



**POSITION STATEMENT ON PATIENT SUPPORT PROGRAM BEST PRACTICES PERTAINING
TO OUT-OF-HOSPITAL TRANSFUSIONS**

**A Joint Collaboration between NAC and the Canadian Blood Coordinating
Program Collaborative**



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ABBREVIATIONS

CBCPC	Canadian Blood Coordinating Program Collaborative
CSA	Canadian Standards Association
NAC	National Advisory Committee on Blood and Blood Products
PSP	Patient Support Program
PT	Provincial/Territorial
TMS	Transfusion Medicine Service

DEFINITIONS

Authorized Prescriber – a health care provider who is qualified and has the legal right by provincial or territorial licensing to order blood components and/or products, done within their scope of practice and in accordance with jurisdictional policies.

Blood Product – a therapeutic product derived from human blood or plasma and produced by a manufacturing process as noted in the Canadian Standards Association (CSA) Standards Z902. In practice, this includes plasma proteins and related products as per policy in many Canadian jurisdictions, transfusion medicine services, and/or dispensing programs. In some jurisdictions, “related products” (proteins and molecules created in a laboratory) may be exempt from certain policies otherwise applicable to products derived from human blood or plasma.

Capable Adult – an individual, identified by the client, who is of the age of majority, has the capacity and physical ability to assist the client in accessing emergency health care services should an emergency arise during or following the infusion. This individual must be someone personally chosen by the client.

Dispensing – the process of secure release where a medication or blood product as it pertains to this document, is prepared and released for provision to a patient. This is often restricted to pharmacists and pharmacy programs in jurisdictions.

Issuing – the process of secure release of blood components and/or products from the issuing TMS for provision to a patient.

Order – a formally documented order from an authorized prescriber, authorizing the issuing transfusion medicine service and/or dispensing program to securely release a blood product for provision to a patient. Based on CSA standards (CSA Z902: 10.2.1), this includes: a) two unique identifiers, b) the recipient’s location, c) the product being requested, d) the required volume or quantity; and e) any special requirements.



1.0 INTRODUCTION

Patient Support Programs (PSPs) play a significant role in the support of out-of-hospital infusion of blood products that are part of the formulary from Canadian Blood Services. There is a need for a standardized national framework for PSPs that promotes consistency, patient safety and system coordination, while providing patients with the same standard of care regardless of their circumstances.

PSP supported infusions include “home infusion programs” and “third-party” non-hospital infusion clinics but do not include pre-hospital and inter-hospital transportation programs. Expectations for a blood product manufacturer to also provide an accompanying PSP are defined in the Canadian Blood Services Request for Proposal process, and the cost of each program is built into the negotiated price for individual blood products. While some hospitals and health regions across Canada have programs that facilitate home infusion of blood products, PSPs routinely provide the necessary infusion supplies, and, where hospital/health authority programs do not exist, patient training, and coordination with the health care system.

While practices and policies may be variable based on issuing transfusion medicine services (TMS) and the clinics they serve, national and provincial/territorial (PT) accreditation standards and Health Canada regulations (notably the Canadian Standards Association (CSA) Z902 and the Canadian Society for Transfusion Medicine Standards) must be adhered to by all stakeholders of the blood system. Policies and procedures are well defined, accredited, and consistent for hospital infusions but less so for out-of-hospital administration of blood products. Concerns include ensuring informed consent, traceability, and reporting of all adverse events to the transfusion medicine service or a PT database. For jurisdictions where blood products for out-of-hospital infusion are dispensed by a pharmacy, rather than a TMS, the same standards of practice must be met. PSPs may also subcontract some of their roles and responsibilities to delegates who have less awareness of them, but they still must be met.

The National Advisory Committee on Blood and Blood Products (NAC) and the Canadian Blood Coordinating Program Collaborative (CBCPC), the latter of which reports to the Ministries of Health through their PT representative, sought to collaborate on developing recommendations for the roles and responsibilities of PSPs. This aims to ensure harmonization of the standard of care and equity of services are provided by all blood stakeholders, regardless of where patients receive blood.

2.0 CONFIRMATION OF APPROPRIATENESS

PSPs supporting the out-of-hospital administration of blood products provided by Canadian Blood Services must confirm, before enrolment and at each treatment renewal or material change in therapy, that the patient is appropriate for participation in the PSP in accordance with the following two requirements (CSA Z902: 14.3.1, 14.3.2, 17.1.2, 17.2.1):

1. The determination of eligibility of the authorized prescriber; and,
2. The authorization of the issuing TMS and/or authorization for dispensing from the applicable PT program.



They must be applied to support equitable access to services, including for patients in rural, remote, or otherwise underserved settings.

Confirmation of eligibility and authorization by the PSP includes the following and must not be done independently without the following:

- The patient has been unequivocally identified;
- A current, documented order has been issued by an authorized prescriber, as per approved jurisdictional operational procedures (e.g. clinical information systems);
 - The prescribed product, route, dose, frequency, and administration plan are current and consistent with the authorized order.
- The authorized prescriber has determined that treatment in the proposed setting is clinically appropriate for out-of-hospital administration; and,
- The issuing TMS or dispensing program has completed any required review or approval before the product is issued/dispensed and PSP services begin.

