

History and legal aspects of bone marrow donor banks in Brazil

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ABSTRACT

Introduction: Bone marrow transplants primarily depend on people who previously registered to be donors. From then on, the search for compatibility between donor and recipient begins. **Objective:** To describe the historical landmarks and the legal apparatus of bone marrow donor banks in Brazil based on an integrative review. **Methods:** LILACS database and PubMed and SciELO journals were used. The term bone marrow transplantation was the descriptor. Eligibility criteria were: articles with the theme of Bone Marrow Transplantation (BMT) and studies carried out on the national territory. **Results:** A total of 88,855 articles were identified, among which 185 met the eligibility criteria. After they were thoroughly read, 14 articles were selected. The studies pointed out fragments that dealt with important historical landmarks for the establishment of bone marrow transplantation as a conventional treatment for oncohematological diseases. **Conclusion:** The use of BMT has a history of more than thirty years in Brazil. However, none of the articles identified specifically addresses the historical content of bone marrow transplantation.

Keywords: Bone marrow transplant; Stem Cell Transplantation; history of nursing; legislation; Public Health.

INTRODUCTION

Studies on diseases have evolved, resulting in more effective treatments, cures, and a better quality of life for patients. In oncohematology, it has not been different, so much so that today bone marrow transplantation (BMT), along with the use of drugs, has promoted an increase in patients' survival rates.

Although the term Hematopoietic Stem Cell Transplantation (HSCT) has gradually been replacing the term BMT, for this integrative review the term BMT was used due to the fact it is better known and also more easily found in the scientific literature, enabling the retrieval of a greater number of articles from the databases.

Stem Cell Transplantation (SCT) includes three types of treatment with these types of cells: BMT, when stem cells are collected from the bone marrow; peripheral blood stem cell (PBSC) transplantation, when stem cells are mobilized and collected from peripheral blood; and the transplant of stem cells from the umbilical cord¹.

Stem cells from bone marrow and peripheral blood can be transplanted from the patient itself (autologous transplant) or a related or unrelated donor (allogeneic transplant). Additionally, there is also the possibility of a transplant from a single twin sibling (syngeneic transplant)²⁻⁴. In sum, the patient's stem cells, those of family members, or

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unrelated donors (in the event of incompatibility between family members and the recipient) can be used in BMT. For the latter case, there is a bone marrow donor bank³.

In Brazil, the Volunteer Bone Marrow Donor Registry (REDOME) is the database in which all bone marrow volunteer donors are registered. It is managed by the Brazilian National Cancer Institute (INCA) and funded by Hematology and Hemotherapy Centers in each state as well as non-governmental organizations (NGOs)⁵. Currently, there are about 5 million volunteers registered in the REDOME and 800 patients in line waiting for compatibility with unrelated donors⁶.

For those willing to register as a donor, it is necessary to initially provide information about personal and clinical data. Volunteers between 18 and 35 years old, in good health conditions, and without blood-borne infectious diseases are eligible⁷.

REDOME database is used when an allogeneic transplant is necessary. Despite the fact it is a one-time registration process, the database needs to be updated whenever the donor changes their address and /or phone number. Moreover, besides keeping their data up to date, potential donors are advised to ask for clarification on what the procedures are and how they are performed. The guidelines should allow individuals to agree to register responsibly so that when there is a donor/recipient match, the donor will be able to conduct the donation procedure.

Given the fact that the Brazilian donor bank is one of the largest in the world, BMT procedures are widely performed in the country⁸; therefore, this historical path is expected to be recorded in the literature as well as the creation of laws for treatment regulation.

Thus, this study aims to describe the historical landmarks and the legal apparatus of bone marrow donor banks in Brazil based on an integrative review.

METHODS

An integrative literature review seeks to synthesize the knowledge derived from research results on a given topic through the use of well-designed techniques for the reliability of the answers found⁹. The idea to conduct this study started from the following research question: what are the historical milestones and the legal apparatus on bone marrow donor banks in Brazil?

Latin American and Caribbean Literature in Health Sciences (LILACS) was used as a database, and the research was also conducted in the directories of PubMed and Scientific Electronic Library Online (SciELO). To search for specific legislation on the topic, the website of the Brazilian Society of Bone Marrow Transplantation (SBTMO) was used because it showed a complete list of all specific legislation on the topic. In addition, the list of references of the articles included in this integrative review was

checked to complement the data on the historical aspects of bone marrow donor banks.

