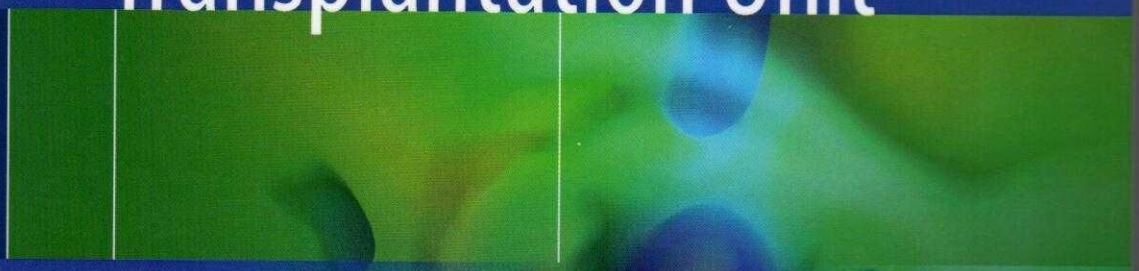
Establishing a Hematopoietic Stem Cell Transplantation Unit



A Practical Guide

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Inpatient HSCT Unit

Simone Cesaro

Introduction

The location of a hematopoietic stem cell transplant (HSCT) unit should allow easy access to out-of-unit diagnostic and treatment facilities, such as radiology, radiotherapy, an intensive care unit, and a blood bank. Moreover, an HSCT unit must comply with structural and system requirements. In particular, rooms, and spaces must be adequate for the type and volume of treatment activity and must adhere to the standards for the safety and comfort of patients, caregivers, visitors (if any allowed), and healthcare personnel, according to national laws or international recommendations [1].

The establishment of an HSCT unit must consider the following general requirements for spaces or rooms:

- Space or location for secretarial activity related to patient admission, discharge, registration, and storage of clinical charts or patients' files
- Location or dedicated space for the storage of health instruments or facilities; for instance, portable electrocardiogram or ultrasound machine, X-ray machine
- Dedicated areas for deposit of dirty materials
- Toilets for healthcare personnel, separate from those for the patients
- Toilets for caregivers or visitors (if any allowed), separate from those for the patients and the healthcare personnel
- Sink and tap in every location or room to allow hand-washing for healthcare and hospital personnel and caregivers before and after approaching the patient. The use of a non-manual tap opening is highly recommended

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- Medical oxygen system complying with national law or international recommendations for the safety of the patient, caregivers, visitors (if any), and healthcare personnel
- Medical system for respiratory tract aspiration
- Waterbed (or possibility of acquiring one quickly) to prevent bedsores
- Changing rooms with shower and toilet for the staff, in the same unit or building, or in an adjoining unit, with a double cabinet to separate work clothes or uniforms from ordinary clothes.

Medical and nursing assistance shall be guaranteed all day long with the possibility that nurses can consult the transplant physician in charge during working days, at night, and on public holidays. The ratio of nurses to patient beds may vary according to the type of patient (adult or pediatric, young or old), type of transplant (autologous or allogeneic), type of conditioning regimen (myeloablative or reduced intensity), and performance status of the patient. Generally, a ratio of one nurse to every two to three transplant beds is reasonable to allow adequate assistance in a high-demand unit such as an HSCT center. The days, times, and names of healthcare personnel who are in charge during the day or the week shall be clearly indicated in order to allow family members to talk with the doctors or nurses to get information on the patient. The nursing coordinator shall have a safety key (passkey) to open any location, room, or window of the unit that can be locked.

Patient Area

In the patient area, floors and walls up to 2 m in height shall be easily washable and disinfectable. All cabinetry and furniture shall have smooth, nonporous, cleanable, wipeable surfaces that are resistant to scratching. No decorative water features, fish tanks, plant boxes, or containers with live or dried plants are allowed. Every location or room shall have a sink and tap for hand washing.

