective hemovigilance system.

1 HC-PHAC 2023. *Evaluation of the Public Health Agency of Canada's Blood Safety Contribution Program 2017-18 to 2021-22.* The Office of Audit and Evaluation of Health Canada and the Public Health Agency of Canada.

2 WHO (2016) *A guide to establishing a national haemovigilance system.* Geneva. Available at https://iris.who.int/server/api/core/bitstreams/1a491336-afb2-4e27-a960-38982209f5ac/content

The above factors are directly relevant to expectations for hemovigilance in Canada, and are important considerations for the development of recommendations for a renewed system. Therefore, they were used as annotations to the description of the options in the White Discussion Paper and the Consensus Conference guidance document. The options were described in terms of their alignment with the elements that are important for an effective system, and their feasibility in the Canadian system.

The options presented are robust and relevant to the discussion on a future renewed Canadian hemovigilance system, as most were mirrored by the WHO guidance for best practice in hemovigilance, and in many of the functions performed by the international programs that were reviewed.

The suggestions fell into the following categories, which structured the discussions that were held in the Consensus Conference:

- Program leadership and governance
- National hemovigilance system components
- Adverse transfusion reaction and error reporting
- National system data reporting
- Ancillary national office functions
- Data infrastructure
- Cluster identification

1.3 Options discussed at the Consensus Conference

The options presented for discussion at the Consensus Conference were described in the White Discussion Paper, which was circulated to registered participants in advance of the conference. Consensus Conference participants received this document by email on March 6, 2026, and again on March 16, 2026, accompanied by a shorter Consensus Conference guidance brief that summarized each issue and associated options, with relevant annotations to support informed discussion.

The Consensus Conference took as its starting point two fundamental positions on which interviewees were unanimous.

First, hemovigilance is necessary in Canada to assure three critical values: blood safety, patient safety, and trust in the blood system and the public health system.

Second, a national hemovigilance system is necessary for Canada, to meet three key needs:

- The system must be national in scope, providing national leadership and oversight, and ensuring equitable access to safe transfusion for all Canadians;
- National-scale leadership is necessary to coordinate the functions of all provinces and territories. This includes harmonizing data collection, providing a national overview of transfusion and blood safety and an analysis of trends;

- Monitoring and reporting of adverse events need to be national in scope to track trends and identify clusters of events related to the collection and dispersal of blood throughout the country. Aggregate data is needed to identify rare signals and support valid analysis, as well as to enable the awareness of, and response to, quality problems in all areas where transfusion recipients had received a product.

Building on the above critical values and functions, the purpose of the Consensus Conference was to consider and refine options that could be put forward as recommendations for a renewed national hemovigilance system, addressing four main questions:

- What leadership organization, structure and capacity are most appropriate for a renewed national hemovigilance system to fulfill these values and functions?
- What aspects of a hemovigilance system should be harmonized among all jurisdictions?
- For what functions should the national organization be responsible, related to collecting, analyzing and reporting PT hemovigilance data; and in communicating and collaborating with stakeholders?
- On what infrastructure and process functions should the national organization collaborate with PTs, related to features and functions on which they interact?

The Consensus Conference addressed these questions through structured discussions on the following specific topics:

1. Program Leadership and Governance
    a. Governance options
    b. Expert capacity or support
    c. Funding options

2. National Recipient Hemovigilance System Components
    a. Structure of hemovigilance surveillance systems

3. Adverse Transfusion Reaction and Error Reporting
    a. Mandatory or voluntary reporting
    b. Data to collect on adverse reactions
    c. Standardization of definitions

4. National System Data Reporting
    a. TTISS reporting frequency
    b. TTISS and TESS report data presentation
    c. TTISS data analysis
    d. Data access and data sharing

5. Ancillary National Functions
    a. Feeback and communication
    b. Education and training
    c. Increased collaboration and coordination

6. Data Infrastructure
    a. Integrated databases
    b. Reporting processes and tools
    c. Database functionalities desired

7. Cluster Identification

2. The Consensus Conference

2.1 Participants

A total of 104 participants attended the conference; a total of 111 persons when RSI's seven staff were included. Forty-three individuals participated in person, with another 61 joining virtually on an online MS Teams meeting. There were no major technical difficulties which limited the participation of online attendees.

Participants in the conference were representative of the relevant sectors and jurisdictions in Canada. Participants included 29 individuals from the transfusion medicine community, 13 representatives of patient groups and 12 representing blood services; government representatives included 13 from the federal government and 35 from provincial and territorial governments. A detailed list of representatives is found in the Appendix.

In addition to the Canadian participants, two representatives of other countries' hemovigilance systems attended online: a representative of the UK's SHOT system, and an individual representing the Haemovigilance Programme of India and the International Society for Blood Transfusion, attended some sessions according to their availability.

2.2 Consensus Conference discussion process

The Consensus Conference discussions were structured to address each issue described in the White Discussion Paper. A more concise summary of the issues and options to be discussed were presented in a second document, Canadian Recipient Hemovigilance System Renewal Consensus Conference: Overview, Orientation, Purpose, which was provided to all participants by email before the conference; printed copies were also distributed at the conference. Each issue presented in the document was summarized in two slides displayed to attendees that were used to guide the discussions in the Consensus Conference. The first slide was an overview, with background of the issue, questions to be addressed and a list of the options proposed to address the issue; the second slide presented the options in more detail, including description, rationale and proposed benefits, alignment with relevant external comparators, and additional questions and considerations. Proceedings were recorded and transcribed, to enable the preparation of an accurate and representative summary of comments in this Recommendations Paper.

At the conference, the slides were shown on a screen for all participants. The facilitator briefly reviewed each issue and the related options, then invited participants to comment on the options, suggest a modification or propose an entirely new option. In-person and online participants spoke alternately in the order in which they indicated their desire to speak, and online participants were shown on the screen when they spoke.

The summaries of the discussions presented in section 2.3, below, following the format used in the Consensus Conference, with a statement of the background of the issue, the main questions to be addressed, and the results of the preference poll that determined the option to be put forward as a recommendation. This is followed by a summary of the comments made on the options in the discussions, expressing the strengths, weaknesses and challenges with each. Where an option was modified or a new option introduced, this is indicated in the option descriptions and the listed preference polls.

2.2.1 The option preference polling process

As the ultimate purpose of the hemovigilance renewal process, the discussions at the Consensus Conference were intended to select, modify or reframe an option for each issue that would be put forward as a recommendation to decision-makers. The preferred option on each issue was determined through an anonymous poll that reflected consensus or a significant majority of the participants. Polls were conducted with Mentimeter™ software: in-person and online participants accessed the polls on their devices through the associated website and a conference-specific code.

Poll questions and format were prepared for each issue and, if necessary, were revised during discussions to reflect modifications that emerged to express participants' understanding of the issue and of the appropriate options. Three types of preference polls were used, as suited to the choice to be made. Some issues involved more than one poll, to determine a structural choice and then select preferred options under the first choice. These were:

- Single choice among multiple choices;
- Yes/ No questions regarding desirable attributes of systems, where multiple options can be chosen;
- Rank ordered preferences where multiple items are desirable.

All participants in the conference voted on each poll, with two notable exceptions. Representatives of the following two groups declared that they would not participate in voting during the Consensus Conference:

- Federal and PT government representatives, who participated in discussions but not in the polls;
- RSI attendees.

The results of each poll were expressed by percent supported, individual yes/no, or by item ranking; results were shown to participants as soon as the voting was complete. The options that were preferred by the participants were carried forward to form the recommendation for each issue.

Section 2.3 on page 12, summarizes comments made in the discussion of each option. Although the text does not reflect all comments made, it is a comprehensive compilation of points that pertain to each option. The software did not link votes to voters, so results are not reported for individuals or groups represented. Results of preference polls are shown for each option in order of the amount of support, generally expressed as a percentage of the votes received and shown in **bold/green font**, in descending order from the preferred option.

"Special topics" on page 38 presents a broader discussion of some contextual issues related to hemovigilance and the hemovigilance renewal process. The recommendations are presented in "Summary of recommendations" on page 46.

2.3 Conference Proceedings - Day 1

2.3.1 Introductory remarks

The Consensus Conference was opened with remarks from six individuals representing the major stakeholder groups involved in the issue of hemovigilance in Canada. These individuals expressed the perspective of their organization or sector on the need for national recipient hemovigilance, and the importance of developing recommendations that can help structure a renewed national system.

- **Graham Sher**, *CEO*, Canadian Blood Services
- **Marc Germain**, *VP Medical Affairs and Innovation*, Héma-Québec
- **Sarah Ford**, *CEO*, Canadian Hemophilia Society, representing patient groups
- **Kerry Robinson**, *VP*, Public Health Agency of Canada, representing the Federal Government
- **Madeleine McKay**, *Director, National Blood File* (Nova Scotia Department of Health and Wellness) Chair, Provincial and Territorial Blood Liaison Committee, representing the Provinces and Territories
- **Andrew Shih**, *Chair, National Advisory Committee on Blood and Blood Products (NAC),* TTISS-Ontario Medical Director, Associate Professor, McMaster University, representing the Transfusion Medicine Community.

On Day 1 — March 23, 2026 — participants addressed the first three categories, involving nine issues with their associated options. The issues addressed on Day 1 included the fundamental questions concerning governance structure and roles of organizations in a renewed national system, as follows:

1. Program Leadership and Governance
    a. Governance options
    b. Expert capacity or support
    c. Funding options

2. National Recipient Hemovigilance System Components
    a. Structure of hemovigilance surveillance systems
    b. Transfusion Safety Officers in hospitals
    c. Sentinel site approach for ATR reporting

3. Adverse Transfusion Reaction and Error Reporting
    a. Mandatory or voluntary reporting
    b. Data to collect on adverse reactions
    c. Standardization of definitions

2.3.2 Leadership and governance

The Consensus Conference discussions took two premises as foundational:

- Hemovigilance is necessary in Canada to assure three critical values: blood safety, patient safety, and trust in the blood system and the public health system. It should apply across the full spectrum of blood and blood product administration and encompass the entire therapeutic process of transfusion.

