

General Policies: Transfusion of Blood Components and/or Blood Products

Site Applicability

- VCH
- BC Cancer Vancouver Centre

Practice Level

- Registered Nurse (RN)
- Physician (MD)
- Nurse Practitioner (NP)
- Critical Care Paramedic (CCP)
- Resident MD or Perfusionist
- Anesthesia Assistants (AA)
- Licensed Practical Nurse (LPN)*

Documentation of annual review is required.

*On designated Patient Care Units approved by Professional Practice, Clinical Operations and Transfusion Medicine, an LPN trained in the process of Patient and Product Verification pre transfusion may participate as the second checker.

Policy Statement

 Vancouver Coastal Health Transfusion Medicine Service establishes, maintains and is responsible for written policies and procedures that are compliant with the CSA Z902 Standards for blood and blood components and the Canadian Society of Transfusion Medicine Standards (CSTM) for Hospital Transfusion Services.

Note: The Z902 Standards for blood and blood components (current version) establishes through scope, the minimum criteria for acceptable performance for transfusion practice including on-going training, competency assessment, documentation, policies, and procedures

2. VCH Transfusion Medicine (TM) is responsible for maintaining compliance with the Blood Regulations managed under the Health Products and Food Branch, Health Canada.

Note: The Blood Regulations introduce specific regulations for blood and its components intended for transfusion or for further manufacture into drugs for human use. This guidance document interprets the requirements of the Blood Regulations to provide necessary information for establishments that process, label, distribute, transform, or store blood for transfusion or for further manufacture, and establishments that import blood for transfusion, to comply with the requirements of the Blood Regulations.

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3. All polices, processes and procedures related to transfusion shall be approved by the VCH TM Medical Leader.

- 4. To ensure compliance with current Accreditation Standards and Blood Regulations, the procurement of equipment used for the collection, testing, processing, storage, or transfusion of blood components shall be determined in consultation with TM.
- 5. All Equipment (Rapid Infuser, Apheresis, and Dialysis) must be used according to manufacturer's recommendations, inspected and validated to avoid any risks of mechanical induced hemolysis.
- 6. Provincial blood and blood product utilization and recipient data is maintained by the BC Provincial Blood Coordinating Office (PBCO), Central Transfusion Registry (CTR) for the purpose of traceability, surveillance, and utilization management.
- 7. For traceability and surveillance, products issued for transfusion and not returned to TM are considered "presumed transfused". Allocated and issued product that is not transfused must be returned to TM for recipient data reconciliation and appropriate inventory management.
- 8. The minimal requirements for patient identification are:
 - a) First and last name and
 - b) A unique identifier number defined as the medical record number (MRN) or unique TM number.
- 9. Inventory utilization is managed by TM and may require Pathologist or Hematopathologist consult and approval prior to the release of product.
- 10. In situations of inventory shortages, TM shall implement procedures to manage inventory based on the established site, Regional, Provincial and National blood supply contingency plans.
- 11. Consultation with a Pathologist is available at all VCH sites and 24/7 on-call.

Need to Know

- 1. Safe transfusion is the goal of the multidisciplinary team members involved in transfusion medicine. The skills and expertise of the health care team members are key in providing the patient with an uneventful therapeutic intervention such as transfusion.
- There are policies and procedures related to each of the essential steps associated with transfusion administration. VCH TM requires all clinicians who administer blood components or products to complete an annual review of the VCH Safe Transfusion Module located on the <u>Learning Hub</u>. To assist clinicians to identify learning needs related to transfusion, refer to the <u>Nursing Transfusion Competency</u> Tool.