The locations or rooms required for daily activity are:

- Working location or room for nurses for activity related to patient assistance
- Location or room for doctors that can be used as a meeting room for the daily briefing
- Location or room for the nursing coordinator
- Location for medical visits and invasive surgical or medical procedures (bone marrow aspiration, bone marrow biopsy, lumbar puncture)
- Room for medical doctor on duty during the night (if provided)
- Location or room for drug storage

Moreover, the patient area shall include a relaxation room for caregivers or parents or other family members and, in a pediatric unit, adequate spaces for playing, school activity, and socialization for self-sufficient children and adolescents.

The essential instruments for patient assistance and treatment are: emergency cart with drugs for resuscitation, Mayo or Guedel cannula, Ambu ventilator, pocket mask, cardio monitor and defibrillator; surgery cart for patient medication; pharmacy cart for the daily therapy, and machine for lifting an (adult) patient if they are uncooperative.

The patient room shall allow adequate comfort and respect the patient's privacy and have windows that provide natural light. Room windows shall have fixed sashes and must be well sealed to prevent external air, dust, or small-insect infiltration. Electric lighting shall be adjustable to allow good visibility for the patient and the healthcare staff during routine assistance and procedures, but also to favor the sleep and the comfort of the patient. The room door shall have a viewing panel to facilitate observation and control by the nursing staff; as well, panels or curtains should be available in the room to cover the viewing panel and protect the privacy of the patient.

All rooms shall be equipped with at least one power point for each bed, a system for oxygen gas and an aspiration system, as well as a cardio monitor to control vital parameters such as respiratory rate, peripheral oxygen saturation, heart rate, and blood pressure. Internet network access by telephone line or WiFi is recommended to facilitate the collection of the patient data in the patient's clinical file and to allow the patient to communicate with family, friends, or school, or to maintain some work activity during hospital admission. The minimum size of a single-bed room is at least 12–14 m^2, and for a double-bed room it is 24 m^2, excluding the bathroom. The bathroom doors should open outwards or be sliding. In a pediatric unit, in considering the size of the room, space must be allowed for a parent or tutor who is usually allowed to stay all day, and the room shall be equipped with a bed or sofa bed for the parent/carer. Every room shall be equipped with a wheel-bed with a scale to allow monitoring of the weight of a non-self-sufficient critical patient and to facilitate the transportation of the patient from the room. The room equipment shall also include a bedside table, a patient wardrobe made of easily washable and disinfectable material, a light and acoustic call facility, and courtesy and safety lights in the room and bathroom.

Infections are among the major complications in patients who have undergone HSCT and they still represent a major cause of morbidity and mortality, especially in the early period after HSCT. Consequently, the establishment of an HSCT unit requires specific attention to preventive infection measures [2, 3]. As with other immunocompromised patients, the diffusion of nosocomial infections in HSCT patients is controlled by isolation of the patient in a single room to avoid contact with other infectious patients, by using barrier precautions (gloves, gown, mask, cap), and by hand disinfection by healthcare or caregiver personnel to avoid the direct transmission of potential pathogens to the patient; also healthcare workers with transmittable diseases (herpes, gastroenteritis, respiratory tract infections) are excluded from taking care of transplanted patients, and water- or food-borne infections are prevented by cooking food and filtering drinking water. These measures are effective against nosocomial and community bacterial and viral infections, but they are insufficient to prevent nosocomial fungal disease. In particular, mold infections

respiratory tract, followed by spore germination, proliferation to hyphae, and tissue invasion. Therefore, the HSCT patient needs to be placed in a protective environment equipped with air-filter systems capable of high efficiency, >99.97%, in removing air particles <0.3 μm in diameter (high-efficiency particulate air [HEPA] filter) from the room. Moreover, the room air pressure needs to be higher than that in the other rooms or spaces of the unit in order to create airflow. The pressure differential is maintained by supplying a greater volume of air than is extracted via the exhaust vent within an airtight room. Typically the intake air is HEPA-filtered, to provide additional protection, and delivered through a diffuser that facilitates air mixing. To maintain a positive pressure of 10 Pa relative to the corridor, all openings within the room must be properly sealed to avoid air leaks. An isolation room lobby and an en-suite bathroom are usually incorporated in this system (Fig. 4.1).