- A national hemovigilance system is necessary for Canada. "National" refers to the scope and scale of functions required, and that are at issue for the National Hemovigilance Renewal Process. It is distinct from the jurisdictional government level.
  - The system must be national in scope, providing national leadership and oversight, and ensuring equitable access to safe transfusion for all Canadians.
  - National-scale leadership is necessary to coordinate the functions of all provinces and territories, to make sense of the data that is produced locally.
  - Monitoring and reporting of adverse events need to be national in scope to track trends and identify clusters of adverse events related to the collection and dispersal of blood throughout the country.

Based on the foundational premises above, a renewed national recipient hemovigilance system would be national in scale and scope, the discussions began by addressing the most appropriate and effective type of governance organization, including the jurisdictional level, or levels, at which it should be located.

2.3.2.1 Governance options

Issue and background

- National leadership is strongly approved
  - Provides a mandate and mechanisms to coordinate PT functions
  - Ensures equitable access to safe transfusion for all Canadians
- Questions
  - What is the preferred governance model for a renewed hemovigilance system?
  - What organizations should have which responsibilities?

Preference poll results

✓ **Federally-mandated collaborative provincial/territorial model (new option): 88%**

- Other options:
  - New decentralized structure:. 9%
  - Leverage existing federal organization: 4%
  - Independent leadership structure:. 0%

General points of discussion

This issue generated the most discussion of any in the conference, revolving around the need for accountability to perform designated tasks and ensure the sustainability of the system, and operational independence.

Leadership is different from governance, though both are critical to any system. In the case of hemovigilance they refer to the following:

- Governance: accountability and structure
  - There was acknowledgement that there has never been a governance structure for hemovigilance in Canada: where should it reside? Interactions between federal and PT governments require that someone take ownership.
  - Governance needs to align with jurisdictional mandates; these are not movable
    - Governance needs federal involvement for coherence and accountability: for example, in TTISS the federal government held PTs accountable to submit reports to the PHAC for funding transfers.
- Leadership: strategic direction, coordination
    - Independent, with experts to provide advice; this should be transfusion medicine expertise.
    - Leadership roles may include maintenance of the national database and data governance, as well as data analysis and reporting.

Options and detailed comments

1. Leverage an existing federal organization
   - Supporting: The simplest and most timely solution, according to some, is to reproduce the previous PHAC arrangements while adding needed expertise to improve the timeliness and quality of reporting.
   - Opposed: History tells us that, if based on existing federal structures, the result will not include a functional system. Federal organizations have too many responsibilities; a separate organization dedicated to hemovigilance is needed.
2. Develop a new decentralized structure with separate oversight and operational responsibilities
   - This model is similar to what was in place with the BSCP - but this was a very bare bones national coordination.
   - The federal government needs to be involved in oversight, setting a bar.
   - Hemovigilance is a local, bottom-up activity: there should be an aim for more coordination activity at the national level to make sense of what is generated locally.
   - Some infrastructure is built into existing organizations, including Canadian Blood Services, the PHAC (or other federal department); and PTs. Not all provinces have the same level of activity in hemovigilance – there are inequalities in the strength of the systems.
   - There are gaps in this option as presented: responsibilities for data management and expertise are not identified.
   - Some responsibilities could be contracted to affiliate organizations with appropriate expertise.

3. Create an independent leadership structure
    - The important principle is functional independence - legal independence is not possible (as an example, the UK SHOT system is only operationally independent).
    - A national hemovigilance system would not fit under any specific single university department or organization - such as the Canadian Society for Transfusion Medicine (CSTM) – but could partner with it; a university (e.g. McMaster Centre for Transfusion Research) could be responsible for housing and maintenance of the national database.
    - It would take time to set up a new structure, identify and engage enough people to sustain a leadership structure; and it might not have the teeth to achieve something functional.
    - Depending on the leadership structure, this option may require a change in legislation: in the current federated government system, Health Canada is responsible for blood safety and the blood systems; the PTs are responsible for health care delivery.
    - Combine options 2 and 3 – hybrid model:
        - Option 2 (decentralized federal/PT) provides accountability; Option 3 (independent) provides independent leadership.
        - National governance provides the mandate, oversight and standardization through centralized independent functional leadership, data management and coordination.
        - An independent body that works at arm's-length from the federal government, tasked with delivering hemovigilance at the national scale, and can be made accountable to the federal and PT governments; rotation of PT lead.
        - General oversight includes groups like medical (advisory) and technical for day-to-day work.
4. New option developed during the conference: a federally-mandated collaborative PT model
    - Governance: involves federal and PT governments, to ensure timely hemovigilance program execution, compatible with existing regulations. This body provides the national mandate for hemovigilance and accountability for its performance.
    - Leadership: independent steering group; medical experts, patients, representatives from operational group from each PT.
    - To be decided later: operational: execution/ implementation of a national hemovigilance program with integrated collaborative provincial responsibility (to the hospital level).

Discussion

- National governance with a standardized mandate and definitions; the objective for governance must be articulated.
- Collaboration of federal and PT governments, national hemovigilance committee with a secretariat and jurisdictional rotation of provincial lead, similar to the National Advisory Committee construct where medical experts provide advice to a national decision-making body.
- This construct appears to be compatible with current legislation.
- Include both the PHAC and Health Canada – Canada Vigilance Program (CVP), as blood products have a drug identification number (DIN); there is a recognition that regulation is in place under Health Canada related to blood product post-marketing surveillance for serious and unexpected adverse reactions and will continue. This should be acknowledged in the design of a new structure, because it may affect what can be done in terms of existing regulatory requirements.

- Leadership:
  - Independent / arm's-length body accountable to federal and PT governments; oversees a national system involving blood operators, patient groups and hospital transfusion expertise; and with centralized data management and coordination.
  - Independent Steering Group: medical experts, patients, representatives from operational group from each PT. There must be a dedicated operational component for execution and implementation.
- Responsibility for maintenance of national database needs to be determined
- A useful example: Pan-Canadian organizations
  - These are federal-led collaborations with PTs
  - They are independent and federally funded, given a mandate on interoperability. The existence of this type of organization could serve as a governance model for a renewed hemovigilance system, and its precedent could expedite its development.

The Conference returned to the proposal of the new option 4 at the end of the program, due to the high level of interest, and a group of participants presented a description of the model that they elaborated. The elaborated option aligns with the Pan-Canadian organization option, and could constitute a better-developed recommendation on governance and leadership.

This is described in more detail in "Figure 5. A possible configuration of a federally-coordinated collaborative FPT model for a renewed national recipient hemovigilance system." on page 41.

2.3.2.2 Expert Capacity

Issue and background

- The PHAC did not have sufficient, or knowledgeable, staff to interpret ATR data or prepare reports from BSCP systems.

Questions

- What is the preferred means of providing necessary expertise for a national office?
- What types of expertise are required?

Preference Poll results (choose one)

✓ **Provide external expert advisory group(s) for a national structure that has internal expertise: 76%**

- Other options
  - Create a national structure that includes several experts in transfusion medicine and data analysis: 20%
  - Create an advisory group that works closely with a smaller national leadership organization without internal expertise: 4%

General points of discussion

Several groups were discussed as important to be included in the establishment of a new hemovigilance system: a steering committee, an advisory group, and a technical group.

The necessary expertise would need to be met though adequately resourced positions. The lack of previous BSCP support for expert capacity was noted.

Options and detailed comments

1. Create a national organization that includes several experts in transfusion medicine and data analysis
    - The national structure leadership could involve expertise, including medical, nursing, technical, and patient representation.
    - Concern: does this imply that the national organization doesn't receive advice from an external expert group because they have their own expertise?
2. Create an advisory group that works closely with a smaller national leadership organization that does not include internal expertise.
3. Provide external expert advisory group(s) for a national organization that has internal expertise.
    - Expertise should be in a steering committee.
    - Ensure dedicated expert(s)
        - A subcommittee could include experts in data, research, and technical solutions.
    - Representatives with different expertise, with PT representatives, could be included.

2.3.2.3 Funding

Issue and background

- Provision of adequate and sustainable funding to support surveillance systems was a concern.

Question

- How should a renewed system be funded?

Preference poll

✓ **Mixed federal with PT contributions: 84%**

- Other options
    - Primarily federal: 11%
    - Primarily provincial/ territorial: 5%

General points of discussion

Two priorities about funding were expressed: one is that funding should be adequate to support necessary activities; the other is that the funding should be sustainable.

With respect to the adequacy of funding for a system with national implications for patient safety and trust in the healthcare system, it was noted that the previous BSCP funding of approximately $2 million at the time of its sunsetting (less than the original $5 million agreement at BSCP inception), was insufficient to meet the needs of a hemovigilance system, and is insignificant in relation to the overall healthcare budget, which is close to $400 billion[3].

Participants also expressed concern that they lacked information necessary at the Consensus Conference to enable them to put forward realistic suggestions. Specifically, no copies of existing federal or provincial memoranda or legislation were available to frame the feasibility of solutions discussed. Participants did not want to endorse "high-end" solutions that could not be supported. Rather, experts expressed the desire to build the best system possible with the resources available. Thus, determining the most important functions was a challenge without an understanding of the legislative and budgetary limits. A federal government representative noted that they cannot comment on funding until they have discussed implementation of the recommendations with their partners. This issue is discussed in more context and detail in "2.5.5 Federal and PT government engagement" on page 44.

Options and detailed comments

1. Primarily federal
    - Necessary in view of the federal responsibility for all of Canada.
    - There must be federal involvement for a system to be sustainable.
    - Allocating sufficient resources to a federal organization, similar to the previous BSCP funding arrangements, may be more efficient.
2. Primarily provincial/ territorial
3. Mixed federal with PT contributions
    - Multi-level funding arrangements will require substantial time, effort and financial resources to create and legislate.
    - Shared funding reflects shared responsibility
        - With only federal funding, the resources will not get down to TSOs, who are necessary to collect information.
        - With only PT funding, the system will not be national in scope.

3 Canadian Institute for Health Information, 2025. News Release *"National health expenditure trends"* https://www.cihi.ca/en/national-health-expenditure-trends

2.3.3 National hemovigilance system components

2.3.3.1 ATR and error reporting systems

Issue and background

- An ATR should be reported with an error that may have contributed to it.
- Contrasting opinion: TESS was not a useful reporting system.

