DOI 10.18471/rbe.v31i2.16604

# HEMATOPOIETIC STEM CELL TRANSPLANTATION: REFLECTIONS ANCHORED IN BRAZILIAN HEALTH LEGISLATION

---

# TRANSPLANTE DE CÉLULAS-TRONCO HEMATOPOIÉTICAS: REFLEXÕES ANCORADAS EM LEGISLAÇÕES DE SAÚDE BRASILEIRA

---

# TRASPLANTE DE CÉLULAS MADRE HEMATOPOYÉTICAS: REFLEXIONES BASADAS LEYES SANITARIAS BRASILEÑA

Ingrid Meireles Gomes[1]
Maria Ribeiro Lacerda[2]
Jéssica Alline Pereira Rodrigues[3]
Debora Cristina Paes Zatoni[4]
Cibelly Aliny Siqueira Lima Freitas[5]

Objective: to reflect on hematopoietic stem cell transplantation in Brazil anchored in the propositions of national legislations. Method: critical reflection on the theme based on Laws n. 8,080/1990 and n. 9,434/1997 and Administrative Rule n. 931/2006. Results: principles such as integrality, universality, equality, autonomy and right are discussed, and information, especially on voluntary donations, is disclosed. The need for research in the area is also discussed. Conclusion: although mostly related to biological aspects, this health area presents important characteristics aimed at integrality; health information is a viable option to reduce the withdrawal of donors; there is a need to advance the discussion on public policies and health care practice and think about regional strategies aimed at meeting the demands of health care related to hematopoietic stem cell transplantation.

Descriptors: Hematopoietic stem cell transplantation. Public health policy. Legislation as topic. Professional practice. Bone marrow transplantation.

*Objetivo: refletir sobre o transplante de células-tronco hematopoiéticas no Brasil ancorado nas proposições de legislações nacionais. Método: reflexão crítica sobre o tema com base nas Leis n. 8.080/1990 e n. 9.434/1997 e na Portaria n. 931/2006. Resultados: são discutidos princípios, como integralidade, universalidade, igualdade, autonomia e direito, além de divulgação de informação, principalmente em relação às doações voluntárias. Aborda-se ainda a necessidade de pesquisas na área. Conclusão: essa área da saúde, embora muito relacionada ao aspecto biológico, apresenta características importantes voltadas à integralidade; a informação em saúde é uma opção viável para diminuir as desistências de doadores voluntários; há necessidade de avançar na discussão de políticas*

---

[1] Master and PhD in Nursing. Nurse of the Bone Marrow Transplantation Service of the Clinical Hospital Complex of the Federal University of Paraná. Curitiba, Paraná, Brazil. inguide@gmail.com

[2] Master and PhD in Nursing. Retired Professor of the Federal University of Paraná. Full Professor of the Graduate Program in Nursing, Federal University of Paraná. Curitiba, Paraná, Brazil. mrlacerda55@gmail.com

[3] Master in Nursing. Nurse of the Bone Marrow Transplantation Service of the Clinical Hospital Complex of the Federal University of Paraná. Curitiba, Paraná, Brazil. jessica.rodrigues@hc.ufpr.br

[4] Master in Nursing. Nurse of the Intensive Care Unit of the Clinical Hospital Complex of the Federal University of Paraná. Curitiba, Paraná, Brazil. debora.zatoni@hc.ufpr.br

[5] PhD in Nursing. Professor of the Nursing Course at Vale do Acaraú State University. Sobral, Ceará, Brazil. cibellyaliny@gmail.com

*públicas e da prática assistencial em saúde e de pensar sobre estratégias regionais que almejem suprir as demandas de atenção em saúde relacionadas ao transplante de células-tronco hematopoiéticas.*

*Descritores: Transplante de células-tronco hematopoiéticas. Políticas públicas de saúde. Legislação como assunto. Prática profissional. Transplante de medula óssea.*

