NON-HOSPITAL MEDICAL AND SURGICAL FACILITIES ACCREDITATION PROGRAM

Accreditation Standards

Blood Products and Blood Components

January 6, 2022

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INTRODUCTION

Non-hospital facilities do not perform procedures where the need for blood replacement might reasonably be anticipated and therefore shall not maintain a supply of cross-matched blood or other blood products or blood components with the exception of Rh Immune Globulin (blood product), Humate-P® (blood product) or Fibrin sealant (blood component), as appropriate.

BLD1.0 BLOOD PRODUCTS AND BLOOD COMPONENTS

BLD1.1	**Blood products and blood components are appropriately stored and managed.**	
BLD1.1.1	**M**	Blood products and blood components are procured through an appropriate supplier. *Guidance: Appropriate suppliers may include Canadian Blood Services, a local source (e.g. hospital re-distribution program), a licensed manufacturer, or a pharmacy.*
BLD1.1.2	**M**	Blood products and blood components are stored in an area not accessible to patients and non-authorized personnel.
BLD1.1.3	**M**	Blood products and blood components are stored as recommended by the supplier's or manufacturer's instructions for use.
BLD1.1.4	**M**	The temperature of refrigerators and freezers used for blood product and blood component storage is checked and recorded daily. *Guidance: Logs of the temperature of the refrigerators and freezers used for blood product storage are maintained for, at minimum, 5 years.*
BLD1.1.5	**M**	Blood product and blood component records are maintained. *Guidance: The facility must be able to trace blood products (e.g. Rh Immune Globulin, Humate-P®) and blood components (e.g. fibrin sealants) from their supplier (e.g. Canadian Blood Services) to their final disposition (i.e. administered to a patient, returned to supplier, destroyed/disposed). Records include the receipt voucher or the copy of the purchase order provided by the supplier that should detail the blood product/component name, quantity and lot numbers, the supplier name, and the date received. These records are filed sequentially and can be easily retrieved. These records are to be maintained for, at minimum, 50 years.*

BLD1.1.6	**M**	Blood product and blood component final disposition is documented. *Guidance: A log is kept to track all blood products and blood components from time of receipt from the supplier (e.g. Canadian Blood Services) to their final disposition (i.e. administered to a patient, returned to supplier, destroyed/disposed). Each blood product and blood component received into inventory at the facility is documented in a log. The log includes the name of the blood product/component, the supplier name, lot number, the date received, and, when appropriate, details of its final disposition including patient name, unique identifier, and date administered (or date of return/destruction as appropriate). These logs are to be maintained for, at minimum, 50 years.*
BLD1.2	**Rh Immune Globulin (RhIG) is safely administered.**	
BLD1.2.1	**M**	Facilities with RhIG inventory and/or performing Rh type and antibody screening hold current accreditation with the Diagnostic Accreditation Program (DAP). *Guidance: Clinical indications for administration of RhIG include Rh(D) negative pregnant women following spontaneous or therapeutic abortion, threatened abortion and ectopic pregnancy. All women undergoing abortion or invasive obstetric procedures have their Rh group determined.*
BLD1.2.2	**M**	RhIG is administered to Rh negative women not known to be immunized to the D antigen following a procedure or event known to be associated with increased risk of Rh immunization due to fetomaternal hemorrahage.
BLD1.2.3	**M**	Consent is obtained from the patient prior to the administration of any blood products. *Guidance: Consent is obtained before health-care treatment is provided. At minimum, the consent process includes a discussion with the patient about the administration or potential administration of any blood products (e.g. RhIG) and documentation of the consent discussion in the patient's medical record. Because these products are made from human plasma, they may carry a risk of transmitting infectious agents.*
BLD1.2.4	**M**	There is a written order for any RhIG administered. *Guidance: Nurses may act upon pre-printed orders when the authorized health professional has made those orders patient-specific by reviewing them, adding the client's name, customizing them, and signing and dating them. The RhIG order specifies the patient's first and last name, a unique patient identification number, and the amount/dose.*
BLD1.2.5	**M**	RhIG is prepared in accordance with the manufacturer's instructions for use.
BLD1.2.6	**M**	At least two unique patient identifiers are used when verifying patient identification. *Guidance: Immediately before administration in the presence of the patient, the health-care professional confirms and documents that all identifying information linking the patient and the blood product matches. Unique patient identifiers include name, date of birth, and Personal Health Number.*
BLD1.2.7	**M**	Patient identity discrepancies are resolved before the administration of any blood product. *Guidance: If any discrepancy is found in the identification information, blood products are not administered until the discrepancy is resolved.*