Questions regarding eligibility, dosing, product selection, suitability for home administration, or a change in the patient's clinical status must be referred promptly to the authorized prescriber; followed by coordination and confirmation of compliance with policies/procedures of the issuing TMS or dispensing program (CSA Z902: 14.1.3, 17.1.3).

3.0 COORDINATION ROLE BETWEEN STAKEHOLDERS

In the absence of a hospital or regionally managed out-of-hospital infusion program, PSPs act as the primary coordinating mechanism between the authorized prescriber, the issuing TMS (and/or dispensing program), and the patient. Their role is to ensure therapy is delivered safely, consistently and in ensuring there is TMS and/or program authorization (alignment with defined prescribing criteria/policies of the jurisdiction). Key responsibilities include:

- Ensuring the authorized prescriber is aware of jurisdictional utilization criteria, including adjusted body weight dosing requirements for immunoglobulin, and confirming authorization of the issuing TMS and/or the applicable PT program (see section [2.0 Confirmation of Appropriateness](#));
- Communicating and collaborating with the authorized prescriber and coordinating with the issuing TMS and/or dispensing program to best maintain uninterrupted, policy-compliant therapy;
 - This includes communicating when renewals are required, where an alternative process is agreed upon by the issuing TMS and/or dispensing program is also appropriate.
 - Communication may include a shorter duration of product quantity issued prior to patient training completion, due to non-compliance, due to intolerability, or due to supply challenges.
 - This includes collaboration to determine the appropriate pickup site, delivery modality, and/or workflow/logistics to ensure safe product availability and timely access for the patient; and during unexpected events including product recalls, quarantine, shortages, and labelling changes.



- Direct communication to patients in the setting of a recall, to return affected/unsafe blood products to the issuing TMS and/or dispensing program as well as coordinating product exchange, is required unless otherwise stated by the issuing TMS and/or the dispensing program.
- After patient enrollment, reviewing infusion logs with the authorized prescriber to monitor compliance, tolerability, and any issues requiring clinical follow-up;
 - Non-compliance and intolerability should be communicated to the issuing TMS and/or dispensing program.
- For the purposes of supply planning, accurate inventory management, and documentation of disposition:
 - If adjustments to vial size and/or formulation are required, providing timely information to the authorized prescriber, issuing TMS, and/or dispensing program.
 - If the patient discontinues therapy, providing timely information to the issuing TMS and/or dispensing program.

If there are questions regarding eligibility, dosing, suitability for out-of-hospital administration, or changes in clinical status, they are to be referred back to the authorized prescriber and coordinated with the applicable TMS and/or dispensing program.

4.0 PATIENT INTERACTION

PSPs must, before signing off on completion of training, ensure:

- Authorization (see section [2.0 Confirmation of Appropriateness](#)) and informed consent for the treatment are documented as part of the patient record;
- Training and competency meet relevant requirements from accreditation standards;
- Patients acknowledge storage and handling requirements of product (CSA Z902: 17.5);
- Patients report adverse events and affirm procedures for handling potential complications (in concert with the issuing TMS and/or dispensing program requirements, see section [6.0 Adverse Event Reporting](#)); and,
- The capability to contact emergency services in the setting of an adverse event is individually established, which may include an identified capable adult.

PSPs also have the primary responsibility for provision and ensuring ancillary supplies for out-of-hospital transfusion (ensuring a minimum supply based on the blood product received by the patient).

As above, in the event of an applicable manufacturer recall for patients to return affected/unsafe blood products, PSPs must contact patients to facilitate return of product to the issuing TMS and/or dispensing program as well as coordinating product exchange.

Best practices identified are that the PSP facilitate disposal of sharps if there is no process via the issuing TMS and/or dispensing program with permission from the recipient (CSA Z902: 17.6.3); and facilitate travel letters denoting medical need for treatments when requested.



5.0 INFORMED CONSENT TO RECEIVE A BLOOD PRODUCT

The Krever Commission of Inquiry on the Blood System in Canada (1997) led to some key recommendations that resulted in generational improvements in transfusion practice, including the recommendation for specific patient informed consent prior to infusion of blood components and products. This is standard of care and reflects adherence to national and PT accreditation standards and regulations described above (see section [1.0 Introduction](#)); thus, applying to out-of-hospital transfusions.

The role of the PSP is to confirm the patient's informed consent to receive a blood product and documentation is current at each encounter, where consent and documentation is the authorized prescriber's responsibility.

- For the authorized prescriber, the purpose of informed consent for the blood product is to make the patient aware of relevant risks and benefits of therapy as well as therapeutic alternatives; reflecting changes which may occur over time depending on the patient's condition, evolving knowledge of risks, and the availability of alternatives.
- The policy of the issuing TMS and/or dispensing program should be consulted if confirmation of consent is unclear.

