



ADULT AND PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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Overview of Clinical Units

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APBMT-COMM-018 OVERVIEW OF CLINICAL UNITS

1 PURPOSE

- 1.1 This document serves to outline an overview of the characteristics of the inpatient and outpatient clinical units for both the adult and pediatric blood and marrow transplant (APBMT) programs.

2 INTRODUCTION

- 2.1 The Program at Duke is a combined adult and pediatric program with distinct sites of clinical care and a shared stem cell transplant processing laboratory. There are two inpatient units located in Duke Hospital with distinct care teams, one for adults and one for children. This is necessary because the training, certification and credentialing of medical, nursing and allied health care personnel are different for adult and pediatric professionals.
- 2.2 The dedicated pediatric and adult inpatient units are staffed by a full complement of registered nurses (RNs), hospitalists, advanced practice providers (APPs) including Nurse Practitioners (NPs) and Physician Assistants (PAs), experienced in the care of transplant patients. Generally, the patient to nurse ratio is 2:1, but an alternate nursing ratio, such as 1:1, may be provided as determined by the patient's acuity. A pediatric or medical oncologist, trained in transplantation and cellular therapy is available 24 hours a day and 7 days a week for each unit.
- 2.3 There are distinct outpatient facilities and care teams for adult and pediatric patients. The Adult Outpatient Clinic is located in the North Pavilion building and the Pediatric Outpatient Clinic is located on the 4th floor of the Children's Health Center (CHC). Both outpatient locations have 'day hospital' facilities that protect the patient from transmission of infectious agents and designed to minimize the risk of airborne microbial contamination. The facilities allow for each of the following as needed:
 - 2.3.1 Appropriate patient isolation
 - 2.3.2 Confidential examination and evaluation
 - 2.3.3 Infusion therapy
 - 2.3.4 Transfusion therapy
 - 2.3.5 Administration of chemotherapy, cellular therapy products, and immunotherapy
- 2.4 Both inpatient and outpatient facilities employ a diverse complement of dedicated, experienced, medical, nursing, and support staffs for the clinical care of these patients. All inpatient location patient rooms are single rooms with private bathrooms. This greatly facilitates appropriate isolation and care of the neutropenic or immunocompromised patient. Most levels of care are delivered on the transplant and cellular therapy inpatient units. Patients requiring mechanical ventilation are transferred to the adult medical or pediatric intensive care units for this therapy. Guidelines are in place for communication, patient monitoring, and

initiation of “Rapid Response Team” consult and/or prompt transfer of patients to an intensive care unit. In the intensive care units (ICUs), care is shared by the Transplant and ICU teams. The ICUs have selected rooms which are under high-efficiency particulate air (HEPA) filtration (pediatric) and positive or negative pressure as required. All facilities are maintained in a clean, sanitary, and orderly manner. Safety manuals that include instructions for action in case of exposure, as applicable to liquid nitrogen; communicable disease; and to chemical, biological, or radiological hazards, are available online to all staff caring for the pediatric and adult blood and marrow transplant patient.

- 2.5 Patient care is delivered by a comprehensive team including but not limited to: appropriately certified physicians, fellows in hematology/oncology or transplantation medicine, nurse clinicians/transplant coordinators, advance practice providers, registered nurses (RNs), and allied health professionals. Donors and prospective transplant patients are evaluated in the adult and pediatric transplant clinics, respectively. Inpatient care, specifically, is delivered by a team consisting of an attending physician, advance practice providers, fellows, RNs, pharmacists, and nutritionists. Adult and pediatric patients are cared for by distinct care teams because of requirements for population-specific competencies. There is generally no cross-coverage between the clinical teams. However, common treatment and supportive care protocols are employed whenever possible.

- 2.5.1 RNs are trained accordingly in age-specific management of patients receiving transplant and cellular therapies.

- 2.5.1.1 Competency Assessments are completed upon initial hire, at a minimum, for both the adult and pediatric programs, via online modules which are driven by health system requirements and processes. Additionally, programs hold periodic skills assessments check offs as an additional assessment of competency. (see training modules titled: *DUH Annual Competency Revalidation; DUHS Clinical Education and Professional Development Competency Validation Criteria*)

- 2.5.1.2 Additional assessments may be completed, specific to each patient population at set intervals as established by program specific training requirements.

