

APPLICATION FOR RECOGNITION

Area of Focused Competence/Diploma

HEMATOPOIETIC STEM CELL TRANSPLANTATION

Adult and Pediatric

GREFFE DE CELLULES SOUCHES HÉMATOPOÏÉTIQUES

Adulte et pédiatrique

Submitted to the

ROYAL COLLEGE OF PHYSICIANS AND SURGEONS OF CANADA

**IDENTIFICATION OF APPLICANT BODY
AND/OR SPONSORING ORGANIZATION**

Name of the proposed diploma discipline (in both official languages):

**Hematopoietic Stem Cell Transplantation
Adult and Pediatric
Greffe de Cellules Souches Hématopoïétiques
Adulte et pédiatrique**

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Application supported by:

*Canadian Blood and Marrow Transplant Group and affiliated centres
Université de Montréal*

GENERAL INFORMATION

1. What is the name of the proposed diploma discipline (in both official languages)?

Hematopoietic Stem Cell Transplantation - Adult and Pediatric / Greffe de cellules souches - Adulte et pédiatrique

2. What are the entry criteria for this discipline?

Type A: Royal College specialty (*please specify*):

**Type B: Royal College subspecialty (Area of Focused Competence):
Pediatric or adult hematology program**

Type C: Any MD

Type D: Conjoint program with the CFPC (*still under development*)

3. For Type A and Type B above, describe the relationship of this proposed diploma discipline to the parent specialty(ies) or subspecialty(ies).

The research work that made it possible to identify and characterize hematopoietic stem cells of bone marrow origin led to the development of processes permitting the collection, processing and cryopreservation of stem cells and the development of hematopoietic stem cell transplantation as a therapeutic modality with curative intent for patients with malignant (leukemia, myelodysplasia, myeloproliferative neoplasm, lymphoproliferative syndromes and plasma cell dyscrasia) and benign (bone marrow aplasia, hemoglobinopathies, congenital and acquired bone marrow failure, etc.) hemopathies, immune deficiency syndromes and certain autoimmune pathologies. Hematopoietic stem cell transplantation is therefore a therapeutic approach intended to treat benign and neoplastic pathologies usually managed by adult and pediatric hematologists. The discipline is part of the therapeutic axis for the treatment of hemopathies and hematological cancers and constitutes a subspecialization of the field of hematology-oncology which combines basic, immunohematological, clinical and laboratory competencies. In addition, to obtain certification, all residents completing their specialty training in hematology must do a rotation of a minimum of four weeks in hematopoietic stem cell transplantation in order to acquire knowledge in autologous and allogeneic transplantation and be familiar with the indications and main complications.

4. Is there a National Specialty Society for the parent specialty(ies) or subspecialty(ies)?

Yes

Canadian Hematology Association

Association des Hématologues et Oncologues du Québec/Quebec Hematologist and Oncologist Association

American Society of Hematology (ASH)

European Hematology Association (EHA)

5. Is there a National Specialty Society for the proposed diploma discipline?

Yes

Canadian Blood and Marrow Transplant Group (CBMTG)
Canadian National Transplant Research Program (CNTRP)
American Society for Blood and Marrow Transplantation (ASBMT)
European Group for Blood and Marrow Transplantation (EBMT)

6. Describe the relationship between these societies (if applicable).

These various associations already collaborate in organizing conferences and developing research projects. The CBMTG and the affiliated transplantation programs as well as the Canadian Hematology Association support the process for obtaining recognition of certification in hematopoietic stem cell transplantation.

SPECIFIC INFORMATION

1. Please describe the unique nature of the proposed diploma discipline.

(What supplemental competencies or highly specific scope of practice is included that requires distinct recognition? What is the defined and recognized societal health need not currently being satisfied by any other recognized discipline? What positive contribution towards improving medical care and health outcomes does this discipline make?)

Area of focused competence in hematopoietic stem cell transplantation

A) Description of the program

Specific scope of practice of the discipline:

Hematopoietic stem cell transplantation (bone marrow transplantation and/or peripheral stem cell transplantation) is the specialty responsible for managing the use of cellular products in the treatment of immune and degenerative diseases, cancers and hematological diseases. This ultraspecialized training combines the clinical and laboratory sciences and encompasses the entire transplantation process, i.e. determination of eligibility of the pathology and of the candidate (recipient) for transplantation, selection of the donor and confirmation of donor eligibility, selection of the graft, selection of the transplant conditioning regimen, determination of the immunosuppressive regimen to minimize the risks of rejection and graft-versus-host disease, the transplantation procedure itself, and the immediate and long-term post-transplantation follow-up in order to prevent, diagnose and treat the infectious, organic and immune complications that may arise following transplantation.

This training requires acquiring knowledge of and competencies in the immunological principles in transplantation, an understanding of the stem cell and its microenvironment, and of the blood and histocompatibility system, and entails acquiring the competencies necessary for evaluation of the cellular quality of the graft, and for graft selection, collection, processing, cryopreservation and infusion. It also entails the development of competencies for obtaining the consent of donors and recipients, the acquisition of knowledge about the standards of practice in transplantation and medical quality control/assurance, both in the laboratory and in the clinical setting, and compliance with the standards established by the regulatory authorities: Health Canada, Foundation for Accreditation in Cellular Therapy (FACT), etc.

During the training program, fellows must acquire a body of knowledge specific to transplantation, as well as knowledge in the sciences related to this practice, i.e. in immunohematology, pharmacology and pharmacokinetics, medical and molecular biology and cytogenetics. The training also requires an understanding of the histocompatibility system and training in the cellular therapy laboratory for the selection, processing, cryopreservation and management of cell grafts. Fellows must also develop their CanMEDS competencies in order to act as transplantation consultants and participate in or develop a clinical research project applied to transplantation.

Health care needs of Canadian society:

It is estimated that nearly 1,500 hematopoietic stem cell transplants are performed in Canada annually. This figure is continually increasing (10-15% annually) since the advances in research and the use of grafts from alternative donors (unrelated donors, haploidentical donors and stem cells from umbilical cords) have increased significantly during the last decade.

In addition, the improvement of support measures and the development of reduced-intensity transplantation have contributed to a significant increase in the median age of recipients (HMR and CIBMTR graph). This is a rapidly expanding field of expertise since the development of cellular therapy applied to regenerative medicine is anticipated. Nearly 90% of autologous transplant recipients and more than 70% of allogeneic transplant recipients will still be alive a year after receiving their transplant (see CIBMTR and HMR graph). This cohort of patients therefore requires long-term follow-up.

The vast majority of the transplant hematologists active in university transplantation programs in Canada have already completed training in transplantation, in most cases abroad (United States or Europe), after obtaining their degree in hematology. This subspecialized fellowship training, of a minimum duration of one year, is required in order to obtain accreditation of transplantation programs in Canada. Hematopoietic stem cell transplantation is therefore a discipline requiring the acquisition of knowledge and competencies specific to the field of cellular therapy. There is also an international shortage of transplanters (see references 5, 8, 14 and 15) and the problems of access to transplantation programs and units have made headlines both in Canada and abroad.

Positive contribution to the improvement of care:

The recognition of this area of focused competence will make it possible to offer a training program in Canada focused on the acquisition of knowledge and competencies unique to this field of expertise and focused on Canadian values in terms of health and health care, will improve medical quality assurance, standardize practice, improve access to care and promote the recruitment and retention of transplanters and the recognition of practice.

B) Related information

In addition to gaining a more in-depth understanding of the biology of the hematopoietic stem cell and its environment, knowledge of the indications, donor selection, the immunological concepts of engraftment, tolerance and rejection, the concepts of graft-versus-host disease (GVHD) and graft-versus-leukemia (GVL) disease, as well as strategies for the prevention and treatment of transplant-related complications, fellows will also have to gain experience with different technological platforms in the cellular therapy laboratory. Fellows will also have to develop their skills and competencies in scientific research and participate in or develop a research project, with the goal of increasing their exposure to scientific methodology, fostering the development of research hypotheses and promoting innovative projects in clinical and translational research.

2. Please provide a list of journals and publications that support this special area.

(Demonstrate the value that these add to the medical literature. Indicate if they are peer-reviewed, indexed, the scope of distribution [national/international], the subscription volume, and Canadian contribution to these publications.)

A) Peer-reviewed scientific journals that have an impact on the discipline:

www.bloodjournal.org

Blood Journal, published by the American Society of Hematology, is the most cited peer-reviewed publication in the field of hematology. The journal covers all aspects of hematology, including disorders of leukocytes, both benign and malignant, erythrocytes, platelets, hemostatic mechanisms, vascular biology, immunology, and hematologic oncology.

Impact Factor: 11.847

<http://www.nature.com/bmt/index.html>

Bone Marrow Transplantation Journal publishes high quality, peer-reviewed original research and reviews that address all aspects of basic biology and clinical use of haemopoietic cell transplantation.

The journal also covers all aspects of the research and treatment of transplant-related complications and consequences including quality of life and psychological issues. Basic research studies on topics of relevance are also covered.

Impact factor: 3.6

www.journals.elsevier.com/the-lancet-oncology

The Lancet Oncology is an authoritative forum for key opinion leaders across medicine, government, and health systems to influence clinical practice, explore global policy, and inform constructive, positive change worldwide. As the global leader in clinical oncology research, *The Lancet Oncology* delivers essential original research, expert review, candid commentary, and breaking news to provide context and perspective on today's most important medical advances across the broad spectrum of oncology.

Impact Factor: 26.5

www.journals.elsevier.com/biology-of-blood-and-marrow-transplantation

Biology of Blood and Marrow Transplantation publishes original research reports, reviews, editorials, commentaries, letters to the editor, and hypotheses and is the official publication of the American Society for Blood and Marrow Transplantation. The journal focuses on current technology and knowledge in the interdisciplinary field of hematopoietic stem cell transplantation.

Impact Factor: 3.98

<http://jco.ascopubs.org>

The **Journal of Clinical Oncology** - Official Journal of the American Society of Clinical Oncology - serves its readers as the single most credible, authoritative resource for disseminating significant clinical oncology research. In print and in electronic format, JCO strives to publish the highest quality articles dedicated to clinical research. Original Reports remain the focus of JCO, but this scientific

communication is enhanced by appropriately selected Editorials, Commentaries, Reviews, and other work that relate to the care of patients with cancer.
Impact factor: 9.38

www.journals.elsevier.com/stem-cell-research

Stem Cell Research is dedicated to publishing high-quality manuscripts focusing on the biology and applications of stem cell research.
Impact factor: 4.5

B) Scientific publications in peer-reviewed journals supporting the discipline and referenced in the text.

1. One million haemopoietic stem-cell transplants: a retrospective observational study. Gratwohl A, Pasquini MC, Aljurf M, Atsuta Y, Baldomero H, Foeken L, Gratwohl M, Bouzas LF, Confer D, Frauendorfer K, Gluckman E, Greinix H, Horowitz M, Iida M, Lipton J, Madrigal A, Mohty M, Noel L, Novitzky N, Nunez J, Oudshoorn M, Passweg J, van Rood J, Szer J, Blume K, Appelbaum FR, Kodera Y, Niederwieser D; Worldwide Network for Blood and Marrow Transplantation (WBMT). *Lancet Haematol.* 2015 Mar;2(3):e91-100. doi: 10.1016/S2352-3026(15)00028-9. Epub 2015 Feb 27. Erratum in: *Lancet Haematol.* 2015 May;2(5):e184. PMID: 26687803.

2. Hematopoietic stem cell transplantation activity worldwide in 2012 and a SWOT analysis of the Worldwide Network for Blood and Marrow Transplantation Group including the global survey. Niederwieser D, Baldomero H, Szer J, Gratwohl M, Aljurf M, Atsuta Y, Bouzas LF, Confer D, Greinix H, Horowitz M, Iida M, Lipton J, Mohty M, Novitzky N, Nunez J, Passweg J, Pasquini MC, Kodera Y, Apperley J, Seber A, Gratwohl A. *Bone Marrow Transplant.* 2016 Jun;51(6):778-85. doi: 10.1038/bmt.2016.18. Epub 2016 Feb 22. PMID: 26901703.

3. Quantitative and qualitative differences in use and trends of hematopoietic stem cell transplantation: a Global Observational Study. Gratwohl A, Baldomero H, Gratwohl M, Aljurf M, Bouzas LF, Horowitz M, Kodera Y, Lipton J, Iida M, Pasquini MC, Passweg J, Szer J, Madrigal A, Frauendorfer K, Niederwieser D; Worldwide Network of Blood and Marrow Transplantation (WBMT). *Haematologica.* 2013 Aug;98(8):1282-90. doi: 10.3324/haematol.2012.076349. Epub 2013 Mar 18. PMID: 23508009.

4. Hematopoietic stem cell transplantation activity in Europe. Gratwohl A, Baldomero H, Passweg J. *Curr Opin Hematol.* 2013 Nov;20(6):485-93. doi: 10.1097/MOH.0b013e328364f573. Review. PMID: 24104408.

