Chapter 13
Transplantation and Cellular Therapy

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Introduction

Hematopoietic cell transplantation (HCT) is an established treatment for selected patients with high-risk hematologic malignancies and other malignant and non-malignant diseases. An estimated 50,000 transplantation procedures are performed worldwide annually [1]. The number of patients who need and receive HCT is expected to grow as transplantation becomes safer with advances in transplantation technology and supportive care, greater donor availability, emerging indications, and diffusion of this procedure to lower income and lower middle income countries. The increase in utilization of transplantation has been paralleled by improvement in outcomes, resulting in a larger number of transplant survivors who are potentially cured of their underlying disease [2–5]. Addressing the needs of long-term survivors is, therefore, a growing aspect of transplant programs. An added dimension to this is the advent of cellular therapies, especially chimeric antigen receptor (CAR) T-cell therapies, which are also included within the domain of transplantation programs. A comprehensive center should ideally consider provision of HCT procedures, both in the context of routine care and clinical trials. This chapter will review the foundational aspects required to establish a transplantation and cellular therapy program within an upcoming cancer center. The Worldwide Network for Blood and Marrow Transplantation (WBMT) has also published guidelines on establishing HCT program, with a specific focus on lower middle and lower income countries [6, 7].

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Rationale for HCT and Cellular Therapy Program

HCT and cellular therapy are essential treatments as part of providing comprehensive care to cancer patients. There is a plethora of indications for transplantation, which mainly focus on hematologic malignancies [8, 9]. However, cancer centers will frequently manage patients with nonmalignant but life-threatening conditions that may warrant HCT (e.g., aplastic anemia). Furthermore, indications for transplantation in pediatric patients also include conditions such as inherited metabolic diseases and hemoglobinopathies that are treated with HCT. The expansion of cellular therapies and the emerging role of transplantation for autoimmune diseases is another area where an HCT program can serve a role in providing care for patients. Furthermore, an HCT program can serve as a resource for external referrals to a cancer center [10]. Overall, there continues to be a strong demand for the advanced treatment of patients with hematologic malignancies using HCT and cellular therapies [11, 12].

The need to have a dedicated resource in the form of an HCT program stems from the complexity of the procedure and its associated risks for severe morbidity and mortality, experience and expertise required of the team that manages patients, the logistical aspects around collection and ultimately infusion of hematopoietic progenitor cells, and the highly regulated nature of the procedure. Quality is an important component of care that is provided to patients, and international accreditation organizations such as the Foundation for the Accreditation of Cellular Therapies (FACT) and the Joint Accreditation for the International Society of Cellular Therapy and European Society for Blood and Marrow Transplantation (JACIE) provide minimum standards for a high-quality HCT program [13].

It needs to be recognized that in setting up an HCT program, investment in personnel and infrastructure is also needed for ancillary services that are critical to providing safe and high-quality care to HCT recipients. Some examples of these services include availability of blood bank support, specialized laboratory testing (e.g., for cytomegalovirus (CMV), infectious disease markers, pathology expertise), intensive care unit support, palliative care and hospice, and collaboration with experts in other specialties such as intensive care, nephrology etc. Patients also need a range of supportive care services, such as psychosocial and palliative care services, and local lodging for the patient and caregiver.

HCT Program Structure

Strong institutional commitment and support is needed before embarking on establishment of an HCT program, given the resources required and the expense involved. Planning for an HCT program requires a long-term vision and a phased approach, especially if the cancer center does not have experience with hematologic malignancies. Initial efforts need to be focused towards establishing a robust hematologic malignancy program, since they comprise the majority of indications for transplant,

