Fábio de Barros Correia Gomes

Threats to equity in the distribution of organs for transplantation: an analysis of legal access criteria

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EXAMINATION COMMITEE

Prof. Dr. Debora Diniz Rodrigues – Social Service Dept. (SER) - University of Brasilia / UnB
(Advisor – Committee President)

Dr. Marcelo Medeiros - International Poverty Centre

Prof. Dr. Rosa Helena Stein - SER - UnB

Translation from Portuguese into English by Pablo Regino (reviewed by Fábio Gomes)

ABSTRACT

This dissertation examined the impact of federal legislation in promoting equity in population's access to donated organs for transplantation within the National Unified Health System (SUS). Methodology was qualitative, based on documental analysis of literature review and legal documents analysis of the period from 1963 to 2007. The following types of legal texts were analyzed: laws, decrees, ordinances and resolutions. Documents were placed in a historical, political and social broader context, particularly with regard to the Brazilian Welfare State. The debate on equity considered John Rawls' principles of justice, associated with the fair equality of opportunity, and the multidimensional approach of health equity proposed by Amartya Sen, which values the individual's ability to use the society resources. Ethical principles identified by Nikola Biller-Andorno and Roberto Andorno were also used to analyze the legal criteria for access to organs through the SUS. Among the major findings of this research is identification: of a contextual insufficiency and unequal access to organs for transplantation (present in programs of different countries as well as in Brazil) and of legal criteria for access to organs that are comprehensive and social justice oriented, despite situations that threaten the equity of access have been identified. In the regulatory field, it was demonstrated that the Federal Constitution, SUS 's regulations and the Transplantation Law seek equity, with equal opportunity of access to transplantation. These laws made explicit as basic criteria for access: the principle of solidarity to obtain the organs, since commercialization is forbidden, and the principle of equality, by means of a single waiting list system. It was up to the regulations made by the Executive Power to add criteria of compassion and efficient distribution, in addition to considering equity, through the provision of organs distribution between states. Threats to equity of access were identified in a hierarchy breach between rules setting criteria for clinical severity criteria and in omissions to regulate the weights of some criteria used for the allocation of organs. Securing the highlighted problems will promote procedural fairness, transparency, social control and, consequently, equity in the transplantation program. The existence of unequal access despite the adoption of legal criteria that seeks equity suggests that greater attention must be taken to the relationship between the transplantation program, the SUS and the Brazilian Welfare State.

Keywords: Transplantation - Legal criteria - Organs for transplantation - Equity

SUMMARY

1 INTRODUCTION

Organ transplantation is a therapy that replaces a person's organ or tissue for another one which comes from a donor, alive or dead. The development of this procedure began in the twentieth century, after the first satisfactory kidney transplants, performed in Paris and Boston, in 1951, by Rene Kuss, Marcel Servelle, Charles Dubost and David Hume (CÂMARA DOS DEPUTADOS, 2004a).

The development of immunosuppressant drugs such as cyclosporine encouraged the development of non-kidney transplant programs (liver, heart, pancreas) in the whole world (CÂMARA DOS DEPUTADOS, 2004a). The success of the various types of organ transplantations extended the situations of use at a pace in which the necessary structural conditions were not met to accommodate all of those who needed them. The availability of human specialists and material resources and of donated organs for transplantation are among the necessary factors for the proper implementation of organ transplantation programs.

The excess in demand in relationship to offer for organs is an international phenomenon and has resulted in the formation of waiting lines for the performance of transplants (WORLD HEALTH ORGANIZATION, 2007a). Considering the nature of pathologies that indicate the performance of an organ transplantation, is essential for the well-being and life preservation of those who are in the line, that waiting time should not extend for too long. Currently transplantation programs face a double challenge: to promote an increase in the number of organ donations and to distribute those available in the most efficient and fair way possible. It is in the ability to solve these issues, overcoming cultural resistance and structural problems, how programs differ around the world.

In a context of shortage, limit situations are frequent to those who have the task of deciding about the allocation of donated organs, so legal criteria, previously agreed with the society, which defines how and to whom organs should be allocated, are necessary. In liberal democratic societies, those criteria are aimed to give justice and equity to this procedure, in particular when a context of social and economic inequality is considered. That context can decisively influence the opportunities for citizens to obtain access to organs for transplantation.

In the case of Brazil, the organ transplantation program is frequently referred to as an example of success of the National Unified Health System (SUS). Together with the AIDS and immunization control programs is considered one of the health services which comes closest to the fundamental principles of that system: universality and comprehensiveness. However, the transplantation program is not isolated from the health policy context and, far less from, the Brazilian Welfare State's social policy context. Apart from the difficulties arising from the population's growing demand for transplantation organs, structural problems within the public health system persist.

These structural challenges are also reflected in the transplantation program and can be exemplified by the existence of 69 thousand people waiting for transplants in June 2007 (BRAZIL, 2007), by the complaints of abnormalities in the waiting lines investigated by the Chamber of Deputies (2004a, 2004b) and the Brazilian Court of Audit (TRIBUNAL DE CONTAS DA UNIÃO, 2006) and the reduction of 1.4% in the number of transplants performed in Brazil for the first time since 2001 (AGÊNCIA ESTADO, 2007). A decrease in the number of pancreas, liver and, above all, heart transplants was reported, in addition to the falling donation rate, which fluctuated from 7.4 donors per million persons (p.m.p.) in 2004, to 6.0 p.m.p. in 2006 (AGÊNCIA ESTADO, 2007).