5. Hematopoietic stem cell transplantation: a global perspective. Gratwohl A, Baldomero H, Aljurf M, Pasquini MC, Bouzas LF, Yoshimi A, Szer J, Lipton J, Schwendener A, Gratwohl M, Frauendorfer K, Niederwieser D, Horowitz M, Kodera Y; Worldwide Network of Blood and Marrow Transplantation. *JAMA.* 2010 Apr 28;303(16):1617-24. doi: 10.1001/jama.2010.491. PMID: 20424252.

6. Optimizing Quality and Efficiency of Healthcare Delivery in Hematopoietic Cell Transplantation. Majhail NS. *Curr Hematol Malig Rep.* 2015 Sep;10(3):199-204. doi: 10.1007/s11899-015-0264-3. Review. PMID: 26003329.

7. The National Marrow Donor Program's Symposium on Hematopoietic Cell Transplantation in 2020: a health care resource and infrastructure assessment. Majhail NS, Murphy EA, Denzen EM, Ferguson SS, Anasetti C, Bracey A, Burns L, Champlin R, Hubbard N, Markowitz M, Maziarz RT, Medoff E, Neumann J, Schmit-Pokorny K, Weisdorf DJ, Yolin Raley DS, Chell J, Snyder EL. *Biol Blood Marrow Transplant.* 2012 Feb;18(2):172-82. doi: 10.1016/j.bbmt.2011.10.004. Epub 2011 Dec 14. Erratum in: *Biol Blood Marrow Transplant.* 2012 May;18(5):818. Ferguson, Stacy S [corrected to Ferguson, Stacy Stickney]. PMID: 22178961.

8. Preparing for growth: current capacity and challenges in hematopoietic stem cell transplantation programs. Schriber JR, Anasetti C, Heslop HE, Leahigh AK. *Biol Blood Marrow Transplant.* 2010 May;16(5):595-7. doi: 10.1016/j.bbmt.2010.02.010. Epub 2010 Feb 16. PMID: 20167277.

9. Success of an International Learning Health Care System in Hematopoietic Cell Transplantation: The American Society of Blood and Marrow Transplantation Clinical Case Forum. Barba P, Burns LJ, Litzow MR, Juckett MB, Komanduri KV, Lee SJ, Devlin SM, Costa LJ, Khan S, King A, Klein A, Krishnan A, Malone A, Mir MA, Moravec C, Selby G, Roy V, Cochran M, Stricherz MK, Westmoreland MD, Perales MA, Wood WA; American Society for Blood and Marrow Transplantation Committee on Education. *Biol Blood Marrow Transplant.* 2016 Mar;22(3):564-70. doi: 10.1016/j.bbmt.2015.12.008. Epub 2015 Dec 21. PMID: 26718665.

10. Haploidentical Hematopoietic Stem Cell Transplantation: A Global Overview Comparing Asia, the European Union, and the United States. Apperley J, Niederwieser D, Huang XJ, Nagler A, Fuchs E, Szer J, Kodera Y. *Biol Blood Marrow Transplant.* 2016 Mar;22(3 Suppl):S15-8. doi:10.1016/j.bbmt.2016.01.006. Review. PMID: 26899273.

11. Is There Any Reason to Prefer Cord Blood Instead of Adult Donors for Hematopoietic Stem Cell Transplants? Beksac M. *Front Med (Lausanne).* 2016 Jan 11;2:95. doi: 10.3389/fmed.2015.00095. eCollection 2015. Review. PMID: 26793711.

12. Quality and exploitation of umbilical cord blood for cell therapy: Are we beyond our capabilities? Roura S, Pujal JM, Gálvez-Montón C, Bayes-Genis A. *Dev Dyn.* 2016 Jul;245(7):710-7. doi:10.1002/dvdy.24408. Epub 2016 Apr 28. PMID: 27043849.

13. Global Use of Peripheral Blood vs Bone Marrow as Source of Stem Cells for Allogeneic Transplantation in Patients With Bone Marrow Failure. Yoshimi A, Baldomero H, Horowitz M, Szer J, Niederwieser D, Gratwohl A, Kodera Y; Worldwide Network of Blood and Marrow Transplantation (WBMT). *JAMA.* 2016 Jan 12;315(2):198-200. doi: 10.1001/jama.2015.13706. No abstract available. PMID: 26757470.

- 14. Trends of hematopoietic stem cell transplantation in the third millennium.** Gratwohl A, Baldomero H. *Curr Opin Hematol.* 2009 Nov;16(6):420-6. doi: 10.1097/MOH.0b013e328330990f. PMID: 19680124.
- 15. Lost in transition: the essential need for long-term follow-up clinic for blood and marrow transplantation survivors.** Hashmi S, Carpenter P, Khera N, Tichelli A, Savani BN. *Biol Blood Marrow Transplant.* 2015 Feb;21(2):225-32. doi: 10.1016/j.bbmt.2014.06.035. Epub 2014 Jul 3. Review. PMID: 24999225.
- 16. Training practices of cell processing laboratory staff: analysis of a survey by the Alliance for Harmonization of Cellular Therapy Accreditation.** Keever-Taylor CA, Slaper-Cortenbach I, Celluzzi C, Loper K, Aljurf M, Schwartz J, Mcgrath E, Eldridge P; Alliance for Harmonisation of Cellular Therapy Accreditation. *Cytotherapy.* 2015 Dec;17(12):1831-44. doi: 10.1016/j.jcyt.2015.08.006. Epub 2015 Oct 9. PMID: 26455277.
- 17. Treatment ethics, quality of life and health economics in the management of hematopoietic malignancies in older patients.** Deeg HJ. *Bone Marrow Transplant.* 2015 Sep;50(9):1145-9. doi: 10.1038/bmt.2015.130. Epub 2015 Jun 8. Review. PMID: 26052908.
- 18. Barriers to accessing health care for hematopoietic cell transplantation recipients living in rural areas: perspectives from healthcare providers.** Moore HK, Santibañez ME, Denzen EM, Carr DW, Murphy EA. *Clin J Oncol Nurs.* 2013 Aug 1;17(4):405-11. doi: 10.1188/13.CJON.405-411. PMID: 23899979
- 19. Delivering care to long-term adult survivors of hematopoietic cell transplantation.** Syrjala KL, Martin PJ, Lee SJ. *J Clin Oncol.* 2012 Oct 20;30(30):3746-51. doi: 10.1200/JCO.2012.42.3038. Epub 2012 Sep 24. Review. PMID: 23008296.
- 20. Surviving the cure: long term followup of hematopoietic cell transplant recipients.** Majhail NS, Rizzo JD. *Bone Marrow Transplant.* 2013 Sep;48(9):1145-51. doi: 10.1038/bmt.2012.258. Epub 2013 Jan 7. Review. PMID: 23292238.
- 21. Allogeneic transplant physician and center capacity in the United States.** Majhail NS, Murphy EA, Omondi NA, Robinett P, Gajewski JL, LeMaistre CF, Confer D, Rizzo JD. *Biol Blood Marrow Transplant.* 2011 Jul;17(7):956-61. doi: 10.1016/j.bbmt.2011.03.008. Epub 2011 Apr 12. Review. PMID: 21540121.
- 22. Challenges and potential solutions for recruitment and retention of hematopoietic cell transplantation physicians: the National Marrow Donor Program's System Capacity Initiative Physician Workforce Group report.** Burns LJ, Gajewski JL, Majhail NS, Navarro W, Perales MA, Shereck E, Selby GB, Snyder EL, Woolfrey AE, Litzow MR. *Biol Blood Marrow Transplant.* 2014 May;20(5):617-21. doi: 10.1016/j.bbmt.2014.01.028. Epub 2014 Feb 5. PMID: 24508838.

3. Scope of the meetings or associations listed above and contributions of Canadian physicians.

- **Annual convention of the American Society of Hematology, United States**

The ASH Annual Meeting is the world's premier event in malignant and non-malignant hematology. The meeting provides an invaluable educational experience and an opportunity to review thousands of scientific abstracts highlighting updates in the hottest topics in hematology. Network with top minds in the field, as well as a global community of more than 20,000 hematology professionals from every subspecialty.

The members of the HMR Division of Hemato-Oncology and Transplantation and of the CBMTG-affiliated centres attend on a rotating basis and annually present scientific articles in the form of abstracts and oral presentations.

Scientific publications: scientific journal *Blood* (American Society of Hematology).

- **Annual convention of the ASBMT (American Society for Blood and Marrow Transplantation) / CIBMTR (Center for International Blood and Marrow Transplant Research). BMT tandem meeting.**

The Society's mission is to secure the highest quality of care for all blood and marrow transplantation and cellular therapy patients.

Annual convention reporting the most recent developments in stem cell transplantation and in cellular therapy and proposing standards of practice and the maintenance of medical quality assurance.

Annual participation of the members of the Université de Montréal hematopoietic stem cell transplantation program and of the CBMTG-affiliated centres accompanied by fellows. This convention is also aimed at health care professionals working in transplantation units and programs (pharmacists, nurses, psychologists, nutritionists, social workers, physiotherapists, etc.) and in cellular therapy laboratories (technicians, PhDs).

Scientific publications: *Biology of Blood and Marrow Transplantation* (BBMT).

- **Annual convention of the European Society for Blood and Marrow Transplantation**

The European Society for Blood and Marrow Transplantation (EBMT) is a non-profit organisation that was established in 1974 in order to allow scientists and physicians involved in clinical bone marrow transplantation to share their experience and develop co-operative studies. The EBMT is devoted to the promotion of all aspects associated with the transplantation of haematopoietic stem cells from all donor sources and donor types including basic and clinical research, education, standardisation, quality control, and accreditation for transplant procedures.

Regular participation of the transplant hematologists from the CBMTG-affiliated centres, including posters and oral presentations.

Scientific publications: *Bone Marrow Transplantation — BMT Nature*.

- **Canadian Blood and Marrow Transplant Group**

The Canadian Blood and Marrow Transplant Group is the voice of experts saving lives through Stem Cell Transplant.

Annual meeting and Graft-versus-Host Disease Symposium

Annual participation of the members of the CBMTG.

These meetings of medical associations in which transplant hematologists from Canadian stem cell transplantation centres register and participate are a key driver of recognition and dissemination of scientific knowledge, particularly through the dedication to high academic and professional standards evidenced by their activities.

4. Are there training programs and/or established clinical fellowships for this discipline in Canada?

YES. Several transplantation programs in Canada receive specialist physicians in hematology who are interested in acquiring expertise in hematopoietic stem cell transplantation. These physicians have completed their training in hematology in Canada or abroad. During a recent survey conducted by the CBMTG, 17 transplantation programs were asked whether their transplantation program offered a training program. Twelve centres (71%) responded to this survey. Seven of the 12 programs that responded indicated that they have developed a transplantation training program varying in duration from one to two years and offered, on average, one fellowship position annually.

Training programs in hematopoietic stem cell transplantation in Canada

Vancouver Stem Cell Transplant Program, Vancouver General Hospital, BCCA. British Columbia.

Alberta Blood and Marrow Transplant Program, Tom Baker Cancer Centre, University of Alberta, Calgary, Alberta.

Manitoba Blood and Marrow Transplant Program, University of Manitoba, Winnipeg, Manitoba.

Hamilton Bone Marrow Transplant Program, McMaster University, Hamilton, Ontario.

Princess Margaret Hospital Stem Cell Transplant Program, University of Toronto, Toronto, Ontario.

Ottawa Stem Cell Transplant Program, Ottawa University, Ottawa, Ontario.

Hôpital Maisonneuve-Rosemont Hematopoietic Stem Cell Transplant Program, Université de Montréal, Montreal, Quebec.

Hôpital Sainte-Justine Stem Cell Transplant Program, Université de Montréal, Montreal, Quebec.

Québec Hematopoietic Stem Cell Transplant Program, Université Laval, Quebec City, Quebec.

Halifax Blood and Marrow Transplant Program, Dalhousie University, Halifax, Nova Scotia.

5. How will the recognition of this proposed diploma discipline affect the parent (sub)specialty(ies) and other related specialties? (Will there be overlap of patient populations, procedures, investigative techniques, areas of research? Please include both positive and negative implications.)

By virtue of its mandate to ensure excellence in medical training, recognition of the discipline by the Royal College will confirm the quality of the training program in hematopoietic stem cell transplantation and promote the delivery of safe, high-quality care/services to patients who are candidates for transplantation and their families. This specialty training will be provided in accordance with the standards of excellence to which Canadian transplantation programs subscribe in the delivery of care, in teaching and training activities, and in clinical and basic research inspired by the CanMEDS framework, in order to train experts in this field.

This recognition will help consolidate the standing of the discipline, will promote recruitment and will improve access to care and the quality of care. Hematopoietic stem cell transplantation is a subspecialty of hematology. Its primary goal is to meet the demand for care, in accordance with high standards, safely while offering services of optimal quality in order to contribute to improving the survival of patients with benign and malignant hemopathies who need a hematopoietic stem cell transplant. The goal of this training is the acquisition of exceptional knowledge and expertise in cellular therapy (theoretical, clinical and research) in an environment dedicated to and specifically accredited for these expert practices in the field of the treatment of blood diseases and cancers. The recognition of the discipline will make it possible to improve practice and to offer a new scope of practice. This is a springboard that can only facilitate the development of both disciplines while improving interdisciplinarity and promoting the emergence of advanced practices in centres dedicated to this field of expertise. Consolidating patients in an expert program will also promote the development of training and research programs.

