# Setting up a Hematopoietic Stem Cell Transplantation Unit

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### Abstract

Setting up a Hematopoietic Stem Cell Transplantation (HSCT) unit is a multifaceted activity which requires the transplant physician to wear the hats of a strategist, architect, engineer, project manager, and provider. There are many ways to establish a unit based on the resources and expertise available locally. The residency program in hematology provides little help in equipping a physician with the necessary management skills to establish a program from scratch. Hence a document to navigate through this process becomes vital, especially for a country which is in the early expanding phase of providing transplant services. This article attempts to provide a basic overview to establish a sustainable model which can also be shared with administrators to make them understand the requirements for HSCT. This review highlights the importance of planning the physical infrastructure (with particular emphasis on layout, design, civil work, zoning, and HVAC), personnel, equipment, financial resources, data collection, quality management, legal requirements, and accreditation processes.

### Keywords

Planning · Bone marrow transplant unit · Stem cell · HSCT room · Air quality · Accreditation

### Introduction

Establishing a Hematopoietic Stem Cell Transplantation (HSCT) program is a complex activity which involves assessment of need, defining goals, planning, organizing a team, executing, monitoring, and sustaining the program. For more accurate terminology, the term HSCT will be used in this article instead of bone marrow transplantation (BMT).

A country or an institution decides to set up an HSCT program to meet the needs of patients with many diseases which can be cured by a transplant. Also, it equips to develop expertise in the management of neutropenia, insertion and management of central venous access, blood components, recognition of graft versus host disease and the role of blood irradiation in its prevention, monitoring air quality, etc.: services which improve the quality of patient care in many other specialities. Developing and maintaining a successful hematopoietic stem cell transplant program with a properly function unit enhances the credibility of any tertiary level medical facility.

HSCT is a lifesaving and labor-intensive activity which demands teamwork of several trained personnel, and it integrates with almost all departments in an institution.

This article intends to provide a framework for a transplant physician/administrator who desires to set up the HSCT program as a project. A project life cycle has four phases: (a) defining goals,
specifications, tasks, responsibilities, (b) planning (schedules, budget, resources, risks, staffing), (c) Executing, and (d) evaluating and closing.

This article will deal with the need to conform to international guidelines/standards in developing and sustaining the program.

Defining

“Begin with the end in mind”
Stephen Covey

Strategizing and describing the goals: It is first necessary to estimate the yearly number of autologous and allogeneic transplants to be performed based on the population and the prevalence of malignant or benign diseases in the region that the center is serving. However, in a place where the need for a transplantation unit is high, it is often the availability of the transplant physician, which drives the program. This also involves networking of physicians and other healthcare workers to establish a referral pathway and communication to ascertain adequate post-transplant care. However, this may be dependent on each country’s healthcare delivery process, which is government-funded, insurance-driven, or out of pocket payment by the patient. From the health economic perspective, it is the “net value” the program can generate from the payer, health sector, or societal perspective for the improvement in well-being minus the opportunity cost of resources used to produce that change (Garrison et al. 2018).

As with the “scope triangle” in project management, the primary determinants of a quality program with long term sustainability are the time, cost, and resources. Having a team of experienced transplant physician, nurses, a program manager (resources), and a highly supportive and committed administration (for providing the necessary time and understand the costs) is the first step. The strategies should tie-in with the expansion plans for the transplant program for the years ahead.

The focus of the transplant program could be a graded approach from autologous transplants to matched sibling allogeneic transplants and alternative donor transplants to maximize the efficacy and safety considering the complexity and risks involved in the latter. However, this is highly dependent on the expertise of the team, risk appetite of the team leader, infrastructure, and available support facilities.

Minimum requirements for a transplant program: The Transplant Centre and Recipient Issues Standing Committee for the Worldwide Network for Blood and Marrow Transplantation (WBMT) published requirements for a transplant program through a structured review of various domains of transplants and the ancillary services and classified them as a minimum, preferred and ideal in a graded manner. The levels I, II and III give more objectivity to the aspirational goals of the team and assists in the appropriate fund allocation and future planning. Level 1 emphasizes on safety and basic quality structures. Level 2 intends at making the quality system operational while Level 3 is considered equivalent to full accreditation (Pasquini et al. 2019) (Table 1).

Planning

“If you fail to plan you are planning to fail”
Benjamin Franklin

The success of an HSCT program is centered on proper planning, design and implementation, monitoring and innovating.

Planning is the forecasting and organizing of activities required to achieve the desired goals.

Physical Planning and Design Team

HSCT, in most cases, is not a standalone operation, but one which is developed within a tertiary hospital and therefore, design elements must cater to its interaction with other hospital departments and services. The team needs to evaluate available capacity and the ability of the existing systems to serve the proposed project. Hence it is utmost essential to have all the stakeholders in the team which design and plans the HSCT program.
**Table 1** The three WBMT levels of an HSCT center

