Standards for Clinical Hematopoietic Stem Cell Transplant Services

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Health Policies and Standards Department

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ACKNOWLEDGMENT

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Health Regulation Sector

Dubai Health Authority

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INTRODUCTION

The Health Regulation Sector (HRS) plays a key role in regulating the health sector. HRS is mandated by the Dubai Health Authority (DHA) Law No. (6) of the year (2018) with its amendments pertaining to DHA, to undertake several functions including but not limited to:

- Developing regulation, policy, standards, guidelines to improve quality and patient safety and promote the growth and development of the health sector;
- Licensure and inspection of health facilities as well as healthcare professionals and ensuring compliance to best practice;
- Managing patient complaints and assuring patient and physician rights are upheld;
- Governing the use of narcotics, controlled and semi-controlled medications;
- Strengthening health tourism and assuring ongoing growth;
- Assuring management of health informatics, e-health and promoting innovation.

The DHA Standards for Clinical Hematopoietic Stem Cell Transplant Services aims to fulfil the following overarching Dubai Health Sector Strategy 2026:

- Pioneering Human-centred health system to promote trust, safety, quality and care for patients and their families.
- Make Dubai a lighthouse for healthcare governance, integration and regulation.
- Strengthening the economic contribution of the health sector, including health tourism to support Dubai economy.

EXECUTIVE SUMMARY

Hematopoietic Stem Cell Transplant (HSCT), also referred to as Bone Marrow Transplant (BMT), is a medical procedure that involves administering healthy hematopoietic stem cells into patients with dysfunctional or depleted bone marrow. It has numerous benefits, for e.g., it helps to augment bone marrow function, it may allow for the destruction of malignant tumour cells (depending on the disease being treated) and can also generate functional cells that replace dysfunctional ones in cases like immune deficiency syndromes, hemoglobinopathies and other diseases. Types of HSCT are Autologous or Allogenic.

There are different reasons for HSCT, including:

- Cancer Treatment: For cancers like leukaemia, lymphoma, or multiple myeloma, it can help restore healthy blood cell production after chemotherapy or radiation therapy.
- Blood Disorders: Conditions like aplastic anaemia or certain genetic disorders can affect the bone marrow's ability to produce blood cells, and a transplant can help restore normal function.
- Immune System Disorders: Some immune system disorders or genetic diseases may be treated with a HSCT to replace a malfunctioning immune system.

Procedure Overview

1. Preparation: The patient undergoes pre-transplant conditioning, which may include chemotherapy and/or radiation to destroy any remaining cancer cells or to suppress the immune system.

2. Transplant: Healthy bone marrow or stem cells are infused into the patient's bloodstream through an IV line. The cells travel to the bone marrow, where they begin to grow and produce new blood cells.
3. Recovery: The new bone marrow needs time to start producing blood cells. During this period, patients are closely monitored for potential complications such as infections, graft-versus-host disease (in the case of allogeneic transplants), and other side effects.

HSCT is a complex procedure with potential risks and benefits, so it's usually considered when other treatments have not been successful. It often requires a multidisciplinary team of specialists and a well-coordinated care plan. This standard is aligned with all the applicable United Arab Emirates (UAE) laws and legislations related to the subject and relevant DHA documents which are as follows, but not limited to:

- Federal Decree Law No. (25) of 2023 concerning the Human Organ and Tissue Donation and Transplantation.
- Federal Decree Law (18) of 2023 concerning the Medical Liability.
- Federal Law No. (8) of 2023 amending some provisions of Federal Law No. (4) of 2015 concerning the Private Health Facilities.
- Ministerial Decision no. (19) of 2022 concerning the Standards of Death Determination.
- Cabinet Resolution No. (67) of 2020 Concerning the Executive Regulations of Federal Law No. (5) of 2019 Regulating the Practice of Human Medicine Profession.

- Cabinet Decision No. (25) of 2020 concerning Federal Decree No. (5) of 2016 concerning regulating the transfusion and transplantation of human organs and tissues.
- Council of Ministerial Decision No. (6) of Year 2020 on Endorsement of the Regulations of Cord Blood and Stem Cells Storage Centers.
- DHA Standards for Autologous Hematopoietic Stem Cell Transplantation, Version 1
- DHA standards for Human organ and tissue donation Services (Living donor).
- DHA Guidelines for Organ and Tissue Donation Registry and KPIs.
- DHA Hospital Accreditation Policy.
- DHA Clinical Laboratory Accreditation Policy.

DEFINITIONS

Adverse event: any unintended or unfavourable symptom or condition that is temporary and associated with an intervention that may have a causal relationship with the intervention, medical treatment, or procedure.

Adverse reaction: an unintended response directly or indirectly caused by the administration of cellular therapy.

Allogeneic: the biological relationship between genetically distinct individuals of the same species.

Apheresis: a medical technology in which blood is separated into parts. The required component is removed, and the remaining components are returned to the donor.

Autologous: derived from an individual and intended for the same individual.

Autologous Stem Cell Transplant: is a procedure in which a patient's healthy stem cells (blood-forming cells) are collected from the blood or bone marrow before treatment, stored, and then given back to the patient after treatment. An autologous stem cell transplant replaces a patient's stem cells that were destroyed by treatment with radiation or high doses of chemotherapy. An autologous stem cell transplant is most often used to treat blood cancers, such as myeloma, leukaemia and lymphoma.

Allogeneic Stem Cell Transplant: is a procedure in which a patient receives healthy blood-forming cells (stem cells) from a donor to replace their own stem cells that have been destroyed by treatment with radiation or high doses of chemotherapy. In an allogeneic stem cell transplant,

the healthy stem cells may come from the blood or bone marrow of a related donor who is not an identical twin of the patient or from an unrelated donor who is genetically similar to the patient. An allogeneic stem cell transplant is most often used to treat blood cancers, such as leukemia and lymphoma, and certain types of blood or immune system disorders.

Clinical Privileging: is the process of granting a DHA licensed Healthcare Professional (HP) permission to carry out specific duties as per health facility scope of practice and licensure. This involves the review of credentials and qualifications, training, competence, practical independence and experience, aligning to the needs of the Clinical Privileging Committee (CPC) which is the responsible entity to authorize or deny clinical privileges.

Clinical Program: an integrated medical team housed in a defined location. The program includes a Clinical Program Director who can demonstrate sufficient staff training, adoption of protocols, written Standard Operating Procedures, implementation of quality management systems, clinical outcome analysis, and regular interaction among clinical sites.

Donation: is a legal act indicating that a living individual has legally accepted to donate, during his/her lifetime or after death when formally documented either by the notary public, through Emirates identify card, under a legal will left for his/her heirs or permitted successors, or through consent from next of kin in accordance with published DHA standards, to donate with no compensation one or more of his/her body organs or part thereof or tissues to someone by way of transplantation operation.

Donor: is a human being, living or deceased (brain or cardiac death), who is a source of organs, tissues or cells which are to be used for the purpose of transplantation.

Engraftment: is the process when the transplanted stem cells begin to grow to produce new healthy cells (The reconstitution of recipient haematopoiesis with blood cells and platelets from a donor). It is typical for engraftment to occur between 10-15 days, but there are instances where this may take longer. Engraftment is identified through blood analysis of the white blood cells, neutrophil count, haemoglobin, and platelets.

Graft Versus Host Disease: the condition occurs when donated bone marrow stem cells (the graft) identify the host with healthy tissues as alien and leads to an immune response. Graft-versus-host disease can also occur after an organ transplant or within the first few months of a transplant (acute) or, much later (chronic), damaging human tissue and organs. The signs and symptoms may be severe and life-threatening.

Health Facility: is a facility licensed by DHA to provide medical services to individuals, including areas of prevention, treatment, and convalescence owned and managed by natural or corporate body.

Healthcare Professional: are healthcare personnel working in health care facilities and required to be licensed as per the applicable laws in United Arab Emirates (UAE).

Hematopoietic Progenitor Cells: a cellular therapy product that contains self-renewing and/or multipotent stem cells. The cells can mature into hematopoietic lineages, lineage-restricted

pluripotent progenitor cells, and committed progenitor cells, regardless of tissue source (bone marrow, umbilical cord blood, peripheral blood, or another tissue source).

Informed Consent: refers to an agreement or permission accompanied by full information on the nature, risks, and alternatives of a surgical or interventional procedure before the physician begins the procedure/treatment. Accordingly, the patient either consents to or refuses treatment.

National Center for Donation and Transplantation (The National Center): is the federal center under the Ministry of Health and Prevention responsible to regulate and coordinate organ and tissue donation and transplantation in UAE.