6. How would recognition of this diploma discipline affect: (Impact should be interpreted broadly and include community, the delivery of medical care, cost-savings. Population health data should be included, if applicable.)

A) Impact on:

1) Delivery of medical care?

Recognition of the discipline by the Royal College will confirm the quality of transplantation training programs and will contribute to the improvement of the quality of training and of patient care. It will support, in a positive and unequivocal manner, the efforts made by the medical and paramedical teams in the care of transplant recipients. This recognition will also contribute to the standardization of training and practice in transplantation, will promote the training, recruitment and retention of transplanters, and will improve access to care, which is currently compromised (ref. 3, 9).

2) Meeting community needs?

There is currently a national and international shortage of transplanters (ref. 5, 6, 7, 8, 21, 22). This shortage has severely compromised access to transplantation and adversely affected the progress of certain patients with pathologies at high risk of relapse. Long wait times to access the transplantation unit are contributing to an increased risk of relapse, requiring repeated administration of chemotherapy cycles and exposing patients to risks of morbidity and mortality related to their underlying pathology. In addition, the indications of stem cell transplantation and the eligible patient population are constantly increasing (ref. 1, 2, 3). The recognition of the discipline will promote access to transplantation and the quality of care for the Canadian population.

3) Health care budgets?

The problem of access to transplantation has contributed to rising health care costs in Canada, and to a more critical degree in Ontario and the Maritime Provinces, since some patients have had to be transferred to transplantation centres outside the province or in the United States in order to receive their stem cell transplant since the wait times were placing their lives in danger (ref. 18, 19). Unfortunately, some patients suffered a relapse of their disease while awaiting transplantation and were not able to benefit from this potentially curative procedure. Recognition of the discipline by the Royal College will improve the recruitment and retention of transplanters and access to care. The improvement of access to transplantation should result in a reduction in health care costs by reducing transfers outside the province and outside Canada, by decreasing the number of cycles of chemotherapy given while awaiting transplantation and, especially, will contribute to improving the quality of life and survival of Canadian patients eligible for transplantation.

B) What role will the consultant in the proposed diploma discipline play in meeting community needs?

The transplant hematologist will be responsible for assessing the candidate for hematopoietic stem cell transplantation, determining eligibility for transplantation, selecting the type of conditioning as well as the stem cell source, determining the graft-versus-host disease prophylaxis, the progress of the recipient during the procedure and post-transplantation follow-up. The transplant hematologist must also select the stem cell donor, assess his/her health condition and the potential risks of the donation, authorize the donation after review of the pre-donation work-up, prescribe the graft and the quantity of stem cells required, evaluate the quality of the cell graft collected, authorize its infusion and provide post-donation follow-up.

Transplant hematologists must also explain the transplantation-related risks and benefits and obtain informed consent for the transplant and for the donation of stem cells. They must coordinate the sequence of treatments prior to transplantation with the referring physician and clearly communicate their recommendations to the attending teams. It will also be their role to maintain their knowledge and competencies in accordance with the literature, to offer expert and humane care, to be receptive to the needs and wishes of patients and their families, and to pass on their knowledge in order to clearly inform the community about the indications and recommendations inherent to stem cell transplantation. Transplant hematologists must develop a training plan in order to keep their knowledge and competencies up

to date and contribute, through academic activities, to the standing and promotion of the discipline.

Upon completion of their training, transplant hematologists will have acquired advanced knowledge and competencies in hematopoietic stem cell transplantation and will be capable of assuming the seven roles relating to the CanMEDS competencies as:

1. Medical Expert in hematopoietic stem cell transplantation
2. Communicator in hematopoietic stem cell transplantation
3. Collaborator in hematopoietic stem cell transplantation
4. Manager in hematopoietic stem cell transplantation
5. Health Advocate in hematopoietic stem cell transplantation
6. Scholar in hematopoietic stem cell transplantation
7. Professional in hematopoietic stem cell transplantation

See the Competency Training Requirements for the Area of Focused Competence in Hematopoietic Stem Cell Transplantation.

***C) Describe the academic role of the consultant in this discipline.
(What would be the requirements for teaching and research, if the specialist was part of an academic/tertiary care centre?)***

Transplant hematologists must assume a leadership role within the attending team and the team of residents and fellows in training. Transplant hematologists will therefore be in charge of supervising and guiding the training. They will be supported in their duties by a collaborative interdisciplinary team and will participate actively in the transmission of their knowledge during their duties as teachers to patients and their families, the attending team, the referring physician, and residents and fellows in training. They will contribute to the improvement of care and to the standing and promotion of the discipline by developing, participating and/or collaborating in basic or clinical research projects, and in educational activities in the discipline.

The educational role of transplant hematologists will be reinforced by:

Their constant striving for excellence in the medical, basic, clinical and translational sciences in transplantation;

Their recognized expertise in transplantation and in the main fields of basic, clinical and laboratory competencies relating to cellular therapy;

A keen interest in knowledge transfer and the training of competent new transplant hematologists focused on quality assurance of medical practice and patient care, and the ability to establish effective communications (patients, colleagues, students, etc.);

Active participation in didactic teaching, in direct supervision and training activities, in inter-institutional teaching and research activities, and in compliance with university standards and the standards of accrediting bodies and professional standards.

Their collaboration in coordinating and planning the academic training in their centre;

Their ability to inspire those they work with by their commitment to high professional standards and their dedication to research, publications and scientific communication;

Their motivation to participate in popular scientific education efforts;

Their participation in the progress of knowledge and the impact of that knowledge on the community.

D) Describe the patient population served by this discipline.

The candidate for transplantation is usually a patient with a malignant hemopathy. The main indications for autologous transplantation in Canada and around the world are plasma cell dyscrasias (multiple myeloma) and lymphoproliferative syndromes (NHL, Hodgkin), while for allogeneic transplantation, the primary indication remains acute leukemia. The Canadian and Quebec cancer registries and Statistics Canada estimated that, in 2015, there would be 8,200 new cases of non-Hodgkin lymphoma (NHL), 6,200 new cases of acute leukemia (AL), 2,700 new cases of multiple myeloma (MM) and 1,000 new cases of Hodgkin lymphoma (HL).

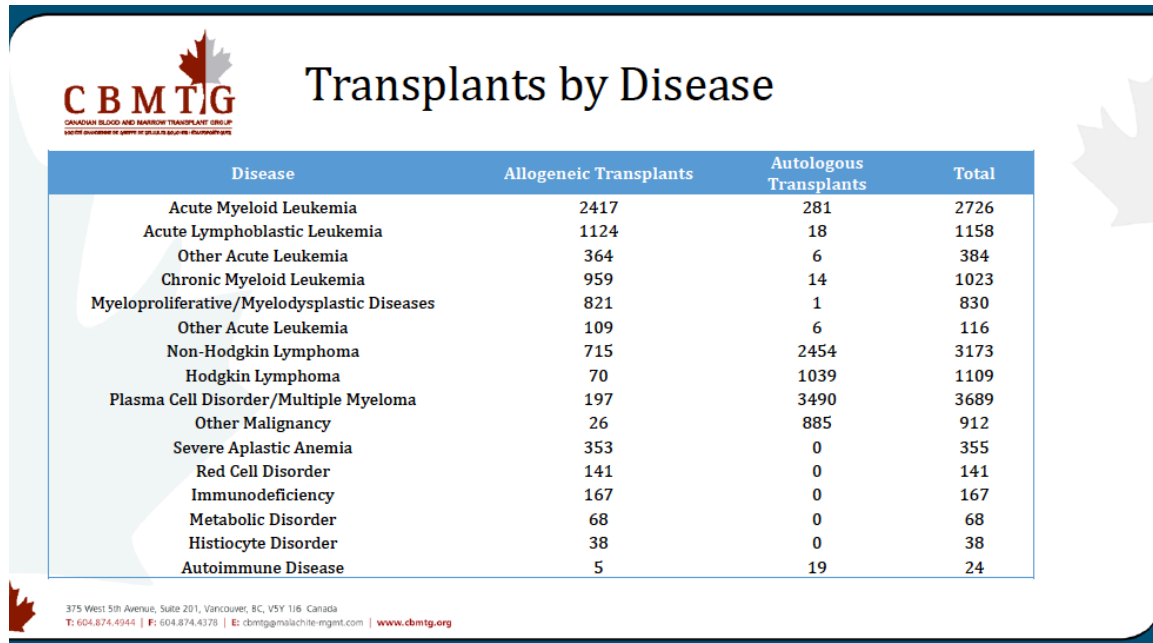
Autologous stem cell transplantation is considered standard therapy as consolidation for first-line therapy for all patients with multiple myeloma under age 65 (up to age 70 in some centres) and for patients with mantle-cell lymphoma, while it constitutes the therapy that offers the best chances of survival for patients with relapsed chemosensitive lymphoma (NHL and HL) or primary refractory lymphoma chemosensitive to second-line therapy. Allogeneic transplantation is recommended as the first-line treatment option for patients with acute leukemias and presenting with risk factors for relapse (80% of cases for adults and 20-30% for children). Post-transplantation survival has improved considerably during the last 20 years and the age of eligibility for transplantation is rising steadily.

1. Numbers of hematopoietic stem cell transplants performed in Canada and reported to the CBMTG registry (1990-)

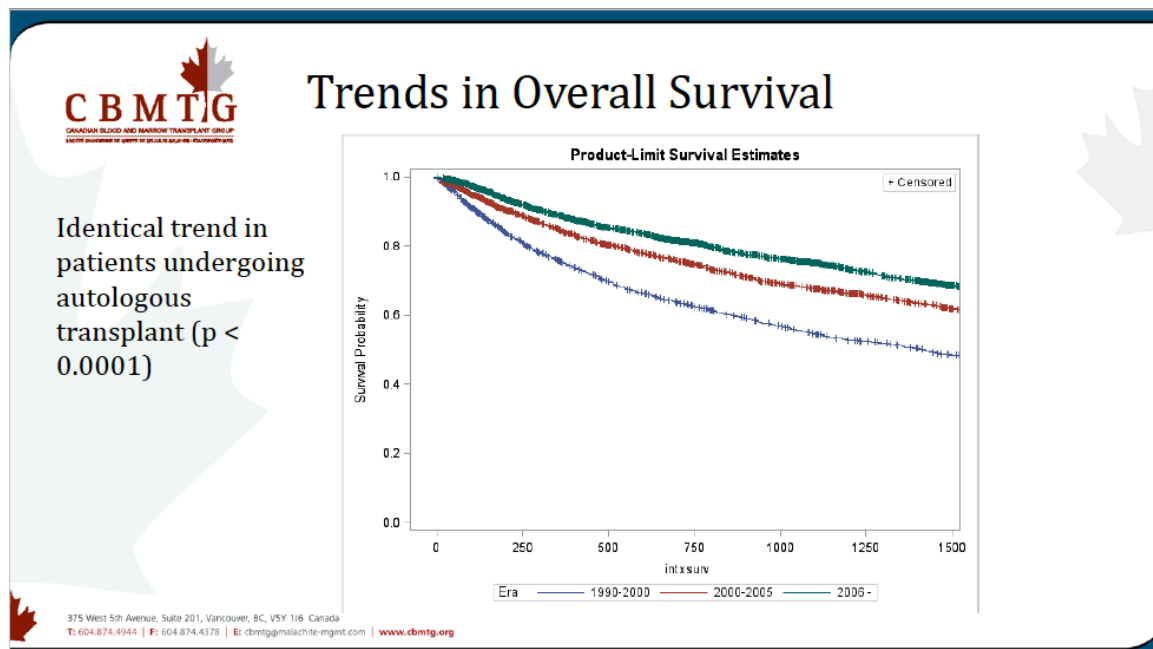
		Patients	Percent
Transplant Type	Allogeneic	7693	16.3%
	Autologous	8794	52.9%
	DLI	126	0.7%
Gender	Male	10740	57.3
	Female	7939	42.3
Graft Source	Bone marrow	3264	18.7%
	Peripheral Blood	13731	78.6%
	Cord Blood	477	2.7%
Year of Transplant	Before 2000	7339	39%
	2000-2005	4260	22.7%
	2006-	7205	38.3%
Age	Median 46.1 years		
	< 18	4539	24.1%
	18-40	4090	21.8%
	40-60	7521	40%
	>60	2654	14.1%

