

## GUIDELINES

# American Society of Blood and Marrow Transplantation Guidelines for Training in Hematopoietic Progenitor Cell Transplantation

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Advances in hematopoietic progenitor cell transplantation (HCT) have led to an increasing number of transplantations and a concomitant requirement for physicians skilled in transplantation care. Guidelines for training HCT physicians were published in 2001; however, the past decade has seen a rapid expansion of the medical knowledge and skill set that these physicians need to deliver the highest quality of care. Recognizing the importance of education for transplantation programs, the American Society of Blood and Marrow Transplantation established a Committee on Education in 2010. The Committee's updated guidelines presented here provide an extensive and detailed framework for use by HCT educators and directors in developing HCT training programs and evaluating and mentoring their trainees.

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## INTRODUCTION

Hematopoietic progenitor cell transplantation (HCT) offers the best chance for cure and/or long-term survival for a broad range of diseases, including hematologic malignancies, bone marrow failure states, immunodeficiencies, and inherited metabolic disorders. From the pioneering clinical efforts of Thomas and others and subsequent efforts culminating in the first successful HLA-matched HCT in 1967 [1], a stream of scientific advances has facilitated clinical breakthroughs in autologous and allogeneic HCT. This has led to a dramatic increase in transplantation volume with more than 50,000 HCTs performed worldwide in 2008 [2]. Nearly 17,000 of these trans-

plantations were performed in North America, including approximately 10,300 autologous HCTs and 6,700 allogeneic HCTs [2]. With increasing numbers of patients medically eligible for HCT, this growth is expected to continue, with the National Marrow Donor Program (NMDP) estimating that we will witness an additional 30%-50% increase in autologous and allogeneic HCT volume and an expected doubling of unrelated and alternative donor HCT volume, by 2015.

## REVISION OF TRAINING GUIDELINES

A primary objective of the American Society for Blood and Marrow Transplantation (ASBMT) is to ensure the highest quality of medical practice in patients undergoing HCT. Given the continued increases in the number of patients requiring HCT, transplantation centers will require a parallel increase in the number of physicians skilled in HCT care. On 2 previous occasions, the ASBMT has developed and published brief guidelines outlining cognitive and procedural skills necessary for providing optimal care for HCT recipients [3,4]. In response to the growing demand for transplantation physicians and the progressive complexity of HCT care, an increasing number of centers have developed dedicated educational programs to train adult and pediatric HCT physicians. In recognition of the importance of education in ensuring the future success of HCT programs, the ASBMT established a Committee on Education in 2010. One of the first priorities of this

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new Committee was to revisit and expand guidelines for HCT training programs. Although HCT training does not currently lead to certification by the Accreditation Committee on Graduate Medical Education (ACGME) [5], the Committee recognized the importance of aligning recommendations to the 6 areas of Core Competencies defined by the ACGME, given the widespread adoption of ACGME core competency frameworks for the establishment and review of educational training programs at academic medical centers.

## GENERAL ASBMT REQUIREMENTS FOR TRAINING PROGRAMS

It is the ASBMT's position that all physicians performing peripheral blood, cord blood, and bone marrow transplantations must be licensed to practice medicine and should be board certified or eligible and have the requisite training and experience in hematology, medical oncology, immunology, and/or pediatric hematology/oncology. In addition, physicians performing HCT must receive specific training in the cognitive and procedural areas listed below. This training should be conducted in a program compliant with the ASBMT Guidelines for Clinical Centers and accredited by the Foundation for the Accreditation of Cell Therapy (FACT) or an equivalent accreditation program. The ASBMT recommends at least 12 months of HCT-specific training for a physician planning a career in transplantation, along with additional clinical mentoring by an experienced transplantation physician as part of the career development of a junior faculty member.

## CURRICULUM GOALS

The training curriculum should provide a systematic framework for advanced training in the field of HCT. Academic training programs should ensure the highest quality of medical practice in HCT, while providing a rigorous educational environment for scientific and clinical training. The training should include clinical excellence in the nontransplantation management of relevant diseases as well.

