

ASBMT POSITION STATEMENT

Joint Public Policy on Legislative and Regulatory Affairs

ADOPTED BY:

American Society for Blood and Marrow Transplantation

American Association of Blood Banks

Foundation for the Accreditation of Cellular Therapy

International Bone Marrow Transplant Registry/Autologous Blood and Marrow Transplant Registry

International Society for Cellular Therapy

National Marrow Donor Program

Blood and marrow transplantation is a cellular therapy that encompasses the collection, processing, and infusion of hematopoietic progenitor cells derived from peripheral blood, cord blood, and bone marrow. The field is represented by several national and international organizations that have the common purpose of achieving the best possible outcomes of patient care and advancing knowledge and understanding in this highly specialized and rapidly evolving medical field.

Although each organization has its own specific objectives, particular constituency, and priorities, all share a common set of values and beliefs. It is because of these shared values that the blood and marrow transplant community can set forth a unified agenda for public policy.

The underlying principle and bedrock belief upon which all other positions are based is that . . .

Patients in need of a blood or marrow transplant and their transplant donors have a right to appropriate, high-quality medical care.

This principle is the foundation supporting the following corollary beliefs.

1. Access to Care

Patients and donors should have access to appropriate transplant therapy irrespective of socioeconomic or geographic limitations. No patient should be denied life-saving therapy.

2. Cost of Care

The cost of blood and marrow transplantation procedures for accepted indications should be appropriately reimbursed.

Donors should not be liable for the costs of donation.

3. Patient and Donor Rights

Patients and donors have the right to make decisions about their own care and a right to the information needed to make those decisions.

The transplant patient has a right to give consent based on clear information about each step of the transplantation process, the associated risks and benefits, and any reasonable alternatives.

The transplant donor has a right to give consent based on clear information about the donation procedures and the risks and benefits of each step of the registration and donation process. No individual should be coerced or pressured to become a donor or join a donor registry.

4. Confidentiality

Patients and donors have a right to privacy. The identity and personal records of patients and donors should be kept confidential, in accordance with federal, state, and local regulations. Medical records management should not impair patient care.

5. Clinical Research

The transplant community has a responsibility to foster activities that seek to improve outcomes for transplant recipients and provide a scientific basis for the standard of care.

Well-designed clinical trials conducted according to good practices are essential for the practice of medicine. Such research should proceed at the most rapid pace possible. Patients should have access to quality clinical trials, which often represent the most appropriate treatment strategy for life-threatening diseases.

6. Safety

The medical care provided for a transplant patient should meet or exceed the standard set by the transplant community.

To ensure maximum safety for the patient and the donor, all blood and marrow transplant personnel should be well trained and qualified to perform their respective roles in cell collection, processing, and infusion. Cellular products should be of high quality and be equally available to every patient.

Transplant facilities should have an active quality management program to ensure safe and effective medical care. Facilities should participate in external review and accreditation that independently documents that standards of care are being met.

Adverse events should be managed, tracked, evaluated, and readily available for study to improve patient safety.

Government regulation is appropriate to protect health and safety but should not place unnecessary, arbitrary, or redundant burdens on transplant facilities.

7. Education and Awareness

Advances in laboratory and clinical research must be communicated rapidly to those providing patient care.

The transplant community has a responsibility to inform patients, families, other health professionals, and the general public about new information that

might benefit or otherwise have an impact on patients or the public at large.

Greater awareness of blood and marrow transplantation by patients, donors, health professionals, payers, and the public is beneficial for improving patient care, increasing donor interest, and diminishing misinformation that might impede access to care.

—Adopted by the ASBMT Executive Committee on August 21, 2003, and by the policy committees and/or governing boards of the other five organizations during the period of August–December 2003.