
Minimum Standards for Hematopoietic Stem Cell Transplantation (HSCT) Units for Blood Diseases

Adapted for India from ASCO/ASH Recommended Criteria for the Performance of Hematopoietic Stem Cell Transplantation (HSCT)

The following criteria are **necessary at a minimum** for the safe and successful performance of the procedure:

1. Patient Volume

- a. A sufficient number of patients must be treated each year to allow the development of a designated transplant unit with an experienced, full-time clinical and nursing team.
- b. This would require, in general, that the center performs a minimum of ten transplants per year.
- c. Sufficient transplants must be performed to never have the unit empty.
- d. If both allogeneic and autologous transplants are performed, at least 10 of each should be performed annually to allow sufficient experience in the technical aspects of both procedures to remain current.
- e. Criteria for matched unrelated donors (MUD)/ Haplo identical donors and cord blood transplants – The centre must have completed at least 20 allogeneic transplants.
- f. For new units, compliance with these volume goals should be reached within **3 years** of operation.

2. Facilities

- a. There must be a designated transplant unit with two or more designated transplant beds. This could be part of a facility for treating immunosuppressed patients that also manages patients with leukemia or similar disorders.
- b. The equipment and experience necessary for handling the marrow outside the body needs to be in place. This includes at least the facilities and a protocol for cryopreservation of autologous hematopoietic stem cells, and management of ABO blood group incompatible allogeneic transplants if both autologous and allogeneic transplants are performed.
- c. If allogeneic HSCT **is** performed, the transplant unit must demonstrate access to a certified histocompatibility laboratory for the necessary tissue typing.
- d. The transplant unit must have facilities in place and a policy for the required isolation to effectively manage these patients. This should include a plan for air-

handling (e.g. positive pressure, filtered air, or laminar air flow rooms) as well as monitoring of its quality. Support of trained housekeeping staff for maintaining the facility is also critical.

- e. Twenty-four hour, high quality support from laboratory, blood bank and radiology needs to be available. This must include the 24-hour availability of red cells, platelets, and other blood components (with facilities available either in house or outsourced for irradiation of cellular blood products).
- f. In most circumstances, a radiotherapy unit with the ability to perform and monitor total body radiotherapy should be available if total-body irradiation (TBI) based conditioning is practiced.
- g. ICU and dialysis facilities should be available for both adults and children in the institution.

3. Personnel

a. Transplant Physicians

Although the management of patients undergoing HSCT is in many ways not much different from those patients being treated for acute leukemia, physicians who actually perform HSCT should have documentable experience with the procedure. (Defined in the next section)

If both autologous and allogeneic transplants are being performed, the treating physicians should have documentable experience with both types of procedures.

b. Consulting Physicians

Access to a broad range of subspecialty consultations in both medical and surgical specialties such as intensivist, ID specialist etc., required to cope with complications often associated with HSCT need to be immediately available.

c. Nursing Team

This is the most important single aspect of a successful HSCT unit. There need to be nurses committed to this program full-time. There should be a high ratio of nurses to patients with the nurse-to-patient ratio of not more than **1:2** on average. The number of patients transplanted must be sufficient to develop and maintain a full-time nursing team.

d. There must be a commitment from the institution to have full-time HSCT coordinators and adequate support from social work and other services needed.

e. Appropriate microbiology laboratory facilities should be available 24 hours.

f. Resident staff, if DM/DNB training facilities are available at the institute, or 24 hour medical cover of transplant unit by Medical Officer (MBBS or MD) / Consultant should be available.

4. Treatment Outcome

- a. A sufficient number of patients in each disease group undergoing treatment at the center is necessary to be able to compare the results with those published from very experienced centers.
- b. An occasional patient from any disease group being transplanted should be discouraged.
- c. The unit must maintain a registry of all transplants performed, and compare outcomes with results in other centers.
- d. There should be a policy in place for identifying deficiencies in results, and for analyzing causes and implementing changes aimed at improving results.

5. Data Reporting

HSCT is a rapidly evolving therapeutic modality. Physicians performing this procedure should report their data to available registries (e.g. Indian Stem Cell Transplant Registry, International Blood and Marrow Transplant Registry) and when appropriate, publish important observations in the medical literature.

Suitable infrastructure for maintenance of treatment records and data reporting must be made available at the institution.

6. Transplant In-Charge Requirements (ref ASBMT guidelines)

Physicians performing peripheral blood, cord blood, and bone marrow transplantations must be licensed to practice medicine and should be board certified or eligible and have the requisite training and experience in hematology, medical oncology, immunology, and/or pediatric hematology/oncology.

Qualifications

- a. DM/DNB Clinical Hematology with specific training in stem cell transplantation
- b. DM/DNB Medical Oncology with specific training in stem cell transplantation
- c. DM/FNB Pediatric Hematology / Oncology with specific training in stem cell transplantation
- d. Candidates with MD / DNB (Internal Medicine /Pediatrics) should undergo at least 2 years of training in a recognized department of Hematology with at least one year of training in SCT.
- e. Equivalent qualifications from USA / UK / Australia with at least one year of training in HSCT.