Although evidence supporting the effectiveness of protective environments is not based on well-executed randomized trials, most authorities and expert committees recommend the use of these environments. The guidelines approved and sponsored by several scientific associations, such as the Center for International Blood and Marrow Transplant Research (CIBMTR), the National Marrow Donor Program

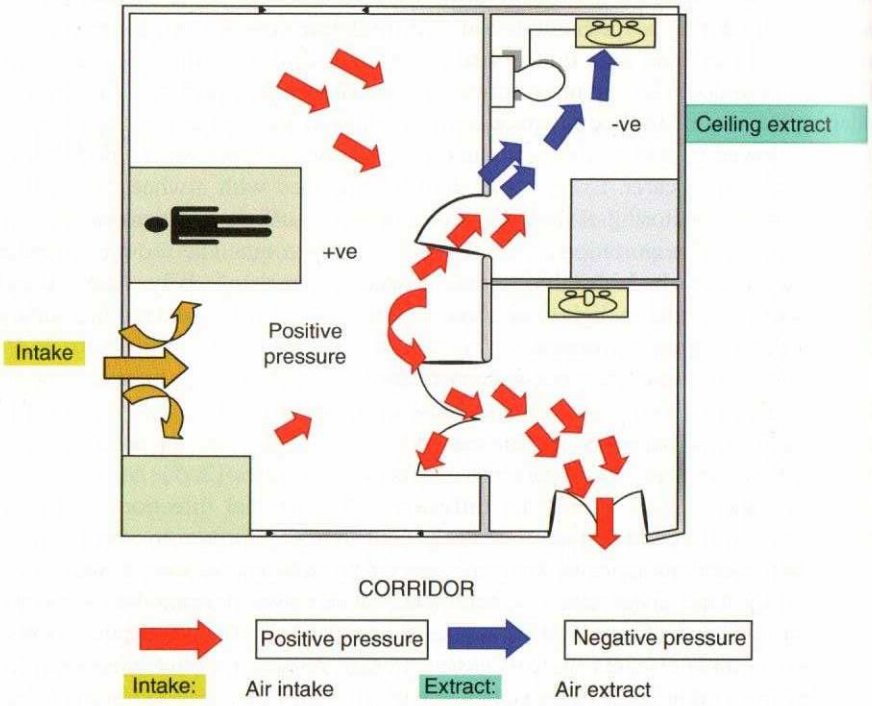

Fig. 4.1 Isolation in a positive-pressure room. The airflow is directed from the patient to the hospital corridor and exterior. The patient is protected from air ingress from the corridor. Extraction of the air is done in the bathroom

the Canadian Blood and Marrow Transplant Group (CBMTG), the Infectious Diseases Society of America (IDSA), the Society for Healthcare Epidemiology of America (SHEA), the Association of Medical Microbiology and Infectious Diseases (AMMI), the Centers for Disease Control and Prevention (CDC), and the European Group for Blood and Marrow Transplantation (EBMT) have clear recommendations with respect to hospital room design and ventilation [4–10]. Recommendations on a protective environment and ventilation for an HSCT room shall include:

- The room must be equipped with HEPA filters with 99.97% efficiency for removing particles ≤0.3 μm in diameter
- The filters should be replaced regularly based on manufacturers' recommendations
- Ventilation must be performed with ≥12 air exchanges/h
- The direction of airflow is that air intake occurs at one side of the room and air exhaust occurs at the opposite side
- The air pressure differential between the patient's room and the hallway, ≥2.5 Pa, must be consistently positive
- Rooms must be well-sealed (e.g., gaps between the walls and windows, outlets, floor, and ceiling must be filled) to prevent infiltration of air from outside the room that could allow entry of spores and hinder the maintenance of the proper pressure differential
- Continuous-pressure monitoring is needed, especially while rooms are occupied
- Adopt room monitoring systems with an alarm that is activated when the pressure differential between any protective environment room and adjacent hallway or anteroom falls to less than 2.5 Pa, to alert staff to possible engineering failures
- Use self-closing doors to maintain constant differential pressure
- Perform visual monitoring of the HSCT recipient even when the doors are closed, through windows installed in either the door or the wall of the HSCT recipient's room (or by internal video-monitoring)

