##### Dispensary and Administration Facilities:

##### Purpose of the Toolkit & Checklist for Transfusion Policies and Procedures

**Purpose**

# Facilities having no licensed laboratory transfusion service are sometimes required to store and/or administer blood products or components. The purpose of the resources contained within the Dispensary and Administration Toolkit are to ensure that all patients in Ontario receive the safest care possible with regard to transfusion and administration of blood components and products.

# Introduction

# What is the difference between a hospital transfusion service provider, a dispensary facility and an administration facility?

**Hospital transfusion service provider:** a licensed laboratory transfusion service that is providing blood components or products that are received from Canadian Blood Services to another facility for either storage or administration.

**Dispensary facility:** a facility that receives, stores, issues and administers blood components or products from a hospital transfusion service provider.

**Administration facility:** a facility that receives and administers (without storage) blood components or products from a hospital transfusion service provider for a specific patient.

# Why should dispensary and administration facilities concern themselves with transfusion policies and procedures? Many of the transfusion standards currently in place in Canada[[1]](#footnote-1),[[2]](#footnote-2),[[3]](#footnote-3),[[4]](#footnote-4) and Ontario[[5]](#footnote-5) do pertain to facilities performing limited transfusions. The intent of these standards and the corresponding policies and procedures surrounding transfusion processes is to provide patients with the safest transfusion possible.

# For example, if a facility periodically transfuses red blood cells (RBCs) to patients, the following processes may need to be addressed by policies and procedures:

* Receipt, storage and transportation of blood and blood components/products including items such as: visual inspection, controlled storage, back-up power and monitoring/maintenance programs for any blood storage units, alarms for storage units, review of temperature charts, records, expiry times/limits, validated shipping processes including appropriate labelling of shipping containers
* Patient requests: patient identification, specimen collection and labelling, tests, blood components/products requests (appropriate product at the appropriate time, volume/ doses, rate, special requirements, patient history), informed consent
* Inspection and acceptance/rejection criteria for blood and blood components/products including their return
* Blood component/product administration: pretransfusion medications, patient identification, special patient needs, blood product storage requirements, blood administrations sets and compatible solutions, administration equipment such as rapid infusers and blood warmers, administration instructions/monographs, emergency issuing of components, blood product expiry dates and times, compatibility, spiking the unit, patient monitoring, transfusion time limitations, documentation, patient notification
* Adverse events/reactions: recognition, treatment and management, investigation, reporting and follow up
* Retrievals, post-donation information, withdrawals/recalls, lookback/traceback and quarantine
* Identification, calibration/validation, maintenance and power supply of equipment
* Emergency disaster plans and contingency planning
* Training, competency assessment and records of employee signatures, identifications and initials
* Laboratory service agreements
* Specimen requirements
* Document and records management
* Continuous Quality Improvement: Nonconformance management (errors, accidents and incidents in any transfusion aspect), complaints, quality indicators, transfusion committee and audits

The following checklists are a starting point for you to assess the policies and procedures that are necessary for your organization. Under each section heading, ascertain if your facility performs any of the itemized processes. If it does, you will require a formalized policy or procedure and a documented process to train the staff required to have this knowledge or skill. There are suggestions for policies/procedures under each section.

The term blood components/products refers both to blood components (RBCs, platelets, plasma, cryoprecipitate) and plasma protein products (PPPs) like Rh immune globulin (RhIG), intravenous immune globulin (IVIG), albumin, and recombinant factor VIII.

# Transporting, Receiving and Storing Blood – Does your Facility:

* Receive blood and/or blood components/products
* Store blood and blood components/products in a refrigerator, freezer, platelet incubator or at room temperature
* Ship blood and blood components/products

Policies and procedures to consider-

1. Inventory management, ordering and reporting of blood components/products
2. Receiving blood and blood components/products
3. Visual inspection (see section C) of shipping containers and each individual blood component or product
4. Blood storage equipment: set up, temperature mapping, validation, temperature monitoring and review, alarms, back-up power supply, maintenance schedules and records, malfunction procedures
5. Storage of blood components/products separately from reagents and specimens
6. Blood components/products expiry
7. Shipping: validation of shipping containers, labelling, notification to the receiving facility, documentation of blood components/products disposition responsibility

# Patient Requests – Does your Facility have Transfusion Needs?

* Are blood components/products transfused or administered at your facility?
* Who provides informed consent and where is it documented?
* What are your transfusion specimen collection requirements?
* Does this facility transfuse blood components/products in urgent care situations (e.g. uncrossmatched RBCs)?