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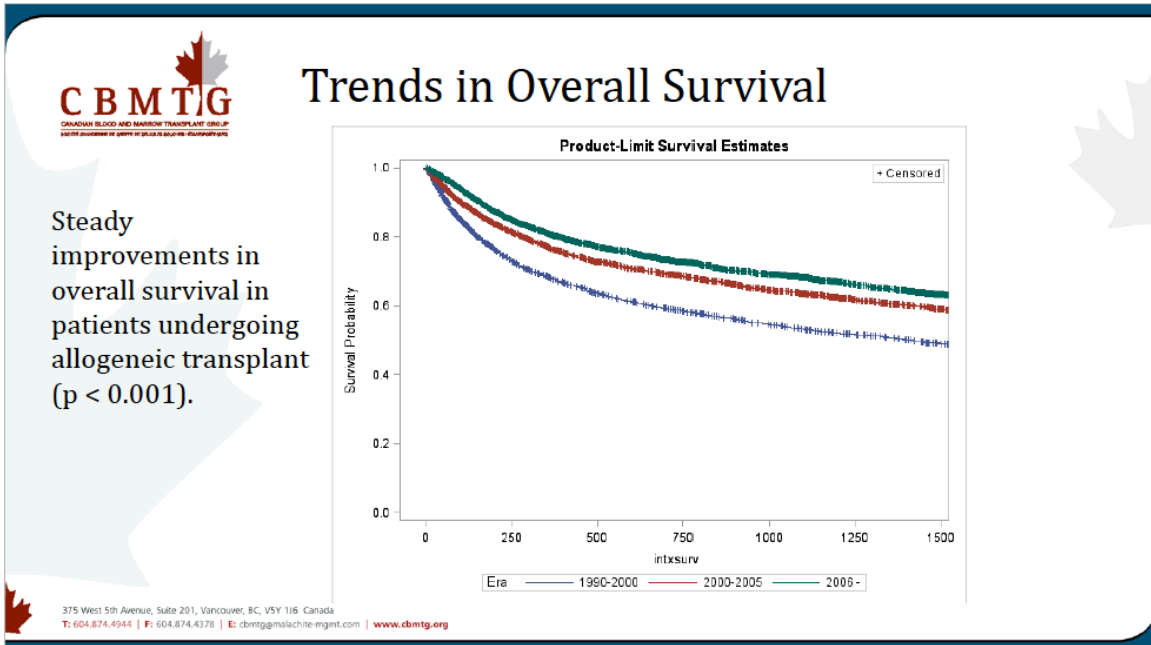
2. Diagnoses for which stem cell transplantation has been performed in Canada



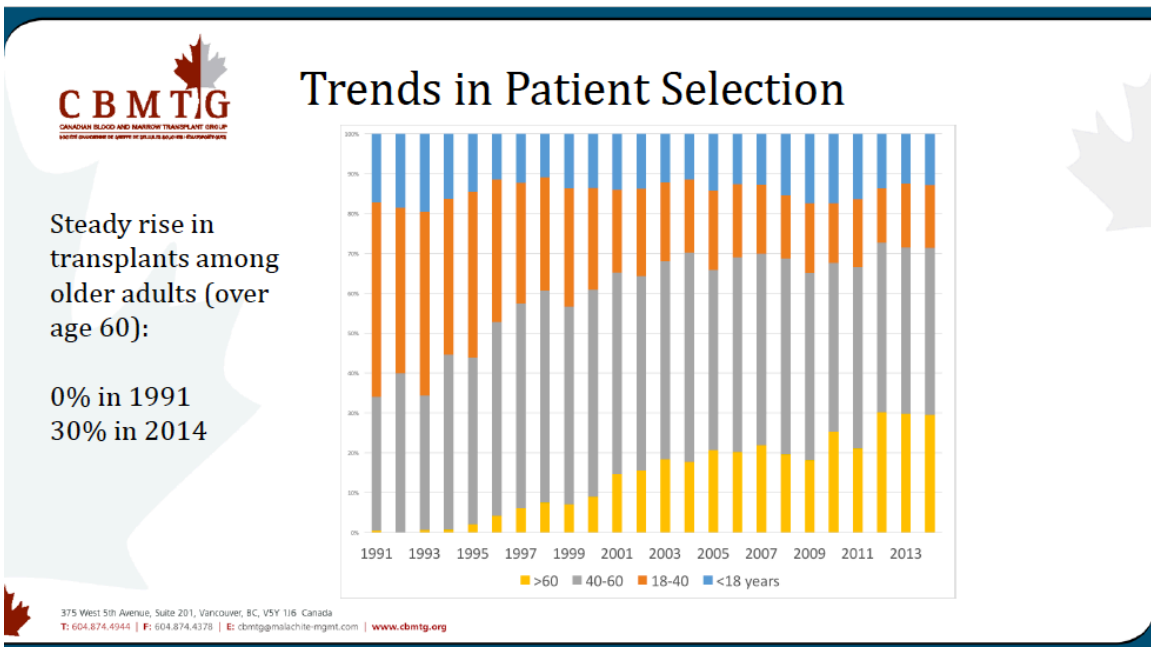
3. Overall survival following autologous hematopoietic stem cell transplantation in Canada



4. Overall survival following allogeneic hematopoietic stem cell transplantation in Canada



5. Age profile of stem cell transplant recipients in Canada



Approximately 1,200-1,500 stem cell transplants are currently performed annually in Canada (source CBMTG). It is easy to understand the magnitude of the unmet needs in Canada by these figures alone.

E) Please estimate how many physicians are currently practicing the proposed diploma discipline in Canada and in which locations. (This should reflect the national physician workforce for the proposed specialty/subspecialty.)

There are currently some 20 hematopoietic stem cell transplantation programs in Canada, distributed in different regions and provinces. Some (5) programs offer only autologous transplantation. Half of the transplantation programs surveyed are designated by their province and duly accredited (FACT, Health Canada). These are university programs that in most cases have developed a training program in transplantation. The resources dedicated to this activity vary significantly from province to province. There is no standard of practice in Canada, and very few references on this subject around the world (ref. 6, 7, 8 and 14) or recommendations designating the desirable number of transplanters relative to transplantation activities.

Summary table indicating medical and professional resources of the six largest transplantation programs in Canada

SCT Program Numbers: (2015)	Montreal HMR	Halifax	Toronto	Calgary	Winnipeg	Vancouver
Total Stem Cell Transplants	202	100	NA	170	87	247
Autologous	113	60	NA	100	40	162
Allogeneic	89	40	NA	70	37	85
BMT physicians	7	4	NA	11	5+2	13.5
BMT clinical associates	0	1	6	2	4	6
BMT nurse practitioners	0	1	NA	0	0	0
BMT coordinators	1+1	2	NA	7.4	1.6	5.5
Dedicated SCT founding	No	Yes	Yes	Yes	Yes	Yes

Legend: The results indicated in the table were collected and confirmed by the directors of each of the transplantation programs surveyed across Canada. We are awaiting the results of the Ottawa transplantation program. Toronto did not respond to the questionnaire. SCT means stem cell transplantation. BMT means blood and marrow transplants.

It is estimated that there are approximately 80 transplant hematologists in Canada, distributed in the various transplantation programs.

List of hematopoietic stem cell transplantation programs in the CBMTG registry

DIRECTOR/DEPT	UNIVERSITY	INSTITUTION	CITY	PROVINCE
Dr. Donna Wass BMT Program	University of Manitoba	Manitoba BMT Program (MBMT), Cancer Care Manitoba	Winnipeg	Manitoba
Dr. Stephen Couban BMT Program	Dalhousie University	BMT Program, QEII Health Sciences Centre	Halifax	Nova Scotia
Dr. Kirsty Tompkins BMT Program	Memorial University of NFL Autologous	Memorial Health Sciences Centre BMT Program	St. John's	Newfoundland
Dr. Gizelle Propradi BMT Program	McGill University Health Centre Pediatric	McGill University Health Centre BMT Program, Royal Victoria Hospital	Montreal	Quebec
Dr. Silvy Lachance BMT Program	University of Montreal	Stem Cell Transplant Program Maisonneuve-Rosemont Hospital	Montreal	Quebec
Dr. David Mitchel BMT Program	McGill University Health Centre Pediatric	Montreal Children's Hospital BMT Program	Montreal	Quebec
Dr. Chris Bredeson BMT Program	University of Ottawa	Ottawa Hospital BMT Program	Ottawa	Ontario
Dr. Ronan Foley BMR Program	McMaster University	Hamilton Health Centre BMT Program	Hamilton	Ontario
Dr. Andrew Daly BMT Program	University of Calgary	Alberta BMT and Blood Cell Transplant Program, Tom Baker Cancer Centre	Calgary	Alberta
Dr. Michael Crump BMT Program	University of Toronto Autologous	Autologous BMT Program Princess Margaret Hospital	Toronto	Ontario
Dr. Hans Messner BMT Program	University of Toronto Allogeneic	Allogeneic BMT Program Princess Margaret Hospital	Toronto	Ontario
Dr. Raewyn Broady BMT Program	University of British Columbia	BMT Program of British Columbia, Vancouver General Hospital	Vancouver	British Columbia
Dr. Mohamed Elemery BMT Program	University of Saskatchewan	Saskatchewan Cancer Agency BMT Program	Saskatoon	Saskatchewan
Dr. Joseph Brandwein BMT Program	University of Alberta	Alberta BMT and Blood Cell Transplant Program	Edmonton	Alberta
Dr. Victor Lewis BMT Program	University of Calgary	Pediatric Oncology, BMT Alberta Children's Hospital	Calgary	Alberta
Dr. Anargyros Xenocostas BMT Program	Schulich School of Medicine	Hemopoietic Stem Cell Transplant Program, London Health Sciences Centre	London	Ontario
Dr. Michel Duval BMT Program	University of Montreal Pediatric	Pediatric BMT and Cell Therapy Center, Hôpital Sainte-Justine	Montreal	Quebec
Dr. Jeffery Davis BMT Program	University of British Columbia	Oncology, Hematology and BMT Program, BC Children's Hospital	Vancouver	British Columbia
Dr. Caron Strahlendorf BMT Program	BC Children's Hospital	Oncology, Hematology/BMT Program, BC Children's Hospital	Vancouver	British Columbia
Dr. Terrance Comeau New Brunswick Stem Cell Transplant Program	New Brunswick Autologous	Horizon Health Network	Saint John	New Brunswick
Dr. Guy Cantin BMT Program	Laval University	BMT Program, Hôpital de l'Enfant- Jésus	Quebec	Quebec
Dr. Sita Bhella Adult Autologous SCT Program	Queen's University Autologous	Kingston General Hospital	Kingston	Ontario

F) Describe the current practice profiles of the physicians engaged in this discipline.

The physicians in charge of and associated with transplantation programs in Canada are in most cases hematologists who have acquired fellowship training (1-3 years) in hematopoietic stem cell transplantation in the clinical and laboratory setting and/or in basic and translational research. All the transplantation programs accredited by FACT (Foundation for Accreditation in Cellular Therapy) require that their members have expertise covering the three fields of transplantation (clinical program, apheresis and cell collection program, and cellular therapy laboratory) and that they maintain their knowledge and competency in transplantation with an annual assessment by the program director according to a predetermined list of competencies covering the various aspects of transplantation. The practice profile of transplant hematologists is therefore divided among the following activities:

1. The inpatient transplantation unit, covering inpatient care in a sterile unit;
2. The day hospital and the outpatient clinic, covering transplants performed on an outpatient basis, transplantation emergencies, pre- and post-transplant consultations and follow-up;
3. The apheresis unit, for the assessment and supervision of stem cell donors and cell collection;
4. The cellular therapy laboratory, responsible for graft evaluation, manipulation and cryopreservation;
5. Teaching aimed at hematology residents and transplantation fellows as well as the various professionals involved in transplantation (pharmacists, nurses, psychologists, nutritionists, physiotherapists, etc.), patients and their families;
6. Clinical, translational and basic research.

In addition, each accredited transplantation program must maintain a quality program with monitoring of transplantation performance indicators. The program director must also perform administrative duties related to the management of the program.

G) Outline future (5 years and 10 years periods) projected workforce needs (FTEs) for practicing physicians in the proposed field.

There is currently a worldwide shortage of transplanters. Few publications address the needs in stem cell transplantation and the ideal or desired ratio between the number of transplants performed and the number of transplant hematologists required (transplantation FTEs) in order to ensure patient safety and medical quality assurance. A general overview was published in 2011 by the National Marrow Donor Program (NMDP) in BBMT (ref. 21, 22) following a study conducted of stem cell transplantation centres in the United States. This survey considered only allogeneic transplants and did not take into account the autologous transplants performed in each centre. Between 2005 and 2009, a 30% increase was noted in the number of allogeneic transplants performed, while bed capacity had increased by 17% and the number of transplanters by 25%: this was well before the phenomenal increase in the number of transplants performed using unrelated and alternative donors (haploidentical and cord blood).

This study defined the size of transplantation programs based on the number of beds dedicated to transplantation in small (less than 10 beds), medium-sized (10 to 20 beds), large (21 to 30 beds) and very large (31 beds and more) centres. In 2009, the median number of allogeneic transplants performed by transplanters per FTE was 4.7, 6.0, 7.4, and 7.7 in small, medium-sized, large and very large centres, respectively. Since nearly 1,500 transplants are performed annually in Canada, and half of these transplants are allogeneic, the estimated number of transplant hematologists necessary to meet the needs in allogeneic transplantation currently ranges from 100 to 160 transplanters. Considering autologous transplants and the increase in the number of transplants performed annually (minimum of 10% growth annually), the needs are increasing considerably and could easily double (ref. 10, 11, 14, 19, 20, 21, 22).