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- 3. Compliance with regional policies and clinical procedures* ensures the safety, quality and efficacy of both product inventory and the transfusion management of the recipient.
- 4. The use of a blood warmer or rapid infusion device requires an authorized prescriber's order except in clinical areas where there is an established hospital policy and procedure. Refer to 6.11
- 5. Emergency Supply: The Emergency Supply is defined as Group O Red Cells. Group O Rh Negative or Group O Rh Positive product may be tagged by TM and identified as the Emergency Supply.
- 6. Group O RBC's are tagged and available 24/7 from TM and should be considered for all urgent transfusions in the absence of Group and Screen (G&S) test results. To conserve Group O Negative inventory, patient age and gender is required.
- 7. In an Emergency Hemorrhage Event
 - Neonates and Females 45 years or less with child-bearing potential should receive Group O Negative
 - (1) Males and (2) Females without childbearing potential can receive O Rh-positive RBC's. Consultation with the Attending MD is required.

8. **Definitions:**

Blood components	Red Blood Cells, Platelets, Plasma and Cryoprecipitate	
Blood products	Products manufactured from fractionated plasma e.g., Albumin, IVIG, PCC, Fibrinogen	
Recombinant products	Products that are manufactured from non-human components using genetic engineering. These are alternatives to some fractionated plasma products (e.g., factor concentrates)	
Phlebotomist	Any health care provider (HCP) trained in obtaining blood samples for diagnostic testing.	
Transfusionist	A care provider who, within scope of practice is trained and competent in the administration policies and procedures required to administer a blood component or blood product.	

^{*}Refer to appropriate DST for all procedures.

Policies related to the Essential Steps of Transfusion:

1. Informed Consent

1.1 Informed Consent for the Administration of Blood Products (VCH Form M-1C or accepted equivalent from another Health Authority) is required for the elective administration of any blood component or blood product.

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1.2 For urgent or emergency transfusion, refer to <u>VCH Consent to Health Care Policy</u>.

N.B. Recombinant (genetically engineered) products do not require Informed Consent for Blood.

- 1.3 <u>Form M-161</u>: Refusal to Accept Administration of Certain Blood Components, Products or Alternatives is to be completed when some or all blood products are refused.
- 1.4 Consent is valid unless the risks, benefits or alternatives have changed or hospital admission for which the consent was intended has occurred. (Excluding chronic transfusion support).
- 1.5 For patients requiring chronic transfusion support, consent must be updated at minimum yearly, where patient status changes may require updates more frequently.

2. Prescriber's Order

- 2.1 A VCH TM Pre-printed Transfusion Order (PPO or electronic order entry) must be completed and retained on the patient health record.
- 2.2 A prescriber's order is required to transfuse and must include:
 - Patient's first and last name and unique identifier number (MRN)
 - Amount and type of blood, blood components and other related products to be transfused
 - Date, time, and duration of the transfusion. (considered as *rate of infusion*)
 - Sequence in which multiple components are to be transfused
 - Use of a blood warmer or rapid infusion device if necessary, except in critical care or specialty areas where there is an established hospital policy and procedure
 - Special transfusion requirements e.g., irradiated
 - Any pre- or post-transfusion medication orders related to the transfusion.
 - The clinical indication for transfusion.
- 2.3 A Registered Nurse (RN) can initiate a verbal order for blood or blood products as per hospital policy. All verbal orders must be documented (e.g., electronic or completed TM PPO).
- 2.4 **Transfusion after Laboratory Hours -** BC Cancer Vancouver, BCGH, PRGH, PHCC, RWL, SGH, SH and WHCC:

In the absence of 24/7 laboratory support, transfusion administration after laboratory hours should be limited to "urgent or STAT" events. It requires *consultation with the ordering prescriber and documentation of the order status as urgent or STAT*.

3. Sample Collection and Identification

3.1 To ensure patient safety, compliance with the established laboratory procedures related to *unequivocal patient identification* is mandatory.