## MENTORING

In addition to the curriculum, a key component of any training program is effective mentoring. Each trainee should have at least one primary mentor throughout the training period. However, it is being increasingly recognized that one mentor is unlikely to be able to provide guidance in all areas, and that a team of mentors is optimal whenever possible. The mentor(s) should meet on a frequent basis with the trainee to monitor progress in each of the core competencies and to

address issues related to balancing a demanding career with non-work-related responsibilities.

## EDUCATIONAL GOALS

By the completion of HCT training, trainees should have achieved the following goals:

- Develop a sound understanding of underlying pathophysiological principles of HCT, including those of hematopoiesis and immunology.
- Become clinically competent in the care of adult and/or pediatric patients with nonmalignant and malignant disorders treated by HCT.
- Achieve competency in the procedural and technical skills required in the evaluation and care of HCT recipients.

## SPECIFIC EDUCATIONAL OBJECTIVES FOR HCT TRAINING BY ACGME CORE COMPETENCY

### I. Medical Knowledge

Trainees must demonstrate knowledge about established and evolving biomedical, clinical, and cognate (eg, epidemiologic and social behavioral) sciences) and the application of this knowledge to patient care. They are expected to demonstrate an investigatory and analytical thinking approach to clinical situations and to know and apply the basic and clinically supportive sciences appropriate to transplantation.

Trainees should have an appreciation of the history and evolution of HCT as a therapeutic modality, to understand the translation of basic science discoveries into clinical practice and the importance of carefully designed clinical trials that further our understanding of the application of HCT as a therapeutic modality for both malignant and nonmalignant disorders. Trainees should understand the underlying pathophysiological principles of HCT, including hematopoiesis and immunology, as well as the indications, evaluation, management, and outcomes for the diseases treated with HCT, and be able to compare non-HCT therapeutic options and outcomes with those of HCT. They should also know the indications for autologous and allogeneic-related and unrelated HCT, along with the differences in patient management, complications, and outcomes by donor source and conditioning regimen, and be able to appropriately evaluate a potential HCT recipient and donor. The trainee must be able to counsel patients about the early and late complications of HCT, including monitoring, diagnosis, and management, and implement an appropriate plan for post-HCT care. Finally, an integral part of an HCT physician's knowledge base includes the ordering and interpretation of clinical laboratory tests and procedures and the appropriate use of

medications, blood products, and chemotherapy and immunotherapy for optimal care of HCT recipients.

The HCT trainee should meet all the following specific objectives related to medical knowledge:

#### A. Pathophysiological principles

##### 1. Hematopoiesis

- Types of hematopoietic stem cells, including pluripotent versus committed progenitors
- Basics of hematopoietic differentiation
- Engraftment of transplanted hematopoietic stem cells

##### 2. Basic immunology

- Major histocompatibility complex function, tissue distribution, and genetics
- Lymphoid development
- T cell, B cell, and natural killer cell biology and functions
- Immunologic memory
- Antigen presentation, antigen-presenting cells, and antigen receptors
- Principles of innate immunity
- Natural and induced T regulatory cells
- Immune reconstitution posttransplantation
- Data supporting/not supporting graft-versus-leukemia/lymphoma effect in allogeneic HCT

#### B. Indications for HCT (adult and pediatric)

1. Acute and chronic leukemias
2. Myeloproliferative and myelodysplastic syndromes
3. Plasma cell dyscrasias
4. Lymphoproliferative diseases
5. Paroxysmal nocturnal hemoglobinuria
6. Aplastic anemia and other marrow failure states
7. Solid tumors
8. Autoimmune disorders
9. Hemoglobinopathies
10. Pediatric metabolic disorders
11. Pediatric primary immune deficiencies, including severe combined immunodeficiency and non-severe combined immunodeficiency forms

#### C. Pre-HCT evaluation of recipients and donors

1. Recipient disease staging
2. Evaluation of recipient comorbidities
3. Donor selection, evaluation of suitability for donation, and ethical issues pertaining to donor choice
4. Stem cell mobilization and collection from peripheral blood and bone marrow
5. Selection and understanding of conditioning regimens
6. Planning for posttransplantation therapy if indicated (eg, radiation therapy, maintenance therapy).
7. Assessment of a patient's caregiver situation and availability of adequate resources