and many of the personnel competencies can be applied to the care of HCT recipients. As discussed below, establishment of ancillary support services should be planned in parallel to the plan for the HCT program. Prior to setting up a program for management of HCT recipients, it is prudent to dedicate resources and efforts to set up a robust hematologic malignancy program that gives clinicians and other staff the opportunity to obtain experience in managing patients with acute leukemia, lymphoma, and myeloma. Once the hematologic malignancy program has matured, a rational next step towards HCT is to begin with autologous transplantation, and then expand to human leukocyte antigen (HLA)-matched sibling donor allogeneic transplantation. Once sufficient experience has been obtained with these approaches, the program can expand to allogeneic transplantation using matched unrelated donors, haploidentical donors, and other alternative donor sources such as umbilical cord blood. Additionally, a new program may initially consider transplanting patients who are younger, have less comorbidities, and at lower risk for transplant-related complications. This phased approach gives the transplant team an opportunity to gain expertise as they evolve into the management of patients of increasing complexity, given that center volume and experience have been shown to be associated with outcomes [14, 15]. The availability of local resources that can collaborate or the ability to contract out certain services (e.g., apheresis through a local blood bank) may also be a factor in planning for the setup of a new program. Histocompatibility expertise is fundamental and may be available locally, but is also frequently contracted out.

This suggested approach can be modified based on local priorities and comfort level of the transplant team – for example, in an area with high prevalence of hemoglobinopathies and/or aplastic anemia, an initial focus on allogeneic rather than autologous transplantation may be advisable, especially if key personnel have prior experience in managing allogeneic HCT recipients. Although this chapter will not go into the details of setting up a cellular therapy program, the infrastructure and personnel established for a HCT program can also serve the needs of cellular therapy recipients. Overall, there is significant overlap in resources needed for autologous and allogeneic transplantation and cellular therapies.

Various models of care delivery can be pursued as an HCT program is being developed, and they can evolve as the program grows [16]. In this context, it is also important to understand the flow of a patient who is referred for and comes through the transplantation process (Fig. 13.1). When a program is in early stages of inception and volumes are rather small, the team and resources focused towards HCT can be shared by other cancer services. However, as the program matures and volumes increase, there may be a need to have personnel and resources dedicated towards hematologic malignancies and HCT, and ultimately in the setting of a high-volume program, HCT only.

In a report from the WBMT [7], the following elements were identified as highest priority and thus essential elements for development of an HCT program:

- Institution (or hospital leadership) support to develop a transplant program.
- Leadership by a hematologist, oncologist, or immunologist as a medical director.
- Nursing staff trained in handling chemotherapy and infection control.
- Availability of irradiated blood and platelets.

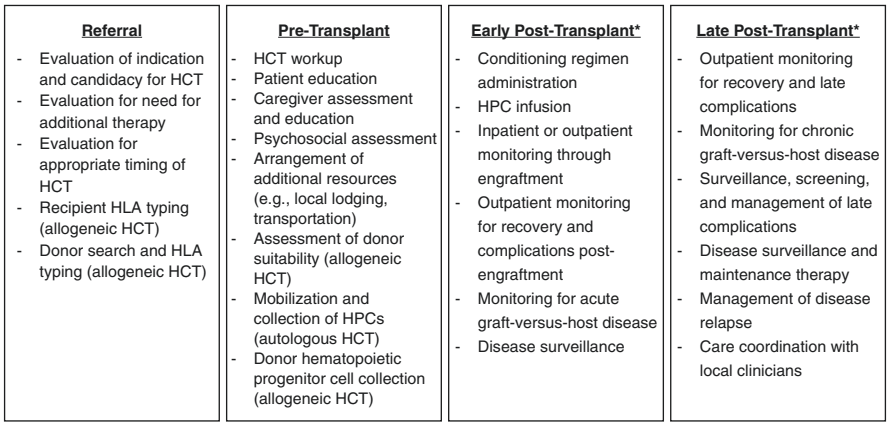

Fig. 13.1 Typical flow of HCT recipient (HPC denotes hematopoietic progenitor cells)

- Laboratory services with blood cell counter, chemistry, microbiology testing for bacteria and fungus, pre-transplant infectious disease markers.
- Access to standard radiology and computed tomography.
- Availability of chemotherapy, antiemetics, and broad-spectrum antibiotics.
- Availability of interventional radiology expertise for insertion of indwelling central venous catheters.
- Access to HLA typing laboratory (for allogeneic HCT).
- Monitoring levels of calcineurin inhibitors (for allogeneic HCT).
- Availability of antivirals and antifungal for treatment (for allogeneic HCT).
- Prophylaxis and agents to prevent and treat graft-versus-host disease (GVHD, for allogeneic HCT).