Many were attempts to find a descriptor that would lead to a greater number of articles for the study. “Bone marrow transplantation” was the descriptor of choice. Inclusion criteria comprised complete and free-of-charge articles on bone marrow transplantation; studies conducted on national territory, since the integrative review is about the Brazilian history and legislation for BMT; scientific productions in their original article format, dissertations, and theses; and scientific productions in Portuguese, English, and Spanish. The electronic survey was conducted between September and November 2018.

Regarding ethical aspects, this study was not submitted to the Research Ethics Committee since its scientific profile (integrative review) does not require ethical evaluation according to Brazilian Resolution 466/2012. However, complying with all the principles of authorship, all the literature used for the construction of this article was duly cited and referenced.

RESULTS

A total of 88,855 articles were initially identified. After applying the eligibility criteria and excluding articles dealing with diagnostic tests, laboratory tests, consensus recommendations, experimental studies with animals, and repeated studies, 185 articles were selected. Titles and abstracts were read, narrowing the number to 27, which were read in full, and 14 articles out of those 27 remained as the final sample (Figure 1).

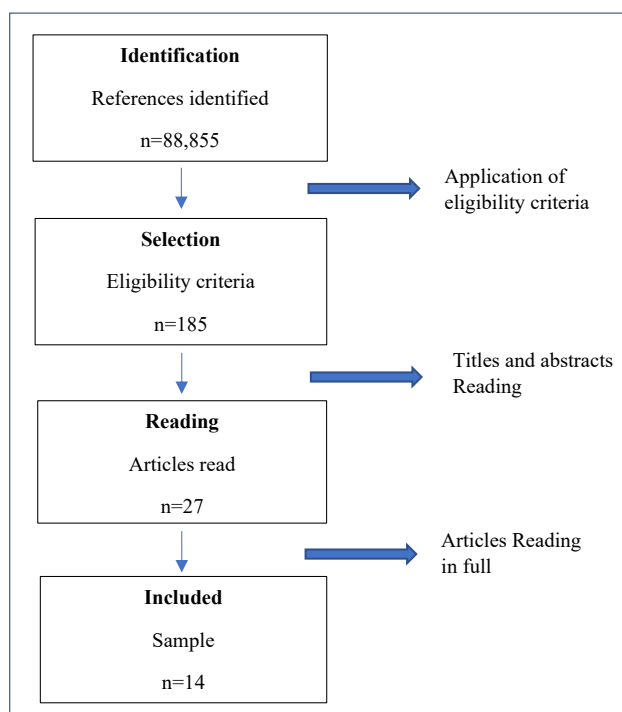


Figure 1: Flowchart of article selection

The content of the 14 articles was read, recording relevant data such as year, nature, and types of research, fragments of articles that mentioned historical aspects, and specific legislation on the topic in a standardized form (Table 1).

The SBTMO website displays a list of 22 items, including laws, observances, and administrative regulations. After reading about the subject of the items, 7 items were analyzed¹⁰⁻¹⁶ and the content of the legislation was recorded¹⁷.

From the 14 articles analyzed, it was possible to identify that the years of publication varied from 2003 to 2017 with a regular distribution over the years. As for the nature and types of research, there was a documentary research, two descriptive studies, two integrative reviews, a descriptive research with a qualitative approach, a literature review, two quantitative cross-sectional studies, a case report, a prospective study and the four others did not mention the type of study. Concerning these four, two were published in the Original Articles section, one in an editorial and the other was an updated article¹⁸.

DISCUSSION

The first BMT in Latin America took place in the city of Curitiba, Paraná, Brazil, in 1979^{5,19,20}. In 1983, a BMT unit was

opened at INCA²¹, and in 1988, at the Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo (USP)²⁰.

During performing autologous and allogeneic transplants, hematopoietic progenitor cells from the umbilical cord and placental blood started to be used. Observance # 903/2000 provides for the creation of an umbilical cord and placental blood bank¹⁰, and the first bank was installed at INCA in 2001²². The country's legislation allowed the operation of two types of banks: public banks for unrelated allogeneic use and private banks for autologous use^{2,11,23}.