#### D. Pathophysiology, diagnosis, evaluation, and management of early HCT issues

1. Management of hematopoietic cell infusion toxicities and guidelines for infusion of ABO-incompatible cell components
2. Principles of infection control (eg, environment, diet, handwashing, masks)
3. Fungal, viral, and bacterial prophylaxis
4. Short-term complications and an understanding of the relative frequencies of each in terms of different conditioning regimens and immunosuppressive therapies, including:
  - Mucositis (preventative strategies, evaluation, scoring, and therapy)
  - Infections (evaluation, diagnosis and therapy of all fungal, viral [including cytomegalovirus, human herpes virus 6, adenovirus, and respiratory syncytial virus]) and bacterial infections
  - Hemorrhagic cystitis
  - Venous-occlusive disease (liver and pulmonary)
  - Interstitial and noninterstitial pneumonias
  - Diffuse alveolar hemorrhage
  - Hemolysis
  - Organ failure
  - Alloimmunization and transfusion strategies
  - Engraftment (neutrophils, red cells, and platelets) and chimerism
  - Minimal residual disease
  - Early graft failure (diagnosis and management options)
  - Acute graft-versus-host disease (GVHD) (including alloimmunity, role of CD4 and CD8 cells, and methods for prevention of disease and treatment)
  - Common side effects and drug interactions from standard transplantation therapies

#### E. Pathophysiology, diagnosis, evaluation, and management of late HCT issues

1. Chronic GVHD
2. Posttransplantation immunodeficiencies
3. Posttransplantation autoimmune cytopenias
4. Late graft failure
5. Relapse (including management with donor lymphocyte infusions)
6. Second cancers, including posttransplantation lymphoproliferative disease
7. Late toxicities of all organ systems
8. Long-term follow-up guidelines and immunization schedules
9. Psychosocial issues, including those of caregivers
10. End-of-life issues

#### F. Methods and interpretations of clinical laboratory testing

1. Blood smears
2. Cell counting technology

3. Flow cytometry
  4. Red cell autoantibody and alloantibody testing
  5. Red cell phenotyping and cross-matching
  6. Basic cell viability assays
  7. CD34<sup>+</sup> cell evaluation
  8. HLA typing
  9. Donor search using the NMDP Traxis system
  10. Apheresis techniques
  11. Testing methods for chimerism
  12. Polymerase chain reaction techniques for minimal residual disease
  13. Infectious disease testing for pathogens, including cytomegalovirus, respiratory syncytial virus, adenovirus, Epstein-Barr virus, and fungal and bacterial pathogens
  14. Interpretation of pulmonary function test results
- G. Indications for, appropriate use of, and interpretation of results of procedures related to HCT
1. Bone marrow biopsy and aspiration
  2. Immunophenotyping, cytogenetics, and molecular studies of blood and marrow
  3. Lumbar puncture and intraventricular access with instillation of chemotherapy by both routes
  4. Management of indwelling catheters, including infections and thrombosis
  5. Accurate ordering of chemotherapy and antiemetics
  6. Hematopoietic cell apheresis for allogeneic or autologous HCT
  7. Cryopreservation of cellular products
  8. Thawing and administration of cellular products
- H. Use of medications, blood product support, and chemotherapies pertaining to the practice of HCT
1. Immunomodulating drugs for prophylaxis and therapy
  2. Monoclonal antibodies (eg, rituximab) in mobilization, preparative regimens, and posttransplantation maintenance
  3. Chemotherapy and modifications by organ function
  4. All types of blood products
  5. Supportive care and medications for pain and symptom management
- I. Knowledge pertaining to the practice of HCT
1. Principles of safe and effective blood banking
  2. Cryopreservation, storage, and manipulation of hematopoietic stem cells and other cellular products used for HCT
  3. Requirements for accreditation of a hematopoietic stem cell laboratory from:
    - American Association of Blood Banks
    - FACT
    - Food and Drug Administration (FDA)

## II. Patient Care

Although the provision of patient care forms the fundamental basis for clinical training programs, the

ACGME specifically suggests that clinical training programs should teach trainees to deliver care that is *compassionate, appropriate, and effective* for the treatment of health problems and the promotion of health. HCT is a complex subspecialty that requires practitioners to integrate information obtained by history and physical examination, in addition to information derived from medical records, from referring physicians, and from laboratory and imaging studies.