Questions

- Is a transfusion error reporting system (comparable to the previous TESS) a useful system that should be maintained or expanded?
- If so, should the error reporting system be expanded beyond the previous TESS implementation, and more closely linked to the ATR reporting system?

Preference polls

✓ **Retain, merge and/ or expand error reporting as part of hemovigilance: 90%**

- Other options:
  - Discontinue error reporting (TESS):. 10%

✓ **Merge ATR and error reporting systems: 71%**

- Other options:
  - Expand error reporting and merge with ATR reporting: 18%
  - Retain status quo: 8%
  - Expand error reporting:. 4%

General points of discussion

It is important to consider what information is needed in hospitals to support decision-making. For example, the structure and elements of the new hemovigilance system are not yet known, so operationalization will be determined at a future time.

There is a partial overlap of hemovigilance reporting with Vanessa's Law, which applies to ATRs and errors. The errors and accidents are only reported for blood and blood components that are regulated under *The Blood Regulations*, however this reporting requirement does not apply to blood products which are regulated as drugs under *Food and Drug Regulations*. For manufactured blood products, a medication error must only be reported by a hospital if it results in a serious adverse reaction. This represents an important gap: many transfusion reactions that harm the patient occur because of errors.

The options that were voted on were modifications of the original options; the comments below pertain to the options that were discussed and on which the preference polls were taken.

Revised options and detailed comments

1. Retain, merge and/ or expand error reporting as part of hemovigilance
    - Many reactions are due to errors; without error reporting within hemovigilance an important source of information on ATRs is lost. Patients may be harmed by errors, and it is essential for blood safety that the system be able to learn from errors and near misses.
    - Prescriber error is a foundation of systemic harm to patients that has not been captured comprehensively, due to the small number of sites at which TESS operated; it is also not covered within the Health Canada - CVP.
        - As the CVP does not collect episodes at hospitals related to the practice of transfusion medicine, such as transfusion-associated circulatory overload (TACO) which may be attributable to transfusion error, it is important that these reactions be captured in a hemovigilance system.
2. Discontinue error reporting
    - Some hospitals are already tracking error data and completing analysis locally, but not necessarily through the hemovigilance system; error reporting as part of hemovigilance duplicates hospital reporting.
    - Hospital systems are functioning; TESS was only partial.
    - ATR reports ask, "was this reaction the result of an error?" Thus, a separate error reporting system is not needed as this information is already captured.
    - TESS was operationally heavy, and it only included a small proportion of hospitals.
3. Merge ATR and error reporting systems
    - The previous TESS and TTISS both reported to CNPHI, but separate platforms within CNPHI were utilized and reports generated.
    - Merging the two systems could result in a very long reporting form.
4. Retain status quo
    - An elaboration of this option is the continuation of the existing TESS sites to identify the most common and/or serious errors and incorporate them in the national ATR report.
5. Expand error reporting
    - Options amended, but not voted on, include:
        - Include near-misses in error reporting
            - They may be captured in local databases but not reported.
        - Have a benchmark in hospital error reporting that the three most serious error-related reactions could be reported to the ATR system.

2.3.3.2 Transfusion safety officers (TSOs) in hospitals

Issue and background

- TSOs are useful for reporting ATRs and supporting transfusion activities in hospitals.

Question

- What is the most appropriate model for providing TSO positions?

Preference poll

✓ **All hospitals have access to a TSO; large hospitals have TSOs; smaller hospitals' access is determined by their network or region: 94%**

- Other options:
  - Each hospital has at least one TSO: 6%

General points of discussion

It was emphasized that TSOs are essential: they complete root cause analysis, training, implementing change and other functions. Their role is not simply to complete data entry.

Without a TSO, neither ATR nor error reporting can operate well and in a sustainable manner. The current hospital transfusion safety system is dependent on adequate TSO staff at the hospital level, including at peripheral hospitals if their care services involve blood transfusion. Currently, national TSO staffing is inadequate at most sites. It was noted that at University Health Network in Toronto, which also covers 30 other hospitals and six additional networks, there is one TSO for more than 1000 beds. This does not allow for entering any but the most serious and atypical reactions.

Options and detailed comments

1. Each hospital has at least one TSO
2. All hospitals should have access to a TSO; large hospitals have TSOs; smaller hospitals' access is determined by the size of their transfusion program
   - It is important to include TSOs in a new hemovigilance program; the provision should be written in an agreement to ensure provision of access. Some PTs do not have any TSOs.
   - Small hospitals that perform low volumes of transfusion annually likely do not need a TSO within their facility, but access to a TSO for hemovigilance and educational activities is imperative to promote a culture of transfusion safety.

2.3.3.3 Sentinel site approach for ATR reporting

Issue and background

- A sentinel reporting system was established in Ontario, in which large sites would report all reactions and support smaller sites with fewer resources.
- The smaller sites report only severe reactions.

Question

- Would a sentinel system be appropriate to support the workload of reaction reporting and review at smaller hospitals?

Preference poll

✓ **A sentinel site approach is not useful: 83%**

- Other options
  - A sentinel site approach should be considered where there are a number of smaller sites that could be supported with reaction reporting and other functions by some high-volume hospitals: 13%
  - A sentinel site approach should be applied: 4%

Options and detailed comments

1. A sentinel site approach should be applied
   - The approach should apply to all regions – there may actually be a larger risk of events, including ATRs and errors, in smaller hospitals; hemovigilance is prudent in smaller hospitals, which should be as well served as hospitals in larger areas.
2. A sentinel site approach should be considered where there are a number of smaller sites that could be supported by some high-volume hospitals with reaction reporting and other functions.
   - All hospitals could be asked to report, and the larger hospitals could be involved as a hub-site of data entry.
   - An observation is that smaller sites do report minor reactions.
3. A sentinel site approach is not useful.
   - A sentinel site approach may lead to missed ATR reports and under-recognition of ATRs and errors, as staff in smaller hospitals will become less familiar with ATR signs and symptoms, thus contributing to a reduction in reporting by smaller facilities.

2.3.4 Adverse transfusion reaction and error reporting

2.3.4.1 Mandatory or voluntary reporting

Issue and background

- Mandatory reporting of all reactions is optimal to provide a full understanding of transfusion and blood safety.
- Full mandatory reporting may be unrealistic.
  - Minor reactions are not always reported.
  - Mandatory reporting of minor reactions is an excessive workload, particularly with insufficient TSOs.

Questions and comments

- Should any adverse reaction reporting be mandatory?
- If so, for what types of reactions should reporting be mandatory?

Preference poll

✓ **Mandatory reporting of all ATRs: 86%**

- Other options
  - Mandatory reporting of more serious subsets of reactions only: 10%
  - Reporting is voluntary: 4%

General points of discussion

Reporting could be incentivized through the production of high-quality resources, data analysis, and recommendations, which inform clinical practice. It was noted that the reactions that are reported to the CVP are not communicated to the community; consideration should be given by the Health Canada CVP as to what is needed by the transfusion community for system improvement.

Options and detailed comments

1. Mandatory reporting for all ATRs
   - Without full reporting, there is the potential to miss important information about non-severe ATR trends.
   - Non-severe reactions are important, as they may portend more severe reaction occurrence to specific blood products, as in the case of clusters.
     - They can indicate effects of a change in constitution of some blood products.
     - This is important for blood operators to know, and also helps with physicians' ordering practice.
   - Reporting non-severe ATRs requires human resources. There could be less burdensome or less detailed reporting for minor/ some types of reactions to enable more comprehensive reporting.
2. Mandatory reporting of more serious subsets of reactions only
   - This can be challenging to implement; it can be difficult to distinguish minor and severe reactions.
     - The problem could be addressed through proper case definitions, which specify the reactions that should be reported.
     - The use of pre-transfusion medications masks reactions, so it is not clear if a reaction is a major or minor reaction.
     - More advanced electronic systems may be able to facilitate distinguishing major and minor reactions.
   - It may be preferable to focus reporting on certain types of reactions that are complex, unexpected, or less well understood, including some minor ones.
     - Report all reactions to new products/ components, processes, to determine any effects improvements.
     - Some minor reactions are well understood and do not need ongoing reporting.
   - Reporting should be required of minor reactions whose cause is unclear, and that may evolve into more significant outcomes.
   - Reporting should reflect impacts on patients, not Health Canada severity criteria.

3. Reporting is voluntary
    - It is hard to ask staff to report reactions if their records are not included in national reports.
    - Without adequate resources, voluntary reporting will be inconsistent, unless there is financial incentive (as there was with the TTISS program).

2.3.4.2 Data to collect on adverse reactions

Issue and background

- Additional information should be collected in ATR reports

Questions

- Is the data gathered on ATRs sufficient?
- If not, what additional information should be captured?

Preference poll

✓ **Optimize information collection and definitions: 98%**

- Other options:
    - Status quo: 2%

Options and detailed comments

1. Information is sufficient (status quo)
    - The current form is too detailed for some ATR types.
2. Optimize information collection (revised option)
    - Should look at the value of data elements and create a list of things that might be changed.
        - E.g. severity, products and brands
        - Consider the utility of data to inform improvement in clinical practice, and for research.
    - Adverse transfusion reactions to blood components, such as TACO and hyperhemolysis, may not be reliably reported: despite the important role of Health Canada – CVP in hemovigilance, the CVP does not categorize or trend these reactions to blood components which are not associated with blood quality under the Blood Regulations.
    - Because adverse transfusion events may occur due to combinations of donor and patient factors, blood component reactions should be captured to determine donor-recipient associations that lead to insights to protect patients (such as in TRALI).
    - Could have more practical data collection for certain types of reactions, such as cascading data elements for routine reporting of common reactions, and more in-depth reporting of severe reactions.

Option removed: Additional information on patient demographics and donor factors should be collected.

2.3.4.3 Standardization of definitions

Issue and background

- Definitions of ATRs in the TTISS manual are outdated.
- Definitions used are not consistent among PTs within jurisdictional hemovigilance programs.

Questions

- Should ATRs in the TTISS manual be updated?
- What definitions should be adopted?
- What group should update the definitions?