For the regulation of the banks created after 2001, Observance # 2381/2004 created BrasilCord, a name given to the set of the umbilical cord and placental blood bank organized in the national network¹². By the year 2010, nine umbilical cord and placental blood banks for allogeneic use had been opened in Brazil, and 16 for autologous use. The latter banks were spread out across the five regions of the country²³. Currently, there are 14 allogeneic and 19 autologous banks²⁴.

Upon reading the articles and the legislation, it could be noticed that the country advanced in a brief period in the implementation of bone marrow transplantation policies, as well as in the organization of umbilical cord and bone marrow banks. Such progress allows for advances in the treatment of oncohematological diseases. Another gain is related to ethical issues, as there is a

Table 1: Distribution of scientific articles, titles, authors, journals, years and natures, and types of research.

Title	Authors/Year	Journal	Nature and types of research
A functional assessment of adolescents who were recipients of bone marrow transplantation: a prospective study	Doro et al. 2003 ¹⁹	Rev Bras Hematol Hemoterapia	Prospective study
Linking between patients' personality and bone marrow transplant survival: bibliographical review	Peres & Santos 2006 ²⁹	Psicologia em Estudo	Integrative review
Altruistic genetic diversity	Bicalho 2008 ²⁸	Rev Bras Hematol Hemoterapia	Not mentioned
Epidemiology of neglected tropical diseases in transplant recipients: a review of the literature and experience of a Brazilian HSCT center	Machado et al. 2009 ²⁶	Rev Inst Med Tropical São Paulo	Literature review
Private umbilical Cord blood Banks for family use, in Brazil – technical, legal, and ethical issues for an implementation analysis	Mendes-Takao et al. 2010 ²³	Rev Bras Hematol Hemoterapia	Not mentioned
Partially matched Family donor allogeneic bone marrow transplantation	Saboya et al. 2010 ¹⁸	Rev Bras Hematol Hemoterapia	Integrative review
Bone marrow transplants in Brazil: the bioethical dimension	Corgozinho et al. 2012 ²⁰	Rev Latinoamericana Bioética	Not mentioned
Anticipated grieving in patients requiring Hematopoietic Stem Cell Transplantation	Cardoso & Santos 2013 ³⁴	Ciência Saúde Coletiva	Descriptive study
Genetic diversity among volunteer donors of bone marrow in southeastern Brazil, according to the HLA system	Roque et al. 2014 ⁵	São Paulo Medical J	Descriptive study
Patient safety culture in a bone marrow transplantation unit	Fermo et al. 2015 ³¹	Rev Bras Enfermagem	Quantitative cross-sectional
Experience of families of children and adolescents submitted to Hematopoietic Stem Cell Transplantation	Mazza et al. 2016 ³⁰	Rev Eletrôn Enfermagem	Descriptive research with a qualitative approach
Professionals' attitudes for patient safety culture in units of bone marrow transplantation	Fermo et al. 2016 ²⁸	Rev Gaúcha Enfermagem	Quantitative cross-sectional
Model of transpersonal caring in nursing home care according to Favero and Lacerda: case report	Rodrigues et al. 2016 ³²	Rev Gaúcha Enfermagem	Case report
Standardization of nursing procedures in the autogenic infusion of hematopoietic stem cells.	Cruz et al. 2017 ²	Rev Enfermagem UERJ	Documentary research

need for regulation to prevent the sale of organs and tissues, and the legislation can strengthen actions that prevent this practice.

Banks, whether of the umbilical cord and placental blood or of bone marrow, need donors to maintain their activities. Therefore, over the years, Brazilian legislation has been organizing the donation process and allowing equal rights for patients on the waiting list for transplantation. Also, it is a way to prohibit the sale of organs and tissues, thus maintaining human dignity²⁰.

About hematopoietic progenitor cells, donation occurs in life according to registered donors. Registrations began to be organized in a network to improve fundraising actions and increase the number of registered donors. In Brazil, this network is REDOME, created in 1993 and incorporated into INCA in 1999 as determined by the Brazilian Ministry of Health (MS)³. Regarding the financing of actions, the literature indicates that it is defined by the Serviço Nacional de Transplant (SNT, National Transplant Service), and that about 95% of the resources for performing transplants, including BMT, come from the Sistema Único de Saúde (SUS, Brazil's publicly funded health care system)²⁵.