To design and implement optimal HCT clinical strategies, trainees must learn to develop therapeutic strategies that include clinical, laboratory, and cellular therapy elements. HCT plans should be devised based on a thorough understanding of the medical literature and of statistical principles underlying diagnostic tests and therapeutic interventions. These plans are often best derived in conjunction with teams composed of nursing and consultants in such areas as infectious disease, pulmonary, gastroenterology, nephrology, cardiology, social services, nutrition services, and occupational and physical therapy. Given the often-significant risk of morbidity and mortality associated with HCT, transplantation physicians need to consider the importance of comorbidity and to consider quality of life in medical decision making. It is the responsibility of the transplantation physician to oversee development of these patient care plans in collaboration with patients and families and to communicate effectively and with compassion to ensure understanding and compliance. The optimum care of HCT recipients also requires strong competency in transplantation procedures, including diagnostic biopsies, collection of autologous and allogeneic cells, and administration of the conditioning regimen and progenitor and lymphocyte products.

Specific objectives that should be included in HCT training programs related to patient care include the following:

- A. Demonstrate clinical skills and the ability to gather pertinent information.
  1. Perform an effective medical interview and physical examination in both the inpatient and outpatient settings.
  2. Choose cost-effective laboratory and imaging studies pertinent to the current problem.
  3. Interact with laboratory personnel to gather relevant information about specialized hematologic and HCT-related testing.
  4. Acquire and carefully review the patient's records and other clinical information.
  5. Manage time effectively.
- B. Problem identification and information synthesis
  1. Synthesize the relevant clinical and laboratory information into a prioritized differential diagnosis.

2. Unify the clinical and laboratory investigation to provide a coordinated and cohesive approach to diagnosis and clinical management.
  3. Generate diagnostic strategies and coordinate laboratory and blood bank efforts to provide effective support for HCT recipients.
  4. Apply principles of diagnostic reasoning that include an appreciation of biostatistics (including probability estimates, Bayes theorem, likelihood ratios, and test performance characteristics).
- C. Development and execution of a treatment management plan
1. Integrate patient-specific information and diagnostic findings into an HCT plan tailored to the individual patient's unique needs.
  2. Understand the importance of comorbidities that may influence the outcomes of HCT.
  3. Understand and respond to common drug interactions and side effects.
  4. Understand the potential impact of HCT strategies on quality of life.
  5. Effectively and compassionately include and engage the nursing staff, patient, and family in the development and execution of the HCT plan.
  6. Identify and discuss clear outcome goals for HCT.
  7. Monitor and encourage compliance.
- D. Procedures
1. Provide adequate information of risks and benefits of procedures to allow patients make an informed decision regarding consent.
  2. Provide skillful procedural services, including:
    - Autologous and allogeneic hematopoietic stem cell apheresis
    - Bone marrow biopsy and aspiration
    - Bone marrow harvest for transplantation
    - Lumbar puncture and other intraventricular access and administration of intrathecal chemotherapy
    - Administration of antineoplastic chemotherapy and immunotherapy
    - Administration of immunosuppressive medical and biologic therapies
    - Cryopreservation of hematopoietic stem cells
    - Thawing and administration of hematopoietic progenitor cells
    - Administration of therapeutic lymphocyte infusions
    - Skin biopsy

### III. Interpersonal and Communication Skills

The ACGME states that trainees “must demonstrate interpersonal and communication skills that result in the effective exchange of information and collaboration with patients, their families and health professionals [5].” The trainees must be capable of communicating across socioeconomic and cultural

barriers to a range of stakeholders, including patients, family members, all medical personnel, and the public as needed to support the provision of medical care. The ability to communicate is a necessary component of being an effective leader or member of a health care team and should also be taught and assessed in an educational program. In addition, the learner must be capable of communicating effectively using forms of media comprising a medical record, including electronic medical records.