H) What is the impact of technology both in terms of requirements to practice and expected impact of future technological development on the need for the proposed diploma.

A significant increase in the number of hematopoietic stem cell transplants is projected over the next 20 years owing to an increase in the number of patients eligible for transplantation, the rising age of recipients and the increased use of unrelated and alternative donors (ref. 5, 7, 8, 14, 17). In addition, a broadening of the indications is anticipated. The advent of targeted therapies, particularly for chronic myeloid leukemia, a disease which represented one of the most important indications for allogeneic transplants, has not halted the rise in the number of allogeneic transplants performed annually. The improvement in the response to treatment, following the development of new drugs, has increased the number of patients eligible for transplantation and transplantation outcomes. The best example is multiple myeloma, where autologous transplantation remains the standard intensity therapy after first-line therapy despite the introduction of second- and third-line therapies. The incidence of hematological cancers is constantly increasing. The advent of immunotherapy for cancer, particularly CAR-T cells, represents a development of cellular therapy inherent to hematopoietic stem cell transplantation. Since the concept of cells as therapeutic weapons is still in its infancy, the transplant hematologist's clinical training in apheresis and in the cellular therapy laboratory places him/her at the forefront of these technological developments.

7. Why is recognition by the Royal College essential for the success of the proposed diploma discipline?

In keeping with its mission, the Royal College of Physicians and Surgeons of Canada monitors compliance with teaching standards and the assessment of the knowledge and competencies of medical and surgical specialists, with the goal of ensuring that Canadians receive safe and high-level care. Recognition of certification in hematopoietic stem cell transplantation will contribute to improving recruitment and to standardizing practice through the adoption of a structured and uniform training program across Canada based on the needs and values of Canadians and on the development of the CanMEDS competencies.

In addition, as specialists, affiliation with the Royal College of Physicians and Surgeons of Canada is extremely significant and constitutes the reference standard for medical training activities. We feel it is important that this affiliation be reflected in a concrete way during our accreditation activities and in our relations with our care partners and our patients.

The RCPSC is an inspiring reference organization, with which candidates are proud to be associated. The Royal College is an invaluable reference in the development of medical practices, training activities and research.

Based on a systematic, professional, ethical and transparent approach, the AFC diploma in hematopoietic stem cell transplantation is inspired by the best practices of the Royal College of Physicians and Surgeons of Canada, with the goal of developing, in collaboration with our partners, the Université de Montréal and the CBMTG, a highly specialized curriculum and a dynamic training environment committed to achieving the highest medical, scientific, academic and humane competencies in the various aspects of medical activities in transplantation. Recognition of the certification program in hematopoietic stem cell transplantation by the Royal College of Physicians and Surgeons of Canada will thus constitute the ultimate way of recognizing, developing and promoting this area of focused competence in Canada.

8. What would be the projected effects on the Canadian health care system from the recognition of the proposed diploma discipline? Include both potential positive and negative impacts.

The recognition of this discipline should contribute to improving the efficiency of the Canadian health care system. Given the current worldwide shortage of transplanters (ref. 22), transplant hematologists are quickly recruited following completion of their training. In addition, there are long wait times for access to transplantation (ref. 18 and 21) across Canada and it is often necessary to transfer patients outside the province or to the United States in order to remedy these wait times. Stem cell transplantation constitutes a standard therapeutic approach for many hemopathies. Recognition of the discipline will standardize training and practice in Canada, will improve the recruitment and retention of hematologists who have acquired this expertise, and will contribute to improving access to care and the quality of care. Cellular therapy is a fertile and developing research field with emergence of new technologies and procedures that may have a positive impact on knowledge and on the Canadian economy.

In order to meet the needs of Canadians eligible for a stem cell transplant, the necessary resources must be allocated to support the facilities dedicated to this practice (space, beds, human resources and specific budgets). This could require a reorganization of care and a prioritization of treatment centres, indications, admissions, etc. This organizational aspect is an integral part of our reflections and of our action plan.

Ultimately, the improvement of practices in this field, already strongly focused on the monitoring of medical quality assurance and on compliance with policies and procedures, will have a positive impact on the health of the Canadian population.

9. Please identify Canadian organizations and stakeholders who should be consulted regarding this application. (Other than the groups identified in the Part II, Consultation section. The applicant is required to provide the names and addresses of the identified organizations and stakeholders.)

Canadian Blood and Marrow Transplant Group and its affiliated centres
Canadian Hematology Association
Canadian Blood Service
Héma-Québec
Canadian universities

DISCIPLINE SPECIFIC INFORMATION

A completed application form must include the following:

1. A draft version of the Competency Training Requirements (CTR) for the diploma discipline.

This document should describe the key competencies to be acquired. The CTR template is provided as an example and should be used as a guide. Please contact COS@royalcollege.ca for the latest version of the template.

See the Competency Training Requirements for the Area of Focused Competence in Hematopoietic Stem Cell Transplantation.

2. A document outlining the proposed strategy for the assessment of competencies to ensure that graduates of postgraduate training programs in this proposed diploma discipline are competent specialists.

This document must include:

- a) A list of possible assessment tools to comprise the summative portfolio.

A) Assessment form

The assessment form is inspired by the seven roles of the physician described in the CanMEDS framework of the Royal College of Physicians and Surgeons of Canada. Consequently, the training framework is focused on the acquisition of competencies and is supported by trajectories for the development of knowledge and competency in hematopoietic stem cell transplantation.

The assessment coordinator and the director of the hematopoietic stem cell transplantation program ask each faculty member involved in the training to complete an assessment form after each rotation that covers all the CanMEDS roles. The assessments are reviewed and discussed with the candidate and the faculty and by the assessment committee. The assessments are compiled and a summary assessment is completed every six months by the program director. Each summary assessment is reviewed and discussed with the resident/fellow and summarizes the knowledge and competencies acquired and includes all the CanMEDS competencies:

1. Medical Expert (central integrative role)
2. Communicator
3. Collaborator
4. Leader
5. Health Advocate
6. Scholar
7. Professional

This summative assessment serves as a basis in order to review the various competencies acquired, the strong points, any areas for improvement and the competencies to be attained, determine the training action plan and draw up a career plan.

OTHER ASSESSMENT PROCEDURES OF THE RESIDENT/FELLOW IN THE AREA OF FOCUSED COMPETENCE IN HEMATOPOIETIC STEM CELL TRANSPLANTATION

B) Interview

During the training, twice a year. The purpose of this interview is to verify the fellow's theoretical knowledge of the major topics specific to transplantation and to explore more complex elements of assessment and management and to verify certain intrinsic competencies (conflict situation in a team, basic principles of communication and effective collaboration, breaking bad news, etc.).

C) Descriptive and reflective portfolio

Residents must develop a portfolio of the pathologies to be covered and of the situations encountered in the course of training and which constitute a challenge for them in their training owing to their complexity, scarcity or interest. Monitoring the portfolio will also make it possible to identify any deficiencies in the resident's training. Elements of this portfolio will be discussed with the assessment coordinator during the assessment meetings, thus providing an opportunity to review certain areas of knowledge acquired or certain problems of the resident/fellow.

D) 360° assessment

This assessment will be completed twice a year. The assessment coordinator and the director of the training program in hematopoietic stem cell transplantation will include this assessment in one of the assessment meetings.

E) Assessment of the quality of communications and opportunities for learning (OFLs)

This point is the subject of constant vigilance by the rotation supervisors, in the various situations both with transplant recipients and their families and with the work teams and referring physicians. The resident's longitudinal clinic constitutes the ideal platform to provide immediate feedback on the handling of the consultation, on the summary of the consultation and the letter to the referring physician, on the relevance and clarity of written communications and, finally, on tumour board presentations.

F) Feedback during the interdisciplinary meetings and resident's mandatory oral presentations

The resident must give at least one conference, lead at least two interdisciplinary meetings and make at least four presentations during the transplantation journal club, in the form of a case study, scientific capsule, literature review and during the weekly interdisciplinary meetings of the transplantation program.

G) Assessment during the continuous quality improvement process

Residents must attend and participate in the meetings of the quality assurance committee of the transplantation program. They must also be familiar with the policies and procedures of the transplantation program and its quality assurance plan. The purpose of this committee is to establish, review and monitor the performance indicators of the transplantation program. All problems, incidents or

accidents related to the transplantation program are presented and discussed and a remediation plan is drawn up. The purpose of this committee is also to establish, review and update the policies and standard operating procedures (SOPs) of the transplantation program and to maintain the highest standards of practice in transplantation in compliance with the requirements of the accrediting bodies of transplantation programs, namely:

Health Canada and Accreditation Canada: <https://accreditation.ca>

"The Qmentum accreditation program is a four-year cycle of assessment and improvement, where organizations work to meet standards and raise the quality of services. The program identifies *and rewards competence and innovation, helping organizations to be more efficient.*"

FACT (Foundation for the Accreditation of Cellular Therapy): www.factwebsite.org - International accreditation organization in cellular therapy. Inspection visit every three years.

The director of the hematopoietic stem cell transplantation program, in conjunction with the program's quality advisor, ensures compliance with and monitoring of the specific standards of accreditation during the monthly meeting planned for this purpose, attended by the physicians in the transplantation program and members of the multidisciplinary team.

H) Evaluation of the quality of training and of the curriculum plan

A specific evaluation form (see appendix) is also completed by the residents (fellows) in order to solicit their comments and suggestions concerning the quality of the training program. The following aspects are evaluated: the curriculum structure and plan, the course content and learning targets, the training rotations, the instructors and teachers, the teaching methods and the program director.

3. Outline the implementation issues for the proposed diploma discipline. Include information on:

a) Number of sites capable of mounting a training program in Canada, including the number of training positions estimated at each site.

Some ten hematopoietic stem cell transplantation programs in Canada already have a training program and/or are interested in standardizing and securing recognition of this training and support the recognition of this discipline as an area of focused competence (see letters of support).

b) Please estimate the number of faculty currently available nationally with expertise in the proposed diploma discipline and identify where they are located across the country.

See the list of stem cell transplantation programs in the CBMTG registry (see page 20 of this document).

It is estimated that there are approximately 80 transplant hematologists in Canada active in these various programs.

c) What will be the funding implications for training opportunities?

Transplantation training programs are already active in various Canadian universities (Montréal, Laval, Halifax, Toronto, McMaster, Alberta, Manitoba and British Columbia) and at the national and international level. The recognition of this field of expertise by the Royal College will standardize the training, improve recruitment and contribute to addressing the shortage of transplanters, which will help improve access and care in hematopoietic stem cell transplantation. The recognition of this area of focused competence will also facilitate the allocation of resources specific to the discipline and can only be beneficial to its development and to the delivery of health care in hematopoietic stem cell transplantation.

d) Please describe any anticipated impacts on Postgraduate Medical Education or practice systems in any region.

This is a field of subspecialization of hematology which combines the clinical and laboratory sciences. Hematologists practising in transplantation programs are already required to possess expertise in these fields of practice in order to meet the standards of the accrediting bodies in transplantation and demonstrate maintenance of this knowledge and competencies through a rigorous process of continuing education. The recognition of this area of focused competence by the Royal College will promote the acquisition of these competencies and the development of resources in Canada.

APPENDICES

Appendix 3: Required/desirable training experiences, milestones, mandatory activities and documentation

REQUIRED TRAINING EXPERIENCES

1. Assess the eligibility of the pathology for transplantation and its curative potential.

Milestones:

Be familiar with the eligibility criteria of the pathologies for which hematopoietic stem cell transplantation is indicated (assessment of the risk factors related to the various hemopathies) and the outcomes in terms of progression-free survival, overall survival and relapse, in order to effectively inform candidates for transplantation and their families and support patients in their therapeutic decision.

Mandatory activities:

- 1.1. Assess patients referred to transplantation for various benign and malignant pathologies, determine the eligibility of the pathology for transplantation in light of the clinical history, pathology results, laboratory data and the evidence in the literature.
- 1.2. Present new cases to the tumour board and participate in the discussion to determine the eligibility of the pathology.
- 1.3. Write the consultation report intended for the referring physician, clearly explaining the reasons for the eligibility or non-eligibility of the pathology.
- 1.4. Attend the academic course reviewing the indications for hematopoietic stem cell transplantation.
- 1.5. Develop and maintain his/her knowledge about the indications of hematopoietic stem cell transplantation through readings and participation in scientific meetings and conventions.

Documentation to be submitted:

- 1.6. Consultation summaries (10) written in the patient's chart determining the eligibility or non-eligibility of the pathology.
- 1.7. Consultation letters (10) intended for the referring physician.
- 1.8. Summaries of presentations (10) to the transplantation tumour board.
- 1.9. Proof of attendance at the academic course on transplantation indications.
- 1.10. Confirmation of participation in two scientific meetings on transplantation annually.

2. Determine the eligibility of the transplant recipient and assess the risks and benefits of the procedure (comorbidities).

Milestones:

Be familiar with the eligibility criteria and exclusion criteria for transplant recipients, and the factors contributing to increased procedure-related risks.