*Objetivo: reflexionar acerca del trasplante de células madre hematopoyéticas en Brasil basada en las proposiciones de legislaciones nacionales. Método: reflexión crítica del tema con la Ley n.8.080/1990, así como la Ley n.9434/1997 y el Decreto n.931/2006. Resultados: se discuten principios como integralidad, universalidad, igualdad, autonomía y derecho y difusión de la información, especialmente por las donaciones voluntarias; se aborda, también, la necesidad de investigación en el área. Conclusión: esta área de la salud, aunque estrechamente relacionada con el aspecto biológico, presenta características importantes dirigidas a la integralidad; que la información de salud es una opción viable para reducir incidencia de renuncia a ser donantes voluntarios; y que hay una urgente necesidad de avanzar en la discusión de políticas públicas y práctica de atención de salud y pensar acerca de estrategias regionales que tengan como objetivo satisfacer las demandas de atención de salud relacionadas con el trasplante de células madre hematopoyéticas.*

*Descriptores: Trasplante de células madre hematopoyéticas. Políticas públicas de salud. Legislación como asunto. Práctica profesional. Trasplante de medula ósea.*

## Introduction

The Constitution of the Federative Republic of Brazil recognized, through the Law n. 8,080, health as a right of all and duty of the State, establishing the basis for the evolution of the current Unified Health System (SUS) in the country. Understood as a social achievement, the SUS presents principles that point to the democratization of health services and can be perceived as the materialization of a differentiated concept of health, which emphasizes the quality of life of the population and not only the cure of diseases(1).

The SUS has a prominent role for its proposal of conceptual change of health relations, which is perceived by the description of some guiding principles, such as universality and integrality. It is known that, despite the difficulties and not having yet fully achieved its principles, this system has advanced a significant deal since its creation. Despite these advances, the coexistence of the perceived challenges requires not a deconstruction, but a permanent reconstruction of the national health system. The greatest of these challenges is the maintenance of its principles in the face of the complexity of the elements involved, such as the great variety of equipment, establishments, inputs, information, funds, professionals, users and instances of participation(2). The path that has been pursued for changing the purely curative concept of health also stands out(2).

Although the new concept of health created the conditions for the commodification of its supply or provision, with a marked expansion of the industrial park connected to this area, it also enabled the demercantilization of access to health, configuring it as a social right. Thus, the risk of an individual to get sick became collective responsibility and duty of the State(3).

Considering health as duty of the State, we proposed the present reflection to examine the relationship between the law n. 8,080 of September 19, 1990, which regulates the functioning of SUS and hematopoietic stem cell transplantation (HSCT). The reflection on health legislation and its relation with the practice of health care makes it possible to understand how national public policies influence the development of health services. Therefore, it is believed that policies and practices should be associated.

The choice for reflection on HSCT was first due to the fact that this is the field of practice of some of the authors, which allowed the experience of incongruities in the work process, besides involving items from the National

Agenda of Priorities in Health Research, such as the thematic groups: neoplasias, hemopathies and priorities common to all non-communicable diseases described in sub-section 05(4). Another motivation was the frank development of this area(5) and the fact that it represents the possibility of cure or improvement of the quality of life for individuals with diagnoses of diseases until recently considered fatal(6).

The HSCT consists in an aggressive procedure of high complexity and cost, in which, intravenous infusion of hematopoietic stem cells from the bone marrow, umbilical cord or peripheral blood of the own patient or from another person who becomes the donor is practiced in order to correct the qualitative or quantitative defect of the bone marrow of the patient(5,7-9). It is a treatment that involves different phases, with relevant morbidity and mortality rates, as well as significant physical and social consequences for the subjects. It is used in cases of malignant or non-hematological diseases, some solid tumors, and hereditary and immunological diseases(5,7).

Considering the relevance and complexity of the HSCT and assuming that the duty of the State of guaranteeing health is associated with the formulation and execution of public policies(10), we propose a reflection on HSCT in Brazil anchored in the propositions of Law n. 8,080 of 1990, as this is the general law ruling health issues. Other legislation items serve as a mainstay for this reflection, in particular the Law n. 9,434 of 1997, dealing specifically with transplant-related issues, and the Administrative Rule n. 931 of 2006, which regulates specifically the practice of HSCT.

## Examining the HSCT in the light of the national health legislation

Law n. 8,080 of 1990 rules the conditions for promotion, protection and recovery of health, among others(10). It points, therefore, general paths to national health. SUS principles such as universality, integrality, equality, preservation of people's autonomy and right, and dissemination of information are mentioned in this Law, and will be addressed in this reflection.