HCT team members must necessarily be competent verbal and nonverbal communicators, given the reliance on multiple stakeholders for a successful HCT experience. A physician must be capable of communicating options, risks, and benefits of complex procedures to patients and some referring physicians who are unfamiliar with the topics but are nonetheless required to contribute to informed decision making. Information must be effectively shared with other providers, insurers, donor search specialists, coordinators, and data managers. At the time of transition to outpatient care, the physician must be capable of engaging and educating support systems, such as families, home health care agencies, and referring providers. Finally, given the often-abrupt transitions of the goals of care from that of cure to end-of-life management, a capable HCT physician will demonstrate excellence in the communication of serious news.

Learners in an HCT training program should achieve competence in interpersonal and communication skills as shown by the following items:

- A. Demonstrate effective communication (both verbal and nonverbal) of medical plans for HCT patients.
- B. Effectively engage the patient and family in the process of informed consent for HCT and clinical protocols.
- C. Effectively communicate HCT-related recommendations, evaluation, and outpatient follow-up care needs to the patient, family, referring physician, and other support personnel.
- D. Effectively communicate serious news to patients and families regarding a transition to end-of-life care.
- E. Effectively discuss advanced directives where applicable.
- F. Effectively facilitate the flow of relevant information to other members of the HCT team, including nurses, social service workers, therapists, financial and other HCT coordinators, laboratory workers, and others.
- G. Effectively communicate and collaborate with other HCT physicians and transplantation programs.

### IV. Practice-Based Learning and Improvement

According to the ACGME, competency in practice-based learning and improvement (PBLI) is

defined as “the ability to investigate and evaluate their care of patients, to appraise and assimilate scientific evidence, and to continuously improve patient care based on constant self-evaluation and life-long learning” [5]. Included in PBLI is the identification of strengths and deficiencies in one’s medical knowledge and the ability to perform appropriate learning activities to improve the overall quality of care. The learner should be able to formulate a system to seek relevant feedback regarding the quality of clinical care and a plan to incorporate that feedback into improvement of daily practice. Competency in PBLI includes demonstrating proficiency in the ability to locate, appraise, and assimilate scientific evidence related to patient care in a manner that improves clinical outcome. PBLI also includes competence in the ability to share and teach medical information. Learners will demonstrate competence as an educator of patients, families, students, residents, and other health professionals.

Operation of a successful HCT program requires participants well skilled in PBLI because of the intrinsic nature of the medical practice of HCT, which demands focused attention to issues of donor and recipient safety, process control and improvement, management of standard operating procedures, and provision of educational services to patients required to provide informed consent for a complex medical procedure. In addition, competence in PBLI is mandated by regulatory bodies with direct oversight of HCT programs, including FACT and the FDA, and is required for participating in the NMDP. A successful HCT program must have a plan in place for continuous quality improvement that includes the clinical, and hematopoietic stem cell laboratory programs. Competent HCT physicians are required to devise and implement quality improvement programs that include multidisciplinary teams that collect and report outcome data, manage databases, perform audits, and organize improvement efforts. They must be knowledgeable in basic concepts of quality improvement programs and “plan, do, study, act” cycles of continuous improvement and how these efforts affect outcome measures that are required to be reported by a US federal mandate.

Successful HCT requires cooperation and commitment from patients, who must comply with a complex medical treatment plan and be knowledgeable in the rationale and pitfalls of the treatment plan. Patients are also required to provide informed consent for HCT, which requires a working knowledge of the HCT process, benefits, and risks. This is a daunting task that requires the HCT physicians and other staff to serve an educational role. Moreover, the multidisciplinary team needed for successful management of HCT recipients needs practical knowledge of the various HCT treatment plans, including complications, risks, and benefits, as well as the rationale for treat-

ment, to effectively provide medical care to patients. A successful HCT physician will by necessity be an excellent educator of patients, staff, and other faculty members to facilitate the dissemination of accurate and timely information and to enable the provision of up-to-date medical care from all members of the HCT team. The learners in an HCT training program should receive training and evaluation of their teaching skills with respect to their interactions with patients and members of the HCT team.