Preference polls

✓ **1: The adverse event definitions need to be updated: 96%**

- Other options
  - Adverse event definitions do not need to be updated:. 4%

✓ **2: The best mechanism to achieve harmonized definitions is that the national organization (as described in Issue 1a, governance) convenes standing expert committee to revise and publish definitions: 100%**

General points of discussion

In the Consensus Conference as well as in the earlier consultation process, there was near unanimity that this was one of the most pressing concerns with the TTISS system. There was uncertainty as to what challenges had prevented a revision and update to the 2007 TTISS manual: this manual contains the official TTISS reaction definitions, which are still used on the national ATR reporting form.

The TTISS-ON Medical Director, Dr. Andrew Shih, sent a communication to the PHAC TTISS staff in July 2024 with a request to meet, in part to plan updating the TTISS manual; he did not receive a response. TTISS-ON subsequently struck a working group with national transfusion expert contribution to revise the definitions and categories of transfusion reactions, to align with the document used in the Québec hemovigilance system that the National Institute of Public Health of Québec (INSPQ) had revised early in 2024.

Options and detailed comments

1. Determine if the adverse event definitions need to be updated.
   - There was unanimous agreement that the TTISS 2007 Manual is out-of-date, which has led to inconsistency of ATR classification as some provinces have adopted updated definitions within their jurisdictions.

2. Determine the method to achieve updating.
    - An ad hoc working group has met collaboratively to develop updated definitions
        - Ad hoc groups do not have consistent membership; a formalized standing committee is needed to provide regular updates of definitions document.
    - The national organization convenes a standing expert committee.
        - TTISS/ PHAC "owned" the TTISS Manual, so the national organization would need to be involved in updates if this resource is to undergo revision. The specific organization that will be responsible hinges on the governance structure that is adopted, and the body that signs off on the actual governance within the renewed hemovigilance construct.
    - Work to develop an updated ATR definitions manual is required by a standing committee or national body with a secretariat that has credibility to propose changes to definitions, and that has authority to bring it through the governance structure; this can ensure representation of all relevant parties.
        - Membership of a standing committee would be defined by Terms of Reference to ensure that all relevant parties are represented.
    - PTs expressed support for efforts to convene a committee to standardize definitions.
    - Adoption of revised definitions should be mandatory, once an updated manual is completed and available.
    - Health Canada expressed the desire to be involved in the ATR definitions manual development – some reactions will be reported under the *Blood Regulations*, and the definitions will need to be aligned and acceptable.

2.4 Conference Proceedings - Day 2

On Day 2 — March 24, 2026 — the remaining four issue categories were addressed, together involving ten issues with their associated options. The issues were as follows:

1. National System Data Reporting
    a. National reporting frequency
    b. ATR and error report data presentation
    c. ATR and error data analysis
    d. Data access and data sharing

2. Ancillary National Functions
    a. Feeback and communication
    b. Education and training
    c. Collaboration and coordination

3. Data Infrastructure
    a. Integrated databases
    b. Database functions

4. Cluster Identification

2.4.1 National data system reporting

2.4.1.1 ATR reporting frequency

Issue and background

- National reports should be produced regularly and with improved frequency.

Questions

- What frequency of national reports is recommended?
- Should other types of reports of information be produced at different schedules?

Preference polls

✓ **Regular reporting frequency: annual: 59%**

- Other options
  - Quarterly: 27%
  - 6-month: 8%
  - Other:. 6%

✓ **Ad hoc reports should be required when an issue is identified: 96%**

- Other options:
  - No: 4%

✓ **Additional features: Not a priority at this time: 73%**

- Other options:
  - Dashboard with rapid 90-day rolling updates on reactions:. 16%
  - Near real-time report:. 12%

General points of discussion

It is important to focus on what is needed from the system. There will be a trade-off between timeliness and quality; if they want a near real-time dashboard, they may be getting a national report only every two to three years. Several participants noted that they would rather get a robust and high-quality report every six months than an incomplete ad hoc report in a day.

Options and detailed comments

1. Regular data reports: annual; 6-month; quarterly; other
   - There was agreement by the majority that regular report publication should occur; however, the frequency of reports should be determined in consultation with the reporting organization, once it is determined.

2. Ad hoc reports should be required when an issue is identified
    - The renewed hemovigilance system will need to be flexible to permit this.
    - If there is a short timeline, ad hoc reports may not have important details, such as lot numbers etc. to clarify the nature of the signal.
3. Near real-time dashboard with 90-day updates on reactions (revised option)
    - Potential benefits
        - Good for providing constant feedback that is truly up to date (provided that data entry is timely).
        - Good for benchmarking and comparing trends in different areas.
    - Need to consider what is needed for the value of reports: give hospitals a rationale for reporting, with a sense of "what's in it for us?"
    - Challenges were raised, such as PT limitations with regards to existing data entry platforms and privacy laws, even though data is aggregated without patient health information.
    - What is "near" real-time?
        - Consideration that there may be a trade-off of timeliness and quality.
            - Reporting takes time, is complex, and can lead to delays. The process requires human resources to review and define reactions and validate data.
                - Within the hospital lab environment, data must be collected and entered into the transfusion medicine lab information system by technologists, the Transfusion Medicine Medical Director must review the report, then the report is entered into appropriate portal (or PT system).
            - To enable real-time, would PTs be required to be required to enter data more frequently? In the current state, for TTISS, staff in PTs entered their data into CNPHI at different intervals.
        - With a dashboard, the data could be quite raw and imprecise without the desired level of detail; there may be an unintentional delay in the production of regular reports due to the need for retrospective data cleaning.
    - There would be a need for an electronic system to flag reactions to the same blood product lot numbers from different provinces, which would alert designated personnel; however, it is not clear how picking up an early signal of a cluster could be done at this time.

2.4.1.2 ATR and error report data presentation

Issue and background

- National reports were cursory and presented only some of the PT data received; reports had limited utility.
- Some appreciated the simpler infographics to supplement statistical information.

Questions

- Is it feasible for data to be reported for each province and territory?
- What level of detail is most useful for users of the data?

Preference polls

1. ATR and error data presentation

✓ **Report data includes provincial and territorial comparisons: 85%**

- Other options
  - Report national data in aggregate only:. 15%

2. Data **reporting options**

✓ **Include additional ATR data entry fields: 90%**
✓ **Include infographics and focus on key outcomes: 88%**
✓ **Include more of the data submitted in published reports: 84%**

General points of discussion

The current inability of PTs to share their data for publication in the national report, and to support comparisons across provinces, was a matter of much discussion in the Consensus Conference. Government representatives suggested that constraints are stricter on the sharing of more granular data; this led to a discussion on the best balance of granularity and "shareability" of PT data. Participants strongly preferred that the national report present comparator data to enable benchmarking hot spots. Participants also noted that "if increased granularity means lower shareability, they lose"; thus, there is an acknowledgement that access to data within defined PT parameters is necessary. There is a more general discussion on the issue of constraints on the sharing of PTs data in "Jurisdictional responsibilities and constraints" on page 42.

Options and detailed comments

1. Report data for each province and territory
   - It is not typical for national infectious disease surveillance data to report PT data, or to have national public reporting that compares one province to another; PTs are not "keen on" such comparisons.
     - The more granular the data, the more constraints there are: PTs are custodians of their data and must protect it.
     - There are negotiations rather than strict rules on data sharing.
   - PTs consider their own data: but there was acknowledgement that a national hemovigilance system is needed to share data with other PTs.

2. Report more of PT data submitted
    - Although high-level ATR results are currently reported based on hemovigilance data submitted, the availability of granular data is important, in case of a desire to report more detailed information.
    - ATRs have not been tracked by or linked to patients within TTISS databases and provincial hemovigilance programs; thus this ATR data is de-identified.
        - This reaffirms that it is not possible to track recurrent reaction development in a hemovigilance database; this protects privacy.
        - Within hospital laboratory information systems, individual patient histories can be viewed and recurrent reactions tracked. These systems are separate from provincial hemovigilance programs; information with patient identifiers is within the custody of the hospital or health system and is utilized by clinicians for direct patient clinical care purposes.
3. Include additional ATR data entry fields
    - Additional data fields such as 'underlying diagnoses' (e.g. sickle cell disease), 'ethnicity' were discussed.
        - It may be a disservice to specific patient populations if ethnicity is not captured, as it may relate to groups that are vulnerable to certain adverse transfusion complications.
    - Including a breakdown of age ranges, to allow benchmarking within categories - and identification of specific groups has the potential to be helpful when tracking ATR risk.
        - Neonatal or pediatric patients have more reactions to plasma components.
        - SHOT looks at reactions for individuals with specific blood disorders.
4. Include infographics and focus on key outcomes
    - Infographics can be useful for action purposes: they are a means of communication support to efficiently convey information, but are insufficient alone as reporting tools.
    - SHOT graphics are very helpful for action purposes; they provide guidance on how clinicians should respond to a situation. However, these are supplementary to a complete, detailed report.

2.4.1.3 ATR and error data analysis

Issue and background

- National reports contained minimal analysis, limiting utility and learning.

Question

- What types of analysis should be included in national reports?

Preference Poll

✓ **Track all adverse reactions: 96%**
✓ **Analyze patient data in relation to intervention or product: 88%**
✓ **Impacts of changes in products, processes or practices on outcomes: 87%**

Options and detailed comments

- All are necessary: they should not choose among them.
  a. Track all adverse events
  b. Analyze patient data in relation to intervention or product
  c. Impacts of changes in products, processes or practices on outcomes

2.4.1.4 ATR and error reporting data access and sharing

Issue and background

- Interviewees had concerns about the limited sharing of PT data and access to data.

Questions

- What information do / should PTs share with the national system, for more complete reporting and access?
- What groups should have access to hemovigilance data?

Preference Poll

✓ **PTs are able to pull information from the national system: 98%**
✓ **Renewed national system preserves historic data: 93%**
✓ **Hospitals have access to their data for comparative purposes: 88%**
✓ **Open access for researchers to de-identified data: 81%**

General points of discussion

There was a strong consensus on the value of all the options considered, though there were some caveats on the matter of open access to PT data.

The importance of continued access to historical BSCP data in CNPHI through the sunsetting of the BSCP and transition to a new system was stressed. Participants wanted to be assured of the integrity and accessibility of historical data belonging to each PT through the transition period for the purposes of ATR and error trend comparison over time.