Policies and procedures to consider-

1. Requests for blood components/products: authorized health care provider, type of product, volume/dose, rate, method of administration, special requirements, provision of patient history to the transfusion laboratory
2. Emergency requests and release of blood components/products
3. Instructions for drawing transfusion specimens including the required patient identification process and the phlebotomist’s identification
4. Informed consent policy and documentation. Is there a patient information pamphlet or education package? Who is authorized to perform the informed consent process? Where will it be documented? How is the patient advised of the risks and benefits of the proposed transfusion?
5. Administration guidelines: when are blood components/products appropriate or inappropriate? What are the indications? What testing should be performed before, during and after a transfusion? What is the recommended dose/volume and rate of infusion? What are the alternatives to blood components/products?

# Inspection, Acceptance/Rejection Criteria for Blood Products

* Are blood components/products received from other facilities?
* Do the clinical areas return blood components/products to the laboratory, pharmacy or other areas?
* Does the dispensary or administration site return unused units or products to the hospital transfusion service provider?

Policies and procedures to consider-

1. Visual inspection. What are the instructions for the visual inspection of blood components/products? How do staff members know when to accept or reject a blood component or product? Are the visual inspection points defined? How are the results of the inspection documented?
2. Returned blood components/products. If blood component or product is returned from the clinical areas for any reason, what are your product assessment criteria? How should the products be handled? What is the documentation required?
3. How are blood components or products packaged and shipped?

# Blood Administration

* Do staff members have instructions or monographs on how to administer blood components/products?
* Is the process for recipient identification defined?
* How is product suitability assessed?
* How is the patient notified of the transfusion?

Policies and procedures to consider-

1. Identification and verification. Is the there a process defined that verifies the identification to match the “order to the patient and to the blood component or product? Is the patient involved where possible in the identification process?
2. Administration instructions. Is there a procedure that explains the rate of infusion, mode of infusion, maximum infusion time, how to administer the product, determining product compatibility and expiry, how to monitor the patient (e.g. taking vital signs at prescribed intervals) and where it is documented? Where is premedication information or other special instructions found?
3. Administration equipment, supplies and compatible solutions. Do staff members have instructions for the appropriate product administration sets and compatible solutions? Are there instructions for ancillary equipment like rapid infusers and blood warmers? Are they validated and calibrated and is their use documented along with any quality control checks prior to use?
4. A policy to notify inpatients of transfusions

# Adverse Events/Reactions

* Clinical area: are there instructions for the identification, treatment and management of adverse transfusion events?
* What is the investigation process?
* Are required people/organizations informed?
* How are these events reported and analyzed?

Policies and procedures to consider-

1. Recognize, treat and manage adverse events
2. Investigation of adverse events
3. Define the reporting process, both internally and externally
4. Follow-up and preventative measures, if applicable

# Retrievals/Post-Donation Information, Withdrawals/Recalls, Lookback/Traceback and Quarantine

* How are compromised blood components/products managed (lookback)?
* Is there an audit trail?
* Is the storage of non-transfusable blood components/products secure and clearly separate from transfusable product storage?
* Is the blood product supplier notified when a *Post Transfusion Notification* is received?
* How is the supplier notified in a traceback situation (post transfusion infection in a recipient)?

# Policies and procedures to consider-

How are the processes initiated? Who is responsible? Where is the investigation documented? Who is notified? Is the supplier officially notified as soon as possible when a product communiqué is received?

