Competency Portfolio for the Diploma in Transfusion Medicine

Guide for AFC Committee, Educators, and Candidates

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DEFINITION

Transfusion Medicine is that domain of laboratory and clinical medicine concerned with all aspects of the collection, testing, preparation, storage, transportation, pre-transfusion testing, post-transfusion follow up, indications for, infusion, and safety of human blood components and products, nonhuman alternatives, and alternative products manufactured by recombinant DNA technology. These activities are undertaken in such a way that the rights of blood donors, patients, and families are respected, and scarce resources are appropriately allocated.

GOALS

Upon completion of training, a diplomate is expected to function as a competent specialist in Transfusion Medicine, capable of an enhanced practice in this area of focused competence (AFC), within the scope of Internal Medicine, Hematology, Pediatrics, Hematological Pathology, Anesthesiology, or General Pathology. The AFC trainee must acquire a working knowledge of the theoretical basis of the discipline, including its foundations in science and research, as it applies to medical practice.

The discipline of Transfusion Medicine includes responsibility for

- the diagnostic and therapeutic aspects of immunohematology, apheresis, histocompatibility, and related molecular biology and biotechnology;
- management of the medical laboratory and blood centre, including quality, safety, and regulatory aspects;
- ensuring the appropriate use of blood;
- ensuring the adequacy of blood for the blood system;
- supervising the provision of a safe and effective blood supply;
- supervising the banking and provision of cell therapy products and human tissues for transplantation purposes;
- engaging policy-makers, other physicians, and other health professionals in transfusion medicine; and
- the advancement of the discipline through basic scientific and clinically applied research.

Note: In this document, "blood" refers to blood, blood components, and blood products.

Note: All markers must be signed off by supervisor prior to adding to portfolio.

Note: All submitted cases or clinical material must be de-identified to preserve patient privacy. This requires the removal of key identifiers, including but not limited to name, birth date, date of consultation, and location (e.g., hospital/clinic, city). In some cases, even without these identifiers, a patient could be identified by other information included in the case or clinical material (e.g., if the patient has a very rare condition, or lives in a remote area with a limited population size). In these instances de-identification may not be sufficient to ensure patient privacy. In such exceptional cases it would be advisable to obtain patient consent for the submission.

The Transfusion Medicine diplomate will respect the rights of the individual and family and must demonstrate the requisite knowledge, skills, and behaviours for effective patient-centred care and service to a diverse population. In all aspects of specialist practice, the diplomate must be able to address ethical issues and issues of gender, sexual orientation, age, culture, beliefs, and ethnicity in a professional manner.

At the completion of training, the AFC trainee must demonstrate evidence of acquisition of the competencies listed on the following pages.

	YES	**NO**
In the view of the AFC Program Committee, this candidate has acquired the competencies of the diploma program as prescribed in the *Competency Portfolio* and is competent to practice as a diplomate.	☐	☐

COMMENTS

1. The diagnostic and therapeutic aspects of immunohematology, apheresis, histocompatibility, and related molecular biology and biotechnology

Milestones	Standards of Assessment	Documents to be Submitted
1.1 Manage the transfusion needs of a complex patient	The documents must include the patient's history and clinical scenario, an interpretation of basic lab and diagnostic data, and a description of the trainee's role in the case (e.g., as a transfusion medicine front-line consultant, as a clinician transfusing the patient, or in the lab doing the complex workup). The submissions must demonstrate appropriate knowledge of risk and prognosis based on available data. The submissions must clearly identify the most clinically important transfusion issues in each case, to whom they need to be communicated, and with what level of urgency. The case mix must include at least one (1) from each of the following: • complex red cell antibodies • autoimmune hemolytic anemia • obstetrical complications • platelet refractoriness • red cell genotyping • transfusion support in hematopoietic stem cell transplant • pediatric transfusion issues	Seven (7) de-identified clinical case summaries