These principles need to be considered in the reality of health performance, which is largely guided by curative and quantitative aspects, as in the case of transplants and organ donation, as seen in studies on methodologies enabling measurements and quantifications(11). In the HSCT area specifically, this can be perceived in the understanding of its purpose – to produce perfect blood cells to achieve higher survival or the cure of the patient(9). There is a biologicist aspect in which the patient is often understood as a diseased body only, given the biological factors that represent relevant predictors of transplant success such as HLA compatibility, stem cell type, myeloablation, pancytopenia, medullary disease, graft versus host disease, decreased contact with microorganisms, infections, central catheter, and others(5,12-14).

However, even in this scenario, it is possible to see the need to walk towards integrality of health care. Because of the specific characteristics of HSCT as well as the aforementioned biological aspects, the understanding and action of health teams on issues related to quality of life, emotional and instrumental support(9,15), and family care(8) are indispensable. It is worth to emphasize the attention to the autonomy of the subjects regarding the preparation of patients for self-care(6), especially domiciliary care.

According to what is set forth in the legislation(10), integrality must be understood "[...] as an articulated set of preventive and curative actions and services, in individual and collective basis, required by each case at all levels of complexity of the system". In this perspective, HSCT, as a highly complex treatment, requires effective integrality of the assistance, since the patient as well as his family need services of different levels, before and after the transplant.

Although it is a specific procedure, recovery does not depend only on the transplant. It is necessary to think about the prevention of complications, health promotion and autonomy of the patient and the family, as well as their rehabilitation and return to normal life. This understanding should include, in particular, those who come from small towns with few resources in the health area, and who usually perform the procedure in large urban centers, but return to their cities of origin where they remain and may need care for possible complications.

Thus, it is pointed out that there is a need for greater articulation between the components of the health service network for the continuity of care actions. This includes both the work processes of the health team and the public policies(16). This panorama must be reflected, understood and sought from basic care to highly complex services, so as to contribute to the most integral care possible.

This scenario includes the principle of universality, which emphasizes the right of everyone to the necessary health care targeted at the expressed needs, as well as equality, i.e. access to health free from discrimination and prejudice(10). People are subject to the need of HSCT regardless of financial conditions, gender, age, race or any other condition. They need, an egalitarian health service, which must also be accessible, without legal, economic, physical or cultural barriers and, therefore, universal.

However, access to HSCT in non-public health services is restricted, especially due to its high-cost. In this way, one has to think that an egalitarian nation does not exist in social terms and, therefore, giving priority to the principle of equality could end up in the maintenance of inequalities. Thus, it is necessary to consider the practice of the principle of equality, through the concept of equity, which, although not present in the Law n. 8,080, is very relevant in the context of strong social inequalities in Brazil. Equity promotes the idea of prioritizing the most needy according to clinical or epidemiological-social criteria, not disregarding the access to all without discrimination and in an egalitarian manner(17).

Integrality can still be thought from the point of view of its relation with care and its fundamental multidimensionality(16). Regarding the concept of integrality of the care, it is noticed the need for understanding the factors beyond the biological aspects in the experience of the practice of HSCT. The search for the understanding of the multidimensionality necessary for the integrality of care is evident in the Law n. 8,080, in the sense of the proposition of health determinants described as food, housing, basic sanitation, environment, work, income, education, physical activity, transportation, leisure and access to goods and essential services(10). Therefore, we must think of actions and services that involve the entire social system to enhance the success of HSCT.

These determinants and conditions contribute to the effectiveness of the transplants and make a two-way line between biological aspects and integrality of care, which seeks to understand the subjects in their totality. For example, food is one aspect modified after HSCT, to reduce the possibility of contact with potentially infectious microorganisms(13), avoid gastrointestinal disorders and adequate the hydroelectrolytic recovery of the patient to biological aspects. There is also a simultaneous higher cost and time to prepare and acquire food to the family, besides the adequacy to the alteration of the patient's taste (13) and dietary, personal or social preferences.

Similarly, considering the integrality of care, we can list all the other conditioning factors and determinants in the experience of subjects in HSCT, including in the pre- and post-transplant phases. It is also possible to perceive the necessity of integrality of the assistance in what concerns the offer the necessary actions and services in the different levels of attention and in the different phases of the treatment.