The WBMT report also outlines preferred and ideal elements for developing an HCT program. With this foundation, HCT programs can evolve as they gain experience and grow and can add on personnel and infrastructure as they care for increasingly complex patients and perform more sophisticated transplantation procedures. Other guidelines are also available that can be used as a platform to define the required elements as a new HCT program is considered [17].

HCT Program Infrastructure

A good starting point for considering infrastructure and personnel requirements for an HCT program are FACT/JACIE standards. Table 13.1 describes the minimum infrastructure requirements for setting up an HCT program. It is not necessary for all of these resources to be available within the institution that offers HCT, since some of these services can be contracted out (e.g., HLA typing, cell processing, apheresis, blood bank).

Table 13.1 Infrastructure requirements suggested for establishing an HCT program (examples below highlight requirements above what a typical resource may be structured for in a high-functional medical institution)

Service	Examples of infrastructure requirements
Outpatient clinic	Single patient examination rooms Infusion chairs
Inpatient unit	Private (single bed) rooms with isolation capability
Pharmacy	Pharmacy equipped to handle chemotherapeutic agents
	Access to specialized medications (e.g., immunosuppressants, antimicrobials)
Radiology	CT scan and MRI Interventional radiology services (e.g., placement of central venous catheters, biopsy)
Radiation oncology	Setup and experience in providing total body irradiation (if radiation-based conditioning regimens are planned)
Blood bank	Adequate red blood cell and platelet blood product support Ability to irradiate and leukocyte reduced blood products Ability to store/cryopreserve hematopoietic progenitor cell product Apheresis
Laboratory medicine	HLA lab Ability to perform HCT-specific tests (e.g., drug levels)
Microbiology	Ability to perform infectious disease markers Monitoring for CMV (antigen or PCR) Monitoring for other organisms (e.g., fungi, viruses)
Pathology	Expertise in hematopathology Flow cytometry Cytogenetics and molecular pathology
Emergency medicine	Emergency department with experience in handling cancer patients
Other services	Intensive care unit, including ventilator support Nephrology services, including dialysis Gastroenterology services, including endoscopy services Operating room services if bone marrow harvests are planned

In general, an HCT program is best served by a dedicated outpatient and inpatient area. FACT/JACIE standards for clinical programs require presence of designated areas that have adequate space and design that minimizes microbial contamination, and allows for patient isolation and administration of intravenous fluids, blood products, and medications. This approach has the benefit of consolidating personnel and enhancing their experience. Furthermore, there are some infrastructural advantages to this approach. For example, HCT units will frequently have laminar flow rooms or rooms with high-efficiency particle air (HEPA) filtration systems, which are most economically installed in a concentrated area. Depending on the existing layout for an institution, there may be value to having dedicated areas for procedures within the outpatient area (e.g., for bone marrow biopsy). Quality assurance is a major component of a high-functioning HCT program, and a specific area for caring for transplant recipients helps ensure that processes and outcomes are monitored appropriately.

Other hospital services are also critical for optimal care of HCT recipients. For example, specialized imaging services such as interventional radiology are necessary for placement of central venous catheters and organ biopsies (e.g., for GVHD), gastroenterology and endoscopy services for evaluation and diagnosis of GVHD and alimentary tract infections, intensive care services for management of patients who have hemodynamic compromise or need ventilator support, and nephrology services for dialysis. The pharmacy services should be able to handle and dispense high-dose chemotherapy medications. Similarly, in addition to providing routine support for cancer patients, laboratory, pathology, microbiology, and transfusion medicine services need to evolve to support HCT recipients. For example, patients who are going through the transplantation process need monitoring for levels of calcineurin inhibitors and monitoring for CMV. If the center is planning to pursue allogeneic transplantation, the laboratory needs to be equipped to test (or send out to another lab) HLA typing and donor-specific antibodies and conduct chimerism testing post-transplantation. The blood bank should have a process for ensuring adequate blood product support for the HCT program, including ability to irradiate and leucocyte reduce blood products. Blood banks will often provide apheresis and hematopoietic progenitor cell (HPC) storage/cryopreservation services for HCT programs. Obtaining and maintaining accreditation from national organizations (e.g., American Association of Blood Banks (AABB), American Society for Histocompatibility and Immunogenetics (ASHI), European Federation for Immunogenetics (EFI), College of American Pathologists (CAP)) ensures that ancillary services have the required infrastructure, processes, and experience to support the HCT program.