Mandatory activities:

- 2.1. Assess the recipient, review the relevant medical and surgical history, family and psychosocial history, sexual contacts and high-risk practices, lifestyles and substance/drug use.
- 2.2. Determine the patient/recipient's procedure-related risk factors.
- 2.3. Determine the recipient's comorbidity index (HCT-CI) and the mortality related to this index.
- 2.4. Prescribe the pre-transplant work-up and the additional tests/examinations necessary to determine eligibility.
- 2.5. Rule out the exclusion criteria for hematopoietic stem cell transplantation.
- 2.6. Review and sign the pre-transplant work-ups and determine the recipient's eligibility or non-eligibility.

Documentation to be submitted:

- 2.7. Consultation summaries (10) written in the patient's chart determining the eligibility or non-eligibility of the transplant recipient.
- 2.8. Consultation letters (10) intended for the referring physician.
- 2.9. Document summarizing the comorbidity index score (HCT-CI score) (10).
- 2.10. Reviewed and signed pre-transplant work-ups (10) confirming the eligibility or non-eligibility of the transplant recipient.

3. Determine the donor's eligibility for donation.

Milestones:

Be familiar with the eligibility criteria for hematopoietic stem cell donors, the exclusion criteria for donation and the factors contributing to increased risks associated with stem cell donation.

Mandatory activities:

- 3.1. Assess the donor, review the relevant medical and surgical history, family and psychosocial history, sexual contacts and high-risk practices, lifestyles and substance/drug use.
- 3.2. Determine the donor's donation-related risk factors.
- 3.3. Prescribe the pre-donation work-up and the additional tests/examinations necessary to determine eligibility.
- 3.4. Rule out the exclusion criteria for hematopoietic stem cell donation.
- 3.5. Review and sign the pre-donation work-up and determine the eligibility or non-eligibility for donation.

Documentation to be submitted:

- 3.6. Donor assessment report (6).
- 3.7. Reviewed and signed pre-donation work-ups (6) confirming the donor's eligibility or non-eligibility for stem cell donation

4. Obtain consents for hematopoietic stem cell transplantation and donation.

Milestones:

Know how to explain clearly and concisely to a transplant recipient the rationale for hematopoietic stem cell transplantation as a therapeutic modality for the treatment of the patient's hemopathy, summarize what the procedure involves, the risks and benefits of the transplant, the expected outcomes, answer the patient's questions, and obtain free and informed consent.

Know how to explain clearly and concisely to the stem cell donor the health work-up preceding the hematopoietic stem cell donation, what the procedure involves, the risks associated with stem cell donation, the post-donation follow-up, answer the donor's questions, and obtain free and informed consent.

Mandatory activities:

- 4.1. Meet with the recipient, inform him/her about the transplantation procedure, explain the risks and benefits of the procedure, assist the patient in reading the consent forms, answer his/her questions and obtain consent.
- 4.2. Meet with the donor, inform him/her about the procedures, explain the risks associated with stem cell donation, assist the donor in reading the consent forms, answer his/her questions and obtain consent.
- 4.3. Review the consent forms and ensure that all questions were answered.
- 4.4. Review the exclusion criteria for donation and transplantation.
- 4.5. Countersign the consent forms.

Documentation to be submitted:

- 4.6. Completed and signed information and consent forms (6) for hematopoietic stem cell transplants (autologous (2) and allogeneic (4)).
- 4.7. Completed and signed information and consent forms for hematopoietic stem cell donation (6) (bone marrow harvesting in the operating suite (2) and harvesting of peripheral stem cells (4)).

5. Select the type of donor (autologous, allogeneic, related, unrelated, alternative) and the cell source (type of graft).

Milestones:

Understand the rationale for the selection of the donor in relation to the pathology to be treated and the urgency of performing the transplant. During the selection process, consider the availability of family or unrelated donors, HLA compatibility, gender, viral serologies and the blood groups of the donor and recipient, and select the best available donor. Once the donor is selected, prioritize the stem cell source (bone marrow, peripheral, cord blood) and complete the request for collection of the cell graft.

Mandatory activities:

- 5.1. Review the basic principles of the human histocompatibility system and HLA typing techniques in the histocompatibility laboratory, and participate in the donor selection decision-making processes.
- 5.2. Review the impact of HLA typing and antigen disparities on transplantation outcomes.
- 5.3. Understand the process involved in the search for related and unrelated donors and the disclosure of the results of this search by participating in the process of initiating the search (4) for donors by contacting the transplantation coordinators.
- 5.4. Understand the impact of CMV status and blood groups of the donor and recipient, gender, and number of previous pregnancies in the case of female donors, on the prioritization and selection of donors and transplantation outcomes.
- 5.5. Understand the impact of ABO incompatibilities between donor and recipient on the choice of the stem cell source.
- 5.6. Be familiar with and observe, in the cellular therapy laboratory, the processing required in connection with RBC depletion of the marrow graft (1) in the case of major ABO incompatibility between donor and recipient, and the impacts of this processing on graft cellularity.
- 5.7. Depending on the type of pathology and the availability of donors, select (10) the donor, record in the chart the rationale for the selection, and complete, sign and date the selection and stem cell request forms.

Documentation to be submitted:

- 5.8. Confirmation of training in the HLA laboratory, review of HLA typing (6) and (4) post-transplant chimerism study.
- 5.9. Donor selection file and forms (10).
- 5.10. Hematopoietic stem cell selection and request forms (10).
- 5.11. Confirmation of observation of RBC depletion of a marrow graft in the cellular therapy laboratory (CTL).

6. Supervise cell collection and graft transport, storage and cryopreservation when indicated, and evaluate the quality and safety of the cell graft.

Milestones:

Be familiar with the various methods of hematopoietic stem cell collection, the criteria for evaluating the cell graft and the number of cells required in order to perform a transplant depending on the type of graft.

Mandatory activities:

- 6.1. Understand the criteria authorizing the collection of hematopoietic stem cells and review the standard operating procedures describing the various steps in the collection of cell grafts using apheresis and by multiple bone marrow aspirations in the operating room.

- 6.2. Review the peripheral stem cell mobilization protocols and the rationale for the use of growth factors. Prescribe the mobilization (5).
- 6.3. Authorize and supervise (10) the collection of peripheral stem cells based on the CD34+ blood count and authorize the cessation of collection once a satisfactory cell graft has been obtained.
- 6.4. Participate in the collection of bone marrow grafts in the operating suite (2) and authorize the cessation of collection once a satisfactory marrow graft has been obtained.
- 6.5. Understand the criteria determining the eligibility of the graft for transplantation and the exceptional release and exclusion criteria.
- 6.6. Follow the trajectory of the cell graft, its transport, processing in the cellular therapy laboratory (determination of volume, anticoagulation, cell count and sterility study), storage and cryopreservation.
- 6.7. Observe the processing for determining the cell count of the graft (5) and the cryopreservation technique (2) in the CTL.

Documentation to be submitted:

- 6.8. Confirmation of training in the stem cell collection centre (apheresis).
- 6.9. Stem cell donors' follow-up record (10).
- 6.10. Confirmation of bone marrow harvesting (2) in the operating suite, operative report and donor post-op follow-up (2).
- 6.11. Confirmation of reading of the policies and procedures governing donor selection and stem cell collection and the factors authorizing infusion of the graft.
- 6.12. Confirmation of reading of the exceptional release policies and procedures.
- 6.13. Confirmation of training in the cellular therapy laboratory.

7. Determine and prescribe the transplantation conditioning regimen, and supervise its administration and the steps in the transplantation process.

Milestones:

Be familiar with the rationale for the selection of the transplantation conditioning regimen (myeloablative and nonmyeloablative) based on the type of pathology and the associated risks (benign or malignant disease, intermediate or high risk, myeloid or lymphoid pathology) and the recipient's risk factors (comorbidity index).

Mandatory activities:

- 7.1. Be familiar with the definition of the myeloablative and nonmyeloablative conditioning regimens.
- 7.2. Review the various transplantation conditioning regimens, the rationale for the use of radiation therapy in the conditioning regimen, the indications and contraindications of the various regimens and the associated complications (treatment-related mortality (TRM)).
- 7.3. Select the patient's transplantation conditioning regimen, describe the rationale for the selection and prescribe the conditioning regimen (10).

- 7.4. Review the prescriptions with the pharmacist specializing in transplantation (10), the dose and the drug interactions, and understand the pharmacokinetics (busulfan).
- 7.5. Supervise the administration of the conditioning regimen and monitor the complications.
- 7.6. Be familiar with the complications related to the various conditioning regimens, more particularly:
 - 7.6.1. Oral and intestinal mucositis
 - 7.6.2. Peri-transplant nutritional support and nutritional follow-up
 - 7.6.3. Cardiotoxicity, cardiopulmonary complications and volume management
 - 7.6.4. Interstitial pneumonitis
 - 7.6.5. Hepatotoxicity, hepatic complications and sinusoidal obstruction syndrome
 - 7.6.6. Nephrotoxicity and renal complications
 - 7.6.7. Hematologic toxicity and infectious and hemorrhagic complications
 - 7.6.8. Neurotoxicity

Documentation to be submitted:

- 7.7. Completed and signed transplantation conditioning protocol (10).
- 7.8. Confirmation of training in the inpatient transplantation unit with longitudinal management of the transplanted patient population.
- 7.9. Completed and signed transplantation summary (10) summarizing the steps in the procedure, including the diagnosis, disease status at transplantation, disease-related risk index, Karnofsky index, comorbidity index (HCT-CI), type of transplant, conditioning regimen, type of graft, graft cellularity, blood group and CMV status of the donor and recipient, viral serologies (HSV, VZV, toxoplasmosis), engraftment and post-transplant complications.

8. Prescribe the cell graft and supervise its administration.

Milestones:

Be familiar with the graft release criteria and prescribe the cell graft, volume, cellularity and administration technique, taking into account the ABO status of the donor and recipient. Supervise graft administration and be familiar with the management of adverse effects related to its administration.

Mandatory activities:

- 8.1. Prescribe and authorize the infusion of cell grafts composed of peripheral stem cells (6), bone marrow stem cells (2) and cord blood stem cells (2).
- 8.2. Supervise the infusion of grafts composed of peripheral stem cells (6), bone marrow stem cells (2) and cord blood stem cells (2).

- 8.3. Supervise the infusion of ABO incompatible grafts (2).
- 8.4. Supervise donor lymphocyte infusion (DLI) and the infusion of cellular therapy products.
- 8.5. Supervise the infusion of grafts with exceptional release (2) and document the reasons for this release in the medical chart. Verify and document the recipient's consent to receive the graft.
- 8.6. Document the engraftment criteria in the patient's medical chart (10) and determine the post-transplant monitoring of chimerism (4) when indicated.

Documentation to be submitted:

- 8.7. Prescriptions of the cell graft (10).
- 8.8. Completed and signed graft infusion form (10) and adverse effects form, when indicated.
- 8.9. Completed and signed transplantation summary and documentation of engraftment (10).

9. Determine and prescribe the anti-infectious prophylaxis and the immunosuppression regimen for prevention of graft-versus-host disease.

Milestones:

Be familiar with the immediate and late infectious risks associated with hematopoietic stem cell transplants (myeloablative and nonmyeloablative), with neutropenia, lymphopenia, mucositis, the presence of a central catheter and immunosuppressive therapy, and determine the anti-infectious prophylaxis to apply, taking into account the type of transplant (autologous, allogeneic), the conditioning regimen, the viral serologies of the donor and recipient, and the evidence in the literature.

Be familiar with the risk factors associated with the development of acute and chronic graft-versus-host (GVH) disease following allogeneic transplantation (intensity of the conditioning regimen, type of transplant, antigen disparity, type of graft, stem cell source, age and gender of donor and recipient) and determine the prophylaxis regimen to apply.

Mandatory activities:

- 9.1. Prescribe the anti-infectious prophylaxis (bacterial, viral and fungal) (10) in the transplantation protocol, taking into account the type of transplantation (autologous and allogeneic, related, unrelated, alternative), the conditioning regimen (myeloablative, reduced-intensity and nonmyeloablative) and the viral serologies. Review the viral serologies of the patient and donor, and record this information in the chart. Document the rationale for the recommendations.
- 9.2. Prescribe the appropriate microbiological and virological monitoring/tests and record this information in the chart.
- 9.3. Determine and prescribe the graft-versus-host disease prophylaxis regimen for hematopoietic stem cell transplant recipients (10), taking into account the type of transplant, conditioning regimen, stem cell source and antigen

disparities between donor and recipient, and record this information in the transplantation protocol. Document the rationale for the recommendations.

- 9.4. Obtain two signatures of the transplantation protocol as a reflection of the consensus of the medical and pharmaceutical team concerning the choice of anti-infectious and graft-versus-host disease prophylaxis.
- 9.5. Longitudinal follow-up of recipients and documentation of infectious complications and viral reactivation.
- 9.6. Management and treatment of post-transplant infectious complications:
 - 9.6.1. Febrile neutropenia
 - 9.6.2. Bacteremia and bacterial infection
 - 9.6.3. Fungal infection and aspergillosis
 - 9.6.4. Viral infection and CMV reactivation

Documentation to be submitted:

- 9.7. Completed and signed transplantation protocol, including anti-infectious and graft-versus-host disease prophylaxis (10).
- 9.8. Confirmation of training in the inpatient transplantation unit and longitudinal follow-up of recipients hospitalized in the peri- and post-transplantation period (10).
- 9.9. Confirmation of training in the transplantation outpatient clinic and longitudinal post-transplant follow-up of patients. Documentation of the management of infections and viral reactivations in the recipient (CMV, EBV, adenovirus, etc.) (10).