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3.2 Patient or Sample ID verification includes confirmation of unique patient identifiers on the patient ID band, requisition, and sample label. Inaccuracies or discrepancies in patient identifiers must be resolved prior to collecting blood samples

- 3.3 Any alternative or deviation from the established VCH Lab Patient Identification Processes must be approved by the Transfusion Medicine Director.
- 3.4 Patient Identification must occur *in the presence of the patient at the time of draw.* Refer to procedure for Phlebotomy and Specimen Labeling.
- 3.5 In the case of an "Unknown" patient or computer downtime follow established site-specific policies and procedures.
- 3.6 **BCGH and RWL:** Refer to site-specific laboratory policies for Patient ID requirements using a unique TM identiband with pre-set numbers.
- 3.7 TM shall not *process* an inappropriately labeled sample or sample accompanied by an incomplete requisition.
- 3.8 A Group and Screen (G&S) is required to determine a patient ABO Rh blood group and detect if any unexpected red cell antibodies are present. G&S testing is considered in-date if drawn within 4 days e.g., 2359 hours 4th day, Day 1 is considered the day of collection. Retesting is required to detect if any newly formed red cell antibodies are present
- 3.9 A <u>current admission</u> G&S is required to confirm the patient ABO blood group prior to a plasma or platelet transfusion.

3.10 VGH / RH and LGH Pre-Surgical Patients ONLY:

- **Samples for G&S testing** can be held up to 35 days prior to scheduled surgery if the patient has not been transfused or pregnant within 90 days prior to the sample collection.
- A process must be in place to reconfirm the patient has not be transfused or pregnant prior to the surgical procedure; Refer to Pre op Checklist
- In the absence of the patient ID band used for sample ID at the time of *pre surgical testing*, refer to Appendix A for the approved alternate process for unequivocal Patient ID in the perioperative setting.

4. Transport / Storage

4.1 The Transportation and Storage of Blood Components is Regulated under the Health Products and Food Branch, Health Canada

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- 4.2 Persons who have received training in the related policies and procedures can transport blood components or products.
- 4.3 Blood storage access is restricted to designated personnel ONLY: All satellite blood fridges must be locked or located in a secured area with no public access. To comply with Standards related to traceability, all blood components and blood products not required must be returned to TM for electronic product or patient reconciliation and appropriate discard.
- 4.4 To avoid wastage, return blood components or products no longer required within 60 minutes of removal from the monitored temperature environment. (refer to time stamp on the tag)
 Note: Components returned to TM after 60 minutes cannot be re-entered to inventory and must be discarded.
- 4.5 Blood components or products *can be initiated any time* after issue from TM, however the transfusion must be **completed within 4 hours of removal from the controlled storage environment**.
- 4.6 Reconstituted pooled products must be administered based on the expiry date or time on the container or syringe label.

4.7 Transport of Blood Products:

4.7.1 Within the Facility:

- Blood components or products should be obtained immediately prior to initiation of transfusion Refer to site-specific procedures for obtaining products from the lab.
- Platelet concentrates should be:
 - transfused immediately or
 - returned to TM for inventory management or
 - stored in/on a platelet shaker in a monitored temperature environment
- VGH ONLY: For product delivery via a large bore Pneumatic Tube System: Refer to DST D-00-12-30103

4.7.2 Outside of the Facility with a Patient:

- Product required for transfusion during inter-facility patient transfer must be appropriately labeled and packaged in a validated shipping container and accompanied with appropriate documentation
- TM will package product upon request when there is a clinical indication for a transfusion of RBC's AND the patient is accompanied by a transfusionist
- Destination of the patient must be provided to TM at the time of request

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4.8 **PHCC Only:** RNs who have completed the Learning Hub module and annual review of procedures can package Emergency Red Cells for transport. Refer to appropriate DST <u>D-00-12-30092</u> for all related procedures.