HCT Program Personnel

Similar to infrastructure requirements, FACT/JACIE standards can lay the foundation for determining personnel required for an HCT program (Table 13.2). Ultimately, a high-functioning, experienced, and cohesive team is required to provide high-quality and interdisciplinary care to HCT recipients. Additional training and qualifications specifically in HCT are often preferred for many personnel who participate in the care of transplant patients.

FACT/JACIE standards require an HCT program to have a dedicated clinical program director with background training in hematology, medical oncology, or immunology with at least 2 years of experience in direct clinical management of transplant patients. This individual is responsible for clinical and administrative operations and oversees care provided by the whole program. In addition, at least one other attending physician is recommended with one or more years of experience in the management of HCT recipients. It is not uncommon for programs to have physician trainees participate in the care of transplant patients. Many programs, especially in the United States, use advanced practice providers (APPs) such as nurse practitioners and physician assistants to provide care for their patients.

Table 13.2 Personnel requirements suggested for establishing an HCT program

Physician and related staff
Clinical program director
Additional attending physician
Advanced practice provider
Trainee physician
Consulting specialists
Palliative medicine specialists
Outpatient personnel
Nurse/care coordinator
Educator
Financial navigator
Social worker or psychosocial clinician
Pharmacist
Physical therapists or physiotherapist
Inpatient personnel
Nurse
Social worker
Pharmacist
Physical therapists or physiotherapist
Other personnel
Program manager or administrator
Data coordinator
Quality manager
Dietician
Research nurses and coordinators

Nursing staff with experience in management of HCT patients are a critical component of a successful HCT program. In the outpatient setting, nurses may be involved in patient and donor education, pretransplant testing, and posttransplant care coordination. On the inpatient side, they need to be experienced in the administration of high-dose preparative regimens, infusion of HPC and blood products, providing supportive care, and management of various transplant related complications.

Several other team members are critical for safe and optimal care of HCT recipients. Some examples of such personnel include pharmacists and social workers. Pharmacists with experience in transplantation and dedicated to HCT program are in fact required per FACT/JACIE standards. There is guidance available from the American Society for Transplantation and Cellular Therapy (ASTCT) on the role of pharmacists in an HCT program, which can serve as a foundation for defining their role in patient care, education, research, and quality improvement [18, 19]. Social workers or psychosocial clinicians can assist in pretransplant evaluation of donors and recipients, facilitate with lodging, transportation, financial grants, and other social needs of patients, and screen and triage psychological complications. Guidance that defines the role of social workers in facilitating and optimizing the care of HCT recipients has been published [20].

In addition to clinical staff, several other personnel play a key role in the functioning of an HCT program. FACT/JACIE standards require a clinical program

quality manager whose role involves establishing standard operating procedures and maintaining systems and processes to ensure they are followed and the program is in compliance. These individuals often manage data operations, especially for smaller programs. Additional personnel for data management and research may be required, depending on whether there is the availability and interest in pursuing research. It is advantageous for centers to submit data to a central registry such as the Center for International Blood and Marrow Transplant Research (CIBMTR) or the European Society for Blood and Marrow Transplantation (EBMT) (see below), and additional personnel for data capture and reporting may be needed for this purpose.

Several physician specialists and other clinicians outside the HCT team are also required for the care of HCT recipients. Some examples of these specialties include surgery, pulmonary medicine, intensive care, gastroenterology, nephrology, infectious diseases, cardiology, pathology, psychiatry, radiology, radiation oncology, ophthalmology, dentistry, dermatology, and palliative care.

The expertise of personnel may change and evolve as the HCT program grows. For example, the skillset for managing allogeneic HCT recipients may be different than autologous HCT recipients, since expertise in managing issues such as fungal and viral infections and GVHD is required. Similarly, the models of care and roles for specific personnel may change with the growth of the program – for instance, an outpatient nurse position may get further specialized as the number of patients transplanted increases, with separate nurses focusing on donor search and pretransplant evaluation, patient education, and post-transplant care coordination. An institution has to recognize that there is no one standard model of care for a transplant program, and the roles, types, and number of personnel depends on local infrastructure, priorities, and existing resources.