10. Determine the transfusion thresholds and prescribe the blood products and growth factors in support of the transplantation.

Milestones:

Know how to select the blood products to be administered to a hematopoietic stem cell transplant recipient and determine the post-transplant transfusion threshold, taking into account the type of transplant, the procedure-related risks, the ABO compatibility between donor and recipient, the presence of anti-blood group antibodies and previous transfusion reactions, anti-HLA antibodies, and the patient's clinical condition. Obtain consent to the transfusion of blood products. Be familiar with the rationale for the use of irradiated blood products.

Understand the rationale for the post-transplant use of growth factors to support hematological recovery, the dose and the side effects related to their use.

Mandatory activities:

- 10.1. Review the immunohematology concepts and the rationale behind the selection of blood products, considering the blood groups of the donor and recipient.
- 10.2. Understand the risks related to alloimmunization.
- 10.3. Review the risks related to major ABO incompatibility and document this information in the recipient's chart.

- 10.4. Ensure the monitoring and follow-up of recipients (2) with major ABO incompatibility with the donor and document any changes in immunohematological status in the chart and the change of blood group.
- 10.5. Determine the advisability of using a post-transplant growth factor, record the rationale in the patient's chart and prescribe the growth factor.

Required documentation:

- 10.6. Monitoring form for recipients (2) with major ABO incompatibility with the recipient [Tr. sic: donor?].
- 10.7. Monitoring form for recipients (2) with anti-HLA antibodies.
- 10.8. Prescription form for post-transplant growth factors and rationale for the use of these factors.

11. Monitor immunosuppression following allogeneic transplantation.

Milestones:

Be familiar with the mechanisms of action of the various classes of immunosuppressant drugs, dosage, monitoring, duration of treatment, drug interactions and side effects, and the rationale for their use in the prevention of rejection and of graft-versus-host disease following allogeneic transplantation, taking into account the type of allogeneic transplantation (related, unrelated, haploidentical and cord blood), the conditioning, the stem cell source and the evidence in the literature.

Mandatory activities:

- 11.1. Review the various classes of immunosuppressant drugs, their mechanism of action, dosage, combinations, drug interactions, monitoring and side effects.
 - 11.1.1. Calcineurin inhibitors (cyclosporin and tacrolimus)
 - 11.1.2. Antimetabolites and alkylating agents (methotrexate, cyclophosphamide)
 - 11.1.3. Mycophenolate mofetil
 - 11.1.4. Monoclonal antibodies (ATG, alemtuzumab, rituximab, daclizumab, etanercept, etc.)
 - 11.1.5. Corticosteroids
 - 11.1.6. Rapamycin
 - 11.1.7. Proteasome inhibitors: bortezomid, ixazomib
 - 11.1.8. Tyrosine kinase inhibitors: imatinib, ruxolotinib, ibrutinib
 - 11.1.9. Extracorporeal photopheresis (ECP)
- 11.2. Understand the rationale for the monitoring of immunosuppressant drugs, their therapeutic level and dose adjustment, and monitor immunosuppression in recipients (10).
- 11.3. Be familiar with the duration of treatment and the rationale for tapering and discontinuation of immunosuppression.

- 11.4. Understand the concepts of alloreactivity and immunologic tolerance and the immunological concept behind the graft-versus-leukemia (GVL) reaction.

Documentation required:

- 11.5. Form for monitoring and adjusting immunosuppression in recipients (10) following related and unrelated allogeneic transplantation.
- 11.6. Form for tapering of immunosuppression for related (5) and unrelated (5) allogeneic transplant recipients, prescription and rationale for the discontinuation of immunosuppression.

12. Diagnose and treat graft-versus-host disease.

Milestones:

Be familiar with the risk factors, clinical signs, investigation, diagnostic criteria, grading and treatment of acute and chronic graft-versus-host disease following allogeneic hematopoietic stem cell transplantation.

Mandatory activities:

- 12.1. Be familiar with and determine the risk factors associated with the development of acute graft-versus-host disease in recipients of a related (4), unrelated (4), haploidentical (2) or cord blood (2) allogeneic transplant, and record the risk in the patient's chart.
- 12.2. Be familiar with and determine the risk factors associated with the development of chronic graft-versus-host disease in recipients of a related (4), unrelated (4), haploidentical (2) or cord blood (2) allogeneic transplant, and record the risk in the patient's chart.
- 12.3. Review the risk factors for the development of acute graft-versus-host disease:
 - 12.3.1. Type of allogeneic transplant
 - 12.3.2. Type of conditioning
 - 12.3.3. Type of GVH prophylaxis
 - 12.3.4. Stem cell source
 - 12.3.5. Histocompatibility
 - 12.3.6. Age and gender of donor and recipient
 - 12.3.7. Viral serologies
- 12.4. Review the risk factors for the development of chronic graft-versus-host disease:
 - 12.4.1. Type of allogeneic transplant
 - 12.4.2. Stem cell source
 - 12.4.3. Histocompatibility
 - 12.4.4. Use of ATG
 - 12.4.5. Development of acute GVH disease

- 12.4.6. Age of donor and recipient
- 12.5. Be familiar with the classification and grading (Glucksberg and NIH) of acute and chronic GVH disease.
- 12.6. Be familiar with the treatment standards for acute and chronic GVH disease and the risks associated with the development of graft-versus-host disease.

Documentation required:

- 12.7. Monitoring forms for allogeneic transplant recipients (4) who have developed acute graft-versus-host (GVH) disease, investigation, diagnosis, grading, management, therapeutic decision and clinical follow-up.
- 12.8. Monitoring forms for allogeneic transplant recipients (4) who have developed chronic GVH disease, investigation, diagnosis, grading, management, therapeutic decision and clinical follow-up.

13. Provide follow-up of donors and assess the impact of the donation on the donor's health status and quality of life.

Milestones:

Be familiar with the immediate and delayed risks for the stem cell donor associated with the donation of peripheral or bone marrow hematopoietic stem cells and with exposure to growth factors, and provide immediate and annual post-donation follow-up.

Mandatory activities:

- 13.1. Provide immediate and annual post-donation follow-up of peripheral stem cell donors (5). Verify that there are no adverse effects related to cell collection or exposure to growth factors.
- 13.2. Provide follow-up of bone marrow stem cell donors (2) immediately, 24 hours and one week after donation; ensure that the hematological parameters are corrected and that there are no adverse effects in the short, medium and long term.

Documentation required:

- 13.3. Post-donation monitoring form for peripheral stem cell donors (5).
- 13.4. Post-donation monitoring form for bone marrow stem cell donors (2).

14. Provide follow-up of the recipient, propose preventive measures in order to prevent complications and treat the immediate and late complications.

Milestones:

Be familiar with the immediate and late risks associated with autologous, allogeneic, related and unrelated hematopoietic stem cell transplantation, and provide diagnosis, treatment and follow-up. Be familiar with the immediate and late risks related to the various transplantation conditioning regimens, stem cell source, immunosuppression

and graft-versus-host disease, and provide diagnosis, treatment and follow-up. Propose preventive measures to reduce the risks of developing certain complications.

Mandatory activities:

- 14.1. Provide longitudinal follow-up of autologous (5) and allogeneic (5) stem cell transplant recipients and monitor their progress.
- 14.2. Be familiar with, diagnose and treat immediate and late post-transplant problems and complications.
 - 14.2.1. Infectious
 - 14.2.2. Organ involvement
 - 14.2.3. Secondary to acute and chronic GVH disease
 - 14.2.4. Secondary to immunosuppression
 - 14.2.5. Secondary to corticosteroid therapy
 - 14.2.6. Relapse
 - 14.2.7. Development of secondary cancer
 - 14.2.8. Psychosocial problems and mental health disorders
- 14.3. Be familiar with the risk factors of post-transplant relapse related to the initial pathology, monitor the disease, diagnose and treat the relapse if it occurs.
- 14.4. Be familiar with the efficacy, risks and role of donor lymphocyte infusion (DLI) to treat relapse following allogeneic transplantation.
- 14.5. Be familiar with, authorize, prescribe and supervise the post-transplant vaccination program for autologous (5) and allogeneic (5) transplant recipients.
- 14.6. Inform the recipient about the importance of maintaining a healthy lifestyle following transplantation and apply the preventive measures recommended in the screening and diagnosis of secondary events.
- 14.7. Assess the development of physical and psychological signs and symptoms.
- 14.8. Be familiar with and administer the questionnaires for assessing post-transplant quality of life and apply the support measures appropriate to the patient's condition.

Documentation required:

- 14.9. Confirmation of participation in the longitudinal follow-up clinic for patients who have received a hematopoietic stem cell transplant.
- 14.10. Development of a personal longitudinal clinic for the management and prospective monitoring of patients who have received an autologous (4) or allogeneic (related (4), unrelated (4) and alternative (2) (haploidentical and cord blood) transplant.
- 14.11. Development of a portfolio describing the various complications (6) that were diagnosed and managed in the longitudinal clinic.

15. Contribute to the advancement of the discipline by participating in the academic, training and research activities.

Milestones:

Carry out three academic activities in the field of hematopoietic stem cell transplantation.

Mandatory activities:

- 15.1. In the course of training, present a scientific article of interest (4) in the field of hematopoietic stem cell transplantation at the transplantation journal club.
- 15.2. In the course of training, give a scientific conference on a topic of interest in hematopoietic stem cell transplantation.
- 15.3. In the course of training, participate in the development, implementation and dissemination of a research project in hematopoietic stem cell transplantation.
- 15.4. In the course of training, attend and participate in the meetings of the quality assurance committee in hematopoietic stem cell transplantation.
- 15.5. In the course of training, read the policies and procedures of the transplantation program, the quality assurance plan and the monitoring of quality indicators.

Documentation to be submitted:

- 15.6. Articles (4) presented at the journal club; summary of the article.
- 15.7. Scientific presentation and references that contributed to the development of the presentation.
- 15.8. Research proposal or funding application to research institutions. Abstract submitted to a convention or article submitted for publication.
- 15.9. Proof of attendance at the meetings (4) of the quality assurance committee.
- 15.10. Signature attesting that the candidate has read the policies and procedures and the quality assurance plan of the transplantation program.

RECOMMENDED TRAINING EXPERIENCES

- 1. Be familiar with the prognostic impact of cytogenetic abnormalities and molecular markers as risk factors associated with hemopathies and their impact on eligibility for transplantation.**

Milestones:

Understand the importance of cytogenetic and molecular abnormalities as prognostic factors of malignant hemopathies and the need to include them in the decision-making process for determining eligibility for transplantation.

Mandatory activities:

- 1.1 Review the main cytogenetic and molecular abnormalities of malignant myeloid and lymphoid hemopathies and the associated classification systems.
- 1.2 Review and understand the various cytogenetic and molecular analysis techniques.
- 1.3 Review the principles of minimal residual disease (MRD), its importance in the follow-up of certain hemopathies, and the techniques for assessing MRD and quality control techniques.

Documentation to be submitted:

- 1.4 Confirmation of training in the cytogenetics and molecular biology laboratory.
- 1.5 Karyotyping.

2. Be familiar with the various techniques for the evaluation, selection, expansion and storage of cellular therapy products, quality controls and management of the cellular therapy laboratory.

Milestones:

Review and understand the techniques used in the evaluation of cell grafts, cell selection and expansion techniques, and essential quality control steps. Be familiar with the basic principles of the management of cellular products and of the cellular therapy laboratory.

Mandatory activities:

- 2.1 Participation in the routine activities of the CTL.
- 2.2 Participation in the evaluation of the CD34 count of a peripheral stem cell graft, a marrow graft and a cord blood graft.
- 2.3 Participation in CD34+ selection of a graft.
- 2.4 Participation in T-cell depletion.
- 2.5 Participation in cell expansion.

Documentation to be submitted:

- 2.6 Confirmation of training in the cellular therapy laboratory.
- 2.7 Confirmation of participation in the stem cell evaluation of a graft, in CD34+ selection and in a culturing and expansion technique.
- 2.8 Review of the standardized technique for evaluation of blood and bone marrow CD34+.

3. Be familiar with the foundations of clinical research and the principles inherent to the development of a research project and to the drafting of a funding application or article.

Milestones:

Understand the ethical principles related to clinical research, and the steps leading to the development and drafting of a research project.

Mandatory activities:

- 3.1 Training modules on research ethics.
- 3.2 Course module on professional practice in research.
- 3.3 Drafting of a research project proposal.

Documentation to be submitted:

- 3.4 Confirmation of successful completion of the module on research ethics.
- 3.5 Presentation of a research proposal.

4. Be familiar with the specific manifestations of the various organs and systems and the therapeutic approach to chronic graft-versus-host disease.