1.2 Supervise and interpret immunohematology testing	(a) The documents must include a brief case summary providing basic clinical information. The submissions must demonstrate an appropriate diagnostic approach, an understanding of the laboratory findings and features of each antibody scenario, and utilization of appropriate additional diagnostic tools as needed. The case mix must include • five (5) red blood cell (RBC) Ab, including one (1) Rare and one (1) hemolytic disease of the fetus and newborn (HDFN) • one (1) human leukocyte antigen (HLA) Ab • one (1) platelet-antibodies (e.g., neonatal alloimmune thrombocytopenia) • three (3) ABO discrepancy • three (3) Rh discrepancy	(i) Thirteen (13) de-identified lab reports (or a mock-up of a report); a standard template for lab reports is acceptable, but not required
	(b) Successful completion of an in-training evaluation report (ITER) documenting achievement of competence in the <u>medical direction</u> of the transfusion service; (must document both adult and pediatric exposure, either as one (1) or two (2) separate ITERs).	(ii) One (1) ITER for the transfusion service; if pediatric and adult experiences are separate, two (2) ITERs are required

1.3 Prescribe and supervise apheresis appropriately	The documents must include a synthesis of each case, including the patient's/donor's clinical status, any supporting investigations, the clinical impression, the apheresis orders, and a summary of the procedure and outcomes. The submission must demonstrate appropriate prescription of apheresis, monitoring for complications and, as appropriate, management of complications. The case mix must include at least two (2) different indications for apheresis, at least one (1) for donor, and one (1) for therapeutic apheresis.	(i) Two (2) therapeutic apheresis cases **AND** **EITHER** (ii) One (1) donor apheresis case **OR** (iii) Completed donor apheresis section of the blood supplier structured examination, with sign-off by appropriate faculty indicating successful completion

2. Management of the medical laboratory and blood centre, including quality, safety, and regulatory aspects

Milestones	Standards of Assessment	Documents to be Submitted
2.1 Develop a transfusion-related standard operating procedure (SOP)	The submission must include a transfusion-related standard operating, technical, or nursing procedure developed or updated by the candidate. The submission must demonstrate understanding of the technical aspects of SOP documents, including the structure, content, and format.	One (1) standard operating procedure (developed or updated), with reflective critique

<table>
<tr><td rowspan="2">2.2 Evaluate a laboratory's compliance with accreditation standards and develop a strategy to ensure a laboratory is compliant with accreditation standards and regulations</td><td rowspan="2">The documents must include a description of an external accreditation standard, the laboratory activities covered by the standard, the level of compliance of the laboratory with the standards, and a reflection regarding likely causes and potential strategies to ensure compliance.

The submission must demonstrate the ability to perform an internal laboratory audit, conduct a gap analysis, and develop a strategy to ensure compliance.

The submission should use a template (as applicable to the jurisdiction doing the accreditation) or checklist, and only one (1) section of a lab is required.

Note: These activities can be completed at the hospital or blood centre.</td><td>(i) One (1) gap analysis, with strategy to ensure compliance

AND</td></tr>
<tr><td>EITHER
(ii) One (1) lab audit report or checklist

OR
(iii) One (1) corrective action response to an accrediting body regarding an area found to be in non-compliance (real or mock)</td></tr>
<tr><td>2.3 Manage the administrative and technical aspects of effective laboratory function</td><td>The report must describe an administrative process to manage a technical issue in the lab.

The submission must demonstrate an understanding of the laboratory activity, roles and responsibilities of laboratory health care professionals, and application of change management and/or principles of negotiation and conflict resolution, as appropriate.</td><td>One (1) report of a procedure or instrument validation, with level of candidate's participation.</td></tr>
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	The collated results must include contributions from at least four (4) respondents. Respondents may include other physicians, laboratory technicians, residents, students, and other health professionals. The collated feedback must demonstrate the applicant's satisfactory ability to communicate, collaborate, and interact professionally with other team members, serving in the role of the manager for day-to-day activities of the transfusion medicine laboratory.	Collated results of multisource feedback
2.4 Evaluate a laboratory's quality management system	The documents must include • a brief overview of the quality management system as it relates to a specific transfusion medicine activity • an in-depth description of the quality issue • strategies used to address the issue The submissions must demonstrate knowledge of the different aspects of a quality management system, appropriate tools to evaluate quality issues, and principles of quality improvement. The cases must include • one (1) case report related to a quality issue (any of the following quality system elements: documents and records; organization; personnel; equipment; purchasing and inventory; process	Three (3) reports (maximum two (2) pages)

