



دائرة الصحة
DEPARTMENT OF HEALTH

DOH STANDARD FOR CENTER OF EXCELLENCE IN
HEMATOPOIETIC STEM CELL TRANSPLANTATION
(HSCT) SERVICES FOR ADULTS AND PEDIATRICS

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Note: Read this Standard in conjunction with related UAE Laws, DOH Policies, Standards and Manuals including but not limited to:

- DOH Clinical Privileging Framework Standard
- DOH Data Standards and Procedures
- DOH Standard on Human Subjects Research

1. Purpose

- 1.1. This Standard defines the service specifications and minimum requirements for healthcare providers to be designated by DOH as Hematopoietic Stem Cell Transplantation Centers of Excellence (COE) in the Emirate of Abu Dhabi.
- 1.2. The Standard defines the eligibility criteria for all HSCT services in line with DOH Standard for Centers of Excellence - DOH/SD/COE/0.9, evidence based and international guidelines.

2. Definitions

- 2.1. **Centers of Excellence (COE):** Specialized and distinguished programs within DOH licensed Healthcare facilities, which can provide an exceptionally high level of expertise and multidisciplinary resources centered on particular service lines and/or services and delivered in a comprehensive, interdisciplinary fashion to achieve the best patient outcomes possible.
- 2.2. **Foundation for the Accreditation of Cellular Therapy - Joint Accreditation Committee (FACT-JACIE):** Foundation for the Accreditation of Cellular Therapy (FACT-JACIE) identifies and establishes standards for high quality medical and laboratory practice in cellular therapies.
- 2.3. **Autologous:** Derived from and intended for the same individual.
- 2.4. **Allogenic:** The biologic relationship between genetically distinct individuals of the same species.



2.5. **Pediatrics Patient:** Pediatric age as defined by DOH.

3. Abbreviations:

3.1. **HSCT:** Hematopoietic Stem Cell Transplantation

3.2. **HEPA:** High Efficiency Particulate Air “an efficiency standard of air filter”

3.3. **HLA:** Human leukocyte antigen

4. Scope

This Standard applies to all healthcare providers, public and private, licensed by DOH who seek to qualify as a “Center of Excellence” in Hematopoietic Stem Cell Transplantation (HSCT) services.

5. Implementation Arrangements

DOH shall:

- 5.1. Ensure that the requirements set out in this Standard are met through its regulatory powers and where necessary, set out further regulatory measures to address the current and future health system needs for developing HSCT Centers of Excellence.
- 5.2. Ensure that the COE comply with Federal Law and DOH regulations.
- 5.3. Develop Jawda key performance indicators (Jawda KPI’s) to monitor the HSCT COE’s performance.

Healthcare Providers shall:

- 5.4. Meet the requirements as set out by DOH in this standard along with the DOH Standard for Centers of Excellence - DOH/SD/COE/0.9 to qualify as a “Center of Excellence” in HSCT services.
- 5.5. Have in place their own operational guidelines, policies and procedures.
- 5.6. Contribute to eliminating International Patient Care (IPC) transfers related to HSCT services.

6. Duties for Healthcare Providers

- 6.1. The COE in HSCT has to ensure equal access to all patients based on medical needs. The designated COE in HSCT must:
 - 6.1.1. Ensure and provide evidence that their practices reflect updated international best practices.
 - 6.1.2. Document and monitor quality and safety of clinical care and outcomes of surgical and non-surgical intervention performed on patients, and make these available to DOH for auditing, as and when requested to do so.
 - 6.1.3. Provide records of HSCT related Jawda - Quality Metrics to DOH inspectors.
 - 6.1.4. Maintain Accreditation by a recognized International Accreditation body aligned with DOH and COE and report the findings to DOH (see Appendix 1).



- 6.1.5. Aim to achieve recognized international accreditation in HSCT within 2-5 years.
- 6.1.6. Follow the clinical and regulatory requirements of this Standard irrespective of provision of COE services to patients who opt not to use health insurance coverage (pre-authorization for coverage and health insurance does not apply in this case).

7. Hematopoietic Stem Cell Transplantation (HSCT) COE Service Requirements and Specifications:

7.1. Facilities

- 7.1.1. Healthcare facilities seeking the COE designation in HSCT should ensure the availability of:
 - 7.1.1.1. A designated inpatient unit that minimizes airborne microbial contamination ideally high efficiency particulate air filtration (HEPA) with positive pressure or laminar airflow for allogeneic transplants.
 - 7.1.1.2. Provisions for prompt evaluation and treatment of patients with complications on a 24-hours basis.
 - 7.1.1.3. Access to stem cell lab services that is having international accreditation for stem cell harvest, enumeration; processing and cryopreservation shall be available within the vicinity. The stem cell laboratory shall conform to the National Standards of stem Cell Procurement, Storage and Allocation.
 - 7.1.1.4. Centers performing Allogenic HSCT shall have access to HLA-testing laboratory with the capability to carry out DNA-based HLA typing. This HLA-Laboratory shall seek international accreditation.
 - 7.1.1.5. Laboratory support with availability of microbiological tests, monitoring of drug levels, chimerism study and histopathology services is important. The pathologist shall have experience in the histopathological interpretations of graft versus host disease.
 - 7.1.1.6. A transfusion service to provide irradiated blood products on a 24-hour basis.
 - 7.1.1.7. A pharmacy to provide essential medications on a 24-hour basis.
 - 7.1.1.8. A radiotherapy service shall be available within the vicinity.
 - 7.1.1.9. Supportive services including specialists in the field of radiology, intensive care, neurology, nephrology, respiratory medicine, gastroenterology, cardiology and infectious disease shall be available for consultations.

