Government of Newfoundland and Labrador

Department of Health and Community Services
Provincial Blood Coordinating Program

RECORDS RETENTION FOR TRANSFUSION MEDICINE DOCUMENTS	NLBCP-060

Office of Administrative Responsibility	Issuing Authority
Medical Advisor to the Provincial Blood Coordinating Program	Dr. Lucinda Whitman
Manager, Provincial Blood Coordinating Program	Daphne Osborne
Author	Melissa Leonard
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Overview

Records and documents are required to be available upon request, easily located and retained for a specified amount of time. The amount of time retained is dependent on the type of information contained in the documentation.

Policy

1. Transfusion Medicine Laboratories (TMLs) shall retain documents and records according to Canadian Standards association's standards on blood and blood components.
2. The following documents shall be retained for one year:
   2.1. The date, time and the phlebotomist's identification when a recipient blood sample was drawn; and,
   2.2. Packing/shipping documentation, related to the transport, when shipping blood components or blood products from Canadian Blood Services (CBS) to a facility and from a facility to a facility.
3. The following documentation shall be retained for three years:
   3.1. Validation of computer systems, including:
      3.1.1. Description of computer system;
      3.1.2. Any changes made to the system as a result of validation;
      3.1.3. Training records of computer system manager and users; and
      3.1.4. The validation plan and all results for the computer system's elements, including:
         - Application programs;
         - Technical environment;
         - Data conversion;
         - System parameters when configured for use;
         - Operating procedures for the computer system;
         - Operating procedures in the event of system failure;
         - Personnel training material;
         - System recovery; and
         - Complete production system.
   3.2. Calibration and performance verification of critical equipment.

Note: If equipment manufacturer's instructions suggest a longer retention period than three years, retain records in accordance with manufacturer's instructions.

4. The following records shall be retained for five years:
   - 4.1. Adverse events of recipients;
   - 4.2. Storage temperatures of blood components and blood products;
   - 4.3. Complaints about products;
   - 4.4. Quality assurance reports and internal audit records; and
   - 4.5. Quality control testing of blood components, reagents, equipment and proficiency testing surveys, including:
     - 4.5.1. Dates;
     - 4.5.2. Testing performed;
     - 4.5.3. Results observed;
     - 4.5.4. Interpretations;
     - 4.5.5. Individuals performing the tests; and,
     - 4.5.6. Any appropriate corrective action).
5. Documentation shall be retained for ten years regarding:
   - 5.1. Investigations and reports related to the safety of a blood component or blood product in the following recipient events:
     - 5.1.1. Errors and accidents that could lead to serious adverse reactions; and
     - 5.1.2. Unexpected or serious adverse events;
   - 5.2. A lookback or traceback process;
   - 5.3. Final disposition for autologous blood components, including recipient identification;
   - 5.4. Qualifications, training, and the competency of each individual who performs any of the following activities:
     - 5.4.1. Preparation of blood components;
     - 5.4.2. Testing and labelling of blood components;
     - 5.4.3. Storage, packing, and transportation;
     - 5.4.4. Requests, pre-transfusion testing, selection of components, and criteria for acceptance;
     - 5.4.5. Transfusion;
     - 5.4.6. TML responsibilities regarding blood products used in the facility;

     Note: This Item refers only to blood products located in the TML.

5.4.7. Home transfusion;

5.4.8. Adverse event monitoring and corrective action; and,

5.4.9. Removal of unsafe blood components and blood products from inventory.

6. The following must be retained for 50 years:

6.1. Donation codes;

6.2. The record of issue of blood components and blood products for transfusion;

6.3. The record of transfusion of blood components and blood products;

6.4. Final disposition for transfused blood components and blood products, including recipient identification; and,

6.5. Records relating to the distribution from CBS to TML, and transfer between TMLs, including exceptional distribution and any recalls.

Key Words

Records, retention, documents

References

Canadian Standards Association. (2020). *Blood and blood components, Z902-20.* Mississauga, ON: Author.