6.0 ADVERSE EVENT REPORTING

PSPs overseeing patient care in relation to out-of-hospital infusion of relevant blood products must have a documented policy for managing and reporting of blood product infusion-related adverse events. All such adverse events required to be reported to the manufacturer and Health Canada by regulations (in alignment with the *Protecting Canadians from Unsafe Drugs Act/Vanessa's Law*; as per Canadian Society for Transfusion Medicine 7.2.2.4), which relate to serious and/or unexpected adverse events, will be managed and maintained by the PSP. The PSP is expected to inform the ordering provider, issuing TMS, and/or the dispensing program of these events; and allow for co-management if required.

The issuing TMS and/or dispensing program is also to report all adverse events related to blood components and products into PT and/or national surveillance programs or hemovigilance schemes.

Thus, upon completion of reporting required by regulations, PSPs will report each adverse event in a timely manner and/or in a regular interval in coordination with the applicable issuing TMS and/or dispensing program. This includes:

- Patient demographics:
 - Full name;
 - Medical health number; and
 - Date of birth.
- Implicated product details:
 - Brand;
 - Lot number;
 - Infusion date & time; and,
 - Volume infused (if available).



- Adverse event reported and details of event, including date and time of occurrence, patient vitals and/or tests performed, symptoms and severity, patient outcome and any medical interventions or follow up performed.
 - Refer to [Appendix A](#) for a list of potential adverse events related to transfusion.

PSPs are required to cooperate with the issuing TMS and/or dispensing programs to complete any missing elements related to the adverse event, to enable complete reporting into PT and national systems (see section [7.0 Documentation, Information Sharing, and Product Disposition](#)). Likewise, the issuing TMS and/or dispensing program may also be able to provide additional context related to reported reactions, back to the PSP (e.g. cluster reactions to blood product lots) where applicable.

7.0 DOCUMENTATION, INFORMATION SHARING, AND PRODUCT DISPOSITION

PSPs collect, use, retain, safeguard, and disclose personal health information in accordance with applicable federal and PT privacy legislation along with their internal compliance measures. However, a PSP providing services related to a prescribed blood product is part of the patient's circle of care for purposes directly connected to treatment, continuity of care, fiduciary responsibilities, and regulatory requirements including patient safety, competency assessment, adverse-event surveillance, recalls, lookbacks and product traceability.

PSPs must therefore provide the issuing TMS and/or dispensing program, authorized prescriber, and affiliated health-care program (e.g. specialty clinic) with the information necessary for those purposes. Broad privacy restrictions unrelated to the circle of care or proprietary business practices must not impede disclosures necessary for these purposes.

This includes, as applicable:

- Evidence of PSP personnel training and competency;
- Confirmation of patient enrolment and treatment status, including coordination with authorized prescribers and other TMSs previously involved in care;
- Confirmation of the existence of a current authorized order and required informed-consent affirmation;
- Patient training and competency completion (see section [4.0 Patient Interaction](#)) including retraining if applicable;
- Infusion records and clinically relevant treatment information;
- Details of all reported adverse events, including patient identification and relevant product traceability information; and,
- Information needed to respond to a recall, lookback, traceback, treatment interruption, or other patient safety concern.

For traceability of blood, while the issuing TMS and/or dispensing program retains ultimate responsibility for traceability based on accreditation standards and regulations, the PSP often has access to information that cannot otherwise readily be obtained. This includes product use vs. non-use, patient inventory, and final disposition (administered, expired, discarded, recalled, or lost).



- PSP best practices are to collaborate with the issuing TMS and/or dispensing program to develop and maintain processes that support reconciliation of blood products supplied to the patient and communicate relevant disposition information to the issuing TMS and/or dispensing program. This is to be done when required and/or in a regular interval, in coordination with the applicable issuing TMS and/or dispensing program.
- Disposition reconciliation also includes when discontinuation of treatment occurs: the return of blood products to the issuing TMS and/or dispensing program for disposal and, if applicable, correction of transfusion records.

PSPs must maintain appropriate administrative, technical, and physical safeguards against unauthorized access, use, disclosure, loss, or alteration of personal health information. Information must not be disclosed outside the circle of care, or used for marketing, commercial, analytics, or other secondary purposes, except where permitted or required by law and, where applicable, with appropriate patient authorization.



APPENDIX A: POTENTIAL ADVERSE EVENTS IN TRANSFUSION RECIPIENTS

Known adverse events to blood include, but are not limited to:

- Acute/immediate hemolytic reactions;
- Allergic reactions (minor, severe, anaphylactic);
- Aseptic meningitis;
- Bacterial infection;
- Bacterial sepsis;
- Deaths;
- Delayed hemolysis;
- Febrile non-hemolytic reactions;
- Hypotensive reaction;
- Immunoglobulin headache;
- Other infections;
- Other serious reactions;
- Other transfusion-transmissible infections;
- Post-transfusion purpura;
- Systemic immunoglobulin reaction;
- Transfusion associated circulatory overload (TACO);
- Transfusion-associated graft versus host disease (TA-GVHD);
- Transfusion-related acute lung injury (TRALI); and,
- Viral infection.