	control; information management; occurrence management; assessment (internal and external); process improvement; customer satisfaction; and facilities and safety) • one (1) report related to external proficiency testing • one (1) root cause analysis and corrective action/preventive action (CAPA) document	

3. Ensuring the appropriate use of blood

Milestones	Standards of Assessment	Documents to be Submitted
3.1 Serve as an effective consultant for clinical services requiring blood management for individual patients	The submission must include a description of the clinical scenario, laboratory results, relevant co-morbidities, specific reason for consultation, further investigations, conclusions and recommendations, with rationale, details of the blood used, and clinical outcomes. The submission must demonstrate knowledge of the pathophysiology of complex clinical conditions commonly requiring transfusion medicine consultation. The submission must clearly identify the most clinically important transfusion issues in each case, including goals of care and level of urgency.	Seven (7) case summaries or consults

Milestones	Standards of Assessment	Documents to be Submitted
	The case mix must include at least one (1) of each of the following: • massive transfusion • sickle cell transfusion management • inherited bleeding disorders • transfusion support of hematopoietic stem cell or solid organ transplant • reversal of anticoagulant • urgent consultation relating to bleeding • inappropriate blood order	
3.2 Serve as an effective consultant on behalf of the blood supplier for hospital clinical services	The case summary must be related to a complex consultation to a blood supplier, including details of any blood used, relevant investigations, conclusions, recommendations, and reflection on the case. Examples of complex cases include: rare RBC request; unexpected antibody in transfusion recipient; special access request; products applicable for prevention of graft-versus-host disease; or post-transfusion purpura. The submission must demonstrate knowledge of complex or uncommon transfusion-related issues, and knowledge of Canadian policies and processes for blood suppliers.	One (1) case summary, with reflective critique

Milestones	Standards of Assessment	Documents to be Submitted
3.3 Supervise the process of obtaining informed consent for the provision of blood products for patients	The submission must be for the consent process in a patient reluctant to receive blood products. The submission must clearly describe the clinical scenario, the indication for blood transfusion, an analysis of clinical risks and benefits, and the patient's concerns about receiving blood products. The submission must demonstrate an understanding of the importance to respect patient autonomy while advocating for evidence-based clinical interventions to decrease patient risks.	(i) A summary of the consent process **OR** (ii) A list of questions asked in a structured examination, related to clinical risks, benefits, and concerns relevant to the consent for provision of blood products; with supervisor sign-off that the candidate passed
3.4 Manage the appropriate utilization of blood products	The submission must include a description of a specific blood utilization issue and its current clinical practice guideline for a hospital or a certain patient group, an analysis of the actual blood utilization, and its compliance with the guidelines. The submission must demonstrate understanding of the importance of adequate utilization of blood supplies, attention to safety and quality issues, and adaptation of practice to different clinical contexts in order to meet specific patient needs. The submission must be one (1) of the following: • an audit of blood utilization in a given context, including an analysis of any variance with current clinical practice guidelines • an updated clinical practice	One (1) audit, clinical practice guideline, or report, with reflective critique

Milestones	Standards of Assessment	Documents to be Submitted
	guideline related to utilization of blood to address the findings of an audit • a report for a transfusion committee related to an issue of appropriate utilization of blood in a hospital, indicating when it was presented to the committee	
3.5 Develop and implement blood conservation strategies	The submission must include a description of the clinical scenario, surgical procedure, blood conservation techniques chosen (with rationale), details of the blood used, and clinical outcomes. The submission must demonstrate knowledge about blood conservation techniques and adaptation to the clinical context. The submission must include one (1) of the following: • pre-operative consultation • simulated case	One (1) pre-operative consultation or simulated case report involving blood conservation techniques