4.9 Transfusion during Patient Transport - Within Facility

 A patient requiring transfer during transfusion shall be accompanied by a trained and competent transfusionist who shall monitor, evaluate, and manage the signs and symptoms of a transfusion reaction

4.10 Transfusion during Patient Transport – Outside Facility

- <u>Refer to D-00-12-30084</u>- A recipient requiring transfusion shall be accompanied during transfer by a trained and competent transfusionist
- The tamper proof seal on any transport container system shall only be removed
 when the requirement for transfusion is confirmed. Note: In the event the tamperproof seal has been broken on a transport container, all remaining product will be
 discarded
- The transfusionist is responsible for completing the Interhospital Exchange Form IM007F- Blood Product Transport with a Patient

4.11 Receipt of Blood Products with an inter-facility patient transfer:

Do Not Open or Transfuse product associated with a patient transfer.

- Ensure the transport box, any remaining product, and the completed Interhospital Exchange Form, is sent to the TM immediately upon arrival for visual inspection
- If transfusion is clinically urgent, request Emergency Group O Supply from the TMS

Transport Cooler: PHCC and WHCC ONLY

 Return the Credo® Series 4-248EMT Transport Bag and Shipping Container and any remaining product to the issuing site lab (PHCC or WHCC). Place the cooler in the lab, Do Not Place Product in the blood fridge. If Weekend or Holiday, notify the WHCC lab or on-call Technologist

5. Unequivocal Patient / Product Identification Verification

5.1 Patient/Product Identification Verification

- **BCGH, RWL Sites:** the use of a unique TM identiband (Ident A[™] Blood System Card) is required for all patient, sample, or product identification steps
- Alternative patient identification processes are approved in designated patient care units.
 See Appendix A

5.2 Product Identification or Verification – Transfusion Administration

• In the absence of an appropriate ID Band (or approved alternate process), a new Group and Screen (G&S) shall be initiated STAT

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- The initial and final Patient/Product 2-person verification checks are completed by the same two trained staff members, one of whom is the transfusionist
- Whenever possible, the patient shall be asked the patient to spell their name and state their date of birth during the 2-person Patient/Product verification check.
- 5.3 Refer to DST D-00-12-30223 for related procedures.
- 5.4 **Do not apply labels or ink markings** to any blood component or product container. Adhesives and ink used for this purpose must meet all applicable standards.

6. **Initiating and Terminating Transfusion**

- 6.1 Refer to DST D-00-12-30223 for specific administration procedures.
- 6.2 The recommended practice for all acute VCH sites is to transfuse blood components and blood products using an Alaris infusion pump. Infusion via gravity is also an acceptable option if the infusion pump is not available. Do not delay transfusion.
- 6.3 To facilitate a controlled infusion rate over a desired period, the use of an infusion device should always be used for:
 - Neonatal or pediatric transfusion
 - CMV IG infusions
 - Plasma Protein Products where maximum infusion rates are identified as per manufacturer recommendations
- 6.4 When transfusing components to gravity, if required, the use of an external pressure device (cuff) is acceptable to increase the rate of infusion of a component. The pressure cuff must have a sphygmomanometer and must maintain an infusion pressure of **equal to or less than 300 mm Hg** (or risk compromising the integrity of the component unit).
- 6.5 All new blood administration sets can accommodate infusions by both Alaris infusion pump and gravity.
- 6.6 As per the Standards, **all BLOOD COMPONENTS** shall be filtered at the bedside through a blood administration set with an in-line filter **with-in the range** of 170 to 260 microns.
- 6.7 BLOOD PRODUCTS: Different types of IV tubing or administration techniques are needed for administration depending on the blood product requirement (see below). For product specific information, refer to Blood Product Fact Sheets.
 - Administer via a vented regular straight set (e.g., albumin, IVIG) OR

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- Filter at the bedside through a blood administration set with an in-line filter (15 micron) (e.g., CMV IG) **OR**
- Pre-filtered by TM, during the pooling preparation prior to issue and administer via an IV infusion set (e.g., Fibrinogen, Hepatitis B Immunoglobulin IV) OR
- IV direct (e.g., Factor Concentrates)

