PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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PBMT-GEN-010
SUPPORT STAFF

1 PURPOSE

1.1 To provide an outline of support staff and the services provided to the Pediatric Transplant and Cellular Therapy (PTCT) Program.

2 INTRODUCTION

2.1 Pediatric patients undergoing Hematopoietic Stem Cell Transplantation (HSCT) and/or receiving cellular therapy (CT) require coordinated care provided by an integrated team of all disciplines. Support staff provide essential services to the ongoing complex care of this patient population.

3 SCOPE AND RESPONSIBILITIES

3.1 All support staff providing care to the PTCT patient are responsible to adhering to the contents of this document.

4 DEFINITIONS/ACRONYMS

4.1	CCRU	Children's Clinical Research Unit
4.2	CHC	Children's Health Center
4.3	CIBMTR	Center for International Blood and Marrow Transplant Research
4.4	CT	Cellular Therapy
4.5	DOCR	Duke Office of Clinical Research
4.6	FSP	Family Support Program
4.7	HSCT	Hematopoietic Stem Cell Transplantation
4.8	IND	Investigational New Drug
4.9	IV	Intravenous
4.10	IS	Information System
4.11	IRB	Investigational Review Board
4.12	LCSW	Licensed Clinical Social Worker
4.13	OT	Occupational Therapy
4.14	PTCT	Pediatric Transplant and Cellular Therapy
4.15	PT	Physical Therapy
4.16	PN	Pediatric Nutritionist
4.17	SOP	Standardized Operating Procedure
4.18	TED	Transplant Essential Data

5 MATERIALS

5.1 N/A

6 EQUIPMENT

6.1 N/A

7 SAFETY

7.1 N/A

8 PROCEDURE

8.1 Dietary/Nutrition Staff

8.1.1 There is a Pediatric Nutritionist (PN) assigned to the program.

8.1.1.1 The PN:

8.1.1.1.1 Provides regular services to patients hospitalized on the Inpatient Unit.

8.1.1.1.2 Participates in rounds with the inpatient care team and also provides outpatient consultations on an as needed basis.

8.1.1.2 Additional services:

8.1.1.2.1 The inpatient unit contains a "galley", which is stocked with age-appropriate snacks, formulas, high calorie drinks, popsicles, long shelf life food and frozen entrees for patients who prefer to eat outside of meal times.

8.1.1.2.2 A "galley" technician is assigned and provides individual food trays and assists with requested patient nourishments.

8.2 Social Services

8.2.1 There are dedicated Licensed Clinical Social Workers (LCSW) assigned in the program.

8.2.1.1 The LCSW:

8.2.1.1.1 Provides psychosocial assessments, diagnosis, treatment, input into discharge planning, access to financial resources, and consultation regarding patients and their families and caretakers.

8.2.1.1.2 Assist patients and families with coping with hospitalization, illness, diagnosis, treatment and/or life situation, including emotional, mental and substance abuse disorders in patients and parents/caretakers.

8.3 Clinical Research Team

8.3.1 The program has dedicated staff to assist with the Investigational Review Board (IRB) submissions, Investigational New Drugs (IND), protocol development, patient screening, patient education and consenting, enrollment, protocol compliance, study related procedures, data management and research samples.

8.3.1.1 The team is comprised of an Assistant Research Practice Manager and clinical research coordinators or clinical research nurse coordinators.

8.3.2 The Clinical Research Team:

8.3.2.1 Ensure, in collaboration with all protocol study team members, protocols are carried out in accordance with institutional polices and applicable law.

8.3.2.2 Participates in a variety of independent activities involved in the collection, analysis, documentation and interpretation of data related to many protocols.

8.3.2.3 Confer with Principal Investigators regarding data elements needed for protocols and assure all pertinent tests are performed and data is collected for all research studies.

8.3.2.4 Collaborate with the Duke Children's clinical research unit (CRU) and the Duke Office of Clinical Research (DOCR) during study start up, throughout the course of the study and close out.

8.3.2.5 Collaborate with the CCRU and DOCR to create order sets for the electronic medical record for various studies and for patient related financial reconciliation.