| Category         | Level I                                      | Level II (includes facilities of Level I) | Level III (includes facilities of Level I and II) |
|------------------|----------------------------------------------|------------------------------------------|--------------------------------------------------|
| Definition       | (Required: a program to be implemented only with this element. (mean score of 1–2) | (Important for further expansion of the program) (mean score >2–4) | (Important but not needed at early implementation: Ideal element but not critical for the day-to-day operations) (mean score >4 to ≤7) |
| Scope of transplant | Only Autologous transplants | Autologous and Allogeneic transplants | Autologous and Allogeneic transplants |
| Infrastructure   | Cell Processing laboratory (laboratory services access for cell count and sterility assessment). Tertiary care center. Intensive care unit (ICU) access. (mechanical ventilatory support, Non-invasive ventilation, vasopressors, dialysis). | Apheresis services | Collaboration with registries |
| Staff            | Medical Director: hematologist/oncologist or immunologist. With a minimum of 6 months training in an HSCT unit (recommendation: To collaborate with an experienced HSCT unit) Nurses with hematology-oncology experience or trained in handling chemotherapy and infection control. Pharmacist/Nurse with experience in handling chemotherapy | | |
| Cell processing  | | Cryopreservation procedures and storage capability | Cryopreservation procedures and storage capability |
| Quality          | | Accreditation with local, regional or international HSCT quality entities. Data collection with demographic details and outcome data according to the international standardized forms. Data-sharing with local, regional or international outcomes registries through standardized forms. Quality program development in the process. Collaborative efforts with an established transplant program for the first year. Develop standard operating procedures (SOPs) for the HSCT program. | Involvement in the junior faculty training program in HSCT. |

(continued)
HSCT Project Team

- Hospital administrator/General Supt /Medical Supt
- Project manager
- Architect
- Engineers – Civil, Mechanical, Electrical, Air conditioning plant and plumbing dept. representative
- Fire safety officer
- Information technology (IT) division representative
- Finance team representative
- HSCT Nurse
- HSCT physician with adequate experience

Layout and Design

Location: The area of HSCT should be away from dampness, infection wards, and construction site (Das et al. 2018). Most hospitals locate their HSCT rooms on the top floors.

Designing Principle and Minimum Requirements

In 2019, WBMT put forward the minimum requirements for starting an HSCT program, based on a structured valuation of essential elements for a program which was reviewed by a team of experienced transplant physicians from different countries. A scoring was used to rank the elements to make the recommendations (Pasquini and Srivastava 2018).

- Space: should be predetermined based on the number of rooms one is planning to construct. It may be a good idea to have a phased-out plan based on the projections of demand, which can cater to the increase in patient load. The HSCT unit could be an extension of a facility/ward for treating leukemia and immunosuppressed patients. A minimum of 3000 sqft area may be suitable for a 5–6-bed unit along with ancillary facilities/space in intermediate, restricted, and inner aseptic zones (see “Zoning” below).
- One-way movement of traffic: Visualizing the workflow and patient flow (coming in and taken out for procedures and scans) will enable better layout and efficient design. In general, avoid backtracking of sterile goods.
- Materials: Surfaces should be Impervious and contaminant free. Stainless steel panels can provide durability, sturdiness and easy maintenance. However, there are alternative materials like pre-painted galvanized iron (PPGI) (also known as pre-coated steel, color-coated steel), and antibacterial vinyl sheets which may not be highly durable but cheaper. Epoxy painting of the surfaces is an alternate.
- Back-up equipment: It is vital to provide a 100% redundancy for critical mechanical systems and 70% back up for noncritical central systems.

Civil Work

- Flooring – Wallcoverings, window shades, and countertops used in HSCT centers should

Table 1 (continued)

|                          | Level I                                      | Level II (includes facilities of Level I)                                      | Level III (includes facilities of Level I and II)                        |
|--------------------------|---------------------------------------------|--------------------------------------------------------------------------------|----------------------------------------------------------------------------|
| Inpatient unit           | Clean single bedded rooms with isolation capability | HEPA filtered positive pressure rooms. Preferable with anteroom.               | Separate air handling unit with positive pressure and HEPA filters for individual rooms. |
| Outpatient clinic        | Single patient examination rooms            | Single patient examination rooms                                               | HEPA filtered unit in daycare                                              |
| Intensive care unit      | ICU with positive/negative pressure isolation rooms and ventilator support | Level III ICU with capabilities for Hemodialysis/CVVH/ECMO                    |                                                                            |

Table 1

| Level | Description |
|-------|-------------|
| Level I | Inpatient unit Clean single bedded rooms with isolation capability |
| Level II | HEPA filtered positive pressure rooms. Preferable with anteroom. |
| Level III | Separate air handling unit with positive pressure and HEPA filters for individual rooms. |

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be jointless (if possible), scrubbable, non-porous, disinfected effortlessly, and they should collect minimal dust, be anti-static, waterproof, with coving at the junction to the wall.

- **Terrazzo**: Composite material, poured in place or precast, for floor and wall treatments. Terrazo contains chips of quartz, marble, glass, granite, or any other suitable material. Laying takes longer time but once laid. It is long-lasting but challenging to repair if broken.

- **Polyvinyl flooring with thermal sealing**: Made from a plasticized PVC (polyvinyl chloride) impervious to water. Thermal sealing averts formation of creases. Creases can otherwise lead to dirt accumulation. Easy to fix but can get stained and scratches can cause dirt accumulation.

- **Epoxy**: Epoxy resins, are a class of reactive prepolymers and polymers also known as polyepoxides, which contain epoxide groups. It creates a shiny high-gloss surface. Epoxy is poured on a pre-prepared floor and generally recommended for clean rooms. Repairing isolated sections can be trying.

- **Vitrified tiles**: They are similar to ceramic tiles. However, here the clay is mixed with silica, quartz and feldspar before being fired in the kiln. When baked at high temperatures, they fuse, creates a glossy and hard surface. The process of manufacturing is called vitrification. Tiles may have the disadvantage of having space between the tiles. However, this can be minimized by using larger tiles and using epoxy to fill the spaces. Tiles are much longer-lasting than PVC and Epoxy.