Options and detailed comments

1. PTs are able to pull information from the national system
2. Hospitals have access to their data for comparative purposes
   - Hospitals should be able to complete local trend comparisons, as well as compare and benchmark their data to trends in other hospitals.

3. Open access for researchers to de-identified data
    - The potential for access to accurate (cleaned), high-level data, would be an asset for quality improvement research. Research ethics board approval would be required to permit the specific use of data by investigators.
    - Clarification was provided that current BSCP data within the CNPHI system of the PHAC is not owned by the PHAC; rather, it is reported and owned by provinces and territories. Thus, open access is an important part of any future data sharing agreement that would be developed between the hemovigilance system data repository and PTs.

2.4.2 Ancillary national functions

2.4.2.1 Feedback and communication

Issue and background

- More feedback and communication were desired from the national authority.

Question

- What types of communication should a national system produce?

Preference poll

✓ **Targeted safety alerts when an issue arises:. 100%**
✓ **Monthly or quarterly newsletters: 80%**

Options and detailed comments

1. Monthly or quarterly newsletters
    - Consider the audiences for different types of newsletters
        - Plain language versions should be prepared for non-specialists.
        - The organization should have a plan for preparing and disseminating reports for the public.
    - The national organization should have a stakeholder communication plan; stakeholders include patients
        - Stakeholder mapping, newsletter from patient perspective.
        - Patient groups need full information, not filtered or simplified.
    - Internal feedback reporting systems are also necessary; this could feed into public communication and strategies if blood safety concerns arise.
2. Targetted safety alerts when an issue arises
    - There should be two-way interaction and stakeholder engagement when an issue arises, a contact in the national office when patients need to get or provide information.

2.4.2.2 Education and training

Issue and background

- Many in the transfusion community supported provision of training and education sessions and material.

Question

- What kinds of educational resources should the national coordinating office provide?

Preference poll

✓ **Guidelines and case reviews: 94%**

Options and detailed comments

1. National education sessions
    - Training and education should focus on why hemovigilance matters, and how it can improve the safety of transfusion.
        - Education and training need to include not only proper surveillance, but also patient-centered management of adverse events and potential adverse events.
    - Different formats of educational materials provided for different groups.
        - TSO Staff training
        - Nurse training: nursing is where patient interaction occurs; nurse turnover can make it difficult to keep up with training.
    - Sustainable resources need to be ensured to support training, and to update training with regards to acceptable transfusion practices.
        - A patient advocacy group representative spoke of a common practice of pre-medicating transfusion recipients to prevent minor reactions, which may lead to excess medication exposure. This can also lead to over-medicalization and increased healthcare burden.
2. Guidelines and case reviews
    - Practice guidance and quality improvement initiatives could be adopted by health jurisdictions across Canada.
    - Case reviews are popular and also improve reporting.

2.4.2.3 Collaboration and coordination

Issue and background

- Coordination of events and networks had been very helpful in previous years of the TTISS and TESS systems.

Question

- What kinds of collaboration and coordination activities should the national office provide?

Preference poll

✓ **National office collaborates with existing groups in transfusion community: 95%**
✓ **Foster a national community of practice: 86%**
✓ **Create networks for sharing experiences and harmonizing practices: 79%**

Options and detailed comments

1. The national office collaborates with existing groups in the transfusion community.
2. Foster a national community of practice.
    - There is a national community of transfusion practice – but it is missing a national forum, or glue to hold members together.
    - The CSTM exists, and has subcommittees (e.g. Transfusion Safety Network), and educational events. However, it is not a coordinated ATR monitoring and reporting system, as this work is beyond the scope of this organization.
3. Create networks for sharing experiences and harmonizing practices
    - A national organization process management team for coordinating events with a focus on hemovigilance; there should be a recipient hemovigilance office that helps foster specific events/ education directly related to the work that office does.

2.4.3 Data infrastructure

2.4.3.1 Integrated databases, reporting processes and tools

Issue and background

- The use of different and non-compatible national and PT databases has contributed to challenges in ATR reporting.

Questions

- What is the most useful configuration of national and PT databases for collecting data and reporting ATRs?
- If the error surveillance system is retained and combined with the ATR surveillance system, should the two reporting systems be combined?

Preference polls

✓ **1. Database configuration: Single standardized data collection system: 64%**

- Other options
  - National database with provincial platforms: 36%

✓ **If error and ATR reporting systems are merged, reporting forms are integrated: 89%**

- Other options:
  - If error and ATR reporting systems are merged, reporting forms are not integrated: 20%

✓ **Automate and streamline reporting forms: 98%**

- Other options:
  - Do not automate and streamline forms 2%

✓ **4. Explore the use of digital tools for reaction detection: 91%**

- Other options:
  - Do not explore digital tools for reaction detection at this time: 9%

General points of discussion

The options are not mutually exclusive. An incremental and phased approach will be needed to achieve the objectives of modernized databases. An important consideration is that hospitals and healthcare systems vary in their information technology resources, and not all are in a position to adopt automated data entry and analysis.

Options and detailed comments

1. Database configuration
   - National database with provincial platforms.
     - There are feasibility aspects of inter-relation of data systems; incremental changes towards modernized systems are possible.
   - Single standardized data collection system.
     - There can be no blanket statement that everything should be harmonized
       - There are many databases that PTs use for reporting different things to the federal government.
       - There are several different [national] databases for tracking various components of healthcare that would need to be harmonized.
     - It is desirable to have one report that can be submitted to all databases, and to avoid making multiple reports- a smart system that knows where reports are to be directed and submitted.
       - This is aspirational – but other countries are doing this, and in theory, the same should be possible in the Canadian context.

2. Integrate ATR and error reporting forms
    - Forms for both national and PT reporting would need to be adjusted when definitions are updated and new fields added.
    - This could pose a challenge for jurisdictions that have existing electronic provincial hemovigilance program electronic systems.
3. Automate and streamline reporting forms
    - The UK SHOT system has a category-specific questionnaire for the various reporting categories; some of the information is common to all categories, but there are also distinct questions for some.
4. Digital tools for reaction detection
    - It is acknowledged that health records are PT responsibilities.
    - There is potential for automating or using artificial intelligence to identify events occurring across PTs to the same lot number, that warrant an ad hoc report.
    - It is a priority to explore the potential for the use of digital tools; it would be the responsibility of PTs to consider the way these electronic tools could be used, including the implications of privacy laws.
        - For instance, in the future there may be the potential for electronic medical records (EMRs) access integration – if the digital tools are applied at a national system level, there may be interfaces within healthcare system EMR platforms introduced to analyze clinical data and identify trends of associated ATR signs and symptoms.

2.4.3.2 National database functions

Issue and background

- Updated databases could provide many useful functions.

Question

- What database functions are important for a renewed hemovigilance system?

Preference poll: options ranked 1- 4

1. Enable the detection of rare patterns
2. Have customizable data fields to add specific diagnoses
3. Dashboard interface that allows real-time data entry by PTs
4. Enable correcting past entries when revision needed

Options and detailed comments

- Enable the detection of rare patterns; rarer patterns than a sub-national system could
- Dashboard interface that allows real-time data entry by PTs
- Have customizable data fields to add specific diagnoses
- Enable correcting past entries when revision is needed

2.4.4 Cluster Identification

Issue and background

- Identifying a cluster of minor reactions is important
  - To enable communication of cluster to other sites and PTs
  - To enable reporting to CVP for follow-up
- Identifying a cluster of minor reactions is challenging
  - Data reporting and monitoring are not timely enough, or accessed at sufficient scale, to detect a cluster.
  - CVP's definition of a cluster is not clear for reporting purposes.

Question

- What mechanism can be developed to provide timely reporting and monitoring of data, at a scale that enables detection of a cluster?

Preference polls

✓ **Health Canada's CVP clarifies definition of cluster for reporting purposes: 83%**
✓ **Create national coordinated hotline for communication in transfusion community: 72%**
✓ **Dashboard interface that allows real-time data entry by PTs: 68%**

- Other options:
  - Local hospitals and PTs are responsible for identifying clusters: 28%

General points of discussion

Cluster identification and communication have, in the past, been conducted through personal networks of transfusion clinicians who have noted local spikes in blood product lot-number related ATRs. At present, developing a more reliable and sustainable system remains a challenge. A participant included the following comment: cluster detection requires a mechanism that is different from overall hemovigilance, subsequently posing questions, including what defines a cluster; how can this information be rapidly explored across jurisdictions; how can this be formalized and made redundant? The development of a robust communication and networking process is required.

Options and detailed comments

- Local hospitals and PTs are responsible for identifying clusters.
  - Without a minimum definition, it is possible that low numbers of reactions in some jurisdictions may be missed as important parts of a cluster event, if there is no awareness of similar reactions to the same product lot number occurring in other facilities.
- Create a national coordinated contact centre for communication in the transfusion community.
  - Although this would be an improvement over current personal networks, there is a current lack of ownership, of who would receive the information and how this system would be managed.

- Adopt near real-time surveillance.
    - For example, a 72-hour period could be allocated for data cleaning.
- Health Canada's CVP clarification of the definition of cluster for reporting purposes.
    - Health Canada knows this definition requires urgent clarification to ensure consistency of the application of the term cluster.
        - Clinicians report the lot number and incident to the Health Canada - CVP which is subject to internal signal detection, and for CVP staff to investigate.

2.5 Special topics

Several topics of concern were raised at the Consensus Conference that were considered to require separate attention for the full understanding of the development of the recommendations. Six topics are summarized in the sections below.

2.5.1 Québec's hemovigilance system

Dr. Pierre-Aurèle Morin was invited to describe Québec's hemovigilance system, as a system that is considered to be successful.

The following is a summary of Dr. Morin's comments, and responses to questions from other participants.