Standard Operating Procedure: a written document that describes the process or steps taken to accomplish a specific task.

Stem Cell Laboratory: is a unit in the health facility for extracting, processing, and preserving stem cells from human body for potential future use in stem cell therapies and treatments.

Transplant Candidate: is a person registered in the organ or tissue transplant wait list awaiting a transplant. When an organ is offered on behalf of the candidate, they are then called a Potential Transplant Recipient.

Transplant Coordinator: serves as a facilitator, educator and point of contact as well as assisting patients with all details of care involved in preparing for transplantation.

Transplantation: is a medical procedure in which an organ, tissue, or cell is removed from one part of the body and placed into another part of the same body (autograft) or from a donor

(allograft) to replace damaged or diseased structures. The primary goal of transplantation is to restore normal function and improve the patient's quality of life

Types of Transplantation

- **Organ Transplantation**: involves the transfer of whole organs, such as kidneys, liver, heart, or lungs, from a donor to a recipient. This is often performed to treat organ failure or severe disease.
- **Tissue Transplantation**: includes procedures where tissues such as skin, corneas, or bone are transplanted. These are typically used to treat injuries, burns, or degenerative conditions.
- **Cell Transplantation**: involves transferring specific types of cells, such as stem cells or pancreatic islet cells, to treat diseases or conditions affecting cell function. For example, bone marrow transplants involve the transplantation of hematopoietic stem cells.

Workup: is a thorough potential donor or recipient review, which may include diagnostic assessments such as laboratory tests, imaging, cancer screening and other evaluations for the purpose of ensuring successful transplant outcomes.

ABBREVIATIONS

BMT	:	Bone Marrow Transplantation
DHA	:	Dubai Health Authority
DM	:	Dubai Municipality
ER	:	Emergency Room
FACT	:	Foundation for the Accreditation of Cellular Therapy
GVHD	:	Graft Versus Host Disease
HCP	:	Healthcare Professional
HEPA	:	High-Efficiency Particulate Arresting
HF	:	Health Facility
HFG	:	Health Facility Guidelines
HLA	:	Human Leukocyte Antigens
HPC	:	Hematopoietic Progenitor Cells
HPSD	:	Health Policies and Standards Department
HSCT	:	Hematopoietic Stem Cell Transplant
HRS	:	Health Regulation Sector
ICU	:	Intensive Care Unit
KPIs	:	Key Performance Indicators
MoU	:	Memorandum of Understanding
NCDT	:	National Center for Donation and Transplantation (The National Center)

PBSCT	:	Peripheral Blood Stem Transplant
QMS	:	Quality Management System
SAE	:	Serious Adverse Events
SAR	:	Serious Adverse Reaction
SOP	:	Standard Operating Procedures
UAE	:	United Arab Emirates

1. BACKGROUND

Hematopoietic Stem Cell Transplantation (HSCT) is a life-saving procedure used to treat a variety of hematologic malignancies, immune deficiencies, and other serious blood disorders. HSCT involves replacing a patient's damaged or diseased hematopoietic stem cells with healthy ones, which can regenerate the blood and immune systems.

There are two primary types of HSCT: autologous and allogeneic.

In autologous HSCT, a patient's own stem cells are collected, stored, and then reinfused after intensive treatment, such as high-dose chemotherapy or radiation. This approach is beneficial when the patient's own stem cells are free from disease and minimizes the risk of immune rejection. Autologous transplants are commonly used in treating conditions like multiple myeloma and certain lymphomas.

In contrast, allogeneic HSCT involves stem cells obtained from a genetically compatible donor, often a sibling or unrelated match from a donor registry. This type is essential for patients whose stem cells are diseased or insufficiently functional, as in certain leukemias and genetic disorders. Allogeneic transplantation offers the potential advantage of a "graft-versus-tumour" effect, where the donor immune cells can help eliminate residual malignant cells in the patient. However, allogeneic HSCT carries risks such as graft-versus-host disease (GVHD) and requires careful donor-recipient matching, typically based on human leukocyte antigen (HLA) compatibility.

Both forms of HSCT offer curative potential but differ significantly in indications, risks, and management considerations, making personalized patient selection crucial.

2. SCOPE

2.1. Autologous Hematopoietic Stem Cell Transplantation services and Allogeneic Hematopoietic Stem Cell Transplant services in DHA licensed health facilities.

3. PURPOSE

3.1. To assure provision of the highest levels of safety and quality of Autologous & Allogenic HSCT services in Dubai Health Authority (DHA) licensed health facilities.

4. APPLICABILITY

4.1. DHA licensed healthcare professionals and health facilities providing Autologous & Allogenic HSCT services.

5. STANDARD ONE: REGISTRATION AND LICENSURE PROCEDURES

5.1. Autologous & Allogenic HSCT services shall only be performed in DHA Licensed Hospitals.

5.2. Hospitals providing HSCT services shall adhere to the United Arab Emirates (UAE) Laws and DHA requirements and shall comply with the DHA licensure and administrative procedures available on the DHA website https://www.dha.gov.ae.

5.3. Hospitals involved in importing, using, or transplanting Autologous & Allogenic hematopoietic stem cells shall adhere to standards in this document.

5.4. Transfer/shipments of hematopoietic stem cell, in or out of the health facility within or outside the UAE, shall obtain all necessary approvals from relevant health regulatory authorities i.e. MOHAP and follow current international best practices with approved interfacility contracts.

5.5. The hospital providing the hematopoietic stem cell transplant services shall be accredited as per DHA Policy for Hospital Accreditation before the commencement of the service.

5.6. The hospital laboratory providing the hematopoietic stem cell transplant services shall be accredited as per DHA Policy for Clinical Laboratory Accreditation before the commencement of service.

5.7. The clinical hematopoietic stem cell transplant services shall be accredited by Foundation for the Accreditation of Cellular Therapy (FACT) or equivalent within 24 months from licensure activation to ensures that the service meets the highest standards of care and safety.

5.8. All HSCT related products shall be registered and approved by MOHAP or other relevant authorities.

5.9. The hospital shall have an in-house procurement and collection facility.

5.10. Health facility shall have policies and Standard Operating Procedures (SOPs) related to the HSCT Service. The relevant staff shall be trained to abide by these SOPs. The SOPs could include, but are not limited to:

5.10.1. Patient acceptance criteria

5.10.2. Patient assessment and admission

5.10.3. Patient education and Informed consent

5.10.4. Donor identification, evaluation, selection, eligibility determination and management

5.10.5. Stem Cell Collection and Apheresis

5.10.6. Stem Cell Mobilisation

5.10.7. Administration of the preparative regimen

5.10.8. Administration of blood products

5.10.9. Central venous access insertion and device care

5.10.10. Administration of HPC as well as other cellular therapy products, such as products under exceptional release

5.10.11. Management of cytokine release syndrome and toxicities of the central nervous system

5.10.12. Transfusion blood products and monitoring of blood counts

5.10.13. Infection control measures and hazardous waste management

5.10.14. Sterility testing and cryopreservation protocols

5.10.15. Communicable disease testing and management

5.10.16. Monitoring infections and use of antimicrobials

5.10.17. Cellular Therapy Product Storage

5.10.18. Cellular Products Traceability

5.10.19. Safe administration of cellular therapy products

5.10.20. Monitoring organ dysfunction or failure and institution of treatment

5.10.21. Monitoring graft failure and institution of treatment

5.10.22. Management of side effects such as vomiting, nausea, pain, and other discomforts

5.10.23. Post-Transplant clinic follow-ups

5.10.24. Medication Management for both donor and recipient

5.10.25. Nutrition Management

5.10.26. Medical equipment management and maintenance

5.10.27. Patient Safety for Radiology and Chemotherapy

5.10.28. Post treatment vaccination protocol (including close family vaccination)

5.10.29. Long-term follow-up, treatment, and plans of care

5.10.30. Palliative Care

5.10.31. Rehabilitation

5.10.32. Morbidity and Mortality Management.

5.10.33. Patient health record

5.10.34. Incident reporting

5.10.35. Patient privacy

5.10.36. Emergency action plan

5.10.37. Patient discharge/transfer.

5.11. The health facility shall provide documented evidence of the following:

5.11.1. Transfer of critical/complicated cases, when required

5.11.2. Patient discharge

5.11.3. Clinical laboratory services

5.11.4. Blood bank service

5.11.5. Diagnostic Radiology services (if not available in-house)

5.11.6. Equipment maintenance services

5.11.7. Laundry services

5.11.8. Medical waste management as per Dubai Municipality (DM) requirements

5.11.9. Housekeeping services.

5.12. The health facility shall maintain charter of patients' rights and responsibilities posted at the entrance of the premise in two languages (Arabic and English).