- **Sidewalls**: In the patient area, wall up to two meters and floors should be jointless, easily washable and disinfecatable. Alternatively, dadoing (the lower portion of the wall of a room made with tiles or any other nonporous material) can be done which will enable regular washing down with a wet cloth. A coved junction between the wall and the floor prevents dust accumulation.

- **Paints**: Easy to clean plastic/rubber material.

- **Ceiling**: Whenever possible, avoid false ceilings. If the use of false ceilings is unavoidable (especially for A/C ducting) make provision for the vacuuming the area above false ceilings or for robot cleaning.

- **Electrical**:
  - Lighting must be adequate with a seamless surface which locks with the adjacent surface.
  - Incorporate measures to prevent electrical sparks and other hazard safety measures, sockets with earthing in the construction plan.
  - Designate a zone for charging the infusion pumps and other equipment which are not in use (could be in a storeroom).
  - Power back up and alternative power supply is essential for ahus to maintain constant air exchanges and room pressurization. UPS power back-up/Generator/Inverter for electrical equipment.

- **Furnishings**: A dust-free environment is a goal while designing and selecting furnishings. A smooth non-porous and quickly disinfecatable upholstery will minimize potential nosocomial pathogen contamination. The window shades, countertops, wall coverings, and finishes should be nonporous, non-water absorbent, scrubbable, and effortlessly disinfected to reduce dust accumulation.

- **Emergency Shower and Eyewash Systems**: Connect all emergency shower and eyewash stations or water systems to a domestic (potable) source. Provide a mixing valve to provide tepid water to a shower or eyewash station. Central water mixing station can provide a designated water loop if many stations exist.

- **Service lines**: Suction, medical oxygen system and compressed air systems for ventilators need to be planned complying with national law or international recommendations.

- **CCTV camera**: Electrical lines, nurse call wiring and CCTV camera wiring are to be concealed within conduits behind the panels to avoid reopening the area a second time.

- **Design theme**: To remove the monotony of the unit, one may place wall paintings preferably framed with glass or laminated. The frames
could have slanting rounded edges which do not accumulate dust. Go ahead and choose an innovative theme which leaves the observer thinking for a while.

**Zoning**

A term borrowed from land demarcation which represents a means of classifying locations based on functions and level of sterility required. Zoning may not be entirely applicable in centers where environmental pollution is minimal.

**Outer Zone**
- Secretarial space or location for patient admission, discharge. Can be an area far away from the transplant center also.
- A consenting and counselling room.
- CCTV monitored HSCT unit entry with safety key (Biometric lock system – to ensure restricted entry).

**Intermediate Zone**
- Footwear changing area as one enters the intermediate zone, depending on the local requirement.
- Refreshment room.
- Changing-room with lockers: Double cabinet to separate ordinary clothes from work clothes or uniforms.
- Relative counselling room.

**Restricted Zone**
- Toilet for health care workers and patient relatives (number based on the HSCT rooms).
- Scrub area with non-manual or feet operated mechanical wash area.

**Inner Aseptic Zone**

**Drug Reconstitution and Drug Storage Room**
An area for drug preparation equipped with a laminar hood. This is applicable where the central pharmaceutical reconstitution and supply is unavailable.

**Clean Utility Room**
To house all the linen, clean items required for the unit. If space allows, one can keep the electrical gadgets also.

**Equipment Room/Charging Room**
Dedicated space for storing instruments and other equipment like portable electrocardiogram, ultrasound machine, X-ray machine, defibrillator etc.

**Duty Room**
Can be in the restricted zone also based on the availability of space.

**Patient Rooms**
The patient room should be designed to provide natural light, reasonable comfort and respect his/her privacy. Large Belgian windows overlooking a scenic place would be ideal. If the hospital is in a city, higher floors tend to offer the city view, which can itself be soothing. It should have well-sealed fixed sashes (panels) to prevent external air, dust, or small insect infestation. Electric lighting shall be adjustable for acceptable visibility. A viewing panel on the door or the wall could facilitate observation by the nursing staff, and curtains/blinds will protect the privacy of the patient.

- **Single rooms** with Size of 10 ft. × 15 ft. × 8 ft. (1200 ft³) is reasonable. Fittingly sealed windows and electrical outlets are essential to maintain positive pressure.
- **Doors**: Self-closing doors will maintain constant pressure differentials among the HSCT recipients’ room and hallways to direct the airflow from the patient’s room to the hallway and not vice versa.
- **Wheel bed** with cardiac massage option, detachable head end for intubation. Three- or four-fold firm mattress.
- **Materials for cabinetry items**: All cabinetry surfaces and furniture shall have non-porous, smooth wipeable and cleanable surfaces resistant to scratching.
- **Clean hatch** - to take clean and sterile items into the patient’s unit.
• **Dirty hatch** - to send dirty and unsterile items out of the patient’s unit.
• **Sink and tap** for handwashing in every location or room apart from the one in the toilet.
• **Bed panel**: Should be provided with oxygen gas, an aspiration system and compressed air. Electrical connections are made available with patient call facility, cardiac monitor control panel, BP monitoring, internet network access, WIFI socket, mobile charging socket, and Internal telephone line.
• **Television/Computer facility inside the room**.
• **Bedside table/cardiac table**.
• **Nursing care trolley**.
• **Patient wardrobe**: Should be made of easily washable and disinfectable material.
• **Patient toilet**: Better to have the whole toilet tiled. The bathroom doors should open outwards or be the sliding door, exhaust and patient safety railings. Depending on the water supply status, one could place a head shower filter, which contains 0.2-micrometre filter membrane, which is changed after the discharge of each patient. Water can be UV treated - the entire water supply in the patient’s unit is UV treated. The UV tube is to be changed once in 6000 h or as per the product instructions.
• **Anteroom**: Anterooms in an HSCT unit are optional. The anteroom is considered helpful in HSCT recipients requiring airborne precautions. These rooms can ensure appropriate air balance between the hallway and the patient space in a negative pressure room (see negative pressure isolation room) (Yokoe et al. 2009).
• **Laminar airflow (LAF)**: Laminar airflow is NOT recommended for newly constructed rooms as it has not shown overall survival benefit (Yokoe et al. 2009).
• **Carpeting** is avoided in the rooms and hallways as contaminated carpets and lead to aspergillosis outbreaks among HCT recipients.
• **Construction or renovation**: A sealed plastic barrier is necessary between the patient and renovation or construction areas to prevent dust contaminated with Aspergillus spores.
• **Decorative items like flower pots, fish tanks, or containers with live or dried plants are not allowed in the HSCT unit**.