Trainees in an HCT training program should achieve competence in PBLI as demonstrated by the following items:

- A. Demonstrate an ability to devise and implement a plan for continuous quality improvement that is applicable for an HCT clinical program, stem cell laboratory, or apheresis collection programs.
- B. Analyze HCT program experience and outcome and perform practice-based improvement activities using a systematic methodology (eg, plan-do-study-act) that meets FACT standards.
- C. Locate, appraise, and assimilate evidence from scientific studies related to patients’ health problems and demonstrate the ability to critically analyze scientific studies.
- D. Use information technology to manage patient information, access on-line medical information, and support educational efforts.
- E. Demonstrate understanding of clinical epidemiology and medical statistics, including clinical study and experimental protocol design, data collection, and analysis.
- F. Demonstrate the ability to teach patients and members of an HCT team.

### V. Systems-Based Practice

Of the 6 ACGME core competencies, systems-based practice is one of the most challenging to define and incorporate into clinical practice. The focus is on understanding how parts of a system of health care are interdependent and identifying changes that can be both made and measured to improve care within the system [5]. Transplantation physicians also need the knowledge and ability to call on other resources within the system to provide optimal care of HCT recipients.

Given the high cost of HCT, it is imperative that trainees receive training in all of the unique financial aspects, quality control procedures, and program administration associated with the procedure, as follows:

- A. Recognize financial issues related to HCT, including the cost of donor search and acquisition, as well as the costs associated with the prolonged nature of HCT therapy and its complications.
- B. Understand the impact of contracts with insurance companies, health maintenance organizations, and

Medicaid and Medicaid on financial coverage for HCT and patient care.

- C. Practice cost-effective health care and resource allocation that does not compromise quality of care; advocate for quality patient care and assist patients in dealing with system complexities.
- D. Demonstrate the leadership and management skills necessary to provide clinical services in an HCT program, cell therapy laboratory, and apheresis collection programs.
- E. Understand quality control procedures and program administration:
  1. Understand the need for and be able to develop standard operating protocols.
  2. Understand the need for and be able to develop record keeping, error tracking, and personnel development methods.
  3. Understand the process for and participate in inspection proceedings of regulatory agencies, (eg, FACT, FDA).
  4. Understand the need for conducting cost analyses and for developing and adhering to budgets.

## VI. Professionalism

According to the ACGME, the 3 major components of professionalism are commitment, adherence, and sensitivity [5]. Commitment includes respect, integrity, compassion, empathy, and dependability, as well as accountability and a professional commitment to excellence. Adherence means accepting responsibility for continuity of care and practicing patient-centered care that encompasses confidentiality and respect for privacy and autonomy through appropriate informed consent and shared decision making. Finally, sensitivity relates to showing sensitivity to cultural, age, sex, and disability issues for both patients and colleagues.

The job of transplantation physician is often stressful given the critical nature of issues that arise on a daily basis. Transplantation physicians must be mindful of the need to act in a professional manner when interacting with patients, staff, and colleagues at all times, particularly during times of stress. Professionalism, including medical ethics, should be emphasized throughout the program curriculum.

In the context of becoming a transplantation physician, a trainee should develop the following skills indicative of a professional in the field:

- A. Develop and demonstrate a commitment to carry out professional responsibilities and adhere to ethical principles at all times:
  1. Complete records in a timely manner
  2. Provide for continuity of care.
- B. Provide patient-centered care at all time points in the transplantation process in a confidential

manner that demonstrates sensitivity to cultural issues.

- C. Identify and manage conflicts of interest.
- D. Demonstrate respect, empathy, and compassionate use of medical skills for HCT patients receiving either active therapy or comfort care

## EVALUATIONS

All core competencies should be evaluated with a variety of methods to best determine the trainee's progress and ultimate competency. The ACGME recommends using self-assessment tools, individualized portfolios, chart reviews, and global and multisource (including staff, patients, peers, and colleagues) evaluation tools [5]. Evaluation of competency in counseling patients, obtaining informed consent, and the performance of procedures requires direct observation by an experienced HCT physician.

## CONCLUSION

We have provided HCT trainers and educators with a detailed training curriculum for advanced training in all aspects of transplantation within the context of the 6 ACGME core competencies in medical knowledge, patient care, interpersonal and communication skills, PBLI, systems-based practice, and professionalism. These training guidelines incorporate advances in HCT since the guidelines were last revised in 2001 and provide recommendations for evaluation and mentoring of trainees. As with any curriculum, these guidelines should be used as a foundation for training requirements and be adapted to the particular needs of the trainee and environment of the individual training program.

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