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To cite this article: Julie M. Vose & James O. Armitage (1990) Developing a Bone Marrow Transplantation Unit, *Oncology Issues*, 5:2, 17-19, DOI: [10.1080/10463356.1990.11905002](https://doi.org/10.1080/10463356.1990.11905002)

To link to this article: <https://doi.org/10.1080/10463356.1990.11905002>



Published online: 19 Oct 2017.



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DEVELOPING A BONE MARROW TRANSPLANTATION UNIT

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Bone marrow transplantation, in itself, is not a new treatment for malignancy or immunodeficiency states. However, marrow transplantation serves as a means of rescuing the patient from the consequences of intensive antitumor therapy or aplasia secondary to marrow-lethal chemotherapy/radiotherapy. Depending on the source of the bone marrow used for transplantation, three types of marrow transplantation can be performed: allogeneic, syngeneic, or autologous.

Allogeneic marrow transplantation involves the use of an HLA-compatible bone marrow donor to reconstitute the recipient's bone marrow after the patient has been prepared with high-dose chemo/radiotherapy for cytotoxic therapy. A syngeneic transplant involves the use of the marrow from an identical twin donor. An autologous bone marrow transplant involves a freezing technique to preserve the patient's own marrow for future use following high-dose therapy. Each of these transplantation types can be used for the treatment of a variety of diseases. Allogeneic and syngeneic transplants would seem to be of optimal use in disease that involves the marrow; however, problems with a lack of HLA-compatible siblings and graft-versus-host disease (GVHD) make this option available only in approximately 20 percent of cases.

Many hematologic diseases, including acute and chronic leukemias, Hodgkin's disease, non-Hodgkin's lymphoma, aplastic anemia, and congenital disorders, such as Fanconi's anemia, have been treated successfully with high-dose therapy and marrow transplantation. Marrow transplantation has long been the treatment of choice for all forms of severe combined immunodeficiency disease (SCID), as well as other immunodeficiency syndromes, such as Wisknott-Aldrich syndrome. More recently, high-dose therapy with marrow transplantation has been

evaluated in solid tumors, such as melanomas, breast carcinoma, and sarcomas. The exact indications for marrow transplantation in these various diseases will evolve with ongoing clinical trials.

If the development of a bone marrow transplantation unit is to be successful, a large commitment on the part of the hospital, nursing and ancillary personnel, and physicians, is required. Many months of planning and preparation must go into the initial organization and opening of a transplantation unit. This article will outline the various steps involved in that process.

Facilities

There are several fundamental items that are necessary for the initiation of the bone marrow transplantation unit. One of the most important is the actual facility in which bone marrow transplant patients will be housed. The American Society of Clinical Oncology (ASCO) and the American Society of Hematology (ASH) recently recommended minimum criteria for the performance of bone marrow transplantations (see the table on page 18). Their criteria require that at least a two-bed unit be designated for housing bone marrow transplant patients. The unit must have facilities in place, a policy for patient isolation, and a plan for air handling. Several different methods are available for air handling in the unit. For example, high efficiency particle air (HEPA) filtered units should be used in areas where *Aspergillus* contamination is a problem. Alternatively, laminar air flow units are used in some transplantation units.

Operating room facilities, as well as the equipment and personnel necessary for handling marrow outside the body, need to be in place. If autologous transplants will be performed, a protocol for cryopreservation of autologous hematopoietic stem cells and adequate facilities for their long-term

storage must be available. This includes freezers to store the marrows in the vapor phase of liquid nitrogen (-150 to -180 C). Adequate alarm systems for the freezers, in the event of power failure, are also critical. If allogeneic transplants will also be performed at the institution, mechanisms for the management of ABO incompatible transplants will be necessary in the event of red cell depletion of the marrow and forced diuresis of the recipient to prevent a hemolytic reaction. The performance of allogeneic transplants also requires the presence of a certified histocompatibility laboratory for necessary tissue typing.

Because bone marrow transplantation patients require very specialized intensive care, there must be 24 hour per day laboratory, radiology, and physician coverage. The increase in volume of laboratory tests and blood products used must be anticipated and provisions made for this proliferation. The demand for platelets, in particular, may increase, placing a strain on the blood supply system. The blood bank that supplies blood products for the transplant center should be consulted prior to the opening of a transplant unit so that plans can be made for increased demand.

Staffing

In addition to the proper physical facilities, a dedicated staff is essential for a successful bone marrow transplantation unit. A number of different disciplines must work together in a team effort in the transplant unit. Probably the single most important aspect of a successful bone marrow transplantation unit is nursing staff support. Nurses should be full-time committed oncology nurses with appropriate training in the care of immunocompromised patients. The ratio of nurses to patients should be approximately 1:2 to ensure appropriate attention to patients' needs. Critical care experience may also be need-

ed if patients are to stay in the bone marrow transplantation unit when they are critically ill. The overall number of patients in the unit should be sufficient to develop and maintain a full-time nursing team.

In addition to the nursing staff, a number of ancillary personnel are crucial. Bone marrow transplantation coordinators are essential for the organization of individual patients pre- and post-transplant testing and care. These coordinators can include a variety of health care professionals, such as nurses, physician assistants, or nurse practitioners. Social workers, as well as volunteers and clergy, are also needed to assist patients and families with emotional and personal support, as needed.

The physicians who are directly responsible for the patients' care need to be well versed in the care of bone marrow transplantation patients. Immunocompromised hosts who have received toxic chemotherapy, and perhaps radiation therapy, require meticulous, detailed care to decrease the morbidity and mortality associated with the procedure. A number of consulting physicians should also be readily available to assist with the care of these patients. For example, pulmonary, infectious disease, nephrology, gastroenterology,

and surgical specialists are all necessary at times in the care of various patients. Also, most programs will require a radiotherapy unit that has the capability of performing and monitoring total body irradiation.