**Corridor**
• Crash cart with drugs for resuscitation
• Trolley bay

**Work Station**
• Computers
• Cabinets for stationary, registers, SOP files
• CCTV monitor
• Patient calling bell alert panel

**Dirty Zone**
• Dirty sluice and wash: Ensure that the dirty utility is taken from a different pathway from the incoming items.
• Laundry.

**Fire Protection System**
Wet pipe sprinkler systems in all rooms and suitable equipment for electrical fires (Fig. 1).

**HVAC – Heating, Ventilation, and Air Conditioning**

HVAC provides indoor environmental thermal comfort and acceptable air quality. Infections can occur through direct (body to body) or indirect (body to a contaminated inanimate object) contact, droplet transmission (microorganisms propelled through short distances of less than 1 m) and airborne transmission by particles of 5 μm or smaller in size.

Apart from providing comfort by ambient room temperature of 22–25 °C and normal humidity, the HVAC design is also intended to minimize the risk of airborne infections.

Air-handling unit design and specification guidance should be implemented as per the Health Technical Memorandum for heating and ventilation systems, for design/Validation and operational management/ performance verification. This should address AHU location, access, deep cleaning options, efficiency, recirculation of air,
Fig. 1 A sample layout and design: HSCT unit layout design of CMC Vellore 2008
variable air volume valve (VAV) (Department of Health / Estates and Facilities Division 2007a, b).

AHU’s should be located in an accessible area secured from unauthorized entry. Load calculations and equipment sizing/selection needs to be done based on the volume of the rooms. Placing these units in ceiling voids above the occupied spaces is not ideal. Units may have a working life of 25–30 years, and there will be a need to access every element within the unit for deep cleaning.

- CDC recommends air exchanges of ≥12/h.
- Filters: Microfilter, prefilter, terminal HEPA filter: Diameter of fungal spores range from 1–10 μm and the HEPA filters to remove at least 99.97% of airborne particles of 0.3 micrometers (μm). This has shown to efficiently reduce fungal infections (especially Aspergillus) in transplant patients (Nihtinen et al. 2007). Filters need to be replaced once in 3–6 months as per the manufacturer’s instructions and particle counts.
- Air conditioning with central chiller plant: Cool water from the chiller plant will be circulated through the air handling unit to provide air conditioning effect. This is more electricity efficient if the unit is large and there are other areas which can be included in the supply. Temperature control in the room can be a challenge with the chiller plant supply. In such situations, having a heating coil after or before the terminal HEPA filter can be considered if space allows; else an oil room heater in each room is a cheap alternative. Recirculation of air is generally kept at 90% (10% replacement) to be more energy, cooling efficient and this will also provide a longer life for the HEPA filters.
- Positive pressure maintenance: Consistent positive pressure in the recipient’s room should be maintained with a pressure differential of >2.5 Pa (i.e., 0.01 inches by water gauge) between the patient’s room and the hallway. Variable air volume valve (VAV) is generally installed in the room to close the return air damper when the door is opened.
- UV light in the HEPA filter unit: Could be considered for sterilizing the air just before the throw into the room. May help in COVID like situations.
- Individual AHU for HSCT rooms: This can be considered for transplant units which have a smaller number of units (2–5 rooms). Can be advantageous if a patient has a Respiratory syncytial virus (RSV) infection and recirculation of air to other rooms needs to be avoided. Also, a negative pressure facility can be inbuilt in the design. If a larger unit is planned with common AHU, then a few negative pressure rooms with separate AHU can be kept for emergency use.
- Negative pressure HEPA isolation room: Recipients with diseases which has airborne transmission mode (Chickenpox, Mycobacterium tuberculosis, Respiratory syncytial virus, measles) should ideally be kept in negative pressure rooms. The air replacement in such rooms should be 100%, and the air exchanges should still be maintained (≥12 per hour). A separate Air Handling Unit (AHU) and HEPA filter at exhaust duct if return air is required in such situations. Although this may be helpful in COVID-19 like situations, this can increase electricity consumption and increase humidity (seasonal) with moisture accumulation.
- Differential cooling: Usually seen in places with high humidity. This happens when only one floor of the hospital is air-conditioned, and the floor below is not. High humidity leads to condensation of water on the ceiling with aero-biocontamination enabling fungus growth. Usually, the floor below the HSCT unit is at risk for this problem. Having a fully airconditioned floor below the HSCT unit will solve this.
- Alarms: All alarm modules must be served by the emergency power system. Label all alarm functions as to what is served or monitored, including areas and rooms served, equipment, and pressures.
- Cleanroom: It is a room where the concentration of airborne particles is controlled, and introduction, generation, and retention of particles inside the room are minimized. Cleanroom classifications are based on the quantity and size of particles per volume of air. Particles of size ≥0.5 μm are taken as the reference for defining the ISO standard. Old FS
209 (US Federal standards) classes were calculated in cubic feet of air where an HSCT unit was defined to be Class 1000. However, by the International Standards Organization (ISO), an HSCT unit should be ISO 6, which allows a maximum of 35,200 particles/m$^3$ of size $\geq 0.5 \mu m$. All these considerations are critical to prevent the spread of infections in transplant patients as these patients are at very high risk for acquiring infections and are highly immuno-compromised (ISO – ISO 14644-1:2015; Ljungman et al. 2020).