- 2.6 Patients may elect to come to Duke for a consultation to help which their decision about selection of a transplant center for their treatment. After Duke has been identified as their transplant center, patients who may be candidates for transplantation therapy are evaluated at Duke for 2-3 weeks before admission to the hospital. Donors are generally identified and financial clearance obtained before the patient travels to Duke. Organ function, status of underlying disease and infectious disease risks are established during this evaluation. Education regarding the potential risks and benefits, side effects and toxicities, details of therapy to be administered, required follow-up and projected efficacy are discussed in detail. After this process is completed, the patient or their parent or legally authorized representative gives written informed consent for the transplant

procedure and related care. Appropriate venous access is established and confirmed before initiation of chemotherapy or radiation therapy. Conditioning regimens which may include high dose chemotherapy and/or total body irradiation (TBI) may be administered in the outpatient or inpatient unit depending on the patient characteristics and unit protocol. Depending on the treatment protocol and type of transplant, the stem cell infusion is delivered either on the inpatient unit or in the outpatient clinic. Post-transplant care is delivered in both the inpatient and outpatient settings depending on the acuity of the patient's condition and the aggressiveness of the conditioning regimen. After hospital discharge, care is continued in the outpatient clinic and day hospital for several more weeks/months. Generally, patients are discharged to their home community under the care of their referring physician after 100 days allogeneic (allo) or 30 days autologous (auto) post-transplant. Routine post-transplant evaluations are performed at scheduled intervals as specified by the patient's protocol or treatment plan. Chimerism is monitored routinely through RFLP or other DNA-based technologies available in the Duke Hospital Molecular Diagnostics Laboratory.

3 SCOPE AND RESPONSIBILITIES

- 3.1 Multidisciplinary: All faculty and allied staff, as outlined in section 2, who care for the transplant and cellular therapy patient are responsible for maintaining and supporting the characteristics of each unit.

4 DEFINITIONS/ACRONYMS

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|------|-------|---|
| 4.1 | APBMT | Adult and Pediatric Blood and Marrow Transplant |
| 4.2 | APP | Advanced Practice Provider |
| 4.3 | ASHI | American Society of Histocompatibility and Immunogenetics |
| 4.4 | BMT | Blood and Marrow Transplant |
| 4.5 | CHC | Children's Health Center |
| 4.6 | CMV | Cytomegalovirus |
| 4.7 | CT | Cellular Therapy |
| 4.8 | HEPA | High-efficiency particulate air |
| 4.9 | HLA | Human Leukocyte Antigen |
| 4.10 | ICU | Intensive Care Unit |
| 4.11 | NP | Nurse Practitioner |
| 4.12 | PA | Physician Assistant |
| 4.13 | RN | Registered Nurse |
| 4.14 | TBI | Total Body Irradiation |

5 MATERIALS

- 5.1 N/A

6 EQUIPMENT

6.1 N/A

7 SAFETY

7.1 N/A

8 PROCEDURE

8.1 Clinical Units

8.1.1 Inpatient:

- 8.1.1.1 Both inpatient units have separate air-handling systems, HEPA filtration and positive pressure ventilation.
- 8.1.1.2 Each unit has support space for patients and nurses, workrooms, storage space, and pharmacy Omnicell units which are also under protective air filtration.
- 8.1.1.3 Most patient rooms in Duke Hospital are single rooms with private bathrooms. This greatly facilitates appropriate isolation and care of the neutropenic or immunocompromised patient.
- 8.1.1.4 Most levels of care are delivered on the BMT inpatient units, however, patients requiring mechanical ventilation are transferred to the medical or pediatric intensive care units for this therapy.
- 8.1.1.5 There are written guidelines for communication, patient monitoring, and prompt transfer of patients to an intensive care unit.
 - 8.1.1.5.1 In the intensive care units (ICUs), care is shared by the Transplant and ICU teams. The ICUs have selected rooms which are under HEPA filtration (pediatric) and positive or negative pressure as required.
- 8.1.1.6 Characteristics of each unit include:
 - 8.1.1.6.1 Appropriate patient isolation
 - 8.1.1.6.2 Administration of Intravenous (IV) medications
 - 8.1.1.6.3 Access to administration of cytomegalovirus (CMV) appropriate blood products, 24 hours a day and 7 days a week including leuko-depleted and irradiated blood products
 - 8.1.1.6.4 Availability of 24-hour treatment areas for outpatients needing urgent evaluation and includes 24-hour pharmacy provision to ensure availability of required medications