- The National Institute of Public Health of Québec (INSPQ) is mandated by their Ministry of Health to conduct hemovigilance activities, and to receive ATR reports from hospitals. The Ministry of Health would submit provincial reports to the national TTISS system.
- Governance
    - The Biovigilance Committee advises the Québec Ministry of Health on all questions related to safety of blood and blood products (as well as other biological products); this committee includes three hematologists, a TSO, a microbiologist, a physician representing organ transplantation, a member from the INSPQ and patient representatives.
    - The province is divided into regions, each of which has a designated transfusion centre.
- Transfusion Safety Officers
    - TSOs are funded by the province and are allocated to designated regional transfusion centres according to their transfusion volumes. For example, several TSOs may be assigned to a larger hospital to save a region; others may share a TSO, but all hospitals are covered.
    - Consideration is currently given to redefining TSO positions within Québec, and the way they are allocated to regions and healthcare facilities.
- Reaction reporting and review
    - Reporting is functionally mandated due to the presence of provincially-funded TSOs.
    - Hospitals are asked to report all reactions. There are differences in reporting among TSOs, with help required in training to make reporting more efficient and consistent.
    - Hematologists work with the INSPQ to review reactions as needed.
    - A strong structure for error reporting does not exist provincially, beyond hospitals' own transfusion error-reporting processes, which are required under the Blood Regulations.

- Data reporting
  - The INSPQ's goal is to produce a report annually; there is currently a delay of approximately three years. In an effort to get more timely reporting there are attempts to streamline reporting processes, but resourcing is always a challenge.
- Updated Québec ATR definitions manual and reporting form
  - The manual used in Québec[4] was updated by a group of experts convened to address certain definitions.
  - There is no standing committee for the adverse transfusion reaction definition manual: the Biovigilance Committee identifies a need to update definitions and convenes a group to address these questions.
  - There is a single form for all reports to the INSPQ; the form contains all the information necessary to adjudicate a reaction. The form for reporting ATRs to blood banks is available online[5]; the full form is available on request to the INSPQ or Ministry of Health.

2.5.2 International hemovigilance systems

Information on six international hemovigilance systems was provided for context as Consensus Conference participants considered options for a renewed hemovigilance system for Canada. Participants were aware that most developed countries have a national hemovigilance program: the WHO (2023)[6] reports that 81% of European countries have a recipient hemovigilance system, and 74% of hospitals in high-income countries have a system for reporting adverse transfusion events.

All the six countries that were reviewed - United Kingdom, France, Germany, the Netherlands, Norway and Australia – have a national recipient hemovigilance system. Five of these countries (all but Australia) have a centralized system led by a national government agency that applies uniform national standards throughout the system and may communicate directly with reporting hospitals. This structure is aligned with these countries' unitary government systems.

Australia, like Canada, has a federated government system: it has a central national government and six states and two territories that share jurisdiction for health care. Hemovigilance activities in Australia are carried out by states and territories, and there is a national authority that has coordinating, monitoring and reporting responsibilities.

In all systems reviewed, the national organization is responsible for publishing national ATR data, mostly on an annual basis. Some national organizations, such as those in the UK, Norway and Australia, analyze the data, monitor data trends, and provide advice and training.

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4 Available at https://www.inspq.qc.ca/publications/3355

5 Available at http://msssa4.msss.gouv.qc.ca/intra/formres.nsf/29d0d6ae68a554f485256e1a006ba71c/a1ae26f44b225ecd85256ed600678317/$FILE/AH-520_DT9260(2017-01)D.pdf

6 *WHO Factsheet, Blood Safety and Availability*. 2023. Accessed at https://www.who.int/news-room/fact-sheets/detail/blood-safety-and-availability.

Most countries use a unified set of standards and ATR definitions: the UK's SHOT system has nationally standard definitions, which the SHOT team reviews and updates; France, Germany have standardized ATR definitions derived from the International Society for Blood Transfusion and the International Haemovigilance Network. The Australian National Blood Authority (NBA) is responsible for promoting uniform national standards across jurisdictions, and states and territories report adverse events in accordance with the national dataset: the NBA and the Haemovigilance Advisory Committee review relevant definitions in the National Health Data Dictionary against international usage, and update definitions as necessary.

2.5.3 A federally-coordinated collaborative FPT model of governance

The first issue discussed at the Consensus Conference — Governance Options — was a primary concern for conference participants. It generated considerable discussion, which resulted in strong support for a new fourth option: a federally-coordinated collaborative FPT model. In discussions with participants after the conference, it has been determined that the initial phrase used, federally-mandated, was less suitable and was not the actual intent of the proponents. The phrase has been replaced by 'federally-coordinated' which entails not only a central federal role, but also the funding that would support the function of coordination, including data curation and report generation.

As there was interest in further fleshing out this option to formulate a more mature recommendation, a group of participants described a possible structure for this governance model. The structure consists of several bodies which together provide both governance and leadership. This was presented as conceptual, with details to be developed, and with reminders that a new structure must align with current legislation.

- Governance
  - Federal and PT governments to ensure timely HV program execution, compatible with current legislation
- Leadership
  - Independent Expert Advisory Group: medical experts, patients, representatives from operational group from each PT. This should play a significant role in providing input to operational managers.
- Operational
  - Execution/Implementation of a national HV program with integrated collaborative provincial responsibility (to the hospital level)

Figure 5 on page 41, was suggested as a possible configuration of a governance model that could meet the needs and considerations for a renewed hemovigilance system.

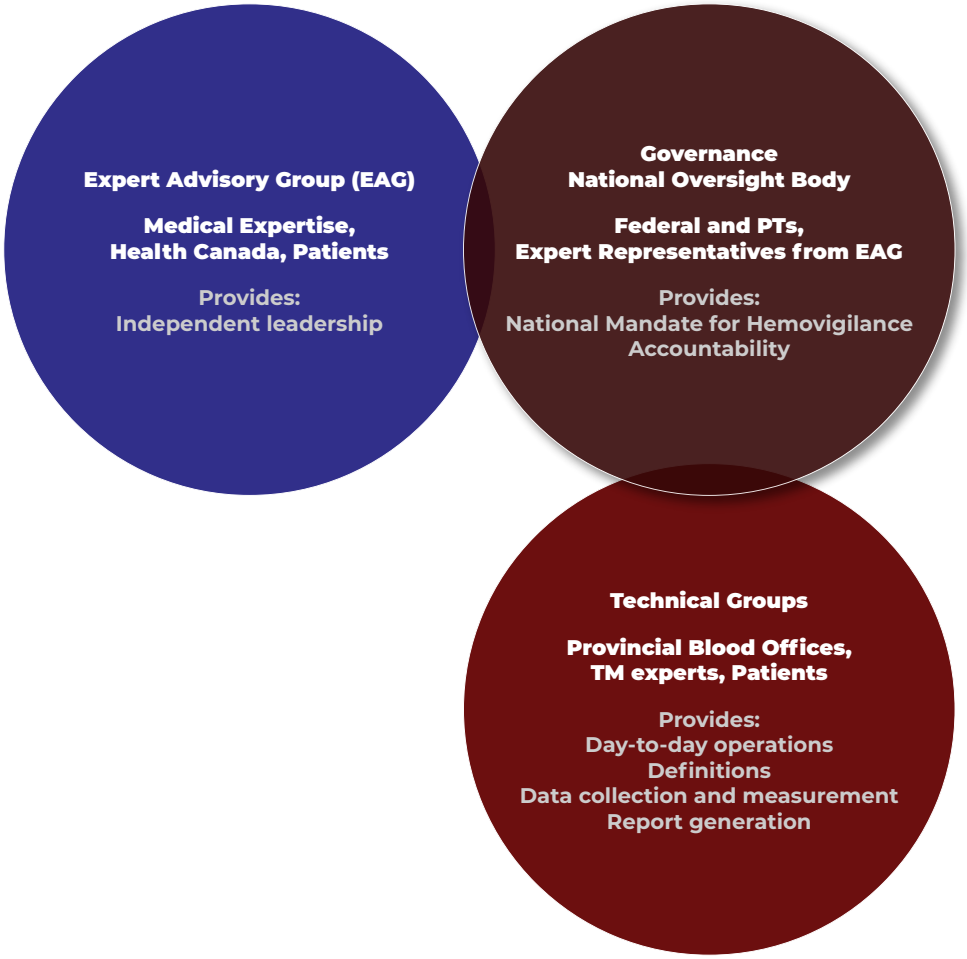

Figure 5. A possible configuration of a federally-coordinated collaborative FPT model for a renewed national recipient hemovigilance system.

Participants emphasized that this conceptual model needs significant discussion and further development. Some noted that creating and implementing this arrangement will take time and resources, which might not be required if the previous governance structure was preserved, with a higher level of funding.

It was pointed out that an analogous structure has been developed for several different health-related programs and could serve as a model for a renewed hemovigilance system, and as a precedent it may expedite the development of a governance model for national hemovigilance. This is a pan-Canadian governance organization, a federally-funded independent body that has a mandate and structure for interoperability with PT governments. There are seven organizations in Canada that are under a pan-Canadian organization, including the Canadian Institute for Health Information, Canadian Partnership for Health, and Canada Health Infoway.

Another example of such a structure that is analogous to hemovigilance surveillance is the Pan-Canadian Governance Body for Organ Donation and Transplantation, endorsed by the FPT Conference of Deputy Ministers of Health. This structure is described on its website as "a transparent and formalized structure with clearly defined roles and responsibilities to support effective and efficient Pan-Canadian decision-making on funding, policy and program-related matters at the systems level."[7]

A Consensus Conference participant who was involved in the framework explained that the top structure of this body is an Assistant Deputy Minister (ADM) Steering Committee that functions across the FPT governments. The FPT ADM Steering Committee operates as a non binding advisory and coordination forum in support of the formal roles and responsibilities of PT Ministers, PT Blood Liaison Committee, the Lead Province, and Canadian Blood Services. Health Canada and Canadian Blood Services act as co-secretariats of the framework.

There is recognition of the legislative pathways and requirements that exist for PTs versus the federal government, and PTs oversee the clinical care provided in their jurisdiction.

There are committees that function under the FPT ADM Steering Committee, and report up to it, that represent all the different partners in the system. These include the Patient Advocate Advisory Committee, composed of patient/family/donor representatives, and the System Operators Advisory Committee, represented by clinicians, organ donation organizations, national ODT-related organizations such as CBS, Canadian Society for Transplantation, etc. and Indigenous representatives. There is also a PT Policy Network composed of working-level ministries of health officials to allow for more working level discussions to support administrative matters and briefing of senior PT officials. This structure has only existed for about a year, but it has parallels to the stipulated governance of a recipient hemovigilance system.