BLD1.2.8	**M**	Only regulated health professionals obtain and administer RhIG. *Guidance: Regulated health professionals (e.g. nurses, physicians) preparing and administering RhIG do so in accordance with their regulated scope of practice.*
BLD1.2.9	**M**	RhIG administration practices include the "seven rights" to reduce administration errors. *Guidance: The BC College of Nurses and Midwives requires all nurses to adhere to the "seven rights" of medication administration: the right medication, right patient, right dose, right time, right route, right reason, and right documentation.*
BLD1.2.10	**M**	RhIG administration documentation includes the lot number of the product. *Guidance: Documentation of RhIG administration also includes the name of the product, date and time, dose, route, site (if appropriate), and signature and title of the persons administering.*
BLD1.2.11	**M**	Patients are monitored for an appropriate time after Rh administration. *Guidance: Patients who receive RhIG are monitored by a regulated health professional whose scope of practice includes the administration of blood products. In addition, patients are informed about possible adverse reactions and what to do if they suspect they are having a reaction. Any adverse reactions are investigated and documented in the patient's health record. Any serious adverse reaction to RhIG is immediately reported to the Canadian Blood Services or an appropriate local source (e.g. hospital re-distribution program). Serious adverse reactions also require reporting to the College.*
BLD1.3	Humate-P® is safely administered.	
BLD1.3.1	**M**	Consent is obtained from the patient prior to the administration of any blood products. *Guidance: Consent is obtained before health-care treatment is provided. At minimum, the consent process includes a discussion with the patient about the administration or potential administration of any blood products (e.g. Humate-P®) and documentation of the consent discussion in the patient's medical record. Because these products are made from human plasma, they may carry a risk of transmitting infectious agents.*
BLD1.3.2	**M**	There is a written order for any Humate-P® administered. *Guidance: The Humate-P® order specifies the patient's first and last name, a unique patient identification number, the dose, frequency if repeated doses are indicated and the name and signature of the authorized prescriber (e.g. physician).*
BLD1.3.3	**M**	Humate-P® is prepared in accordance with the manufacturer's instructions for use.
BLD1.3.4	**M**	At least two unique patient identifiers are used when verifying patient identification. *Guidance: Immediately before administration in the presence of the patient, the health-care professional confirms and documents that all identifying information linking the patient and the blood product matches. Unique patient identifiers include name, date of birth, and personal health number.*
BLD1.3.5	**M**	Patient identity discrepancies are resolved before the administration of any blood product. *Guidance: If any discrepancy is found in the identification information, blood products are not administered until the discrepancy is resolved.*