In the context of HSCT, the need to think about the proposition of autonomy disposed in the legislation(10) in association with the right to information and its dissemination are notable. It is worth reflecting on the role of the unrelated voluntary donor in HSCT. These are willing to donate hematopoietic stem cells to the patient, without, however, having blood relations with him. These donors voluntarily present themselves and the control of their registration through the National Registry of Bone Marrow Voluntary Donors (REDOME) is the responsibility of the National Cancer Institute (INCA). INCA is also responsible for carrying out the search for unrelated donors in international banks(18). These donors are sometimes the only option of treatment for patients, since compatibility between blood relatives reaches about 25% to 30% of the cases(19).

The issue of autonomy and accessibility to information is directly related to the availability of registrations in databases of hematopoietic stem cell donors. The donation is voluntary and free and can be revoked at any time before the donation(20). Therefore, the donor has autonomy on the option to perform the procedure or not, but this right, although fair, has severe repercussions for the patient and/or relatives who are awaiting the procedure. Besides the emotional aspect involved, the patient needs to undergo severe immunosuppression before the procedure, which leaves him susceptible to a wide range of complications. For this reason, withdrawal is also onerous for public coffers(12).

The donor's withdrawal may, however, be associated with a lack of information. Although both laws, the n. 8.080(10) and the specific on transplants(20), and also the administrative rule that regulates HSCT(18) cite the right to information on donation of hematopoietic stem cells, it is perceived that this has not been successfully achieved.

Campaigns for donor recruitment have increased, generating the registration of more donors. Furthermore, the increase in donation campaigns can be perceived even in social networks of wide scope, such as the freely available in the internet. This increase, however, is not followed by disclosure of the HSCT itself, which means that donors will only get clear information on the procedure when they are identified as compatible and are selected. Thus, when a withdrawal happens, the recipient has already been informed about the existence of the donor.

The most significant cause of donor withdrawal identified is described as ambivalence about donation, which represents the feeling of giving up in the expectation that someone else makes the donation(12). It is believed that it is important to minimize this ambivalence, not to restrict the donor's autonomy as to whether or not to donate, but rather to guarantee sufficient information about the process since the process of registration as a possible donor. Potential donors who do not want to continue the process after being well informed should be discouraged from registering in order to reduce the traumas to patients and families and also the costs of donor selection and identification(12).

Still in this context, it is worth reflecting on the provisions of law n. 9,434, art. 9, on the guarantee that all women be enlightened about the possibilities and benefits of voluntary donation of umbilical cord(20). This is another item in which flaws are seen. The information about this procedure is still limited, restricted to cities where there are cord and placental blood (CPB) banking. Moreover, the antenatal and maternity hospitals that carry out the collection of this type of cells for public banks are few.

The need for access to information and understanding about the purpose and availability of the service, as well as the therapeutic indications and future possibilities for such cells, as suggested by current research, needs to be taken into consideration so that the population may have autonomy in the decision to store or not CPB. In addition, it is important to provide information on the public and private services available(19).

Regarding the existence and use of public CPB banks (for non-related allogeneic use to patients of the public network) and private CPB banks – those for autologous future use(19) – proceed from the principle of universality of access to health. This is due to the fact that procedures for collecting and storing CPB are not carried out in the public network, and also due to the waste of hematopoietic stem cells stored in private banks. The waste happens because of the large number of patients who need HSCT and do not find donor, and because of the impossibility of transferring the CPB stored in private to public banks, when the woman so wishes.

A study that reflects on the role of the State grounded in the Law n. 8,080 stated that "...

besides quality, efficacy and safety of a health service, access and cost must also be considered in order to limit the vulnerability attributed to socioeconomic differences"(19:236). It is evident, therefore, that access to information is an assertive path to minimized the problems related to withdrawal in voluntary donations, as well as the availability of CPB without interfering in the autonomy of subjects. This would rather contribute to an enlightened autonomy, making it possible to reach the two principles set forth in Law n. 8,080: autonomy and universality.

It would be impracticable to confine the discussion about public policy relations and health practice to a few pages. However, among other issues, there is still a need for greater reflection on the universality and equality in the organizing principle of SUS on regionalization and hierarchization of the health network. In the context of HSCT, few poles of development in the area exist, as well as frequent large displacement of the population, which makes accessibility difficult. In the national context, it is necessary to adopt regional measures to address the distortions of access, due to the lack of conditions in most municipalities to offer certain health services in a comprehensive manner(17).