5.13. The health facility shall have in place a written plan for monitoring equipment for electrical and mechanical safety, with monthly visual inspections for apparent defects.

5.14. The health facility shall ensure it has in place adequate lighting and utilities, including temperature controls, water taps, medical gases, sinks and drains, lighting, electrical outlets and communications.

5.15. The health facility shall have easy access to immunocompromised patients, senior citizens and people of determination to ensure safety and accessibility to all HSCT services as per the local and international practices.

6. **STANDARD TWO:** HEALTH FACILITY REQUIREMENTS

6.1. The hospital shall meet the relevant health facility requirement as per the DHA Health Facility Guidelines (HFG).

6.2. Both the autologous hematopoietic stem cell transplant (HSCT) service and allogenic hematopoietic stem cell transplant (HSCT) service shall be inpatient services with fully equipped supportive services that include bronchoscopy, endoscopy and an operating theatre (if needed) and easy access to renal support areas.

6.3. Autologous hematopoietic stem cell transplant (HSCT) service could be an outpatient service with special permission from DHA.

6.4. For autologous hematopoietic stem cell transplant (HSCT) service the health facility requirements shall be as follows, but not limited to:

6.4.1. Isolation and Patient Care Areas

a. Single Room Isolation shall be available for each patient to minimize the risk of infection, especially during the post-transplant recovery phase when the patient's immune system is suppressed. These rooms shall be positive pressure rooms, with HEPA filtration to

reduce the risk of infections. The HEPA filtration systems shall be maintained and audited regularly for air quality as per the manufacturers specifications.

6.4.2. Stem Cell Laboratory

a. A Stem cell Laboratory could be an in house or outsourced service. In case it is an outsourced service there shall be a contract or Memorandum of Understanding (MoU) between the health facility and the Stem Cell Laboratory elaborating the terms and conditions.

b. A dedicated laboratory shall be available for the processing of stem cells harvested from the patient, including stem cell isolation, cryopreservation, and testing for quality and contamination.

c. Cryopreservation Facilities: Storage for cryopreserved stem cells is crucial. The facility must have appropriate cryogenic storage units (such as liquid nitrogen tanks or ultra-low freezers) for preserving the harvested stem cells until they are infused back into the patient. This service could also be outsourced.

6.4.3. Infusion Room for Stem Cell Transplant

a. Stem Cell Infusion Area: A clean and dedicated room or space for the stem cell infusion procedure shall be available, with equipment

for intravenous administration (IV pumps, monitoring equipment, emergency resuscitation supplies).

b. Access to Emergency Equipment: The infusion room shall be equipped with emergency equipment, such as crash carts (for anaphylactic reactions or other emergencies), oxygen tanks, and defibrillators.

6.4.4. Post-Transplant Recovery and Monitoring Areas

a. Recovery and Monitoring Units: After the transplant, patients should be closely monitored in dedicated recovery rooms or units for complications like infections or reactions to chemotherapy.

b. Intensive Care Unit (ICU) or High-Dependency Units (HDU): For patients requiring intensive care due to complications such as severe infections or multi-organ failure, a facility with an ICU or HDU is needed.

c. To ensure ICU and HDU facility has positive pressure rooms for such patients especially in the immediate post- transplant neutropenic phase.

d. Outpatient Follow-up Clinic: Post-transplant follow-up services should be provided in an outpatient clinic with facilities for regular

check-ups, laboratory tests, imaging, and monitoring of side effects (e.g., long-term effects of chemotherapy, immune recovery)

6.5. For an allogenic hematopoietic stem cell transplant (HSCT) services, the health facility must meet certain physical infrastructure requirements to ensure safety, quality of care, and optimal outcomes for patients. The health facility requirements are as follows, but not limited to:

6.5.1. Isolation Facilities

a. There shall be dedicated single-patient isolation rooms with positive pressure airflow to minimize the risk of infections. These rooms should be equipped with high-efficiency particulate air (HEPA) filters to prevent the entry of airborne pathogens and shall be able to accommodate the patient, equipment, and necessary staff while maintaining infection control measures. Refer to DHA Health Facility Guidelines for the size of the isolation room.

b. The isolation room shall have an integrated monitoring system for vital signs and environmental conditions such as temperature, humidity, and air pressure.

6.5.2. Bone Marrow Transplant (BMT) Unit

a. Dedicated BMT Unit: There shall be a specialized unit designed to handle immunocompromised patients, separate from general

oncology units. This unit should have dedicated nurses trained in stem cell transplant care.

b. Patient Care Stations: Adequate space should be provided for patient care, including dedicated intravenous (IV) therapy stations, nursing stations for monitoring, and equipment storage.

c. Pharmacy and Drug Preparation Area: A sterile environment for the preparation of chemotherapy agents and stem cell products shall be available. This area should be equipped with proper laminar airflow cabinets to avoid contamination.

6.5.3. Stem Cell Laboratory

a. A Stem cell Laboratory could be an in house or outsourced service. In case it is an outsourced service there shall be a contract or Memorandum of Understanding (MoU) between the health facility and the Stem Cell Laboratory elaborating the terms and conditions.

b. A dedicated laboratory where stem cell collection, processing, and testing can be performed under sterile conditions.

c. The facility shall have access to haematology and transfusion services that can quickly perform tests to monitor blood counts and immune function. These include tests for infection monitoring and Graft-Versus-Host Disease (GVHD).

d. Cryopreservation Storage: Shall be available for the storage of stem cells, including cryogenic freezers or liquid nitrogen tanks, are essential to ensure stem cells are preserved until they are infused into the patient.

6.5.4. Infusion Room: An area for the infusion of stem cells, preferably located near the isolation rooms for ease of access and monitoring. The room should be equipped with IV infusion pumps, emergency resuscitation equipment, and observation capabilities.

6.5.5. Supportive Care and Recovery Areas

a. Intensive Care Unit (ICU) or High-Dependency Unit (HDU): A dedicated unit should be available for patients requiring critical care, such as those with severe complications like graft failure or infection. The ICU should have capabilities for mechanical ventilation, renal dialysis, and other intensive monitoring and support.

b. Comfortable Patient Recovery Areas: For recovery following the transplant, the facility should have quiet, private, and comfortable rooms to minimize stress, reduce risk of infection, and allow patients to rest.

6.5.6. Equipment and Technology Requirements

a. IV Pumps, Monitors, and Infusion Devices: These shall be available and integrated into patient rooms for continuous monitoring and administration of chemotherapy or medications.

b. Imaging and Diagnostic Services: The facility should have access to imaging equipment (e.g., CT scan, MRI, X-rays) to monitor the condition of the patient post-transplant.

6.6. The health facility shall install and operate equipment required for provision of the proposed services in accordance with the manufacturer's specifications.

6.7. The health facility shall ensure easy access to treatment areas for all patient groups.

6.8. The health facility design shall provide assurance of patients and staff safety.

6.9. The health facility shall have appropriate equipment and trained healthcare professionals to manage critical and emergency cases.

7. **STANDARD THREE:** HEALTHCARE PROFESSIONALS REQUIREMENTS

7.1. The Autologous HSCT Service shall have the following healthcare professionals:

7.1.1. Clinical Program Director [1]

7.1.2. Quality Manager

7.1.3. Minimum of one (1) attending Transplant Physician.

[1] Shall be a licensed consultant physician in Internal Medicine, Hematology, Immunology or Medical Oncology with additional training and experience in HSCT.

7.2. The Allogenic HSCT Service shall have the following healthcare professionals:

7.2.1. Clinical Program Director[1]

7.2.2. Procurement & collection site Director[2]

7.2.3. Transplant Physician(s) depending on service demand

7.2.4. Quality Manager

7.2.5. Nurse In-charge

7.2.6. Transplant Coordinator

7.3. In addition to the above, the HSCT services shall have the following healthcare professionals to provide comprehensive care and ensure the best possible outcomes for patients undergoing HSCT with adequate educational qualifications, training & experience in the field of HSCT and cellular therapy, but not limited to:

7.3.1. Physicians as mentioned below:

a. Haematologists

b. Medical Oncologists

c. Transplant Medicine (with fellowship in Stem Cell)

d. Haematology Oncologist

e. Paediatric Haematology Oncologists.

7.3.2. Laboratory Technologist

[2] Shall be a licensed consultant physician in Clinical Hematopathology, with training in HSCT, with a minimum of five-years' experience in cell collection and mobilisation.