4. Ensuring the adequacy of blood for the blood system

Milestones	Standards of Assessment	Documents to be Submitted
4.1 Manage the supply of blood	The submission must demonstrate knowledge of blood inventory management, including storage limits and appropriate inventory requirements for at least one (1) blood component/blood group. This should include an assessment of current inventory and ongoing needs, as well as consideration of the blood distribution system. Examples of concepts that may be included in the submissions are: assessment of outdates, wastage, possibility for redistribution, minimum/maximum levels and inventory indices.	Any one (1) of the following: (i) One (1) audit related to inventory outdating and wastage, with recommendations for change (if appropriate) (ii) One (1) facility (blood centre, stock holding unit, hospital) assessment of minimum/ maximum levels, with calculation of inventory index for at least one blood component/blood group (iii) One (1) copy of a redistribution proposal for blood components that involves at least one (1) blood centre/stock holding unit and two (2) hospital facilities

4.2 Apply an understanding of the national blood contingency plan to develop a strategy to implement blood shortage management protocols	The submission must include the blood component/blood group, the severity of the shortage, the process followed to allocate the resources, and a reflection on the alignment with the national blood contingency plan. The submission must demonstrate an understanding of the ethical principles of allocation of a finite resource, the role of emergency blood management committees, and the phases of inventory proposed in the national blood contingency plan. The blood shortage event may be real or simulated.	One (1) written reflection (or case report and written reflection) of a blood shortage event (maximum two (2) pages)
4.3 Advise on donor recruitment strategies	The document must include a description and analysis of current donor recruitment, with a discussion of the adequacy and safety of the blood supply, and possible strategies for improvement. The submission must demonstrate an understanding of the various stakeholders in the blood system, an appreciation of the balance of the need for donors with the safety of the blood supply as well as the need to ensure safety for blood donors, and the role of the transfusion medicine physician in the donor recruitment process.	One (1) written reflection of donor recruitment (maximum two (2) pages)

5. Supervising the provision of a safe and effective blood supply

Milestones	Standards of Assessment	Documents to be Submitted
5.1 Manage the appropriate selection and testing of blood donors	The document must include a description of the selection and/or testing strategy, and its efficacy, risks, and the health economic impact. The submission must demonstrate an understanding of the risk of transmissible disease, the details of testing sensitivity/specificity, and the range of alternative options.	A critical analysis of policies or procedures (maximum two (2) pages)
5.2 Advise on the quality of manufactured blood products and components	(a) The submission must demonstrate successful completion of Good Manufacturing Practice (GMP) training within the previous two (2) years.	Evidence of completion of GMP training
	(b) The document must include a description of the issue leading to consideration of deviation from standard operating practices, reference to the usual standards, and the decision regarding the use of the product and rationale. The submission must demonstrate knowledge of the processes of blood product manufacture and appropriate rationale for the decision. Examples include an assessment of the use of a recalled product or the use of a product that experienced non-standard storage.	One (1) summary of a request for deviation from standard blood product use practices

Milestones	Standards of Assessment	Documents to be Submitted
5.3 Manage the safety and surveillance systems for a given blood system	The documents must include details of the blood used, relevant investigations, and the conclusions and recommendations. The submissions must demonstrate an appropriate differential diagnosis, and the data provided must support the probable cause, conclusions, and recommendations. The case mix must include one (1) of each of the following: • transfusion-related acute lung injury (TRALI) • severe allergic transfusion reaction • bacterial contamination • acute intravascular hemolysis • acute severe hypotension • delayed hemolysis • lookback/traceback or recall/ withdrawal The cases may be real or simulated. At least one (1) of the cases must have required reporting through the relevant hemovigilance system.	Seven (7) case summaries