- 8.1.1.6.5 Dedicated Pharmacists
 - 8.1.1.6.6 Dedicated Dietician
 - 8.1.1.6.7 Dedicated Social Workers
 - 8.1.1.6.8 Dedicated Family Support Programs
 - 8.1.1.6.9 Dedicated pharmacy, nutrition, physical and occupational therapists
 - 8.1.1.6.10 Inpatient dialysis under the direction of a pediatric or adult nephrologist and trained personnel
- 8.1.1.7 Pediatric units also include:
 - 8.1.1.7.1 Dedicated Occupational and Speech therapists
 - 8.1.1.7.2 Dedicated Child Life Therapists, Music Therapist
 - 8.1.1.7.3 Dedicated Discharge Coordinator
 - 8.1.1.7.4 Home bound school through the Durham Public Schools
- 8.1.2 Outpatient:
 - 8.1.2.1 There are distinct outpatient facilities and care teams for adult and pediatric patients. The Adult Outpatient Clinic is located in the North Pavilion building and the Pediatric Outpatient Clinic is located on the 4th floor of the Children's Health Center.
 - 8.1.2.2 Both outpatient facilities have 'day hospital' facilities that protect the patient from transmission of infectious agents and designed to minimize the risk of airborne microbial contamination. The facilities allow as necessary, for appropriate patient isolation; confidential examination and evaluation; infusion therapy, transfusion therapy, chemotherapy, cellular therapy product administration, and immunotherapy.
 - 8.1.2.3 Both outpatient clinics have pharmacy and laboratory support, separate waiting and treatment areas, individual examination and treatment rooms and administrative support staff.
 - 8.1.2.4 Both facilities employ a diverse complement of dedicated, transplantation-experienced, medical, nursing, and support staffs for the clinical care of these patients.
- 8.1.3 All facilities are maintained in a clean, sanitary, and orderly manner. Safety manuals that include instructions for action in case of exposure, as applicable to liquid nitrogen; communicable disease; and to chemical, biological, or radiological hazards, are available online to all

staff caring for the pediatric and adult blood and marrow transplant patient. Adults are harvested in the Ambulatory Surgery Center located in North Pavilion. Children are harvested in the Duke Hospital Operating Suites. There are separate waiting, pre-op and recovery room facilities for adult and pediatric patients staffed by nurses and allied health professionals with age-specific competencies. After collection, bone marrow is hand-carried to the Stem Cell Laboratory where it is tested, processed and, if indicated, cryopreserved.

8.1.4 Peripheral stem and progenitor cells are apheresed in specified areas in the adult and pediatric clinics, respectively. If applicable, central venous catheters are placed by licensed surgeons or interventional radiologists in either the operating room or the procedure suite in interventional radiology. All apheresis donors are screened, assessed, and cared for by RNs trained to operate the Spectra Optia blood separation machine.

8.1.5 HIPPA Regulations are observed in all patient care areas. Patient and donor confidentiality and privacy are maintained at all times.

8.2 HLA Laboratory

8.2.1 Duke University Clinical Transplant Immunology Laboratory performs Human Leukocyte Antigen (HLA) typing for the Adult and Pediatric Blood and Marrow Transplant Program. All HLA typing for allogeneic and autologous patients have initial and/or confirmatory typing at Duke. The HLA testing laboratory is accredited by the American Society of Histocompatibility and Immunogenetics (ASHI), College of American Pathologists (CAP) and has the capability of carrying out DNA based HLA-typing.

9 RELATED DOCUMENTS/FORMS

9.1 N/A

10 REFERENCES

10.1 N/A

11 REVISION HISTORY

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08	Sally McCollum	Document updated throughout for current locations of inpatient units and outpatient clinics. Scope broadened throughout to reflect inclusion of cellular therapy. Section 2.5.1 – new section to reflect age competency training Section 8.1.1.6 - updated to reflect pharmacy services Section 8.2 – inserted CAP as an accrediting body.

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