Personnel Planning

Roles are responsibilities that need to be written down with Job descriptions.

a. Organogram and reporting structure
Solid line reporting person: include functional setting, reporting pattern, performance appraisal and communication. Helps in delegation and accountability.
Dotted line reporting person focuses on delivering project-specific activities with or without the inputs to objective setting and performance evaluation.

b. Type of personnel
   i. Transplant physician: Should have verifiable experience with the procedure for both autologous and allogeneic transplants. 24-hour cover by attending/resident doctor or physician assistant. It is important to have at least two transplant physicians in a team to avoid burnout in one.
   ii. Nurses: This is the most important aspect of a successful HSCT unit. Committed full-nurses are the key to any successful transplant program.
      1. Ratio: Generally, the ratio of one nurse to one patient per shift is ideal, particularly for unstable patients, but one nurse for two or three patients is reasonable.
      2. Shift duty: To be planned in a way to cover 24 h.
   iii. Physician assistants.
   iv. General Duty Assistant (GDA).
   v. Janitors.
   vi. Transplant coordinator.
   vii. Medical Social worker/Care coordinator: For financial aid/fundraising.
   viii. Quality manager.

Functional Planning

a. Workforce: Medical and nursing staff coverage should be available 24 h a day, including public holidays.

b. Material management: Linen, stationary, disposables etc. This involves purchase, stores, handling and issue of goods, inventory level maintenance, economical pricing, discourage hoarding of ward stock, pilferages, and waste minimization.

c. Sample transport sops with collaborative laboratories for the samples which are not processed in house.

d. SOP file maintenance: Maintaining SOP for every activity is cumbersome but an essential part of best practices. The team needs to be built around this for efficient execution. This is extremely important for the accreditation process.

e. 5S concept: A simple management principle which can yield many dividends. A workplace organizational method from a list of five Japanese words which translates to “Sort,” “Set In order,” “Shine,” “Standardize,” and “Sustain. The list defines how to establish a work area for efficiency and effectiveness by categorizing and storing the items and sustaining the new order. The decision-making process builds understanding among employees on the way things are.

f. Lean management, waste elimination, and value stream mapping: Lean hospital management principles can be applied to the HSCT unit for creating value without wastes. In an HSCT unit, the wastes that can be eliminated are excessive use of disposables, overt decision-making time (by protocols), unnecessary investigations (pre-planned protocols),
resources, posting more than optimal man-
power (by appropriate training), poor inventory
maintenance (regular audits), non-utilized tal-
ett (non-threatening environment for taking up
responsibilities). Value stream mapping
focuses on maximizing the output by eliminat-
ing duplication and redundancies.
g. **Kanban**: A visual inventory and process con-
trol system through color coding and just in
time supply. Time is valued to ensure effi-
ciency in the operations.
h. **Kaizen**: A quality lean tool that focuses on
small, continuous improvements throughout
the HSCT unit through small changes that pro-
gresses to significant steps forward in effi-
ciency, quality, safety, and workplace culture.
i. **Near miss and error reporting**: Disclosure of
medical near misses and errors in a blame-free
environment, promotes patient safety and
forms the base to provide one of the most potent
tools towards quality care.

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**Equipment Planning for Direct Patient Care**

- a. Patient beds.
- b. Attendant sofa/bed.
- c. IV stands.
- d. Crash cart.
- e. Computer terminals.
- f. Defibrillator.
- g. Portable USG.
- h. Portable X-ray machine.
- i. Portable ECG machine.
- j. Infusion and syringe pumps: to administer reg-
ulated infusions, including large volumes.
  Syringe pumps can administer regulated infu-
sions of smaller volumes up to 50 ml.
- k. Weighing scales for each room.
- l. Portable BP apparatus, stethoscopes, measur-
ing tapes, torch for each room.
- m. Autoclave drums to keep sterile cotton or
  pre-packaged sterile cotton and dressing gauze.
- n. Laminar hood for drug reconstitution – To be
  placed in the drug reconstitution room.
- o. Platelet agitator: If the HSCT unit stores plate-
lets for emergency use and the blood bank is at
  a considerable distance to procure platelets immediately.
- p. Blood irradiator: To be placed in the blood
  bank for the regular supply of irradiated
  blood product.
- q. Cryopreservation unit set up: Long term cryo-
  preservation of stem cells at minus 196 °C
  liquid nitrogen freezer in the vapor phase,
  Minus 80 freezer (Detety et al. 2014) especially
  at the stem cell cryopreservation facility. Helps
  in centers doing autologous stem cell trans-
  plant where dump freezing is to be offered.
  Alarm systems which can alert a few mobile
  numbers would be helpful especially if the
  center has frequent electricity shutdowns.
- r. Electronic weighing scale to measure the stem
  cell volume.
- s. Rate controlled freezer and liquid nitrogen stor-
age facility.
- t. Stem cell apheresis machine: To be procured
  either by outright purchase or reagent rental. To
  be kept in the aphaeresis room either in the
  blood bank or adjacent to the transplant unit
  under the blood bank physician or under the
  transplant physician.
- u. Air particle counter – 2 channel or 6 channel.
- v. BIPAP machine.
- w. Ventilator/(s).