Quality Management

A successful HCT program requires a robust quality management program to monitor its performance, ascertain consistency of established processes, identify areas for improvement, implement corrective action for deficiencies, establish a culture of continuous improvement, and demonstrate operational effectiveness to internal and external entities. Recognizing its importance, FACT/JACIE standards require that HCT programs identify an individual who serves as quality manager and that programs have a quality management plan. Given its complexity, use of healthy donors, and economic impact, transplantation tends to be highly regulated by many countries, and the quality program also supports compliance with requirements laid out by national regulatory authorities.

A successful quality program requires collaborative and interdisciplinary interactions between all stakeholders who are involved in the care of HCT recipients (Fig. 13.2). The program director and the quality manager ultimately maintain responsibility for engaging these stakeholder groups and ensure cohesive interactions that focus on continuous program improvement and high-quality patient care.

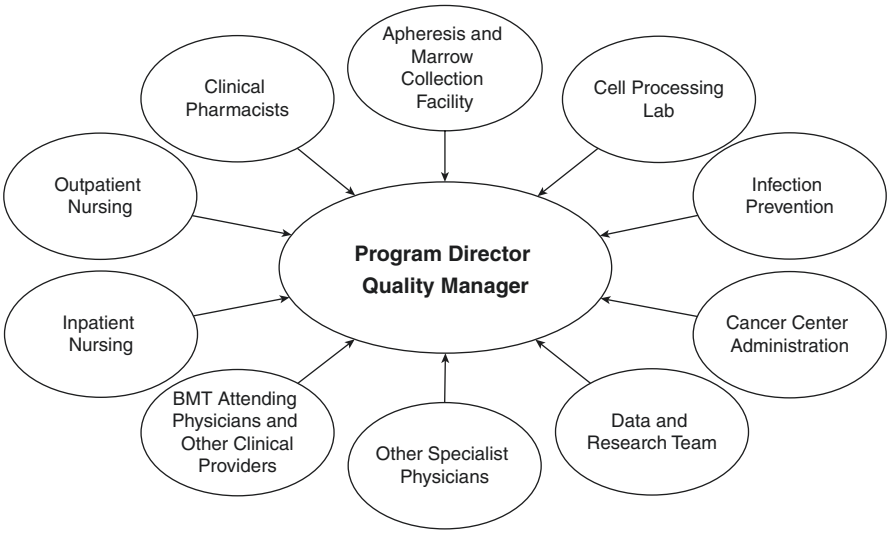

Fig. 13.2 Example of various stakeholders required for an interdisciplinary and effective quality program

The FACT/JACIE standards are a good starting point to define the scope of the quality program. How the quality program is structured and what aspects of transplant recipient care are under its oversight can vary by program. The HCT program should also establish certain benchmarks where it can meaningfully review its performance and use those data as the foundation for program review and improvement (Table 13.3). In general, examples of some areas that may be under the purview of a quality program include:

- Personnel onboarding, continuing education, and maintaining competency – the quality manager can ensure that HCT program personnel are assigned relevant educational modules and complete all requirements for maintaining educational and professional competency as it relates to transplantation.
- Facility compliance – to meet accreditation and other regulatory standards, facility and equipment routinely used for the care of HCT recipients often needs continuous monitoring (e.g., functioning and maintenance of apheresis machine and cryogenic storage).
- Documentation – HCT programs are required to maintain standard operating procedures (SOPs) that describe their processes and clinical guidelines, and the quality manager's responsibilities typically include their development and maintenance, and ensuring that the HCT program and its personnel are in compliance.
- Audits – One aspect of quality assurance is to review compliance with various HCT program data, processes and SOPs, and the quality manager typically conducts these audits with help from other program personnel.
- Adverse event monitoring – The complexity of HCT procedure and processes does increase risk of adverse events, and one role of the quality manager is to