7.3.3. Pharmacist and Pharmacy Staff

7.3.4. Radiologist

7.3.5. Hematopathologist

7.3.6. Registered Nurses

7.3.7. Dieticians

7.3.8. Social Workers

7.3.9. Staff to collect and analyse data

7.3.10. Health Educator

7.3.11. Physiotherapist

7.4. The healthcare professionals shall be present in the hospital 24/7 during the operational hours.

7.5. The critical care and emergency healthcare professionals shall be trained and have relevant experience in the management of HSCT patients and related complications.

7.6. A DHA licensed Haematologist is the primary speciality to perform HSCT. They are integral to the HSCT process. They diagnose and manage blood disorders, including leukaemia, lymphoma, and other conditions that might require a transplant. Haematologists often oversee the pre-transplant evaluation, conditioning regimen, and post-transplant care.

7.7. Healthcare Professionals, including physicians, nurses, and other healthcare professionals, shall have relevant certifications in Haematology, Oncology and HSCT.

7.8. Effective communication and coordination among team members is crucial for providing comprehensive care and managing complex cases.

7.9. The Privileging Committee and/or Medical Director of the health facility shall privilege the physician and other healthcare professionals involved with the BMT services aligned with his/her education, training, experience and competencies. The Clinical Privileging of physicians and other Healthcare professionals shall be reviewed and revised on regular intervals.

8. **STANDARD FOUR:** PATIENT CARE

8.1. **Pre-Transplant:**

8.1.1. All cases shall be discussed in a HSCT committee meeting led by the Clinical Program Director. The Autologous Stem Cell Transplant is elaborated in **Appendix 1.**

8.1.2. For Allogenic Hematopoietic Stem Cell Transplant service, the health facility shall contact the National Stem Cell Registry to find a safe and suitable donor. The Allogenic Hematopoietic Stem Cell Transplant is elaborated in **Appendix 2**.

8.1.3. A detailed patient informed consent should be obtained, after HSCT committee approval before HSCT commencement, aligned with what has been mentioned earlier in this document.

8.1.4. Recipient Pre-transplant eligibility workup shall be done in accordance with current international best practices, including HLA typing. Comprehensive evaluation is required to assess the patient's suitability for a transplant. This includes assessments of organ function, comorbid conditions, and psychological readiness. Eligibility criteria for an autologous and allogenic stem cell transplant is elaborated in **Appendices 3 & 4.**

8.1.5. Donor medical eligibility and safety assessment should be done to identify and limit the risk of transmitting infectious, genetic or neoplastic diseases transmission to the recipient for safer collection and to maintain donor and recipient health.

8.1.6. Provide appropriate referral system, this include but not limited to the following:

a. Assessment of referred cases for autologous and allogeneic HSCT.

b. Referral to reproductive medicine (for storage of ova or sperm) as chemotherapy and radiation may affect family planning.

c. Counselling and psychological services should be offered to the patient and their families to manage emotional stress.

d. Sub-speciality referral, if required.

8.2. **Transplant Procedure:**

8.2.1. The transplant procedure should be conducted following established protocols for conditioning regimens, stem cell administration and supportive care.

8.2.2. Strict infection control measures are necessary to prevent and manage infections, particularly in immunocompromised patients.

8.2.3. Provide a safe administration of cellular therapy products and recognition of its related short term and long-term complications and emergencies that require a quick response.

8.2.4. Provide proper monitoring and management of patients receiving ABO incompatible Hematopoietic Progenitor Cells (HPC) products.

8.2.5. Provide proper apheresis collection, bone marrow harvest procedures and extracorporeal photopheresis for Graft Versus Host Disease (GVHD).

8.3. **Post-Transplant**

8.3.1. Refer the patient back to the primary treating physician after HSCT with structured follow-ups, reintegrated support systems, and clear protocols for transitioning patients from inpatient to outpatient care.'

8.3.2. Ensure availability of monitoring, prompt evaluation and treatment of patient for the first 24 hours.

8.3.3. Ensure availability of emergency medical service for donor and recipients.

8.3.4. Ensure proper monitoring and management of patients with suspected infection, graft failure, organ dysfunction, acute and chronic GVHD.

8.3.5. Ensure availability of treatment related to acute and long-term post HSCT complications including GVHD treatment.

8.3.6. Ensure a supply of immunosuppressants and all needed therapy during the peri-transplantation period for the duration of planned therapy.

8.3.7. Maintain a comprehensive discharge plan, which include drug management to manage potential complications, key contact numbers to seek advice on symptoms or side effects.

8.3.8. Pre/post procedure requirements for donors and transplant recipient undergoing autologous and allogenic stem cell transplant are elaborated in **Appendices 5, 6, 7 & 8.**

9. **STANDARD FIVE:** INFORMED CONSENT

9.1. It is the responsibility of the hospital to ensure a clear pathway related to stem cell transplant service is informed to the patient before starting the treatment which included but not limited to clinical aspect, storage, laboratory requirements and financial requirements.

9.2. Informed Consent shall be obtained from all recipients prior to the transplant procedure. Consent for storage of autologous cells is elaborated in **Appendix 9.**

9.3. Consent for allogeneic donor's peripheral blood stem cell is elaborated in **Appendix 10.**

9.4. Consent for allogeneic transplantation is elaborated in **Appendix 11.**

9.5. The healthcare professional must provide the recipient with comprehensive information, including:

9.5.1. The objective and foreseeable outcomes of the indicated treatment, potential benefits and the treatment approach.

9.5.2. Information on alternative treatments, if available.

9.5.3. A description of any adverse outcomes reported.

9.5.4. An estimate of the frequency of these adverse outcomes.

9.6. The patient should sign a consent form that should include at least the following elements:

9.6.1. Confirmation that the recipient is aware of the use of HSCT in the procedure.

9.6.2. Confirmation that the recipient was appropriately informed of any risks involved in the transplant process.

9.6.3. The acceptance by the recipient of the risks described above considering the potential benefits of the treatment.

9.7. The informed consent form shall be signed by the recipient or the guardian of the patient.

9.8. The health facility shall maintain detailed records of the informed consent process, including signed consent forms and documentation of all information provided to the recipient.

9.9. Healthcare professionals involved in the transplant process shall be adequately trained in obtaining the informed consent, with a clear understanding of the ethical and legal requirements.

10. **STANDARD SIX:** QUALITY CONTROL AND MONITORING

10.1. All HSCT service Health facilities shall have the following, but not limited to:

10.1.1. Quality Management System (QMS) for comprehensive quality assessment, as an assurance, control and improvement system.

10.1.2. Regular internal and external audits to ensure compliance with clinical guidelines and safety protocols, structured deviation handling, and root cause analysis for continuous improvement.

10.1.3. Monitor patient outcomes, including survival rates, GVHD incidence, and infection rates, to evaluate and prove quality of care.

10.1.4. Conduct HSCT community awareness programs.

11. STANDARD SEVEN: PATIENT AND FAMILY SUPPORT

11.1. Patients and their families should receive education about the transplant process, post-transplant care and potential complications.

11.2. Psychological and emotional support services should be available to help patients and families cope with the stress of the transplant process.

12. STANDARD EIGHT: REGISTRY AND GENERAL KEY PERFORMANCE INDICATORS (KPIs)

12.1. The health facility shall report the KPIs, and all transplantation information defined by these standards to DHA, HRS at monitoringKPIS@dha.gove.ae.

12.2. Data from KPIs and registries should be used to identify areas for improvement in the HSCT treatment process. health facility should implement strategies and interventions to address identified issues and enhance overall outcomes.

12.3. The health Facility shall maintain transparency in their KPI reporting and be accountable for the results.

12.4. KPIs should be reviewed and updated regularly to reflect the evolving nature of tissue management, new technologies, and emerging trends in patient outcomes.

12.5. The accuracy and reliability of the data collected for KPIs shall be regularly audited and validated to ensure that the information used for decision-making is trustworthy and actionable.

12.7. Key Performance Indicators (KPIs)

12.7.1. Percentage of trained healthcare professionals involved in HSCT service on the DHA Standards for Clinical Hematopoietic Stem Cell Transplant Services and relevant policies and procedures.