8.4 Programmer

8.4.1 There is a full-time programmer assigned to the program.

8.4.2 The programmer:

8.4.2.1 Identifies and analyzes specific program-related information system (IS) and office automation requirements.

8.4.2.2 Develops, maintains, and modifies IS programs to meet program needs.

8.4.2.3 Responds to data requests and special projects for internal staff and external departments/organizations.

8.4.2.4 Investigates and evaluates new IS technologies to determine appropriateness and usability in the program.

8.5 Pharmacists

8.5.1 There is a dedicated full-time Clinical Pharmacist dedicated to the inpatient unit. In addition, the outpatient pediatric pharmacy, located in

the Children's Health Center (CHC), dispenses compounds and verifies all medications used by patients in the outpatient setting. The Day Hospital also has a dedicated pharmacy team to fill medication orders during the daily operations of the clinic.

8.5.2 The Clinical Pharmacist is responsible for:

8.5.2.1 Providing specialized pharmaceutical services to improve drug usage and therapeutic outcomes including, but not limited to, advising physicians on issues concerning drug therapy, the inherent toxicity of drugs and their side effects, as well as assisting in the prescription of appropriate doses.

8.5.2.2 Mentoring pharmacists in training including, but not limited to, Duke Pharmacy Practice Residents, University of North Carolina and Campbell University students; activities should include both practical and didactic experiences.

8.5.2.3 Maintaining liaison relationships with medical and nursing staff; providing timely information pertaining to pharmaceutical supplies, drug usage and compatibility, state and federal regulations regarding drug controls, and Joint Commission Standards.

8.5.2.4 Conducting and evaluating medication histories, assessing compliance and suggesting modifications to achieve desired outcomes; instructing patients in the proper use of prescribed drugs and making Patient Care Rounds with physicians to evaluate patient progress.

8.5.2.5 Individualizing medication regimens using sound principles, accounting for pharmacodynamic and pharmacokinetic variations in drug absorption, distribution, metabolism and elimination with responsibility for establishing and continually improving the delivery of Pharmaceutical Care to patients within areas of direct responsibility and assisting others in the department with the same.

8.5.2.6 Conducting and participating in research, including, but not limited to, performing as the primary investigator or co-investigator for research programs which will impact on the delivery of quality care or examine the pharmaco-economic impact of providing care to the patients in the Duke Health System.

8.5.2.7 Participating in development and implementation of guidelines or Standardized Operating Procedures (SOP) related in the pharmaceutical management of transplant recipients.

8.5.3 Education/Training

8.5.3.1 Requires a Doctor of Pharmacy degree and a North Carolina Pharmacist's License.

8.5.3.2 Licensed to practice in the jurisdiction of the clinical program and shall be limited to a scope of practice within the parameters of their training and licensure.

8.5.3.3 Training shall include:

8.5.3.3.1 An overview of hematology/oncology patient care, including cellular therapies.

8.5.3.3.2 Therapeutic drug monitoring, including, but not limited to, anti-infective agents, immunosuppressive therapy, anti-seizure medications, and anticoagulation.

8.5.3.3.3 Monitoring for and recognition of drug/drug and drug/food interactions and necessary dose modifications.

8.5.3.3.4 Recognition of medications that require adjustment for organ dysfunction.

8.5.3.3.5 Adverse events including but not limited to, cytokine release syndrome and neurologic toxicities.

8.5.3.4 Participation in ten hours of education activities related to cellular therapy annually at a minimum.

8.5.3.5 Continuing education shall include, but is not limited to, activities related to the field of HSCT.

8.6 Childlife Therapists/Art Therapy/Family Support Program (FSP)

8.6.1 A full time childlife therapist is employed to work with and support the program and its patients during their inpatient stay.

8.6.2 Childlife and FSP offer art therapy for children in the inpatient setting and childlife offers art therapy in the outpatient setting.