For further information: Refer to Blood Product Fact Sheets

- 6.8 All transfusion administration sets (including IV sets) should be primed and flushed with 50 mL Normal Saline upon completion and discarded. Priming with a blood component is acceptable however, precautions must be taken to avoid contamination or wastage.
- 6.9 Blood Administration sets, and IV sets used for blood product transfusion must be changed:
 - after 4 units RBC's, or 4 hours, whichever comes first AND
 - between different blood components AND
 - upon completion of the transfusion
- 6.10 Medications shall not be co-infused, introduced into a blood component or product container or administered through an administration set used to transfuse infuse a blood component or product. Do not access any port before, during or after transfusion of a blood component or product.
- 6.11 The use of a blood warmer or rapid infusion device requires a physician order except in critical care or specialty areas where there is an established hospital policy and procedure.
 - Equipment must be used according to manufacturer's recommendations and inspected and validated to avoid any mechanically induced hemolysis
 - Blood warmers must have a temperature alarm
 - In the event of a transfusion reaction, the equipment type, serial number and temperature reading shall be documented in the patient record for quality review purposes
 - Note: Not all blood warming devices can be used in conjunction with an Alaris infusion pump. Blood warming devices require a designated flow to achieve the target temperature. Increased flow can decrease output temperatures; decreased flow can compromise the component. Confirm the manufacturer's recommendations; if in doubt, follow Physician's order to transfuse via a blood warmer and transfuse to gravity. For additional information refer to: <u>Equipment and Supplies - Professional Practice</u>
 - 6.12 **IO Device:** Volume resuscitation with IO crystalloid is preferable with rapid RBC transfusion after IV access is achieved. If IO RBC infusion is attempted a pressure infuser is generally required as there is considerable variation in the rate of infusion. There is no supporting evidence that there is damage to red blood cells (RBC's) transfused. If essential to the resuscitative effort and no

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- other option is available, the IO route of RBC administration may be attempted. Caution is especially necessary when using IO devices to transfuse RBC's outside of the pediatric population.
- 6.13 The product allocation tag associated with the product shall remain attached to the component, product or product container until the transfusion is complete.
- 6.14 Autologous blood collected perioperatively via cell saver shall be appropriately labeled with (a TM approved label) that includes the Patient's first and last name and MRN and expiry time. Product must be initiated prior to patient transfer out of the OR and completed within 8 hours of collection.

7. Monitoring, Identifying and Managing a Transfusion Reaction

- 7.1 Patients must be monitored by a trained and competent transfusionist during transfusion.
- 7.2 Transfusion Reaction: Identification and Management: Refer to DST <u>D-00-12-30224</u>
- 7.3 All suspected Transfusion Reactions must be managed immediately as per protocol. A completed Transfusion Reaction Report Form M-292 and specimens (if applicable) must be sent to the TMS for follow up investigation.
- 7.4 All Cerner sites: Complete the M-292 and retain a copy for scanning purposes.
- 7.5 All Outpatients should be provided with the "After your Transfusion of Blood and/or Blood product Discharge Information" prior to discharge. Refer to Patient Health Education Materials for appropriate site specific version.
- 7.6 All incidents or events related to product quality, patient and /or staff safety associated with any step of the transfusion process shall be documented in the Safety Learning System and reported immediately to TM.

Related Documents

All related VCH TMS Lab Procedures.

References

- CSA Z902-20 Standards for blood and blood components, March 2020
- CSTM Standards for Hospital Transfusion Services, Version 4: April 2017.
- BC Provincial Blood Coordinating Office Clinical Transfusion Resource Manual, March 2019

Appendices

Appendix A: Alternate process for Patient Identification

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Appendix A: Alternate process for Patient Identification

(Approved by VCH Transfusion Medicine)