The need to carry out research and studies in the health area on this topic, as suggested in Law n. 8,080, also stands out(10). The importance of scientific developments for the improvement of HSCT and for the potential for improvement of quality of life and healing of patients is noticeable. Within 60 years, the subject advanced from ignorance to experiments with animals, human application and significant advances nowadays with results and application of transplants.

It is recognized that much of the flow of scientific and technological information in the health area is associated with universities, research institutions, health providers, regulatory institutions and industry(3). There is a need for a comprehensive structure of superior education(3). It is believed that this is an aspect to be highlighted in public policies, not in order to improve the quantity, but rather to strengthen the quality of the training proposed at the national level, so that the country can be also creator and propagator, besides a receptor of technologies and innovations.

In order to achieve the principles of the SUS and unlink the curative image associated with HSCT, it is important to think about the health care system in its range, with agencies and agents who carry out specific health actions such as health services, or non-specific health actions such as those related to education, communication and financing(17). The responsibilities of users, managers and professionals need to coexist, promoting the continuous improvement of the services that perform this procedure. In addition, it is necessary to reflect on the subjective issues associated with the experience of HSCT, which, given its high specificity and technological nature, is usually presented in objective studies.

## Conclusion

The reflection on hematopoietic stem cell transplantation in Brazil anchored in national legislation propositions made it possible to perceive that, although the HSCT seems to perpetuate the curative system of health, it is evident the relevance of integrality of care and the need see the subjects beyond their illness, but covering emotional, financial, cultural and social aspects, including the family. Therefore, we argument that the restriction to the *biological* model alone does not support the HSCT. It is necessary to think on patients and their environmental and social environment throughout the transplant process, that is, the pre-, trans- and post-transplant phases.

As regards the principles set out in law n. 8,080, it was evident that the right to access to information needs incentive. This flaw of access to information on HSCT has reduced the probability of conscious and citizen donation, both to CPB banking and unrelated HSCT donor.

The study also showed that the incentive to superior education is indispensable in order to improve the development of research, technologies and innovations at national level. It is noteworthy that here is only one essay on this subject. This is not a finite, but rather a temporal and partial discussion. Temporal because it understands that both legislations and public policies are historically constructed, and discoveries and innovations on HSCT show to be increasingly dynamic, whether in their consequences or in the way they are and will be addressed and solved, especially if SUS principles are considered. This study is still partial with respect to the wide range of articles, paragraphs and items that make up a legislation, which cannot be included altogether in this discussion.

With regard to the need for large population displacement in the search for the few national reference centers in the area, this study showed that it is important to think of regional strategies that may help to meet the health care needs related to HSCT. It is known that there is still much to be reflected on public policies in the HSCT, as well as in other services and spheres of national health. It is hoped that this essay represent an initial stimulus for such reflections to occur internally in health services, but also in new publications.

## Financial support

National Council of Scientific and Technological Development (CNPq).

## Collaborations

1. conception, design, analysis and interpretation of data: Ingrid Meireles Gomes and Maria Ribeiro Lacerda;
2. article writing, relevant critical review of intellectual content: Ingrid Meireles Gomes, Maria Ribeiro Lacerda, Jéssica Alline Pereira Rodrigues, Debora Cristina Paes Zatoni and Cibelly Aliny Siqueira Lima Freitas;
3. final approval of the version to be published: Ingrid Meireles Gomes, Maria Ribeiro Lacerda, Jéssica Alline Pereira Rodrigues, Debora Cristina Paes Zatoni and Cibelly Aliny Siqueira Lima Freitas.