2.5.4 Jurisdictional responsibilities and constraints

As participants considered roles and functions that might be conducted by organizations at different jurisdictional levels, many noted that attention should be paid to "things we can't change," such as legal requirements and agreements between governments on functions with which hemovigilance arrangements must align.

According to a 1998 Memorandum of Understanding between federal, provincial, and territorial governments, the federal government, through the Minister of Health, is responsible for maintaining an effective national system for the surveillance of blood-borne pathogens and conducting national surveillance activities related to the blood system. It also retains regulatory authority under the Food and Drugs Act and works collaboratively with provincial and territorial governments and the national blood authority (such as Canadian Blood Services) to support and coordinate surveillance efforts across Canada.

An issue that was raised several times at the Consensus Conference is the legal arrangements that may require, or constrain, action by certain levels of government. As was described in the White Discussion Paper, the Constitution of Canada divides responsibility for health care between federal and PT jurisdictions, giving responsibility for regulating the safety of the blood supply to the federal government, which it does in part through regulations under the Food and Drugs Act; and health care delivery to the PTs, including hemovigilance activities in hospitals. Interviewees in the consultation process and participants in the Consensus Conference acknowledged

7 https://www.canada.ca/en/health-canada/services/healthy-living/blood-organ-tissue-donation/organ-tissue/pan-canadian-governance.html?hl=en-CA

these different responsibilities, illustrated by the near-consensus support they gave to a governance structure that is federally-coordinated and collaborative with PTs, as described above. This recognizes the necessity for a federal role to coordinate alongside the PTs, which do not have national scope mandates – interaction and harmonization of standards and processes are required to achieve coherence in a national system. An example of this, the need for federal coordination to convene an expert committee to revise and harmonize the ATR definitions that are published in the national manual, has already been noted.

An important gap in national reporting that received significant attention in the Consensus Conference, as in the prior consultation process, relates to limits on PT data that can be shared with the national system and published in the national report. In the Consensus Conference, some constraints on PT data sharing were attributed to jurisdictions' privacy laws. All jurisdictions have privacy laws that set out conditions for the ways governments collect, use and disclose personal information. As hospitals are subject to PT privacy legislation, information on patients and donors that can be included in data that is shared with other jurisdictions, and published in a national report, is defined by each PT's privacy laws.[8]

A participant from a provincial ministry of health stated that the capacity of PTs to share data comes down to the constraints in their legislation: the PTs are the legal custodians of patient data, and they are careful to ensure that no-one's life is impacted by the release of their personal health information. There are no strict rules on what can be done with PT data; it is a negotiation between PTs and the federal government. A general principle is that the more detailed or granular the data, the more constraints there may be on its shareability. A primary consideration is the optimal balance between granularity and shareability of information. Other participants countered that all data is de-identified before being sent to the national database.

Aside from privacy legislation concerns, the fragmentation in reporting has been noted as a more general challenge for the development of national surveillance systems in the Canadian federalist system. Wilson et al., 2004[9] stated that the full implementation of a health surveillance system requires developing agreements on data-sharing and standardization of data, and that such agreements are part of the process of creating and sustaining a national surveillance system.

Consensus Conference participants mentioned that under the BSCP, data-sharing agreements were in place between all provinces and territories individually. For continued sharing to a central group for the purposes of analysis and reporting, there would need to be formal data sharing agreements, either specific to a program or as part of other umbrella agreements between PTs and the federal government. Many of the functions considered in the Consensus Conference would require an agreement: for example, the provision of open access of PT data to researchers would need to be defined in a data-sharing agreement. References were also made to contribution agreements, which could include specifications on the use of federal funds for certain activities.

8 https://www.priv.gc.ca/en/privacy-topics/privacy-laws-in-canada/02_05_d_15/#heading-0-0-3-1

9 Kumanan Wilson, Jennifer McCrea-Logie and Harvey Lazar (2004) *Understanding the Impact of Intergovernmental Relations on Public Health: Lessons from Reform Initiatives in the Blood System and Health Surveillance*. Canadian Public Policy Vol XXX No 2.

2.5.5 Federal and PT government engagement

Many participants regretted the lack of information provided by governments on the hemovigilance renewal process, related to both the sunsetting of the BSCP and the renewal process. The BSCP sunsetting was announced to a small group of stakeholders, and the news subsequently spread among the transfusion community and stakeholders, but there is no mention of the sunsetting on the PHAC website and there is a persistent lack of clarity on the rationale for the decision.

A more pressing concern among participants at the Consensus Conference was a desire for guidance from government representatives on the resources that would be available to a renewed system, so they could prioritize the options they supported and the recommendations they make. Many respondents noted that determining the most important details to be collected is challenging without understanding the limitations and constraints. Experts are enthusiastic about building the best system with the resources available, if these were known.

However, it was announced in the opening remarks of the Consensus Conference that while representatives of the federal and PT government were participants in the conference and would offer explanations of some issues that were raised, they would not be voting on the options for the issues.

Representatives of the federal and PT governments gave a short opening address at the beginning of the conference, and again at the closing. The federal representatives stressed that hemovigilance is a priority for the federal government, and that it has a shared commitment to recipient hemovigilance and to the safety of patients who rely on blood products. They were there to listen and identify the most important needs in a recipient hemovigilance system, and will work with the PTs to review the feedback from the Consensus Conference and determine how they will implement the recommendations at the federal level.

The PT representative expressed their interest in listening to and learning from Conference participants, and to seeing evidence-based recommendations evolve through discussion. The PTs take the recommendations made in the Consensus Conference very seriously; they will continue to work with federal partners to understand how the recommendations will fit into healthcare governance pathways.

It was argued that the Consensus Conference could not pre-suppose the government deliberations on the recommendations that are developed; participants' task was to give governments the best advice and the best expertise. However, participants were concerned that the decision of governments not to vote on the preferred options precluded any feedback and guidance on the acceptability or feasibility of any option that would enable participants to modify an option to ensure it is realistic. They knew that is important to identify the features they feel are required, but they were also aware that if their recommendations are unrealistic, they will fail: they need to be practical and recommend something that can be achieved.

2.5.6 Concerns with transition to renewed recipient hemovigilance system

A concern that arose in discussions about several issues is that of the gap between the sunsetting of the BSPC surveillance systems and the implementation of a new recipient hemovigilance system. Developing the proposed multi-level governance organization will take time, and the longer there is no national system in place, the more serious the gap in support will be.

The cessation of federal funding for hemovigilance activities through the transition period is a concern, for example with respect to hospital staff who were funded through the BSCP. Unless dedicated PT funding is provided to continue funding the positions for these staff, their expertise may no longer be available within jurisdictions. After sunsetting, the recipient hemovigilance system will be wholly reliant on hospital nursing educators or technologist staff that may not have the capacity and/or the expertise to investigate or document adverse transfusion events appropriately.

In a follow-up to the PHAC announcement that the BSCP was sunsetting as of March 31, 2026, the PHAC committed to extending access to the appropriate databases on the CNPHI for an additional year, until March 31, 2027; however, this platform will not be maintained by the PHAC throughout this time. This additional year will give jurisdictions sufficient time to transfer all electronic data from the TTISS (and/or TESS) platform within CNPHI to PT storage drives; it will also enable PTs without a provincial hemovigilance platform a database into which ATR data can be entered, until a national hemovigilance system strategy is developed.

However, participants expressed concern that a longer period for the determination of a complex hemovigilance governance arrangement could leave them without access beyond March 31, 2027. It is anticipated that the loss of access to this national historical data (with only PT data downloaded within each jurisdiction) will be a void that needs to be filled as soon as possible. Ideally, interim steps towards full implementation of a new hemovigilance system will be implemented.

3. Summary of recommendations

As is indicated by the results of the preference polls, there was significant convergence among Consensus Conference participants on the preferred options that should be put forward as recommendations. This convergence is due in part to the consistency of concerns about hemovigilance in the transfusion community, and also to participants' adjusting options that were put to a preference poll to ensure that they represented the most important needs, and that should be possible to achieve. Through discussions, participants modified a number of options, dropping some, combining others, and adding new options that were preferred over the one that had been prepared.

The recommendations listed below are the options that Consensus Conference participants agreed best represent the needs of a new recipient hemovigilance system, and that should be put forward for the consideration by decision-makers for final determination and implementation. Participants discussed the options as they were presented in the White Discussion Paper, and did not have information on other factors, including operational feasibility.

Implementation of the recommendations will require alignment with federal, provincial, and territorial roles and responsibilities, as well as agreement on governance, funding, and data-sharing arrangements.

3.1 Program leadership and governance

3.1.1 Governance

Recommendation 1: The national recipient hemovigilance governance structure should apply a federally-coordinated collaborative FPT model.

A fundamental premise for the governance organization is that governance defines the structure and accountabilities in the organization, but that it also includes leadership, which provides strategic direction and coordination. It was felt that both governance and leadership needs are best met with a multi-body structure.

The renewed governance structure is effective as it involves both federal and PT governments, to ensure representation and coordination of all jurisdictions; and leadership should be independent of governments, blood operators and industry. As represented in Figure 5 on page 41, the important aspects of this model are the following:

- Governance: A national oversight body includes representatives of the federal and PT governments as well as expert groups. This body provides the national mandate for recipient hemovigilance and accountability for its performance.
- Leadership: Independent of the governance body, provided by an expert advisory group representing medical experts, Health Canada, and patient groups.
- Operational: A technical group that manages day-to-day matters including data collection and reporting, and consists of PT blood offices, transfusion medicine experts and patients.

An existing model that is directly applicable for a Canadian hemovigilance system is a pan-Canadian structure, an independent body that has federal or FPT cost-shared funding and has a mandate and structure for interoperability with PT governments. These structures will require both additional content expertise and methods to ensure PT representation. This model has been applied in several systems in Canada, including the Pan-Canadian Governance Body for Organ Donation and Transplantation, and is thus a practicable precedent for a national hemovigilance system.