Established risk factors for healthcare-associated fungal infections are hospital building works such as excavation, demolition, recarpeting, and the installation of new fit-outs. Molds are ubiquitous in soil, water, decaying vegetation, walls, and ceilings and their spores can be aerosolized or dispersed for extended periods or travel long distances in the air. To prevent fungal outbreaks in places with ongoing construction, patients, healthcare workers, family, and other visitors should avoid such construction or renovation sites. The HSCT area should be sealed from the outside and the efficiency of the filtration system should be monitored frequently to determine the appropriate time for replacement. Moreover, the use of high-efficiency masks is recommended for patients who must go outside protected HSCT areas, e.g., to radiotherapy or radiology units, while building construction is ongoing.

If there is an occurrence of an airborne infectious disease (e.g., influenza, varicella) while the patient is in a positive-pressure room, there is a risk of spreading the infection to other patients or to all the staff, because the contaminated airflow occurs toward the corridor of the unit and the closest locations. The isolation room lobby

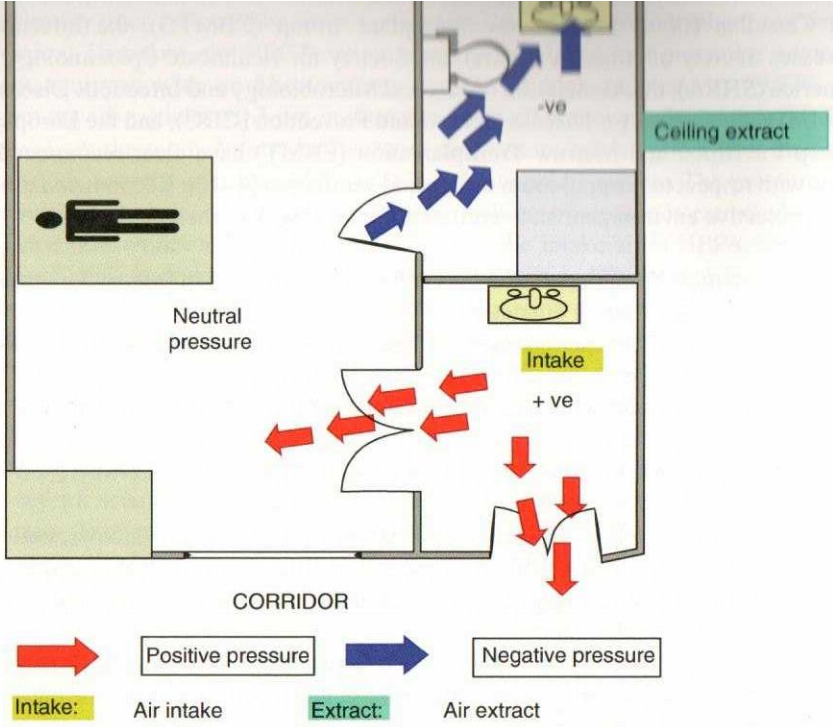

Fig. 4.2 Isolation in a neutral-pressure room. The neutral pressure in the patient's room is obtained from the balance between air intake in the anteroom and air extraction in the bathroom

may act as a barrier, but it cannot totally prevent the egress of air. The consequence is that an immunosuppressed patient in a positive-pressure room who develops an airborne infection must be moved, to minimize risk to other patients. In the past, HSCT rooms were protected with a reversible positive- or negative-pressure switch mechanism, so that the room could operate under either positive or negative pressure. This design is not recommended now, because of the risk that a lack of training by healthcare personnel or the lack of an appropriate operating procedure can result in the activation of the wrong option, nullifying the desired protective effect.

Recently, to overcome the inconvenience of isolating the patient in a positive-pressure room to prevent the spread of airborne infections, a model of isolation in a neutral-pressure room has been proposed. In this model, there is a positive-pressure anteroom lobby with an extensive number of air changes per hour, which has a positive pressure relative to the corridor and prevents corridor air from entering the room. The patient's room is at neutral pressure and air extraction is via the bathroom (Fig. 4.2).

Also, in this model, the neutral-pressure area must be well sealed and it is important that the side doors of the room remain closed. Although this isolation model is feasible from an engineering point of view, data are limited regarding its clinical validation.

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