6. Supervising the banking and provision of cell therapy products and human tissues for transplantation purposes

Milestones	Standards of Assessment	Documents to be Submitted
6.1 Advise on the recruitment, assessment, maintenance, and selection of appropriate stem cell donors	(a) The documents must include a summary of the pertinent recipient and donor factors, all relevant investigations, and the rationale for the decision regarding suitability and selection of stem cell donor. The submissions must demonstrate knowledge of eligibility and suitability criteria, and appropriate selection of donors for a given recipient. The case mix must include one (1) related and one (1) unrelated donor search and selection.	Two (2) summaries of searches for stem cell donors
	(b) The document must include a summary of the self-administered health questionnaire and the standard medical interview and physical examination, and documentation of informed consent for stem cell mobilization and collection. The submissions must demonstrate thorough assessment of donor health and suitability for donation, with appropriate and relevant documentation of informed consent.	One (1) consultation related to stem cell donor assessment

6.2 Supervise the collection, processing, and storage of stem cells	The documents must include a summary of the stem cell collection procedure, any donor adverse events, and a description of the transportation, manipulation, storage, and infusion of stem cells. The submissions must demonstrate thorough knowledge of the process for collection and storage of stem cells as well as risk mitigation strategies for adverse events. Examples include cryopreservation and thawing of stem cell products, and hemolytic risk mitigation strategies for minor and major ABO incompatible stem cell products. The cases may be real or simulated.	Two (2) case summaries

7. Engaging policy-makers, other physicians, and other health professionals in transfusion medicine

Milestones	Standards of Assessment	Documents to be Submitted
7.1 Contribute to the effective functioning of an interprofessional committee related to transfusion medicine (i.e., advising or participating)	The submission must briefly state the purpose and overall membership of, and the candidate's role in, the committee. The committee must include at least two (2) of the following groups: medical laboratory technicians, nurses, physicians, and policy-makers (e.g., government, regulatory, hospital administration). The submission must demonstrate knowledge of the topic; ability to interact collaboratively and professionally with other team members while advocating for transfusion medicine needs of the facility, general population, or individual patient; stakeholder consultation; and evidence of an implementation plan.	One (1) of the following: (i) One (1) written reflective report (maximum two (2) pages) (ii) One (1) briefing note/ business case proposal submitted to a committee that creates hospital, provincial, or national policies/ standards related to transfusion medicine (iii) The collated results of multisource feedback from committee members
7.2 Educate other physicians, other health professionals, members of the public, and policy-makers about aspects of transfusion medicine	(a) The presentations must demonstrate clarity, accuracy, and appropriate depth of information for the audience. There must be at least two (2) different topics. The target audiences must include at least two (2) of the following groups: physicians, other health care professionals, members of the public, policy-makers.	Slides from two (2) presentations

Milestones	Standards of Assessment	Documents to be Submitted
	(b) The list must document the teaching activity, date, topic, and audience. The list must demonstrate a range of topics and sustained engagement in teaching during the period of training.	A list of teaching activities
	(c) The collated teaching evaluations must demonstrate audience satisfaction with the activity.	Collated evaluations of two (2) teaching activities

8. The advancement of the discipline through basic scientific and clinically applied research

Milestones	Standards of Assessment	Documents to be Submitted
8.1 Conduct or contribute to scholarly activity related to transfusion medicine	The submission must demonstrate all aspects of performing scholarly work: identification of a question for investigation, literature review, data gathering, data analysis, reflective critique, and dissemination. This may include scholarly research, quality assurance, or educational projects. The submission may be (but is not limited to): • a completed manuscript suitable for submission to a peer-reviewed journal • a published abstract • a research proposal (including submission of ethics approval)	One (1) completed scholarly project

Milestones	Standards of Assessment	Documents to be Submitted
	• a learning module or curriculum, or other educational innovation • a summary of the literature on a topic suitable for publication or as background to a policy document, business case proposal, or research proposal	

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