REDOME network service increased the number of registrations for bone marrow donation to around 45,000 by the year 2003 and 2,000,000 by the end of 2010 with the collaboration and networking of blood centers, immunogenetics laboratories, and the Registry of Unrelated Volunteer Donors of Bone Marrow via the Internet (RedomeNet)³. They formerly conducted campaigns to capture and register potential donors, and the laboratories performed histocompatibility tests for transplants. Consequently, there was an increase in several transplants with the expansion of many centers across the country, among which the Amaral Carvalho Foundation stood out as the largest transplant center in Brazil in 2009²⁶. Records from the Brazilian Organ Transplant Association (ABTO) show that 2,187 BMTs were performed in 2016²⁷.

The numbers show that over the years there has been an increase in donors registered at the bank, demonstrating that the policies that strengthen these actions and the continuous and systematic effort expended by the agencies that capture and conduct these registrations have been effective. Even so, there is still a waiting list for transplantation since many recipients have specific genes that are incompatible with those of donors already registered²⁸. The intense miscegenation in the country promoted this genetic diversity, leading to a greater need for registered donors³.

As a natural consequence of these policies, there has been a decrease in the dependence on donors from international banks, making the search process for donors faster within the country and lowering expenses due to the fact the procedures are conducted on national territory³. This evolution was marked by the creation of public policies that aligned actions in public institutions which enabled the increase in numbers of new donors and improved the flow of information³. It is

important to highlight that to function properly, transplant centers must have a suitable physical structure, quality equipment, and management processes that allow the strengthening of the team in care actions²⁹.

All this effort needs to put into practice the actions planned within the scope of the oncohematological area³. The existing legislation, as well as the research, conducted, place the BMT as a conventional treatment for several diseases, and no longer as an experimental treatment³⁰.

BMT is an innovative procedure in the area of oncohematology that improves patients' survival rate³¹. Other authors share this same idea when they state that allogeneic Hematopoietic Stem Cell Transplantation (HSCT) has immense potential for healing in hematological and non-hematological diseases¹⁸. It has also shown a high rate of success, with great acceptance by recipients, in procedures performed so far^{23,32}, despite the complications inherent to the transplant that may cause tension and anxiety in patients, family members, and health professionals^{33,34}.

It is up to capture centers, diagnosis, and follow-up services for patients with oncohematological diseases, and transplant centers to organize their services to reduce the demand for patients who need BMT. Finding a compatible donor and speeding up the protocols for the procedure brings hope to those who are waiting in line. Initial treatment can result in greater success in healing, quality of life, and survival rate.

This leads to increasing demands for bone marrow or umbilical cord and placental blood donors. This demand, along with the intense miscegenation Brazil underwent with its colonization process³, means that the collection actions must be broad and seek to reach populations from various regions, with varied sociodemographic and ethnic profiles. By doing so, it is possible to reach a greater number of patients on the waiting list.

As a limitation, the current research noted that no specific literature on the historical aspects was identified, which points to the fact that further studies should be conducted so that historical facts regarding bone marrow donor banks in Brazil can be collected. As the study was conducted searching for articles and legislation, some historical aspects may not have been collected as they would require field research.

The study gathered information on the historical aspects and legal apparatus of bone marrow donor banks in Brazil, pointing out advances in the oncohematological area and showing a gap in the literature that can be filled with novel studies.

In the literature, the following was found: records referring to the first BMT procedure, the creation of REDOME, the organization of the umbilical cord and placental blood banks, and all the legislation to regulate the operation of this system and to develop strategies that may increase the number of donors, these being important facts recorded in the literature. However, these records were repeated in the articles read.

It was also possible to observe that none of the articles read specifically dealt with historical aspects of the legislation, but with other matters pertinent to the BMT. There is a need to create a specific literature database on historical aspects as a way to record

the advances in health achieved in the country. The conclusion is that it is important to know the history to value what has been accomplished so far and to understand its evolution so that future projects can be developed and new achievements can be reached.

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