Table 13.3 Sample metrics to monitor as part of HCT Program quality plan

Clinical program outcome metrics
Overall survival (100 days, 1 year)
Non-relapse mortality (100 days, 1 year)
Acute GVHD rate (100 days)
Chronic GVHD rate (1 year)
Length of stay for transplant hospitalization
Readmission rate
Engraftment and graft failure rates
Patient safety metrics
Rate of center line-associated blood stream infection
Rate of *C. difficile* infections
Rate of chemotherapy safety error events
Rate of other medication safety error events
Rate of falls
Rate of compliance with hand hygiene
Rate of mislabeled specimen events
Rate of infusion reactions
Apheresis collection facility metrics
Days required for adequate PBSC collection
Rate of positive culture for HPC product
CD34 collection efficiency
Rate of central line use (in healthy donors)
Rate of exceptional releases from apheresis
Rate of serious adverse events

establish processes for monitoring and reporting of expected and unexpected adverse events along with their remediation.

- Continuous improvement – Another aspect of the quality program is to provide tools and data for improving processes and outcomes, and the quality manager can lead these efforts under guidance form the HCT program director.

The quality aspects for the HCT program along with the resources needed to manage them will typically evolve with program growth, with implementation of high-risk allogeneic transplant programs necessitating more complex quality-related processes and procedures. Newer cellular therapy modalities add to the complexity, as exemplified by FDA-approved CAR T products which have somewhat different requirements depending on the company providing the cells.

Data and Research

HCT and cellular therapy are highly innovative and rapidly evolving fields. An active HCT program can serve as a platform for academic development and knowledge generation. In addition, data captured for research can be repurposed and support the program from quality and clinical management standpoints.

To support these efforts, we do recommend one or more data managers be incorporated within the HCT program structure from the outset. For an early program still in its establishment phase, the individual overseeing quality can perform many of the duties expected of a data manager. However, as the program grows and becomes busier, investment into a data capture and management software solution along with personnel and resources to support them can be an excellent investment. Some HCT programs use simple systems to capture and manage data, whereas more sophisticated systems can also integrate into the clinical workflow for programs and possibly connect with the institutions' electronic medical record.

Data capture on patient demographics, disease status, transplant regimen, and posttransplant complications and outcomes can serve several purposes. Since HCT is a highly regulated field, these data can be used to provide aggregate information on transplant activity and outcomes to regulatory and accreditation organizations. Payers and policy makers may also request access to these aggregate data to evaluate HCT program capabilities and performance. The data collected often support quality management aspects of the program. It is advantageous to report data to central registries such as the CIBMTR, the EBMT, or another national or international registry, since it provides a foundation for meaningful data that a center needs to capture, provides opportunities for HCT program faculty to participate in collaborative research and discovery, and can help benchmark HCT program data and outcomes with other similar programs. Along with collection of data, there needs to exist robust mechanisms to ensure that the data are accurate. Besides having well-trained and high-functioning data coordinators, regular audits can help in ascertaining the quality of data collected.

Cellular Therapy

Recently, there has been significant interest in the application of non-HCT cellular therapies such as CAR T-cell therapy. Several products are now approved and commercially available for the treatment of lymphoma (axicabtagene ciloleucel, brexucabtagene autoleucel, and tisagenlecleucel), acute lymphoblastic leukemia (tisagenlecleucel), and myeloma (idecabtagene vicleucel). Several CAR T-cell and other cellular therapy products are under clinical investigation for the treatment of a spectrum of hematologic malignancies and solid tumors, and for nonmalignant indications. In essence, the clinical management, infrastructural, resource, personnel, process, and quality components are very similar to HCT, and transplant programs are a natural fit for administering standard of care and investigational cellular therapy products. FACT/JACIE standards are available for immune effector cell therapy and can serve as the foundation for setting up a cellular therapy program. An experienced transplant program should generally be able to offer these therapies within its existing infrastructure. As we look ahead, there will be an increasing use of

cellular therapy for cancer and noncancer indications, and availability of these services within a cancer center will be necessary for provision on comprehensive cancer care services.

In conclusion, a successful HCT and cellular therapy program is a service line that indicates that a cancer center has the infrastructure and commitment to provide comprehensive cancer care services. It provides the opportunity to provide the complete spectrum of care for patients with advanced hematologic malignancies and other diseases. A successful program requires leadership and presence of a high-functioning clinical team in order to optimize patient experience and outcomes.

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