Percentage of Trained Healthcare Professionals involved in HSCT Transplant on the relevant DHA Standards, Policies and Procedures	
Main Domain:	Structure
Subdomain:	Effectiveness
Indicator Definition:	The percentage of HCPs involved in HSCT service, trained on relevant DHA Standards, policies and procedures, but not limited to: 1. Registration and licensure procedure. 2. Import tissue requirements. 3. Consent for HSCT transplant. 4. HSCT products management includes ordering, receiving, storage, handling, and disposal. 5. Traceability. 6. Biovigilance; etc.
Calculation:	**Numerator:** Number of HCPs involved in HSCT service trained on DHA Standards, Policies and Procedures **Denominator:** Total number of HCP involved in HSCT services
Target:	70%
Methodology:	(Numerator/Denominator) x 100
Measuring Unit:	Percentage of trained HCPs involved in HSCT services
Reporting Frequency:	Quarterly
Desired Direction:	Higher is better
Rationale:	Training HCPs involved in HSCT services on relevant DHA Standards, Policies and Procedures, it is crucial to ensure that all personnel are knowledgeable and compliant with best practices, enhancing the safety

	and quality of tissue transplant services, and leading to better transplant outcomes.
KPI Source:	DHA Standards for Clinical Hematopoietic Stem Cell Transplant Services

12.7.2. Percentage of informed consent for HSCT service obtained from HSCT transplant candidates.

Percentage of Informed Consent for HSCT service obtained from HSCT transplant candidates	
Main Domain:	Process
Subdomain:	Patient Safety
Indicator Definition:	The HSCT candidate should sign a consent form before the transplant procedure that should include at least the following elements: a. Confirmation that the recipient is aware of the use of the procedure. b. Confirmation that the recipient was appropriately informed of any risks to their health associated with the planned treatment c. The acceptance by the recipient of the risks described above considering the potential benefits of the treatment. This KPI is defined by the percentage of informed consent for HSCT service obtained from HSCT candidates.
Calculation:	**Numerator:** Number of informed consents for HSCT obtained from HSCT candidates. **Denominator:** Total number of HSCT treatments done.
Target:	100%
Methodology:	(Numerator/Denominator) x 100
Measuring Unit:	Percentage of patients
Reporting Frequency:	Quarterly
Desired Direction:	Ever one hundred percentage
Rationale:	Ensuring patient safety through
KPI Source:	DHA Standards for Clinical Hematopoietic Stem Cell Transplant Services

12.7.3. Percentage of serious adverse events (SAEs) and reactions (SARs) after HSCT treatment reported to DHA

Percentage of Serious Adverse Events (SAEs) and Serious Adverse Reactions (SARs) after HSCT service reported to DHA	
Main Domain:	Process
Subdomain:	Patient Safety
Indicator Definition:	Health Facility must have a Vigilance And Surveillance (V&S) system in place for reporting, investigating, registering, and recording information about SAEs and SARs which may influence the quality and safety of tissues and cells and which may be associated with any licensable activity, as well as any SAR observed during or after clinical application which may be linked to the quality and safety of tissues and cells. This KPI is defined by the percentage of SAEs and SARs after a HSCT service reported to DHA within 90 days after it has occurred.
Calculation:	**Numerator:** Number of SAEs and SARs after a HSCT service reported to DHA within 90 days after it has occurred. **Denominator:** Total number SAEs and SARs after a HSCT Service.
Target:	100%
Methodology:	(Numerator/Denominator) x 100
Measuring Unit:	Percentage of SAEs and SARs after a HSCT service, reported
Reporting Frequency:	Quarterly
Desired Direction:	Ever one hundred percentage
Rationale:	Ensure that all SAEs and SARs after a HSCT service are reported to DHA.
KPI Source:	DHA Standards for Clinical Hematopoietic Stem Cell Transplant Services

12.7.4. Percentage of unplanned return to the hospital within ≤ 24 hours post-HSCT treatment.

Percentage of unplanned return to the hospital within ≤ 24 hours post- HSCT treatment.	
Main Domain:	Outcome
Subdomain:	Effectiveness
Indicator Definition:	The percentage of unplanned returns to the operating theatre within ≤ 24 hours after HSCT treatment.
Calculation:	**Numerator:** Number of unplanned returns to the operating theatre within ≤ 24 hours post- HSCT treatment. **Denominator:** Total number of HSCT treatment performed.
Target:	< 5%
Methodology:	(Numerator/Denominator) x 100
Measuring Unit:	Percentage of unplanned returns
Reporting Frequency:	Quarterly
Desired Direction:	Lower is better
Rationale:	To ensure the quality of clinical competence and surgical skills by monitoring and minimizing the rate of unplanned returns to the operating theatre after HSCT treatment
KPI Source:	DHA Standards for Clinical Hematopoietic Stem Cell Transplant Services

12.7.5. Patient follow-up for a minimum of 24 months after HSCT treatment

Patient Follow-up for a minimum of 24 months after HSCT treatment	
Main Domain:	Outcome
Subdomain:	Long-term patient care
Indicator Definition:	The percentage of patients who complete a follow-up of at least 24 months after undergoing HSCT treatment.
Calculation:	**Numerator:** Number of patients who completed follow-up for at least 24 months. **Denominator:** Total number of patients who underwent HSCT treatment at least 24 months ago.
Target:	90%
Methodology:	(Numerator/Denominator) x 100
Measuring Unit:	Percentage of patients
Reporting Frequency:	Quarterly
Desired Direction:	Higher is better
Rationale:	Ensuring long-term patient follow-up improves patient outcomes, monitors the success of the surgery, and allows timely intervention if needed.
KPI Source:	DHA Standards for Clinical Hematopoietic Stem Cell Transplant Services