7.2. Healthcare Professionals

Healthcare facilities seeking the COE designation in HSCT must fulfil the following requirements related to healthcare professionals:

- 7.2.1. Valid DOH license in their specialty.
- 7.2.2. The Head of Clinical Transplant Services shall be a consultant who has at least one-year specific training in HSCT.
- 7.2.3. The adult HSCT transplant center shall have at least one physician certified in Internal Medicine and accredited in Hematology or Medical Oncology or Immunology.
- 7.2.4. Centers performing pediatric transplants shall have at least a one physician certified in Pediatrics and accredited in Hematology/Oncology or Immunology.
- 7.2.5. The transplant nurses must have appropriate certification in the management of HSCT patients.
- 7.2.6. Other supportive staff members shall include a transplant coordinator, pharmacy staff, dietary staff, social worker and physiotherapy staff and a data manager.



- 7.3. HSCT services provided in an authorized healthcare facility seeking recognition as a COE in HSCT must include a range of integrated clinical services surgical and non-surgical intervention for its patients in accordance with this Standard including the requirements of FACT-JACIE.

8. Performance Management

Health care provider including those providing pharmacological, surgical, and non-surgical intervention will be required to ensure the following from their services and management systems:

- 8.1. Are capable of Tracking Performance, including trends in Clinical Quality/Outcomes for patients by documenting the related Jawda - Quality Metrics (<https://www.doh.gov.ae/resources/jawda-abu-dhabi-healthcare-quality-index>).
- 8.2. Provide seamless care in partnership with other providers, including primary care and hospitals, as required for holistic patient care.
- 8.3. A Center of Excellence in HSCT shall be required to maintain volumes of greater than or equal to ten (10) new patients/year for Autologous transplantation and ten (10) new patients/year for Allogeneic transplantation.

9. Clinical Research and Education

- 9.1. The COE must demonstrate a commitment to education, research and training focusing on HSC and HSCT-related sciences.

10. Data Management

- 10.1. Data Collection
 - 10.1.1. Clinical Programs shall submit clinical outcomes and specified registry data elements to a national or international database in alignment with related DOH standards.
- 10.2. The Clinical Program shall define staff responsible for collecting data maintaining the database.
 - 10.2.1. Defined data management staff should participate in continuing education annually.

11. Payment Mechanism

- 11.1. The appropriate compensation model will be adjusted with additional cost associated with Clinical leadership, Research, Education and Technology.

12. Enforcement and Sanctions

- 12.1. DOH may impose sanctions in relation to any breach of requirements under this Standard in accordance with Chapter on Complaints, Investigations, Regulatory Action, and Sanctions, the DOH Healthcare Regulator Manual.



Appendix I:

Accredited of HSCT Program

- Foundation for the Accreditation of Cellular Therapy (FACT-JACIE) is the only accrediting organization that addresses all quality aspects of cellular therapy treatments:
 1. Clinical care.
 2. Donor management.
 3. Cell collection.
 4. Cell processing.
 5. Cell storage and banking.
 6. Cell transportation.
 7. Cell administration.
 8. Cell selection.
 9. Cell release.

- Staffing requirements for the clinical unit shall meet the FACT requirements:
 1. Clinical Program Director.
 2. Attending Physicians.
 3. Mid-Level Practitioners.
 4. Clinical Coordinator
 5. Nurses.
 6. Consulting Specialists.
 7. Quality Management Supervisor/Data Management.
 8. Support Services Staff (Dietitian, Psychology, Social Service).

- The support service staffs are as follows:
 1. Pharmacy staff knowledgeable in the use and monitoring of pharmaceuticals used by the Clinical Program.
 2. Dietary staff capable of providing dietary consultation regarding the nutritional needs of the transplant recipient, including enteral and parenteral support, and appropriate dietary advice to avoid food-borne illness.
 3. Social Services staff.
 4. Psychology Services staff.
 5. Physical Therapy staff.
 6. Data Management staff.



References:

1. DOH Standard for Centers of Excellence - DOH/SD/COE/0.9
2. DOH Healthcare Regulator Manual Version 1.0
3. FACT-JACIE International Standards for HEMATOPOIETIC CELLULAR THERAPY Product Collection, Processing, and Administration.
4. National guidelines for Haemopoietic Stem cell therapy published 2009 and updated 2011 (ISBN: 978-983-3433-62-9) = NEED TO GET permission to use
5. NHS standards Contract for Haematopoietic stem cell transplantation adult NHS commissioning Board, 2013
6. HSCT charter for KSU (Hematopoietic Stem cell Transplant (HSCT) Program at the Oncology Centre, King Saud University Medical City (KSUMC)