For Pre-Admission Patients Admitted To A Surgical Day Care				
If the Facility Is	In the absence of the patient ID Band utilized at the time of G&SG&S sample collection			
LGH, RH, VGH and UBCH –	Upon admission to the Surgical Day Care: Locate the Patient ID Band (provided by the patient or Admitting DeparTMent).			
Perioperative Care Centre / Surgical Day Care ONLY	Confirm the information on the ID Band with the Patient; verify the patient's full name and date of birth.			
	3. Verify the information on the patient ID band (full name, MRN and date of birth) is consistent with the health record and specifically the TM results review report (if G&S or blood product was requested).			
	4. Confirm the following questions:			
	a. Has the patient been transfused with Red Cells or platelets with the last 90 days?			
	b. Was there a potential for pregnancy within the last 90 days?			
	5. If there is a discrepancy in patient ID <i>OR</i> "yes" to Question (a) or (b), contact the site TMS immediately and <i>initiate a new G&S sample</i> .			
For all other VCH sites and BC Cancer-VC	A new ID band must be provided, <i>and</i> a new G&S sample collected for testing.			

VA BMT Daycare

Limited to BMT Daycare ONLY

- 1. BMT /Leukemia Outpatient Clinic will provide the patient with an approved ID card with their addressograph label on the back.
- 2. The patient is required to sign the card indicating the information is correct.
- 3. The patient ID card is used to confirm ID at the time of blood sample collection and blood product administration. There is NO electronic substitution.
- 4. In the event transfusion may occur outside of the BMT Daycare unit, a Patient ID band is required.
- 5. In the absence of approved ID, a new sample for crossmatch testing must be collected.

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Approved By:	VCH		
	 Transfusion Clinician - VCH Transfusion Medicine Medical Director, Regional Medical Leader, VCH Transfusion Medicine Regional Technical Practice Lead, VCH Transfusion Medicine DST Developer Lead: RN, Regional VCH Transfusion Medicine 		
Owners:	VCH		
	 Transfusion Clinician – VCH Transfusion Medicine Medical Director, Regional Medical Leader, VCH Transfusion Medicine Regional Technical Practice Lead, VCH Transfusion Medicine DST Developer Lead: RN, Regional VCH Transfusion Medicine 		

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REVISION LOG: This form **must** be the last page of each standard operating procedure and **must** be carried forward to any subsequent revisions. Briefly summarize any revisions and indicate the date of implementation. All copies must include this document. A copy must be kept in the Master Standard Operating Procedure File.

DO NOT DISCARD

Version Number	Description of Change	Date of Revision	Reviewed By
0.0		Jan 29, 2008	Regional Medical Lead, Transfusion Medicine Services
1.0	All general policies reviewed and grouped according to the essential step involved. BCCA-VC added, wording to policy statements revised, formatting changes.	Nov 2016	Regional Medical Lead, Transfusion Medicine Services
2.0	Remove 'CMV negative components (if known)' from Policy 2.2	Nov 7, 2016	Regional Medical Lead, Transfusion Medicine Services
3.0	Add Anesthesia Assistants	June 8, 2018	Regional Blood Transfusion Clinician, Transfusion Medicine Services
4.0	Reviewed and minor format and clarification edits (CPD-DST) completed; added link to Nursing Competency Tool; Revised references to blood regulations from the Food and Drug Act to Health Products and Food Branch, Health Canada; updated references; Appendix B deleted (merged with Appendix A)	Feb 13, 2019	Regional Blood Transfusion Clinician, Transfusion Medicine Services
5.0	Minor Content change	Feb 26, 2020	Regional Medical Lead, Transfusion Medicine Services
6.0	Implementation of Infusion devices added; format flow and language revised; reference to LPN participating as the 2nd checker with training in designated TM approved settings	December 10, 2020	TM Clinician or Special Projects, VCH Transfusion Medicine
7.0	Updated informed consent form to include accepted consent form from a different Health Authority; updated tubing section for Blood Products to reflect revised language in DST D-00-12-30223	November 25, 2021	VCH Regional Clinician, Transfusion Medicine
8.0	Updated section on consent to include guidance on frequency of renewal for patients requiring chronic transfusion support	January 23, 2022	VCH Regional Clinician, Transfusion Medicine

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