1. Lookback/Traceback
2. Withdrawals/Recalls
3. Post-Donation Information/Retrievals
4. Quarantined blood products

# Calibration, Validation and Maintenance

* Is equipment used in the transfusion process?
* Is it validated and calibrated?
* Does it have an assigned unique number?
* Is there a maintenance and repair record?

Policies and procedures to consider-

1. Validation
2. Calibration
3. Maintenance and Repair

# Emergency/Contingency Planning

* Would this facility be affected by an emergency/disaster situation that could compromise access to blood components/products?
* Is this facility affiliated with a regional emergency/contingency plan forblood components/products?
* Is this facility an alternate storage location for blood components/products?
* Is there a contingency plan in place to manage blood shortages?

Policies and procedures to consider-

1. Emergency/contingency policy/plan for blood and blood components/products
2. Work instructions to report inventory to blood supplier or to affiliated site and possibly return units or products to the affiliated site

# Training, Competency and Qualifications

* Is there a formal training program for those involved in transfusion activities and processes?
* Is competency assessed in regular intervals and this assessment documented?
* How are staff members trained and assessed on changes? How is training documented?
* Are qualifications reviewed and maintained?
* Are past and current records of staff members’ signatures, initials and identification codes maintained?

Policies and procedures to consider-

1. Staff training policy: orientation, qualification review and maintenance, training, initial and on-going competency assessment, training documentation. Provisions should be made for retraining, remedial training and training for changes.
2. Policy for records of staff signatures, initials and identification codes

# Document and Records Management

* Is there a document control process in place to ensure only the current versions of documents, forms, procedures, requests and labels are used?
* Have all policies and procedures been authorized?
* Are document retention standards being met?

Policies and procedures to consider-

1. Document control policy, including regular review and authorization
2. Record retention

# Continuous Quality Improvement

* Is there an error/accident/incident (nonconformance) reporting mechanism in place? Have staff members been trained?
* Do you implement corrective actions and preventative measures and measure them for effectiveness?
* Does your organization have a transfusion committee, or is it involved in a regional committee?
* Do you monitor transfusion quality indicators?
* Do you formally audit your transfusion processes?

Policies and procedures to consider-

1. Nonconformance management policy, procedure and training
2. Policy to have a facility representative on a transfusion committee
3. Policy to monitor quality indicators and audit transfusion processes

# Others

Policies and procedures will have to be in place for items such as:

1. Contract and contract review. Does your facility receive product from another site? This agreement must be formalized with defined expectations and services provided. The contract should be reviewed regularly, but especially before renewal. The provision of service should have a regular review as well for effectiveness, efficiency, accuracy and patient safety.
2. RhIG: There are quite a few requirements for RhIG (see IQMHVI.1 TM060, CSTM 5.4.4.5, CSA 11.9), especially regarding pregnancy. If the facility uses this blood product, a policy should be implemented

**A Final Word**

It has been said that the safest transfusion is the one that never occurs. However, for those in need of blood products, it is incumbent upon the health care professionals involved in all aspects of the transfusion process to ensure that our patients have trust in the blood supply and transfusion process. Our patients expect to receive a safe, reliable product supplied and administered by competent staff. As Justice Krever stated in his report on November 26, 1997, in Canada, the “safety of the blood supply system is paramount”.

1. Accreditation Canada, *Standards Transfusion Services*, Version 12, Ottawa ON, January 2018. [↑](#footnote-ref-1)
2. Canadian Society for Transfusion Medicine, *Standards for Hospital Transfusion Services*, Version 4, Ottawa ON, April 2017. [↑](#footnote-ref-2)
3. Canadian Standards Association, *CAN/CSA-Z902-15 Blood and Blood Components*, Ottawa ON, December 2015. [↑](#footnote-ref-3)
4. Health Canada Guidance Document: Blood Regulations, Ottawa ON, March 2016. [↑](#footnote-ref-4)
5. Institute for Quality Management in Healthcare (IQMH) Laboratory Accreditation Requirements, Version 7.1, Toronto ON, April 2017. [↑](#footnote-ref-5)