Milestones:

Be familiar with the various targeted clinical manifestations of chronic GVH disease and its complications, their presentation, and the diagnostic and therapeutic approach involving the following systems:

- a. Skin and mucous membranes
- b. Ocular system
- c. Digestive system
- d. Reproductive system
- e. Locomotor system

Be familiar with the principles and goals of long-term follow-up clinics and their role in the prevention and screening of secondary events.

Mandatory activities:

- 4.1 Participation in the various specialized clinics.
- 4.2 Participation in the longitudinal clinic for assessment and management of graft-versus-host disease.
- 4.3 Participation in the long-term follow-up clinic.

Documentation to be submitted:

- 4.4 Confirmation of participation in the various specialized clinics.
- 4.5 Portfolio of cases of ocular, cutaneous, gastrointestinal and gynecological chronic GVH disease (6) assessed and treated.

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VERSION 1.0

NOTE: Throughout this document, references to the patient's family are intended to include all those who are personally significant to the patient and are concerned with his or her care, including, according to the patient's circumstances, family members, partners, caregivers, legal guardians, and substitute decision-makers.

DEFINITION

Hematopoietic stem cell transplantation is that area of enhanced competence within hematology concerned with the use of hematopoietic cells in the treatment of pediatric and adult hematological diseases and cancers. Cellular therapy relies on knowledge of the stem cell and its environment, of hematopoietic precursors and progenitors, of the human immune and histocompatibility system, and of techniques for cell evaluation, collection, preservation and administration for therapeutic purposes. Upon completion of training, candidates for the AFC diploma in hematopoietic stem cell transplantation will have acquired the basic, theoretical and practical knowledge as well as the foundations in research in connection with the discipline in order to support their practice as experts in this field.

ELIGIBILITY REQUIREMENTS

The Area of Focused Competence (AFC) trainee must have Royal College certification in hematology, or enrolment in a Royal College accredited residency program in this area (see requirements for these qualifications). All trainees must be certified in their primary specialty in order to be eligible to submit a Royal College certification portfolio in hematopoietic stem cell transplantation.

MAJOR TASKS IN HEMATOPOIETIC STEM CELL TRANSPLANTATION

The discipline of hematopoietic stem cell transplantation includes the following responsibilities:

- Assess the eligibility of the pathology for transplantation and its curative potential.
- Determine the eligibility of the transplant recipient and assess the risks and benefits of the procedure (comorbidities).
- Determine the donor's eligibility for donation.
- Obtain consents for hematopoietic stem cell transplantation and donation.
- Select the type of donor (autologous, allogeneic, related, unrelated, alternative) and the cell source (type of graft).

*COMPETENCY TRAINING REQUIREMENTS IN HEMATOPOIETIC STEM CELL
TRANSPLANTATION (2016)*

- Supervise cell collection and graft transport, storage and cryopreservation when indicated, and evaluate the quality and safety of the cell graft.
- Determine and prescribe the transplantation conditioning regimen, and supervise its administration and the steps in the transplantation process.
- Prescribe the cell graft and supervise its administration.
- Determine and prescribe the anti-infectious prophylaxis and the immunosuppression regimen for prevention of graft-versus-host disease.
- Determine the transfusion thresholds and prescribe the blood products and growth factors in support of the transplantation.
- Monitor immunosuppression following allogeneic transplantation.
- Diagnose and treat graft-versus-host disease.
- Provide follow-up of donors and assess the impact of the donation on the donor's health status and quality of life.
- Provide follow-up of the recipient, propose preventive measures in order to prevent complications and treat the immediate and late complications.
- Contribute to the advancement of the discipline by participating in the academic, training and research activities.

Medical Expert

Definition:

As Medical Experts, physicians integrate all of the CanMEDS Roles, applying medical knowledge, clinical skills, and professional values in their provision of high-quality and safe patient-centred care. Medical Expert is the central physician Role in the CanMEDS Framework and defines the physician's clinical scope of practice.

Key and Enabling Competencies: Hematopoietic stem cell transplantation diplomates are able to...

- 1. Practise medicine within their defined scope of practice and expertise in hematopoietic stem cell transplantation.**
 - 1.1. Function effectively as a consultant in transplantation in order to provide optimal, ethical and patient-centre medical care.
 - 1.2. Perform complete and appropriate assessments relevant to transplantation and develop a care plan that meets the expectations of candidates for transplantation and their families.
 - 1.3. Conduct a psychosocial assessment of the life setting of candidates for transplantation in order to provide the support that they need.
 - 1.4. Manage the care of transplant patients and their families using a multidisciplinary approach that respects the psychosocial and cultural aspects and legal and ethical issues related to transplantation and that meets the needs of patients and their families.

*COMPETENCY TRAINING REQUIREMENTS IN HEMATOPOIETIC STEM CELL
TRANSPLANTATION (2016)*

- 1.5. Make effective use of interventions for the diagnosis, treatment and prevention of complications in transplantation while ensuring that donors/recipients have an adequate understanding of the transplantation-related procedures and processes (completion of consent forms).
- 1.6. Use both diagnostic and therapeutic intervention techniques proficiently and appropriately.
- 1.7. Acquire, maintain and apply basic, theoretical and clinical knowledge, as well as specialized skills and competencies in transplantation.
- 1.8. Apply the concepts of continuing medical education in order to implement a personal program to keep up to date and enhance areas of knowledge and competence in transplantation.
- 1.9. Contribute to the enhancement of quality care and patient safety in stem cell transplantation by applying available best evidence and adopting best practices.
- 1.10. Consult, as needed, other health care professionals whose expertise is required for comprehensive patient management (related specialties; multidisciplinary team).

Communicator

Definition:

As Communicators, physicians form relationships with patients and their families that facilitate the gathering and sharing of essential information for effective health care.

Key and Enabling Competencies: Hematopoietic stem cell transplantation diplomates are able to...

- 1. Establish professional therapeutic relationships with transplant patients and their families.**
 - 1.1. Establish therapeutic relationships characterized by trust and high ethical standards with candidates for transplantation and their families.
 - 1.2. Collect and effectively summarize information relevant to the patient's condition.
 - 1.3. Solicit and be receptive to the opinions, hopes and fears expressed by patients and their families, and validate the assessments of colleagues and other professionals who interacted with patients (nurse navigator, social worker, dietician, psychologist and psychiatrist).
 - 1.4. Accurately convey relevant information and necessary explanations to transplant patients, their families, referring physicians, colleagues and other professionals.
 - 1.5. Establish a common understanding of the risks and benefits related to procedures as well as of the treatment plan with patients, their families, colleagues and other professionals concerned, in order to draw up a comprehensive shared care plan.
 - 1.6. Effectively convey and document verbal, written and electronic information in order to optimize patient management, ensure patient safety and maintain confidentiality.
 - 1.7. Provide consistent and efficient follow-up on consultations and medical referrals in a timely and respectful manner.

Collaborator

Definition:

As Collaborators, physicians work effectively with other health care professionals to provide safe, high-quality, patient-centred care.

Key and Enabling Competencies: Hematopoietic stem cell transplantation diplomates are able to...

1. Work effectively with physicians and other colleagues in the health care professions.

- 1.1. Participate effectively and appropriately in the activities of a multidisciplinary health care team.
- 1.2. Be familiar with and respect the individual roles, and collaborate effectively with other health care professionals in order to prevent conflicts.
- 1.3. Be familiar and work with regulatory bodies, community organizations and other professionals or organizations that work on behalf of and support transplant patients and their families.
- 1.4. Participate in activities that contribute to the organizational effectiveness of the health care system for transplant patients (multidisciplinary meetings and conflict resolution).
- 1.5. Manage their practice and career effectively, while balancing career goals and personal life.
- 1.6. Make judicious use of the health care sector's limited resources.
- 1.7. Serve in administrative and leadership roles, as required.
- 1.8. Effectively coordinate admissions and discharges in the treatment unit.
- 1.9. Demonstrate safe handover of care of transplant patients and ensure continuity of care outside the hospital setting through judicious use of community resources (CLSCs, "Maison des greffés" [subsidized accommodation for transplant patients and their families], organization of home care).
- 1.10. Have the necessary knowledge to make judicious use of electronic tools and resources for the transfer of information.

Leader

Definition:

As Leaders, physicians engage with others to contribute to a vision of a high-quality health care system and take responsibility for the delivery of excellent patient care through their activities as clinicians, administrators, scholars, or teachers.

Key and Enabling Competencies: Hematopoietic stem cell transplantation diplomates are able to...

1. Contribute to the improvement of health care delivery in hematopoietic stem cell transplantation in teams, organizations, and systems.

- 1.1. Promote an expert, evidence-based practice in transplantation that respects the individuality of each candidate for transplantation.
- 1.2. Actively participate in the effective management of resources in transplantation and in compliance with standards and patient safety.
- 1.3. Adopt an exemplary clinical practice in transplantation.
- 1.4. Manage, harmoniously and with integrity, their career plan in transplantation and human, material and financial resources in professional practice.

Health Advocate

Definition:

As Health Advocates, physicians contribute their expertise and influence as they work with communities or patient populations to improve health. They work with those they serve to determine and understand needs, speak on behalf of others when required, and support the mobilization of resources to effect change.

Key and Enabling Competencies: Hematopoietic stem cell transplantation diplomates are able to...

1. Respond to the transplant patient's health needs by advocating with the patient within and beyond the clinical environment.

- 1.1. Respond to the health needs and problems of patients with benign and malignant hemopathies, particularly those for whom hematopoietic stem cell transplantation is the only therapeutic option with curative intent.
- 1.2. Respond to the needs of candidates for transplantation and their families (training sessions for patients and their families, discussion forums, information about indications for referring physicians).
- 1.3. Identify and promote the determinants of health of transplant patients.
- 1.4. Promote healthy lifestyles and attitudes in order to reduce the risk of peri- and post-transplant complications and engage in community awareness-raising about these issues (vaccination, healthy diet, exercise program and long-term follow-up and prevention clinic).

Scholar

Definition:

As Scholars, physicians demonstrate a lifelong commitment to excellence in practice through continuous learning and by teaching others, evaluating evidence, and contributing to scholarship.

Key and Enabling Competencies: Hematopoietic stem cell transplantation diplomates are able to...

1. Engage in the continuous enhancement of their professional activities in hematopoietic stem cell transplantation through ongoing learning.

- 1.1. Maintain and enhance professional activities through ongoing learning.
- 1.2. Critically evaluate medical information and its sources, and apply this to transplantation practice-related decisions.
- 1.3. Facilitate knowledge acquisition and transmission for patients, their families, students, residents, other health care professionals, the public and other stakeholders (continuing medical education sessions).
- 1.4. Contribute to the creation, dissemination, application and use of expert, innovative medical knowledge and practices in transplantation and promote them.

Professional

Definition:

As Professionals, physicians are committed to the health and well-being of individual patients and society through ethical practice, high personal standards of behaviour, accountability to the profession and society, physician-led regulation, and maintenance of personal health.

Key and Enabling Competencies: Hematopoietic stem cell transplantation diplomates are able to...

1. Demonstrate a commitment to transplant patients by applying best practices and adhering to high ethical standards.

- 1.1. Demonstrate a commitment to patients and their families, their profession and society through ethical practice in compliance with the standards governing hematopoietic stem cell transplantation.
- 1.2. Demonstrate a commitment to transplant patients, their profession and society by participating in physician-led regulation.

RECOMMENDED TRAINING EXPERIENCES

- 1. Be familiar with the prognostic impact of cytogenetic abnormalities and molecular markers as risk factors associated with hemopathies and their impact on eligibility for transplantation.**

Mandatory activities:

- 1.1. Review the main cytogenetic and molecular abnormalities of malignant myeloid and lymphoid hemopathies and the associated classification systems.
 - 1.2. Review and understand the various cytogenetic and molecular analysis techniques.
 - 1.3. Review the principles of minimal residual disease (MRD), its importance in the follow-up of certain hemopathies, and the techniques for assessing MRD and quality control techniques.
- 2. Be familiar with the various techniques for the evaluation, selection, expansion and storage of cellular therapy products, quality controls and management of the cellular therapy laboratory.**

Mandatory activities:

- 2.1. Participation in the routine activities of the CTL.
 - 2.2. Participation in the evaluation of the CD34 count of a peripheral stem cell graft, a marrow graft and a cord blood graft.
 - 2.3. Participation in CD34+ selection of a graft.
 - 2.4. Participation in T-cell depletion.
 - 2.5. Participation in cell expansion.
- 3. Be familiar with the foundations of clinical research and the principles inherent to the development of a research project and to the drafting of a funding application or article.**

Mandatory activities:

- 3.1. Training modules on research ethics.
 - 3.2. Course module on professional practice in research.
 - 3.3. Drafting of a research project proposal.
- 4. Be familiar with the specific manifestations of the various organs and systems and the therapeutic approach to chronic graft-versus-host disease.**

Mandatory activities:

- 4.1. Participation in the various specialized clinics.
 - 4.2. Participation in the longitudinal clinic for assessment and management of graft-versus-host disease.
 - 4.3. Participation in the long-term follow-up clinic.