8.6.3 The FSP program and childlife offer support for patients, parents and siblings on a regular basis.

8.7 Music Therapist

8.7.1 A trained music therapist rotates between the inpatient and outpatient areas.

8.8 Physical Therapy (PT)/ Occupational Therapy (OT)/Speech Therapy

8.8.1 The PT/OT/Speech Therapists are available, as needed, for the inpatient and outpatient areas.

8.9 Nurse Clinician

8.9.1 Nurse Clinicians/Coordinators are assigned to individual physicians to coordinate the care of all potential patients. The Nurse Coordinator is a Registered Nurse with experience and education in HSCT and cellular

therapies. The Nurse Coordinator is trained and evaluated on the following competencies:

8.9.1.1 Cognitive skills

8.9.1.1.1 Communicates effectively as primary resource and liaison for the patient and the clinical team.

8.9.1.1.2 Understands the informed consent process, confirming signature and appropriate filing.

8.9.1.1.3 Provides protocol and treatment related education to the patient and/or caregiver in a manner that meets their learning style and needs.

8.9.1.1.4 Ensures that the patient/caregiver understands the information given to them.

8.9.1.1.5 Communicates clinical information to physicians and clinical staff to ensure quality care, appropriate clinical decision-making and adherence to protocol requirements.

8.9.1.1.6 Develops individual schedules, systems or processes that facilitate efficient patient access to services.

8.9.1.1.7 Coordinates care between the inpatient and outpatient setting and between multiple ancillary and support departments (i.e. Radiology, Pharmacy, Labs).

8.9.1.1.8 Collaborates with home health, home infusion and/or other services for clinical support needs of the patient

8.10 Discharge Planner

8.10.1 The Discharge Planner rounds with the inpatient team and is involved in each patient discharge. The Discharge Planner is a Registered Nurse with experience and education in HSCT and cellular therapies.

8.10.2 The Discharge Planner is responsible for:

8.10.2.1 Communicating effectively with the clinical team and with patients and families or legally authorized representative(s).

8.10.2.2 Providing patient/caregiver a copy of Discharge Handbook within two weeks of admission to unit.

8.10.2.3 Utilizing comprehensive assessment skills to determine patients' appropriateness of home care and initiates the development plan of care in collaboration with the clinical

team, patient, caregiver, and appropriate home health agency.

8.10.2.4 Providing teaching to patient/caregiver regarding central venous line care, lab draws, infection control, skin care, oral, topical, inhaled and intravenous (IV) medications (including IV pump instructions if appropriate).

8.10.2.5 Ensuring that the patient/caregiver understands the information at time of discharge.

8.10.2.6 Coordinating care between the inpatient and outpatient team to ensure a smooth transition to the outpatient setting.

8.10.2.7 Coordinating infusion therapy for patient with appropriate home health agency.

8.11 Psychology Services

8.11.1 Psychology services are available, when needed, in the inpatient and outpatient areas.

8.12 Data Management Staff

8.12.1 Designated data management staff will collect and maintain all necessary data to complete Transplant Essential Data (TED) Forms of the Center for International Blood and Marrow Transplant Research (CIBMTR) or the Minimal Essential DAT-A forms of the EBMT.

8.12.1.1 Data for both allogeneic and autologous transplants will be submitted to a national or international database. For example, the Stem Cell Therapeutics Outcome Database for allogeneic data.

8.12.1.2 Data will be collected for all patients for at least one (1) year following administration of a cellular therapy product

8.12.2 Designated data management staff will collect and submit all data elements included in the appropriate Cellular Immunotherapy Data Resource (CIDR) form(s) of the CIBMTR or the Cellular Therapy Med-A forms of the EBMT. This includes data for non-transplant cellular therapy, such as CAR-T cell products.

8.12.3 Designated data management staff will participate in continuing education annually.

8.13 In addition to training and competency outline above for each role, applicable staff will complete Current Good Manufacturing Practices appropriate to the processes performed and in accordance with applicable law. (See related procedure for Good Manufacturing Practices: COMM-QA-068 Good Manufacturing Practices - GMP- Referred to as Current Good Manufacturing Practices – cGMP)

9 RELATED DOCUMENTS/FORMS

9.1 COMM-QA-068 Good Manufacturing Practices - GMP- Referred to as Current Good Manufacturing Practices – cGMP)

10 REFERENCES

10.1 N/A

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
07	S. McCollum	Section 8.3 - updated to reflect current roles Section 8.6 - updated to reflect current location setting Section 8.10 - updated to remove home visit on first night out

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