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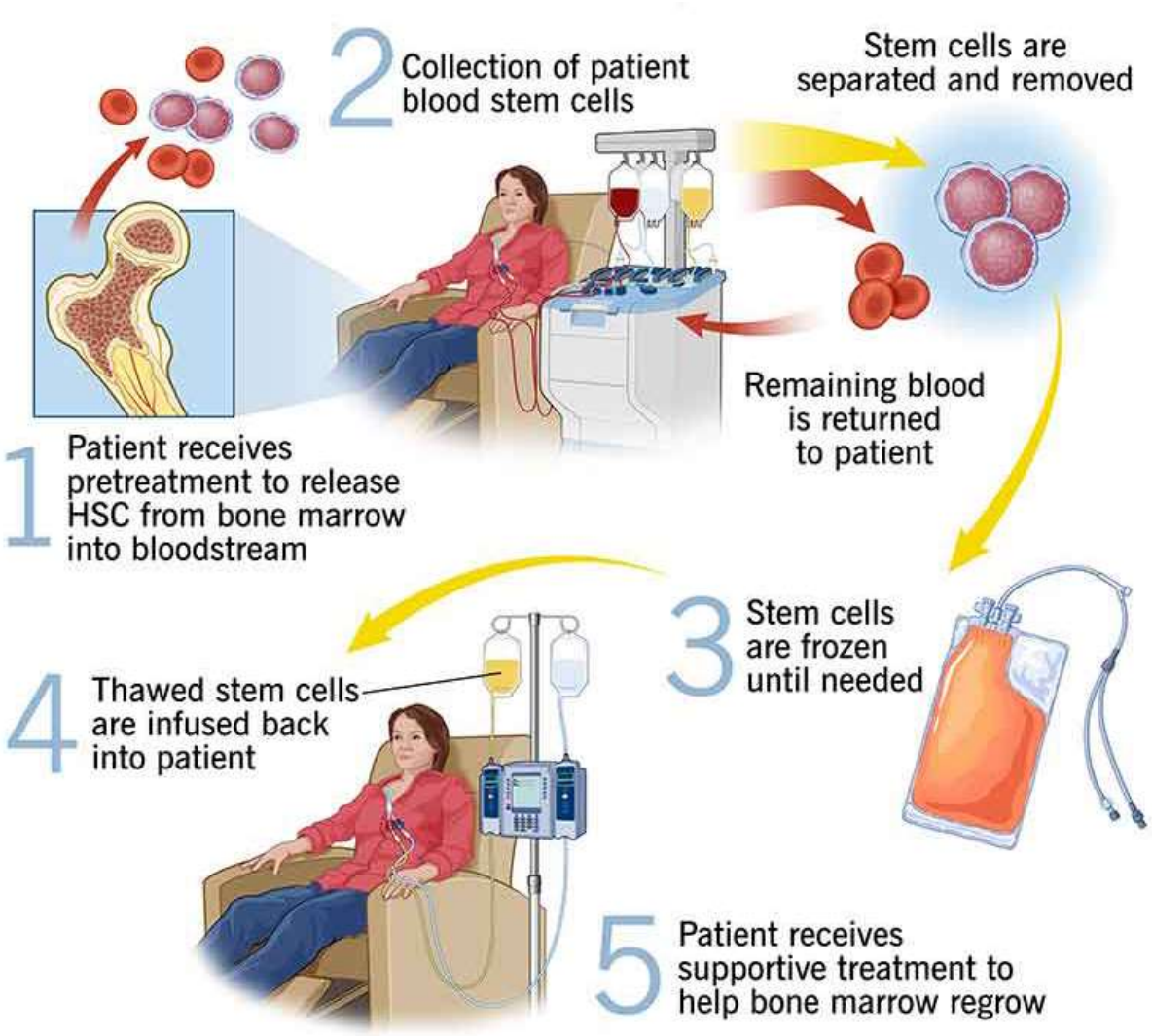
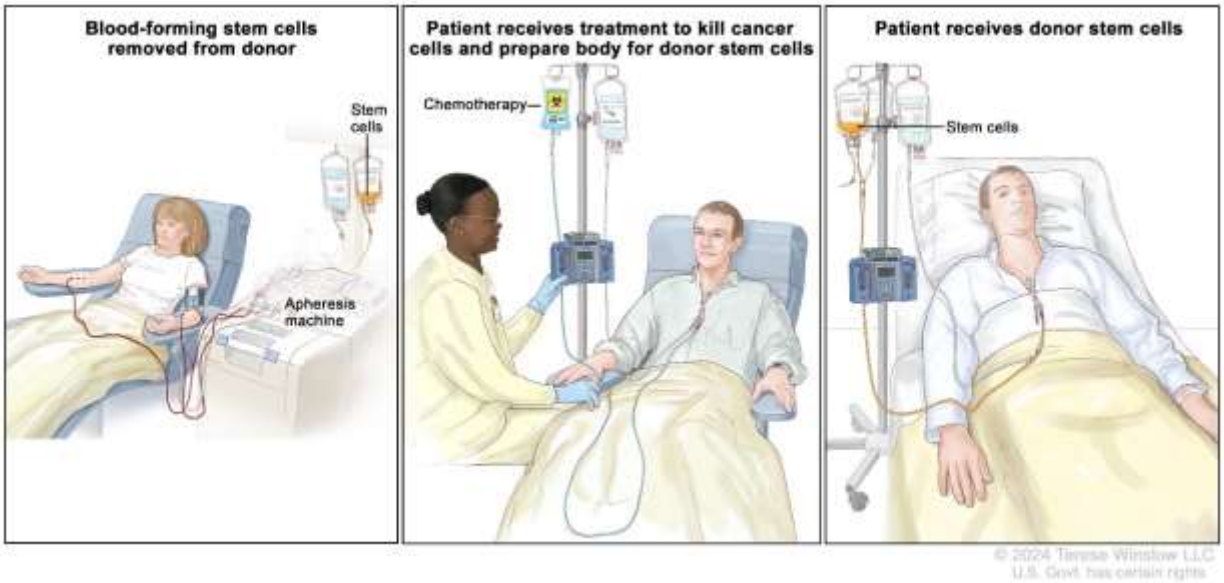
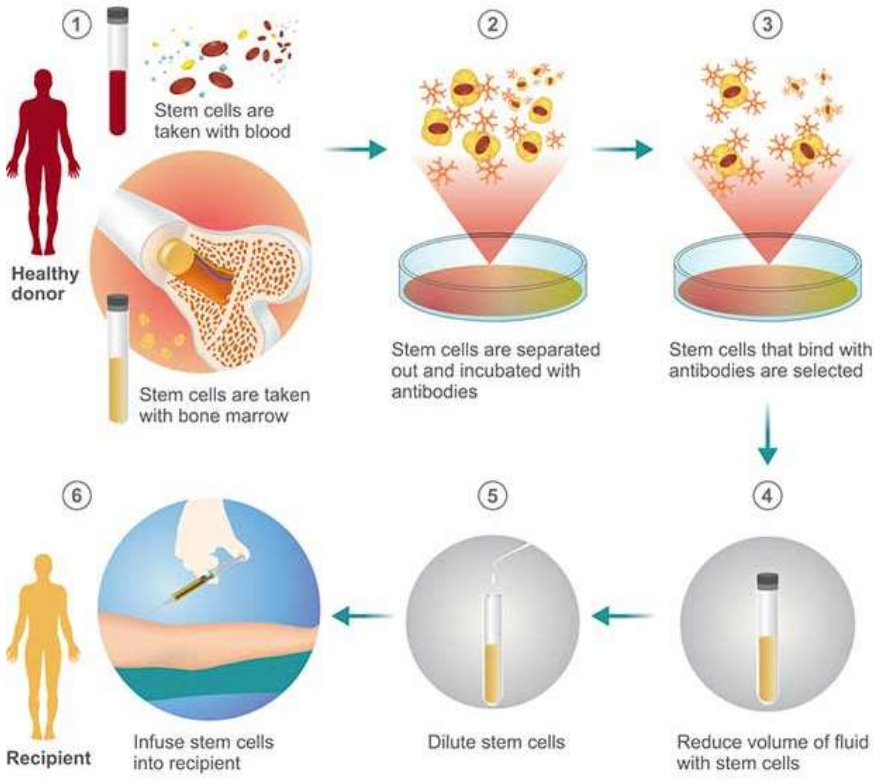
APPENDICES

APPENDIX 1: AUTOLOGOUS HEMATOPOIETIC STEM CELL TRANSPLANT



APPENDIX 2: ALLOGENIC HEMATOPOIETIC STEM CELL TRANSPLANT





Recipient : (low Immunity system, chemotherapy or radiation therapy)

APPENDIX 3: ELIGIBILITY CRITERIA FOR AN AUTOLOGOUS STEM CELL TRANSPLANT

The eligibility criteria for an autologous stem cell transplant can vary depending on the specific condition being treated, but generally include the following:

1. Diagnosis: Common conditions treated include certain types of blood cancers (like multiple myeloma and lymphoma) and other hematologic disorders.
2. Age: Most centers have an age limit, often around 70 years, though this can vary based on the patient's overall health.
3. Health Status: Candidates should be in good overall health, with no significant organ dysfunction or active infections.
4. Response to Previous Treatment: Patients typically need to show a good response to previous treatments, as this indicates a higher likelihood of a successful transplant.
5. Adequate Stem Cell Collection: Patients must have enough healthy stem cells available for collection. This is often assessed through a procedure called apheresis.
6. Support System: A stable support system for post-transplant recovery is often required.
7. Absence of Severe Comorbidities: Conditions like severe heart disease, lung disease, or other serious health issues can disqualify a patient.

It's important for patients to discuss their specific situation with their healthcare team, as they can provide guidance tailored to individual circumstances.

APPENDIX 4: ELIGIBILITY CRITERIA FOR AN ALLOGENEIC STEM CELL TRANSPLANT

The eligibility criteria for an allogeneic stem cell transplant can vary based on the underlying condition, the donor type, and the transplant center, but generally include:

1. Diagnosis: Typically for blood cancers (like leukemia, lymphoma, and myelodysplastic syndromes) and some non-malignant disorders (like aplastic anemia or certain genetic disorders).
2. Age: While there's no strict age limit, older patients may be assessed more carefully for overall health. Many centers prefer patients under 65 or 70, but age criteria can vary.
3. Health Status: Candidates should be in reasonably good health, with functioning organs (heart, lungs, liver, kidneys) and no active infections.
4. Disease Status: Patients may need to be in remission or have a specific level of disease activity that is deemed manageable.
5. Donor Availability: A suitable donor (related or unrelated) must be available. HLA typing is done to find a match.
6. Adequate Pre-Transplant Workup: A thorough evaluation is required, including blood tests, imaging studies, and assessments of heart and lung function.
7. Absence of Severe Comorbidities: Significant health issues, such as uncontrolled diabetes or severe cardiovascular disease, may disqualify a patient.
8. Psychosocial Considerations: Patients need a strong support system and may be assessed for mental health stability.

It's crucial for patients to work closely with their healthcare team to determine their specific eligibility and to understand the risks and benefits of the procedure.

APPENDIX 5: PRE/POST PROCEDURE REQUIREMENTS FOR DONORS UNDERGOING AUTOLOGOUS STEM CELL TRANPLANT

Pre-procedure preparation for donors undergoing autologous stem cell transplantation typically involves several steps to ensure the safety and effectiveness of the procedure. Here are the common preparations:

1. Evaluation and Screening:
    - Complete medical history and physical examination.
    - Blood tests assess overall health, including liver and kidney function, and to check for infections.
2. Stem Cell Mobilization:
    - Donors often receive medication (such as growth factors like G-CSF) to stimulate the production of stem cells and promote their release into the bloodstream.
    - This usually starts a few days before the collection.
3. Apheresis Procedure:
    - The actual collection of stem cells is done through a process called apheresis, which involves inserting a catheter into a vein, typically in the arm.
    - This procedure may take several hours, and the donor may be asked to stay hydrated and comfortable.
4. Education and Counseling:

- Donors receive information about the procedure, potential side effects, and the importance of the transplant.
- They may also meet with a social worker or counselor to address any emotional or psychological concerns.