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**Financial Planning**

Capital expenditure is to be planned based on the
items mentioned above for design, civil work,
HVAC, equipment maintenance (AMC/CMC)
and human resource. The costing of a transplant
should be apportioned with the investment cost,
depreciation, annual maintenance of equipment
and the human resource costs, for the sustainabil-
ity of the program. This can be based on the
perceived need in the area and the estimated num-
ber of transplants to be done annually. This article
is prioritizing the planning required in the estab-
lishment of the HSCT program, and hence costs
for individual transplant is not discussed here.
However, it would be essential to estimate the
financial burden of each region separately. Patient
outcome analysis is important for long-term
sustainability to justify the time and resources invested (Thonon et al. 2015). The variable establishment costs are determined by the disparities in governmental policies, vendor procedures and the strategy and goals for establishing an HSCT unit (for-profit or not-for-profit) (Hashmi et al. 2017).

Cost minimization strategies: Resource pooling of central laboratory and molecular laboratory facility, central/shared blood irradiation facility, step down isolation are some of the steps to reduce duplicate capital investments (Das et al. 2018).

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**Preventive Planning**

**HSCT Unit Infection Control**

Regular interaction with hospital infection control committee (HICC) is advisable.

- **Room ventilation requirements**: (Tomblyn et al. 2009).
  - Replacement of filters should be as per the manufacturers’ recommendations. Filtration efficiency should be re-evaluated after a renovation or construction at the site. Replacement expenditure should be accounted for while calculating the variable costs.
- The airflow direction in the HSCT room should be planned to enter from one side and returned from the opposite side.
- **HSCT unit cleaning protocol**: Scrubbing removes resident bacteria. Washing removes transit bacteria. Cleaning should be performed 2–3 times/day with attention to dust control. In case of ongoing construction, intensified mold control measures are required. Any dusting technique which aerosolizes the particles should be avoided. Wet dusting is an appropriate alternative to reduce aerosolization. Exhaust fans, vents, window sills, and all surfaces are best cleaned using pre-moistened mops and cloths. The chemicals used should be FDA- or Environmental Protection Agency (EPA)-registered hospital disinfectant.

  HSCT center personnel should be mindful about the aerosolization of fungal spores (e.g., Aspergillus species) during floor or carpet vacuuming and avoid exposures of patients when such activities are in progress. If vacuuming is performed in the corridors, doors to patient rooms should be closed. All vacuum cleaners used in the HCT center should be fitted with HEPA filters.

- **Water leaks**: Water leaks can lead to mold proliferation and hence it should be cleaned up and repaired within 72 h.
- **Standard precautions**
  - Hand hygiene: Alcohol-based hand rubs or washing with soap and water.
  - Personal protective equipment (PPE) – Gloves, gowns, masks, goggles or face shield.
  - Physical, droplet and airborne precautions. Preventing and managing sharp injuries.
  - Aseptic techniques.
  - Linen handling and precautions.
  - Spillage of body fluid handling protocol.
- **Play areas and toys**: Toys for pediatric HSCT recipients should be cleaned and disinfected weekly and as needed. Only toys, videos, and games, that can be cleaned and disinfected, should be permitted to the HSCT unit.
- **Visitors**: Hospitals should have written policies for screening HSCT unit visitors, especially children, for potentially infectious conditions. Such screening should be performed by clinically trained healthcare personnel.
- **Food**: Terminally pressure-cooked food is given to the patients when premade low bioload packed food is not available.
- **Transmission based precautions.**
- **Biomedical waste management**: In collaboration with the HICC.
- **Surveillance of the air handling unit and HEPA filter.**

Air quality evaluation: Physical inspection for cleanliness, infection control practices, engineering problems, and general maintenance issues should be verified, and corrective measures should be implemented before air quality monitoring.

The air quality evaluation in an HSCT unit can be broadly categorised into four main methods (Table 2):
1. **Air changes calculation by anemometer**: Verifies the air Velocity profile and monitors the air balance. Air changes per hour are calculated by dividing the air supply rate by room volume.

   \[ \text{HSCT Room volume} = \text{Width} \times \text{Length} \times \text{Height (ft)} = \text{ft}^3 \text{ (cubic feet).} \]

   \[ \text{Anemometer reading} = x \text{ cuft/min} \]

   \[ \text{Air changes per hour} = \left( \frac{\text{Anemometer reading in cuft/Min} \times 60 \text{ min/hour}}{\text{Room Volume (cuft)}} \right) \]

   E.g.: Room Size = 14 ft. (length) \times 12 ft. (breadth) \times 8 ft. (height) = 1344 ft\(^3\).

   Anemometer reading = 400 CFM (cuft/min). Air changes per hour = \(\frac{400 \times 60}{1344} = 17.8\) air changes per hour.

   - If the required air changes are not demonstrable, need to evaluate the power of the air handling unit and the filter blockage. Cleaning of the prefilters may help.

2. **Positive pressure gauge monitoring**: The pressure gauge measures the positive pressure maintained in the room. If the adequate pressure is not maintained in the presence of adequate air changes, look for leakages in the room (false ceiling joints, main or toilet doors, electrical points etc.).