## References

1. Passos E, Carvalho YM. A formação para o SUS abrindo caminhos para a produção do comum. Saúde soc. 2015;24(Suppl 1):92-101.
2. Pavão ALP. SUS: em construção ou desconstrução? RECIIS. 2016;10(3):1-3.
3. Viana ALD, Elias PEM. Saúde e desenvolvimento. Ciênc saúde coletiva. 2007;12(Sup):1765-77.
4. Brasil. Ministério da Saúde. Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Departamento de Ciência e Tecnologia. Agenda nacional de prioridades de pesquisa em saúde. Brasília; 2011 [online] [cited 2017 Apr 13]. Available from: http://bvsms.saude.gov.br/bvs/publicacoes/agenda_nacional_prioridades_2ed_3imp.pdf
5. Mercês NNA, Erdmann AL. Nursing and hematopoietic stem cell transplantation: scientific production from 1997 to 2007. Acta paul enferm. 2010;23(2):271-7.
6. Castro EAB, Andrade AM, Santos KB, Soares TC, Esterci LT. Autocuidado após o transplante de medula óssea autólogo no processo de cuidar pelo enfermeiro. Rev Rene. 2012;13(5):1152-62.
7. Andrade AM, Castro EAB, Soares TC, Santos KB. Vivências de adultos submetidos ao transplante de medula óssea autólogo. Ciênc cuid saúde. 2012;11(2):267-74.
8. Fraguás G, Salviano MEM, Fernandes MTO, Soares SM, Bittencourt HNS. Transplante de medula óssea e a assistência de enfermagem fundamentada no modelo Calgary. Ciênc cuid saúde. 2011;10(1):51-7.
9. Santos CLT, Sawada NO, Santos JLF. Evaluation of the health-related quality of life of hematopoietic stem cell transplantation patients. Rev latino-am enfermagem. 2011;19(6):1322-8.
10. Brasil. Lei n. 8.080, de 19 de setembro de 1990. Dispõe sobre as condições para a promoção, proteção e recuperação da saúde, a organização e o funcionamento dos serviços correspondentes e dá outras providências. Brasília; 1990 [cited 2016 Feb 20]. Available from: http://www.planalto.gov.br/ccivil_03/leis/L8080.htm
11. Martínez FJM, Altamira CP, Medina BD, Pimienta CS. Views of healthcare personnel on organ donation and transplantation: a literature review. Texto Contexto Enferm. 2015;24(2):574-83.
12. Lee SJ. To give or not to give. Blood. 2013;121(8):1252-3.

13. Santos KB, Hallack Neto AE, Silva GA, Atalla A, Abreu MM, Ribeiro LC. Infection profile of patients undergoing autologous bone marrow transplantation in a Brazilian institution. São Paulo med j. 2012;130(1):10-6.

14. Srinivasan A, Wang C, Srivastava DK, Burnette K, Shenep JL, Leung W, et al. Timeline, epidemiology, and risk factors for bacterial, fungal, and viral infections in children and adolescents after allogeneic hematopoietic stem cell transplantation. Biol Blood Marrow Transplant. 2013;19(1):94-101.

15. Nenova M, DuHamel C, Zemon V, Rini C, Redd WH. Posttraumatic growth, social support, and social constraint in hematopoietic stem cell transplant survivors. Psychooncol. 2013 Jan;22(1):195-202.

16. Arce VAR, Sousa MF. Integralidade do cuidado: representações sociais das equipes de Saúde da Família do Distrito Federal. Saúde soc. 2013 mar;22(1):109-23.

17. Granja GF, Zoboli ELCP, Fortes PAC, Fracolli LA. Equidade no sistema de saúde brasileiro: uma teoria fundamentada em dados. Rev baiana saúde pública. 2010;34(1):72-86.

18. Brasil. Portaria n. 931, de 2 de maio de 2006. Aprova o regulamento técnico para transplantes de células-tronco hematopoiéticas. Brasília; 2006 [cited 2016 Feb 20]. Available from: http://www.sbtmo.org.br/a-sbtmo.php?id=8

19. Mendes-Takao MR, Diaz-Bermúdez XP, Deffune E, Santis GC. Private umbilical cord blood banks for family use, in Brazil - technical, legal and ethical issues for an implementation analysis. Rev bras hematol hemoter. 2010;32(4):317-28.

20. Brasil. Lei n. 9.434, de 4 de fevereiro de 1997. Dispõe sobre a remoção de órgãos, tecidos e partes do corpo humano para fins de transplantes e tratamento e dá outras providências. Brasília; 1997 [cited 2016 Feb 20]. Available from: http://www.planalto.gov.br/ccivil_03/leis/L9434.htm

Received: May 17, 2016

Approved: May 8, 2017

Published: Jun 27, 2017