5. Support System:
   - Donors should arrange for transportation to and from the apheresis center, as they may feel fatigued afterward.
6. Avoiding Certain Medications:
   - Donors might be advised to avoid certain medications, supplements, or lifestyle factors (like smoking or alcohol) leading up to the procedure.
7. Follow-Up Appointments:
   - Donors will have follow-up appointments to monitor their health and ensure the successful collection of stem cells.

Each transplant center may have specific protocols, so it's essential for donors to closely follow the instructions provided by their healthcare team.

Post-procedure requirements for donors undergoing autologous stem cell transplantation typically focus on recovery, monitoring, and overall well-being. Here are the common post-procedure guidelines:

1. Monitoring:

- Donors are often monitored for a few hours after the apheresis procedure to check for any immediate complications or side effects.

2. Hydration:
   - It's important for donors to stay well-hydrated after the procedure to help their body recover and to support kidney function.
3. Rest and Recovery:
   - Donors should take it easy for a few days, allowing time for their body to recover. Fatigue is common after the apheresis process.
4. Follow-Up Appointments:
   - Donors may need to attend follow-up appointments for blood tests to ensure their blood counts return to normal and to monitor for any potential complications.
5. Pain Management:
6. Mild discomfort or bruising at the catheter site is normal. Over-the-counter pain relievers may be recommended, but it's best to consult with the healthcare team.890-\
7. Avoiding Strenuous Activities:
   - Donors should avoid heavy lifting, vigorous exercise, or strenuous activities for a few days post-procedure.
8. Dietary Considerations:
   - A balanced diet rich in nutrients can support recovery. Donors may also be advised to avoid alcohol for a short period.

9. Report Symptoms:
    - Donors should be aware of and report any unusual symptoms, such as excessive bleeding, infection signs (like fever or chills), or persistent pain.
10. Emotional Support:
    - It's important for donors to have access to emotional support, as the donation process can be both physically and emotionally taxing.
11. Education:
    - Donors should receive information on what to expect in the following weeks and how to take care of themselves during recovery.

Following these guidelines can help ensure a smooth recovery process for donors after an autologous stem cell transplant.

APPENDIX 6: PRE/POST PROCEDURE REQUIREMENTS FOR AUTOLOGOUS STEM CELL TRANPLANT RECEPIENTS

Here are the pre- and post-procedure requirements for autologous stem cell transplant recipients:

Pre-Procedure Requirements

1. Comprehensive Evaluation:
    - Complete medical history and physical examination.
    - Blood tests assess overall health, organ function, and disease status.
2. Pre-Transplant Imaging:
    - Imaging studies (like CT or MRI scans) may be needed to evaluate the disease and check for any complications.
3. Stem Cell Collection:
    - Prior to the transplant, stem cells are collected through a process called apheresis. Recipients need to ensure that this is scheduled and completed successfully.
4. Education and Counseling:
    - Recipients receive information about the procedure, potential risks, and what to expect during recovery.
5. Vaccinations:
    - Patients may need to be vaccinated against certain infections before the transplant, as their immune system will be compromised afterward.

6. Psychosocial Support:
    - Mental health evaluations may be conducted, and support systems should be in place for emotional and practical support.
7. Preparation for Hospitalization:
    - Recipients should prepare for potential hospitalization for the transplant procedure, including packing personal items and arranging transportation.

Post-Procedure Requirements

1. Monitoring:
    - Close monitoring in the hospital after the transplant for signs of complications, such as infections or graft failure. This usually includes regular blood tests.
2. Nutritional Support:
    - A balanced diet is crucial for recovery. Nutritionists may provide dietary recommendations tailored to the recipient's needs.
3. Hydration:
    - Staying well-hydrated is essential to support kidney function and overall recovery.
4. Managing Side Effects:
    - Recipients may experience side effects from the conditioning regimen (chemotherapy/radiation) and the transplant itself. Pain management and medications to prevent infections will be important.
5. Infection Prevention:

- Strict hygiene practices and possibly prophylactic antibiotics to reduce infection risk during the period of immune suppression.

6. Follow-Up Appointments:
   - Regular follow-up visits to monitor recovery, blood counts, and overall health status.
7. Activity Restrictions:
   - Gradual resumption of normal activities, with initial restrictions on strenuous exercise and crowded places to minimize infection risk.
8. Emotional and Psychological Support:
   - Counseling or support groups may be beneficial to help cope with the emotional aspects of recovery.
9. Reporting Symptoms:
   - Recipients should be vigilant about reporting any unusual symptoms, such as fever, chills, or persistent pain, to their healthcare team.
10. Long-Term Follow-Up:
    - Continued follow-up care is necessary to monitor for late effects of treatment and to ensure the success of the transplant.

Following these guidelines can help optimize outcomes and support recovery for autologous stem cell transplant recipients.

APPENDIX 7: PRE/ POST PROCEDURE REQUIREMENTS FOR DONORS UNDERGOING ALLOGENIC STEM CELL TRANPLANT

Pre-Procedure Requirements

1. Comprehensive Evaluation:
    - Detailed medical history and physical examination to assess overall health.
    - Blood tests evaluate organ function, blood type, and HLA typing to confirm donor compatibility.
2. Psychosocial Assessment:
    - Counseling to discuss the procedure, potential risks, and implications for both the donor and recipient. Emotional support may be provided.
3. Education:
    - Information sessions to explain the apheresis process, what to expect during and after the procedure, and recovery.
4. Stem Cell Mobilization:
    - Donors may receive medications (like G-CSF) a few days prior to collection to stimulate stem cell production and release into the bloodstream.
5. Apheresis Preparation:
    - Arrangements for the apheresis procedure, including transportation and any necessary time off work.
6. Avoidance of Certain Medications:

- Donors may be advised to avoid certain medications or supplements before the procedure.

7. Health Maintenance:
   - Maintaining good hydration and nutrition leading up to the procedure.

Post-Procedure Requirements

1. Monitoring:
   - Donors are monitored for a few hours after apheresis to check for any immediate complications, such as low blood pressure or reactions.
2. Rest and Recovery:
   - It's essential for donors to rest and allow their body to recover. Fatigue is common, and they should avoid strenuous activities for a few days.
3. Hydration:
   - Staying hydrated post-procedure is important for recovery and to support kidney function.
4. Follow-Up Appointments:
   - Blood tests may be scheduled to monitor recovery and ensure that blood counts return to normal.
5. Managing Side Effects:
   - Mild discomfort or bruising at the apheresis site is common. Over-the-counter pain relief may be recommended.

6. Nutritional Support:
    - A balanced diet is important for recovery, with an emphasis on foods that support blood health.
7. Emotional Support:
    - Donors may benefit from counseling or support groups to address any emotional or psychological effects of the donation process.
8. Reporting Symptoms:
    - Donors should be vigilant about reporting any unusual symptoms, such as excessive bleeding or signs of infection.
9. Gradual Return to Activities:
    - Donors should gradually resume normal activities, avoiding heavy lifting or vigorous exercise for a few days.
10. Education on Long-Term Health:
    - Donors may receive information on long-term health considerations and maintaining overall wellness.

By following these guidelines, donors can help ensure a smooth recovery process and contribute positively to the success of the allogeneic stem cell transplant.

APPENDIX 8: PRE/POST PROCEDURE REQUIREMENTS FOR ALLOGENIC STEM CELL TRANPLANT RECEPIENTS

Here are the pre- and post-procedure requirements for allogeneic stem cell transplant recipients:

Pre-Procedure Requirements

1. Comprehensive Evaluation:
    - Detailed medical history and physical examination to assess overall health.
    - Blood tests evaluate organ function and disease status.
2. Donor Matching:
    - HLA typing to confirm compatibility with the selected donor.
3. Psychosocial Assessment:
    - Counseling to discuss the procedure, potential risks, and support systems available.
4. Education:
    - Information sessions to explain the transplant process, potential side effects, and recovery expectations.
5. Pre-Transplant Imaging:
    - Imaging studies (like CT or MRI scans) to assess disease status and any complications.
6. Vaccinations:
    - Necessary vaccinations may be administered to reduce infection risk post-transplant.
7. Preparation for Hospitalization:

- Arrangements for hospitalization and any necessary time off work.

8. Nutritional Counseling:
    - A dietitian may provide guidelines for nutrition leading up to the transplant to ensure optimal health.