3. **Air particle counter**: Measures the integrity of HEPA filter by non-viable particle counting. Usually done using a handheld air particle counter. The Imperial Class 1000 room correlates with ISO 6 (1 cft = 35 cM\(^3\) \(1000 \times 35 = 35,000\)) and is based on airborne particle counts (APCs) of 0.5 \(\mu\text{m/ft}^3\) or/cM\(^3\). An HSCT unit should be class 1000/ISO 6 or below. If the counts are high, one must check the integrity of the filters. The continuous presence of patients, caregivers and staff in the room makes it more challenging to maintain optimal APCs in an HSCT unit compared to operation theatres. Cleanliness of the area, the integrity of the filter units, and the number of individuals in the room are the major factors affecting APCs. Any deviation from the normal counts should trigger a review of cleaning practices, air changes (velocity) checks using anemometers, and air-handling unit maintenance protocol, including cleaning and integrity of prefilters as well as the HEPA filters. The integrity of the HEPA filters is assessed by Dioctyl Phthalate (DOP) or Poly alpha Olien (PAO) test (Bhalchandra et al. 2015). **DOP/PAO test**: Both are challenge tests. They are liquid chemicals which produce mono or polydispersed test aerosol of submicron particles, generated to challenge (evaluate integrity) of HEPA filters. PAO is preferred over DOP due to its noncarcinogenic property.

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**Microbiological Surveillance**

a. **Settle plate culture sensitivity** using blood agar and Sabouraud’s dextrose agar. Measures the bioburden levels for bacteria should be within acceptable parameters of the HSCT unit. No fungal growth is acceptable.

b. **Surface swab culture sensitivity**: Measures the bioburden of adherent bacteria or fungi on the
surfaces. Suppose the culture comes positive, to do repeat cleaning and fumigation with Hydrogen peroxide (not formalin) and once again do the culture. If persistently positive, to do particulate count and examine the HEPA filter.

**Equipment Maintenance**

1. Warranty of all equipment to be noted in the inventory sheet by the central maintenance team or the HSCT team.
2. Internal quality check for the machines.
3. Calibration.
4. Preventive maintenance: Non-conformity of equipment is eliminated through practice. This ensures systematic inspection, detection, and correction of incipient failures and prevents from developing into major defects.
5. Corrective maintenance: The eliminates the detected non-conformity. This task identifies, isolates, and rectifies a fault of the failed equipment, machine, or system and restores it to an operational condition.
6. Annual Maintenance contracts (AMC): It is the legal agreement between the hospital and the manufacturer where the manufacturer agrees to render the maintenance service annually to the hospital in the exchange of a nominal amount, throughout the year regularly only on service charges.
7. Comprehensive Maintenance Contract (CMC): Here the charges include spare parts also.

**Annual Maintenance**

Patchwork, Civil work, breakage in the wall, paint need to be planned annually.

Insurance of the entire physical facility may be considered as per the hospital policy.

**Donor Registry Interactions**

Matched unrelated transplant programs:
1. MOU’s to be executed between the registries.
2. Stem cell procurement process needs to be spelt out through a written document.

**Data Collection and Collaboration with Registries**

Complete maintenance of accurate data is crucial for internal audit and outcome analysis for individual clinical programs. This assists in outcome reporting, research, and compliance evaluations. Timeliness and completeness of data submission is the critical aspect of data collection.

*The Clinical Program shall collect all the data necessary to complete the Transplant Essential Data Forms of the CIBMTR or the Minimum Essential Data-A forms of the EBMT.*

The common databases managed in an individual center are:
1. Institutional Database and Data Manager
2. Regional registries
3. CIBMTR
4. Collaborative studies

**Internal annual statistics**

1. The yearly number of transplants with allogeneic and autologous transplant distribution.
2. Age group distribution of transplants.
3. Indications of transplant.
4. Allogeneic transplants: Distribution of the number of MSD (matched sibling donor), MUD (Matched unrelated Donor), MRD (Matched Related donor), MMUD (Mismatched Unrelated donor), Haplo (Haploidentical donor), C + M (Cord + Marrow transplant).
5. Conditioning types total: MA (Myeloablative), RIC (Reduced Intensity conditioning).
6. Day 30 mortality and survival.
7. Day 100 mortality and survival.
8. State-wise distribution of patients transplanted.
9. Overall survival of all the transplants.
10. Disease-specific OS, PFS.

**Ancillary Services**

(Pasquini et al. 2019 WBMT)

1. Access to a 24-h emergency room and intensive care unit (ICU) services at the same
tertiary care hospital facility are mandatory for a transplant program.

2. ICUs should have the ability to provide inotropic support, mechanical ventilation support and renal replacement therapy facilities.

3. Access to other specialities: Infectious disease for cross consultations for opportunistic infections, gastroenterology for endoscopy services, pulmonary medicine for bronchoscopy services, radiotherapy units for performing total body irradiation who have a radiation oncologist and a physicist.

Other essential ancillary services (Rasheed et al. 2019)

- Intensive care unit
- Emergency room service
- Gastroenterology and pulmonary services
- Outpatient clinic – Single patient examination rooms
- Blood bank
- Blood irradiator
- Hematology and biochemistry laboratory services
- Consulting Physicians
  - Subspeciality consultations in both medical and surgical specialities, intensivist, ID specialist to be immediately available
- Microbiology services
- HLA typing lab – Access to ASHI or similarly accredited HLA typing lab
- Stem cell collection – PBSC apheresis capability
- Bone marrow harvesting facility and expertise for matched sibling donors
- Stem cell processing facility with CD34 enumeration
- Pharmacy
- Radiology
- Human Resources
  - Clinical laboratory director: Clinical pathology trained.
  - Appropriately trained lab scientist and technicians
  - Multidisciplinary medical staff (radiology, pathology, ICU, surgery, gastroenterology, Pulmonary)

- Outcome database management: Monitor patient demographics, treatment, and outcomes (level I data reporting)
  - Institutional Database and Data Manager
- Quality management
  - Written institutional protocols/guidelines
  - Regular audits of various HSCT procedures and patient treatment outcomes
  - System to detect errors or adverse events for corrective or preventative actions

Outpatient Services

OP services include patient assessment, cross consultations, sample draws, a daycare facility for medication administration, early identification and management of complications, and access to inpatient units if the patient requires admission. Early and late transplant-related problems are tackled in this setting. A sound understanding of the emergency department personnel is imperative for smooth functioning (Szer 2018).