Initiating a bone marrow transplantation unit calls for a large investment of money and hours of hard work by all of the professionals involved. Therefore, it is not surprising that a large emotional investment is also put forth by the personnel involved in taking care of the patients. Although most of the patients survive through the immediate transplant period, a percentage of the patients will eventually die from their original malignant process. Furthermore, a percentage of the patients will suffer severe morbidity or death during the transplant procedure itself. This is, of course, very difficult on the patient's family, but also on the personnel who take care of the patient in the unit. They may feel that the death of the patient was more directly due to their interventions, and view this differently than death due to the patient's malignancy. Positive feedback for the staff of the transplantation unit is very important, and could be in the format of weekly conferences, a newsletter, or yearly reunions with patients and families.

Occupancy

An adequate number of patient referrals are necessary to keep the transplant unit in operation. It would be difficult to keep a transplant unit open utilizing only the patients from the institution containing the bone marrow transplant unit and, therefore, continuous outside patient referrals are a necessity. The ASCO/ASH recommendations call for at least 10 to 20 transplants per year to be performed, and for the unit not to be empty at any time. It is unrealistic to expect that a hospital will expend the necessary resources and keep a full-time, committed nursing staff if the unit spends any time empty. Furthermore, if both autologous and allogeneic transplants are to be performed, at least 10 of each per year should be performed at the institution. In the case of new transplantation units, these volume goals should be met within two years of opening the unit.

The types of malignancies that the patients will be treated for is also an important consideration when opening a unit. The most successful transplantation units have initially concentrated on specific patient populations (i.e., patients with leukemia or lymphomas) rather than treating a wide range of diseases at one unit. This facilitates the development of expertise in the unit and participation in clinical trials for a specific disease group. This strategy also helps to develop lines of communication with similar centers and it aids patient referrals for those disease groups.

Treatment Results

The goal of this expensive therapy should be to cure the malignancy for which the patient is undergoing the transplant. The goal of a temporary palliation would not justify the cost in dollars or the psychosocial and physiologic strains placed on patients and families. Transplantation centers should compare treatment results for specific diseases to other centers and change policies or treatment strategies when deficiencies are identified. For the benefit of all physicians, results of all transplant units should be reported to appropriate registries, such as the International Bone Marrow Transplantation Registry (IBMTR), so that decisions regarding patient management for certain diseases can be improved.

ASCO/ASH CRITERIA FOR BONE MARROW TRANSPLANTATION PERFORMANCE

I. Facilities

- Minimum of a two bed bone marrow transplantation unit
- Proper air handling facilities
- Operating room facilities for bone marrow harvest
- Cryopreservation facilities (autologous)
- Certified histocompatibility laboratory (allogeneic)

II. Personnel

- 24-hour laboratory, radiology, physician coverage
- Committed oncology nurses with training in the care of immunocompromised patients
- Bone marrow transplantation coordinators
- Primary oncologists who are well trained in the care of transplant patients
- Sub-Specialists available—pulmonary, infectious disease, cardiology, nephrology, gastroenterology, and surgical specialists may be needed

III. Volume

- 10-20 transplants per year and the unit should not be empty at any time
- 10 autologous and 10 allogeneic transplants per year if both will be performed

IV. Reporting of Results

- Cases should be reported to the International Bone Marrow Transplantation Registry (IBMTR)

Reimbursement

In addition to the facilities and staff needed to support a bone marrow transplantation unit, other issues, such as reimbursement, are important. Currently, third-party reimbursement for bone marrow transplantation of some diseases is fairly uniform, such as for the leukemias and lymphomas. However, newer indications for transplantation, including solid tumors, such as breast cancer or ovarian carcinoma, are sometimes not covered by third-party reimbursement. Because of the high cost of transplantation, each patient's policy must be evaluated prior to initiating any part of the transplant procedure. Furthermore, many third-party payors are negotiating preferred provider agreements for bone marrow transplantations to obtain a discounted rate. If the trend toward preferred provider arrangements becomes widespread in the insurance industry, some of the smaller transplantation units may be forced out of business.

Marketing

The goals of marketing a transplantation

ACCC Fall Conference On Tap

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For further information, contact the ACCC Executive Office, 11600 Nebel St., Suite 201, Rockville, MD 20852; (301) 984-9496.

program must be clearly evaluated prior to initiation. For example, is this a tactic to improve the overall hospital image or to draw patients into the program? If the goal is to attract patient referrals into the system, one must remember that nearby oncologists may be hesitant to refer patients to a local/regional transplantation unit for fear of appearing that they do not have a "full service" oncology practice. They might find it less threat-

ening to their practice to refer patients to a distant transplantation unit.

Finally, publicity can help a bone marrow transplantation unit in the community, but it can also be a two-edged sword. The procedure does carry a chance of death even in the healthiest of patients, and such stories reported in the media are not beneficial to the image of the unit.

Summary

All of the details of the backbone outlined above must fit together to form a unified team approach to obtain a successful final product. One of the most important items is to have an overall strategy in place prior to the initiation of unit development. A haphazard plan without detailed analysis of the market place, reimbursement issues, and personnel is not likely to lead to a successful bone marrow transplantation program. Finally, because the successful treatment of the patient is the overall goal, clinical investigation should be an integral part of the process, so that the results obtained with bone marrow transplantation will continue to improve. ■

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