A challenge with creating and implementing such a structure is the time and resources that are required. It will require a federal government unit to serve as secretariat and operational body, and secure federal or FPT cost-shared funding in order to function.

3.1.2 Expert Capacity

Recommendation 2: An external advisory group should be provided for a national structure that has internal expertise.

It is important that a national body include relevant expertise, including medical, nursing, technical and patient representation, and that it be supported and advised by an expert steering committee with dedicated experts in transfusion medicine, data and research, and other areas. Expertise must be appropriately compensated. An independent expert steering committee was identified as a characteristic of other internationally recognized hemovigilance systems.

This provision is consistent with the federally mandated collaborative provincial/ territorial model governance model presented in Recommendation 1 on page 46.

3.1.3 Funding

Recommendation 3: Funding should be a mix of federal and provincial/territorial contributions.

The essential requirements for funding are that it be adequate to support necessary functions and activities in the hemovigilance system, and that it be sustainable, with equitable distribution. Adequate funding is particularly necessary for expert advisors and TSOs to ensure capacity for surveillance functions.

3.2 National Hemovigilance System Components

3.2.1 ATR and error reporting systems

Recommendation 4: **Error reporting should be retained as part of hemovigilance, merged and/ or expanded as part of hemovigilance.**

Recommendation 5: **The ATR and error reporting systems should be merged.**

It was very strongly recommended that error reporting be merged with ATR reporting and expanded to more sites, as opposed to the current limited implementation of error reporting, to ensure that all relevant information on adverse reactions and root causes is collected across Canada.

3.2.2 Transfusion safety officers in hospitals

Recommendation 6: **All hospitals should have access to a TSO. Large hospitals have TSOs; smaller hospitals' access is determined by their network or region.**

Transfusion safety officers are essential; they do much more than reporting and data entry, including root cause analysis, investigation, training and implementing change. Some larger hospitals have only enough TSOs to report serious reactions: without a TSO, neither ATR nor error reporting can operate, even at peripheral hospitals if they have full services that involve transfusions. The possibility of mandatory reporting of all reactions is dependent on the availability of sufficient TSOs.

3.3 Adverse event and error reporting

3.3.1 Mandatory or voluntary reporting

Recommendation 7: **Reporting of all ATRs should be mandatory, regardless of severity.**

Full reporting is necessary to get information on all reactions. Less severe reactions are important as they can indicate effects of a change in the constitution of some blood components and products or be a marker for insidious dangers to recipients. This is necessary for blood operators to know, for informing physicians' prescribing practice and for informed patient consent. An additional consideration is that minor reactions must be reported if identifying clusters is to be possible.

To minimize the reporting burden on staff of reporting all reactions, less detailed reporting could be required for minor reactions and some types of reactions that are well understood.

3.3.2 Data to collect on adverse reactions

Recommendation 8: **Information collection and definitions should be optimized.**

The value of data elements should be examined and a list prepared of those that should be added or changed. A key consideration is the utility of data to inform clinical practice, research and identifying patient safety threats.

3.3.3 Standardization of definitions

Recommendation 9: **The adverse event definitions need to be updated.**

Recommendation 10: **The best mechanism to achieve harmonized definitions is that the national organization described in Recommendation 1 convenes a standing expert committee to revise and publish updated definitions.**

The current case definitions have not been updated since 2007. A standing expert committee is necessary to provide stable and representative membership and ensure the credibility and authority to propose updates to ATR and error case definitions. Many such definitions can be derived from internationally well-recognized organizations. The national organization responsible for convening the standing committee would be determined by the governance structure that is adopted.

3.4 National data system reporting

3.4.1 ATR reporting frequency

Recommendation 11: **Regular reporting should be on an annual basis.**

Recommendation 12: **Ad hoc reports should be required when an issue is identified.**

The frequency of national reporting should be determined in consultation with the responsible organization, once that is established. The reporting system should be flexible enough to enable the preparation of ad hoc reports, as well as the production of annual reports. A functional national structure ensures that when an issue is identified, there is pan-Canadian reach and action.

3.4.2 ATR and error report presentation

Recommendation 13: **Report data includes provincial and territorial comparisons.**

Recommendation 14: **The following features should be included in reports: (1) Additional ATR data entry fields (2) Infographics focusing on key outcomes (3) More of the data that PTs submit.**

The reporting of PT data will depend on data-sharing agreements that PTs make with the federal government, and on the granularity of the information that is to be shared. Current data reported to the national system does not include patient identifiers and published reporting is in aggregate.

3.4.3 ATR and error data analysis

Recommendation 15: **All adverse reactions should be tracked.**

Recommendation 16: **Patient data should be analyzed in relation to interventions or products.**

Recommendation 17: **The impacts of changes in products, processes or practices on outcomes should be analyzed.**

Minor reactions have been demonstrated to be a signal for significant harms to recipients, as observed in the tainted blood scandal. Root cause and risk-based analyses are necessary for intervention and mitigation of recipient risk.

3.4.4 ATR and error reporting data access and sharing

Recommendation 18: **Access to historic and future data should be ensured for PTs and other approved users.**

The following access provisions should be ensured:

- PTs are able to pull information from the national system;
- The renewed national system preserves historical BSCP data;
- Hospitals have access to their data for comparative purposes;
- Open access for researchers to de-identified data.

It is essential that the historical data in the national system is preserved through the entire period of transition from the BSCP systems to the renewed hemovigilance system, to enable comparison of current adverse transfusion reaction and error rates to historical rates.

3.5 Ancillary national functions

3.5.1 Feedback and communication

Recommendation 19: **Targeted safety alerts should be communicated when an issue arises.**

Recommendation 20: **Monthly or quarterly newsletters should be prepared.**

Electronic newsletter-style communications should report adverse transfusion reactions rates or safety concerns to the transfusion community, including hospitals that submit data to the hemovigilance system. Communications should consider different audiences and plain language versions should be prepared for non-specialists. The national office should have an internal feedback reporting system and a stakeholder communication plan that includes patient groups. Safety alerts require two-way interaction to allow stakeholders to engage on the issue of concern to mitigate recipient harm.

3.5.2 Education and training

Recommendation 21: **The national organization should provide guidelines and case reviews.**

Recommendation 22: **National education sessions should be presented.**

Education should be delivered in different formats for different groups, including nurses and technologist staff, with an appropriate format for each. It should include both evidence-based and patient-centred management of adverse events and of potential adverse events.

Sustainable funding should be assured to support training programs and update training,

3.5.3 Collaboration and coordination

Recommendation 23: **The national office should collaborate with existing groups in the transfusion community, foster a national community of practice, and create networks for sharing experiences and harmonizing practices.**

Many collaborations were facilitated in the past by the previous national organization. There are currently professional groups in the transfusion community, but they lack the national coordinating function that would pull them together for greater effectiveness.

3.6 Data infrastructure

3.6.1 Integrated databases, reporting processes and tools

Recommendation 24: **The national database should be configured as a single standardized data collection system.**

Recommendation 25: **If error and ATR reporting systems are merged, the reporting forms should be integrated.**

Recommendation 26: **Reporting forms should be automated and streamlined.**

Recommendation 27: **The use of digital tools for reaction detection should be explored.**

Each of these functions is partly the responsibility of the PTs, so the issue is not solely a matter of national infrastructure but requires a harmonized mandate and approach on safety surveillance and data collection. The functions identified are not mutually exclusive and can be implemented in an incremental and phased approach. An important consideration is that hospitals and healthcare systems vary in their information technology resources and expertise to report; some use paper-based charting instead of electronic medical records, and not all are in a position to adopt automated data entry and analysis.

3.6.2 National database functions

Recommendation 28: **The national database should have the following four capabilities, in order of importance: (1) Enable the detection of rare patterns (2) Have customizable data fields to add specific diagnoses (3) Dashboard interface that allows real-time data entry by PTs (4) Enable correcting past entries when revision needed.**

3.7 Cluster identification

Recommendation 29: **Health Canada's Canada Vigilance Program should clarify the definition of a cluster for reporting purposes.**

Recommendation 30: **A national coordination contact centre should be created for communication of clusters within the transfusion community.**

Recommendation 31: **A dashboard that allows real-time data entry by PTs should be created.**

Cluster identification remains a challenge, given the lack of clarity, for both communication within the transfusion community and for reporting a significant cluster to the Canada Vigilance Program (CVP).

4. Appendix

4.1 Participants in the Consensus Conference

Consensus Conference participants represented all relevant stakeholder groups. The sectoral representation of participants is as follows, showing the number of individuals (in person | online).

- International (0 | 2)
  - Serious Hazards of Transfusion, United Kingdom
  - Haemovigilance Programme of India/International Society for Blood Transfusion
- Transfusion medicine community
  - 28%, or 29 individuals (11 | 18)
    - from hospitals in PTs across Canada
- Patient groups
  - 13%, or 15 individuals, (11 | 4), representing
    - Network of Rare Blood Disorder Organizations
    - AlphaNet Canada
    - Community-based Research Centre
    - Hereditary Angioedema Canada
    - Canadian Hemophilia Society
    - Thalassemia Foundation of Canada
    - Immunity Canada
    - GBS/CIDP Foundation of Canada
    - Sickle Cell Disease Association of Canada
    - Sickle Cell Awareness Group of Ontario
- Blood system operators: individuals
  - 12% or 12 individuals
  - Canadian Blood Services 9 (6 | 3)
  - Héma-Québec 3 (2 | 1)
- Governments
  - Federal 13 individuals (9 | 4)
    - 9 Health Canada
    - 4 Public Health Agency of Canada
  - Provinces and territories, 34%, including individuals:
    - British Columbia: 6 (1 | 5)
    - Alberta: 2 (0 | 2)
    - Saskatchewan: 3 (1 | 2)
    - Manitoba: 3 (1 | 2)
    - Ontario: 4 (3 | 1)
    - Québec: 3 (2 | 1)
    - New Brunswick: 3 (1 | 2)
    - Prince Edward Island: 2 (0 | 2)
    - Nova Scotia; 5 (2 | 3)
    - Newfoundland and Labrador: 2 (0 | 2)
    - Northwest Territories: 1 (0 | 1)
    - Yukon: 1 (0 | 1)

Canadian Recipient Hemovigilance Renewal Process Recommendations Paper