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. Christopher Sharpe
Provincial Blood Coordinating Program	Daphne Osborne
Author(s)	Denise Callahan Ryan
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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. Records must be accurate, complete, legible, indelible, and readily retrievable. 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 and Health Canada Blood Regulations.
2. All records shall identify the person who conducted the activities and the dates of the various entries.
3. Any handwritten entry of information shall be made using indelible ink. Any correction, entry of information, or notation made after the original date shall be clearly crossed out, initialled, or signed and dated to indicate a change has been made.
4. The donation code shall be a part of all records related to the distribution, transformation, and transfusion of blood.
5. A facility shall store records in a location that has appropriate environmental conditions and that is secure against the entry of unauthorized persons.
6. The following documents shall be retained for one year:
    6.1. The date, time, and the phlebotomist's identification when a recipient blood sample was drawn; and,
    6.2. Packing/shipping documentation, related to the transport (e.g., courier/taxi slips, waybills), when shipping blood components or plasma protein and related products (PPRP) from Canadian Blood Services (CBS) to a facility and from a facility to a facility.
    6.3. Lot number of critical supplies for each process (transformation activity) and the name of the manufacturer.
7. The following documentation shall be retained for three years:
    7.1. Validation of computer systems, including:
        7.1.1. Description of computer system;
        7.1.2. Any changes made to the system as a result of validation;
        7.1.3. Training records of computer system manager and users; and
        7.1.4. 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.

7.2. 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.

8. The following records shall be retained for five years:

8.1. Adverse events of recipients.

8.2. Storage temperatures of blood components and PPRP;

8.3. Complaints related to components and PPRP and their investigation.

8.4. Quality assurance reports and internal audit records; and

8.5. Quality control testing of blood components, reagents, equipment and proficiency testing surveys, including:

8.5.1. Dates;

8.5.2. Testing performed;

8.5.3. Results observed and interpretations.

8.5.4. Individuals performing the tests; and,

8.5.5. Any appropriate corrective action.

9. Documentation shall be retained for ten years regarding:

9.1. Investigations and reports related to the safety of a blood component or PPRP in the following recipient events:

9.1.1. Errors and accidents that could lead to serious adverse reactions; and

9.1.2. Unexpected or serious adverse events;

9.2. A lookback or traceback process;

9.3. Final disposition for autologous blood components, including recipient identification;

9.4. Every version of the operating procedures that were implemented for the transfusion service.

9.5. Qualifications, training, and the competency of personnel who perform any of the following activities (kept for ten years after end of employment):

9.5.1. Preparation of blood components;

9.5.2. Testing and labelling of blood components;

9.5.3. Storage, packing, and transportation;

9.5.4. Requests, pre-transfusion testing, selection of components, and criteria for acceptance;

9.5.5. Transfusion;

9.5.6. TML responsibilities regarding PPRP used in the facility;

Note: This Item refers only to PPRP managed by the TML.

9.5.7. Home transfusion;

9.5.8. Adverse event monitoring and corrective action; and,

9.5.9. Removal of unsafe blood components and PPRP from inventory.

10. The following shall be retained for 50 years:

10.1. Donation codes;

10.2. The record of issue of blood components and PPRP for transfusion and the record of the transfusion.

10.3 Final disposition for transfused blood components and PPRP, including recipient identification; and,

10.4. 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.

Health Canada. (2023). *Guidance document: Blood regulations*. Ottawa, ON: Author.