Outpatient units: Serves two primary purposes:

1. Pretransplant assessment and work-up.
2. Post-transplant follow-up and management.

Telemedicine options can be considered for routine follow up.

Quality Management (QM)

The quality management program comprises of an organisation’s all-inclusive system of quality assessment, assurance, control, and improvement. It is intended to detect, prevent and correct deficiencies that may adversely affect the quality of patient care, apheresis procedure or quality of the cellular therapy product (Pasquini et al. 2019).

The QM oversees the following aspects:

- Certification with local, regional, or international HSCT quality entities.
- Collection of demographic and outcome data according to international standardized forms.
• Data sharing with local, regional, or international outcomes registries.
• Quality program development.
• Collaboration with an established transplant program (telemedicine or a “twinning” partnership arrangement).
• Standard operating procedure (SOP) development for the HSCT program for the whole team.

Quality Audit: An independent inspection and review of a facility’s QM activities to verify by objective evidence and document the degree of compliance.

Quality Benchmarking: Establishment of reference standards to be achieved based on the cumulative outcome data from all centers. Benchmarking leads to error reduction and improvement of outcomes. The internal database should be managed by experienced data managers and staff who can maintain and report the data to global registries (e.g., EBMT, CIBMTR or others) (Aljurf et al. 2020).

One-year overall survival and other patient outcomes. The need for a risk-adapted “benchmarking” system is underdevelopment of the new EBMT MACRO registry. This allows centers to address the new JACIE standards within their HSCT community globally (LeMaistre et al. 2019).

### Legal Requirements

• Necessary approvals and permissions to conduct a transplant from the regulatory agency and governing authority need to be procured. The TC must agree to abide by the standards, policies, and procedures as applicable per the current version of WMDA standards. Regional adaptations may have to be considered based on the local culture, regulations and available resources and time (Yeh et al. 2018; Kulkarni and George 2019).
• Apheresis license for the blood banks.
• Accreditation certificates and internal and external quality program certificates from the internal and outsourced laboratories are required.
• Preventive maintenance contract.
• MOUs with the matched unrelated donor transplant registries.

### Accreditation

FACT-JACIE The Joint Accreditation Committee—ISCT and EBMT (JACIE) based on the FACT (Foundation for the Accreditation of Cellular Therapy) program formed by EBMT and the ISCT (International Society for Cellular Therapy) in 1998, remains the standard for the establishment of HSCT and cellular therapies programs to ensure quality and safety. JACIE standards are helpful guidelines to understand requirements to establish an HSCT, although the accreditation per is not mandatory.

Currently, seventh edition manual (2018) is being followed (FACT-JACIE 2018). Adoption of JACIE standards has shown to improve survival outcomes, especially in allogeneic HSCT. The accreditation system is based on the development and continuous update of four aspects of the transplantation process (Saccardi et al. 2018).

1. Clinical program
2. Bone marrow collection
3. Apheresis collection
4. Processing facility

### Patient Care

• Patient Volume (As per the NMDP and ASBMT recommendations): A minimum number of 10 autologous and allogeneic HSCT per year is required to be performed to allow sufficient current experience in the technical aspects of both procedures.

• Key performance indicators for infections:
  • HCAI – Health care associated infections
    a. Catheter associated urinary tract infections (CAUTI)
    b. Ventilator-associated infections (VAP)
    c. Central line-associated bloodstream infections (CLABSI)
    d. Surgical site infections
The JACIE and FACT standards are revised every 3-years by a group of experts. Except for legal requirements, the standards integrate principles of quality medical and laboratory practice in cellular therapy.

**Process:** The JACIE inspection is a multistep procedure where the voluntary inspectors, trained and coordinated by the JACIE office in Barcelona visit the site after the submission of the necessary documents. An on-site inspection is planned if the first review is successful. An accreditation cycle is 4 years for JACIE, and facilities must complete an interim desk-based audit after 2 years post-accreditation (Snowden et al. 2017).

The standards are focused on guiding effective changes in working practices and encouraging a culture of quality improvement. Even though the standards do not require significant financial investments in technology nor infrastructure; it can be a challenge for the resource-constrained setting (Aljurf et al. 2020). A unique stepped process is under development for transplant programs in low- and middle-income countries (LMICs), where full accreditation might not be feasible due to resources and cultural issues. Fee for accreditation as of February 2018 is €14,600 for EBMT members and €29,200 for non-EBMT members (Snowden et al. 2020; LeMaistre et al. 2019).

**Participation in Clinical Trials**

Participation in clinical trials is an essential aspect for a new HSCT program to consider as it contributes to the overall improvement of the transplant program. This may also depend on whether national or international agencies accredit the center (Pasquini et al. 2019).

**Conclusion**

**Expectations and Hope:** The transplant program is high stakes activity that oscillates between peaks of satisfaction and troughs of disappointment. Endurance to go through the disaster or despair and perseverance in keeping the hope through these times by constant innovation to add value to the society is the key to success (Thomas 2016).

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