BLD1.3.6	**M**	Only regulated health professionals obtain and administer Humate-P®. *Guidance: Regulated health professionals (e.g. nurses, physicians) preparing and administering Humate-P® do so in accordance with their regulated scope of practice.*
BLD1.3.7	**M**	Humate-P® administration practices include the "seven rights" to reduce administration errors. *Guidance: The BC College of Nurses and Midwives requires all nurses to adhere to the "seven rights" of medication administration: the right medication, right patient, right dose, right time, right route, right reason, and right documentation.*
BLD1.3.8	**M**	Humate-P® administration documentation includes the lot number of the product. *Guidance: Documentation of Humate P® administration also includes the name of the product, date and time, dose, route, site (if appropriate), and signature and title of the persons administering.*
BLD1.3.9	**M**	Patients are monitored for an appropriate time after Humate-P® administration. *Guidance: Patients who receive Humate-P® are monitored by a regulated health professional whose scope of practice includes the administration of blood products. In addition, patients are informed about possible adverse reactions and what to do if they suspect they are having a reaction. Any adverse reactions are investigated and documented in the patient's health record. Any serious adverse reaction to Humate-P® is immediately reported to the Canadian Blood Services or an appropriate local source (e.g. hospital redistribution program). Serious adverse reactions also require reporting to the College.*
BLD1.4	**Fibrin sealants are safely administered.**	
BLD1.4.1	**M**	Consent is obtained from the patient prior to the administration of any blood components, as appropriate. *Guidance: Consent is obtained before health-care treatment is provided. If the patient has any religious considerations, (e.g. Jehovah's Witness) or any other reasons for refusing blood products or blood components, a written consent form must be completed prior to the administration of any blood components. For all other patients, facility policy and procedures for consent for blood products and/or blood components are followed and are determined based upon the facility's own risk assessment. Consent requirements may include: not necessary to inform patients, patients informed through consent discussion alone, patients informed through consent discussion and written consent form completed. Because these products are made from human plasma, they may carry a risk of transmitting infectious agents.*
BLD1.4.2	**M**	Fibrin sealants are single-use only. *Guidance: Fibrin sealants (e.g. TISSEEL), also called fibrin glue, are available in different preparations such as freeze-dried kits and pre-filled syringes (frozen). Vials and pre-filled syringes are for single-use only. Any unused product shall be discarded.*
BLD1.4.3	**M**	Fibrin sealants are prepared in accordance with the manufacturer's instructions for use.
BLD1.4.4	**M**	Fibrin sealant administration documentation includes the lot number. *Guidance: The use of fibrin sealant is documented on the intraoperative records and includes the name of the product, lot number and volume/dose.*
BLD1.5	**Policies and procedures contain all the information necessary for the safety of patients, staff and visitors.** *Intent: Policies and procedures ensure that activities/procedures are performed consistently and accurately by all personnel within the non-hospital facility.*	

BLD1.5.1	**M**	There is policy and procedures for blood products and/or blood components. *Guidance: The policy and procedures outline the receipt, handling, storage, consent, preparation for administration (if applicable), administration and documentation for blood products and/or blood components, and guidelines for the recognition and management of all suspected blood product/component reactions.*
BLD1.5.2	**M**	There is policy and procedures for lookback notifications and recall of blood products and/or blood components. *Guidance: The policy and procedures outline the regulated health professional(s) responsible for lookback and recall activities, acknowledgement of lookback or recall notification, notification of the physician of the patient or the patient directly if required, and quarantining of blood products until final disposition is determined. A lookback is the tracing and testing of blood product/component recipients in cases where the blood product/component is determined to be potentially contaminated with a blood-borne infection. A recall is a notification by the supplier regarding blood products/components when a quality problem requiring action has been identified.*
BLD1.5.3	**M**	There is policy and procedures for consent for blood products and/or blood components *Guidance: The policy and procedures outline the type of consent required for blood products and/or blood components. administration of any blood components. If the patient has any religious considerations, (e.g. Jehovah's Witness) or any other reasons for refusing blood products or blood components, a written consent form must be completed prior to the administration of any blood components. For all other patients, facility policy and procedures for consent for blood products and/or blood components are determined based upon the facility's own risk assessment. Consent requirements may include: not necessary to inform patients, patients informed through consent discussion alone, patients informed through consent discussion and written consent form completed.*

Summary of changes	
2021-12-16	The following changes were made: • Addition of Humate-P® as an authorized blood product • Administrative changes to renumber the blood component section from 1.3 to 1.4 and the policies and procedures section from 1.4 to 1.5, reflect nursing regulatory body name change and update the reference list

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