Post-Procedure Requirements

1. Monitoring in Hospital:
    - Close monitoring for complications such as infections, graft-versus-host disease (GVHD), or graft failure. This includes regular blood tests and vital sign checks.
2. Hydration and Nutrition:
    - Ensuring adequate hydration and a balanced diet, often with specialized nutritional support during recovery.
3. Infection Prevention:
    - Strict hygiene practices, including the use of prophylactic antibiotics and antiviral medications to reduce infection risk during immunosuppression.
4. Managing Side Effects:
    - Addressing side effects from the conditioning regimen (chemotherapy/radiation) and the transplant itself, including nausea, fatigue, and pain.
5. Follow-Up Appointments:
    - Regular follow-up visits to monitor recovery, blood counts, and overall health status. This can include outpatient visits after discharge.

6. Activity Restrictions:
    - Gradual resumption of normal activities, with initial restrictions on strenuous exercise and crowded places to minimize infection risk.
7. Emotional and Psychological Support:
    - Access to counseling or support groups to help cope with the emotional aspects of recovery.
8. Reporting Symptoms:
    - Vigilance in reporting any unusual symptoms, such as fever, chills, or persistent pain, to the healthcare team.
9. Long-Term Follow-Up:
    - Continued follow-up care to monitor for late effects of treatment and ensure the success of the transplant.
10. Education on Lifestyle Changes:
    - Guidance on lifestyle changes, including nutrition, exercise, and avoiding infections.

Following these guidelines can help optimize outcomes and support recovery for allogeneic stem cell transplant recipients.

APPENDIX 9: CONSENT FOR STORAGE OF AUTOLOGOUS CELLS

Patient Name: _____

MR Number: _____

Date of Birth: _____

I, the undersigned, have read the patient information sheet entitled: Peripheral Blood Stem Cell Harvest: Autologous Donor in which the form is part of this consent.

☐ I agree to give my Consent for the storage of any blood stem cells collected from me at harvest until they can be of no further use to me.

☐ I agree to give my Consent for the doctor to make the decision for destruction of any stored cells.

☐ I agree that if they are not destroyed, they may be used for research purposes OR

☐ I do not wish my cells to be used for research.

I the undersigned, hereby certify and affirm that upon obtaining the stem cell culture and handing it to the third-party company collecting the product to a cell bank, agree to the conditions and terms set forth below:

1. In no event shall _____ (Name of the Hospital) be liable for any indirect, consequential, or incidental contamination or any contamination of the procured stem cell after it is handed over to the third-party company obtaining the cultures.
2. I am fully aware that certain factors may affect the quality of the stem cell obtained as well as possible contamination of the culture which are not within the scope and responsibility of

_____ (Name of the Hospital) during the transportation of the product. This may be due, but not limited to the following conditions stipulated below:

A. Temperature, atmosphere, and pH level during the transfers of the culture from _____ (Name of the Hospital) to the third-party company's facility.

B. Any other storage or transportation condition not meeting the safety and quality of the stem cell preservation.

I, the undersigned, confirm that I have read and fully understood the consent before signing it. All my questions had been fully answered and all my concerns had been fully addressed by the physician and the medical staff. If I develop any medical problems or any of the mentioned potential risks and complications, I will inform the physician immediately.

I the treating Physician, have fully explained to the patient and/or his/her representative the nature and purpose of the proposed Peripheral Blood Stem Cell Harvest, expected benefits, the attendant risks and possible most common complications involved in the proposed procedure and treatment in accordance with the approved standards. All the patient related queries of his/her medical condition were answered and confirmation of her/his understanding of all the provided information was obtained in the attendance of her/his (representative) and the medical staff.

Patient Signature: 

Date/Time: _____

If the patient is unable to sign the consent form personally, please tick one of the following reasons:

☐ Minor ☐ Unable to understand ☐ Other: _____

Substitute Consent Giver Name: _____

Relationship to Patient: _____

Substitute Consent Giver Signature:

Date/Time: _____

Physician Name: _____

Staff ID No. & Signature:

Date & Time: _____

Witness Name: _____

Witness Signature:

Date & Time: _____

The words "I" and "my" refer to patient, regardless of whether it is the patient or a substitute consent giver signing the form.

APPENDIX 10: CONSENT FOR ALLOGENEIC DONOR'S PERIPHERAL BLOOD STEM CELL HARVEST

Patient Name: _____

MR Number: _____

Date of Birth: _____

PROCEDURE:

Allogeneic donor's peripheral blood stem cell harvest

LIST OF POTENTIAL RISKS AND COMPLICATIONS:

☐ Bone Pain

☐ Flu-like symptoms

☐ Possible insertion of femoral catheter

(Plastic catheter inserted under local anesthetic into a large vein in your groin)

☐ Possible bone marrow harvest in theatre under general anesthetic

☐ Others: _____

- I understand that any abnormal test results generated by the routine tests will be acted upon and communicated to me appropriately.
- I understand that, should I wish, I have the right to review my test results.
- I have received and understood sufficient information on the stem cell harvest procedure.
- I understand I may be required to undergo a bone marrow harvest in theatre.
- I hereby consent to undergo stem cell mobilization not for my benefit but for the benefit of the recipient.
- I hereby consent to the information about the harvest to be made available on the above-named registries.

- I understand that I have the right to withdraw consent to undergo peripheral blood stem cell harvest at any time and the implications of this have been explained to me.
- I understand that I will be sent to an outpatient clinic appointment, between 1- and 4-weeks post donation to which I am expected to attend for follow up assessment.
- I confirm that the information given by me during my medical assessment is true and to the best of my knowledge.

I have fully explained to the patient and/or his/her representative the nature and purpose of the proposed procedure, treatment, expected benefits, the attendant risks and possible most common complications involved in the proposed procedure, treatment, in accordance with the approved standards. All the patient related queries of his/her medical condition were answered and confirmation of her/his understanding of all the provided information was obtained in the attendance of her/his (representative) and the medical staff.

Physician Name & ID No.: _____

Physician Signature: | |

Date & Time: _____/_____

I the undersigned, acknowledge and understand the above information and that the details of the procedure, treatment, the benefits, and risks had been fully explained to me and that I am consciously and freely giving my consent to this procedure, treatment. All my questions had been fully answered and all my concerns had been fully addressed by the physician and the medical staff.

Patient Signature: | |

Date: _____ Time: _____

If the patient is unable to sign the consent form personally, please tick one of the following reasons:

☐ Minor ☐ Unable to understand ☐ Other: _____

Substitute Consent Giver Name & Relation to patient:

Substitute Consent Giver Signature: | |

Date: _____ Time: _____

Witness Name: _____

Witness Signature: | |

Date: _____ Time: _____

The words "I" and "my" refer to patient, regardless of whether it is the patient or a substitute consent giver signing the form.

APPENDIX 11: CONSENT FOR ALLOGENEIC TRANSPLANTATION

LIST OF POTENTIAL RISKS AND COMPLICATIONS:

a. Acute Graft versus Host Disease
b. Blood product support
c. Cataracts
d. CMV reactivation / other viral infections
e. Infection
f. Infertility
g. Primary/secondary graft rejection
h. Relapse Risk
i. Sexual/Hormonal Dysfunction
j. Sickness/mucositis/diarrhea/hair loss
k. Transplant Related Mortality
l. Veno occlusive disease

- Risk of complication mentioned from (A-L)
- Secondary malignancy
- Chronic Graft versus Host Disease

Others: _____

I have fully explained to the patient and/or his/her representative the nature and purpose of the proposed procedure, treatment, expected benefits, the attendant risks and possible most common complications involved in the proposed procedure, treatment, in accordance with the approved standards. All the patient related queries of his/her medical condition were answered and confirmation of her/his understanding of all the provided information was obtained in the attendance of her/his (representative) and the medical staff.

Physician Name & ID No.: _____

Physician Signature:

Date & Time: _____/_____

I the undersigned, acknowledge and understand the above information and that the details of the procedure, treatment, the benefits, and risks had been fully explained to me and that I am consciously and freely giving my consent to this procedure, treatment. All my questions had been fully answered and all my concerns had been fully addressed by the physician and the medical staff.

Patient Signature:

Date: _____ Time: _____

If the patient is unable to sign the consent form personally, please tick one of the following reasons:

□ Minor □ Unable to understand □ Other: _____

Substitute Consent Giver Name & Relation to patient: _____

Substitute Consent Giver Signature:

Date: _____ Time: _____

Witness Name: _____

Witness Signature:

Date: _____ Time: _____

The words "I" and "my" refer to patient, regardless of whether it is the patient or a substitute consent giver signing the form.