In regard to the organ transplantation waiting lines, information concerning difficulties in their operation is not uncommon. In 2006, there were in Brazil 7.5 thousand people distributed across the 11 state liver transplantation waiting lines, of which the Sao Paulo's was the greatest, with 4 thousand people, of which 130 were from Acre State (WESTIN, 2006). Whereas the criteria for the waiting line operation are contained in federal legislation, which indicate a national coverage of access, through the SUS, a need for a deeper analysis of these criteria is perceived.

It is relevant, therefore, to verify whether the distributive justice principles of public resources in a democratic society are being challenged, what would happen if the scarce organs donated for transplantation were not distributed in accordance to a fair criteria. Equally important is to observe whether the SUS, one of the society's basic structure component institution (RAWLS, 1997), may be working with regulations, which may allow the production of inequalities associated with the type of organ to be transplanted and the operational capacity of the federation states. The situations described would have the potential to restrict the equal opportunity of Brazilians to obtain a good, in this case, health, crucial in the exercise of citizenship (SEN, 2006). Moreover, the popular perception of inequities can reduce the level of trust in a program that depends on the population’s credibility to expand, as it operates through organs donations.

Considering the insertion of the transplantation policy in the Brazilian Welfare State and the SUS, the problem of this research was to examine the contribution of the criteria present in the federal legislation and its regulations for the Brazilian people equity of access to donated organs for transplantation within the SUS. The study questioned the existence of legal criteria for access which could threaten the equity in the allocation of organs within the SUS. It was verified the assumption that imprecisions in legal criteria allow the establishment of regulations with the potential to threaten equity in organ allocation, a situation in which constitutional principles, such as equality between citizens and respect to the determination of hierarchically superior regulations, would not be fully considered.

The object of analysis was, therefore, the organ transplantation Federal Law and its regulation, since lies at this level of the federation to establish the general principles of the transplantation program, including the criteria associated with the operation of the transplant waiting line. The principle of equity was selected, given that it is the one derived from the Federal Constitution in force and from the rules that conduct the operation of the Brazilian health system.

Limiting the research problem scope to the contributions of the legal criteria for equity of access to organs excluded the possibility to determine whether the results of the transplantation program are equitable, since other factors, not systematically checked in this study and associated with the operation of the program itself, are involved in the production of such results. On the other hand, it is recognized that equitable results can be hardly obtained by a program whose legal criteria for the organs distribution does not promote equity. Thus, the selected problem addressed a necessary condition for equity in a transplantation program.

The methodology used in the research is presented in the Second Chapter, being basically, a documental analysis. The Third Chapter presents the transplantation programs context at the international level and the Fourth, of the Brazilian program, considering its relationships with our Welfare State and SUS. The Fifth Chapter discusses the concepts of equity and health equity and its interaction with ethical principles in the allocation of organs for transplantation. The Sixth Chapter presents analysis focusing on contributions of legal criteria for equity in the access to organs for transplantation in Brazil. Finally, the Seventh Chapter highlights the conclusions of the study based on the elements identified in previous chapters.

A translated version of the Brazilian transplantation law (No 9,434/1997) is presented in appendix A. Information on the evolution and characteristics of federal legislation on organ transplantation and its regulation are listed in appendix B.

It must be emphasized that this problem of study was only selected because Brazil, through the SUS, has a broad, complex and productive public system of transplants, which can benefit from informations that sponsor their improvement.

2 METHODOLOGY

The present work, qualitative in nature, is based on the review of scientific literature and in documental analysis (federal legislation and public and private documents), as detailed as follows.

Scientific literature review addressed health equity issues relevant to transplantation health policy, highlighting the availability of organs for transplantation in public health systems. The review was done using the Centre of Latin American and Caribbean Information Health Sciences (BIREME) Virtual Health Library (BVS) web site's search engine, available at http://www.bireme.br, making use of the terminology of Health Sciences Descriptors (DeCS) and the Medical Subject Headings of the U.S. National Library of Medicine (MeSH).

With regard to health equity, the national and international scientific articles published in the last 10 years addressing its guiding principles were prioritized, highlighting those studies which also related to the availability of organs for transplantation. The following terms were used for searching: *"eqüidade"*, *"saúde*" and *"transplante"* ("equity", "health" and "transplant"). The literature review on the transplant policies stressed on organ transplantation and SUS services. The expressions *"política de saúde"* ("health policy"), *"transplante"* (“"transplant") and *"SUS"* were used in the investigation. Greater specificity was obtained through the employment of the following expressions identified in DeCS/MeSH terminology: *"listas de espera"* ("waiting lists"), *"normas jurídicas"* ("legal rules") and *"legislação sanitária"* ("health legislation").

The documental analysis used three groups of documents, produced by August 2007. The first group included the federal law on transplants (shown in appendix A) and their regulations, and therefore, public and official in nature. Federal Constitution, laws, decrees and regulations of the Federal Executive (particularly edits from the Ministry of Health) were analyzed, obtained through the Internet sites of the Federal Executive, Brazilian Senate, Chamber of Deputies and Ministry of Health (including the search engines "Saude Legis" and "Visalegis"). These documents are part of the Brazilian transplants policy normative component, and a vital source for identification of transplantation organs access criteria.

The second group was composed of public reports, containing secondary information collected by investigations within the Brazilian National Congress and the Court of Audit, related to organ transplantation. Two of these reports came from the work of the Chamber of Deputies temporary committees (CÂMARA DOS DEPUTADOS, 2004a, 2004b).[1] Complemented that group, the donation program evaluation report from the Court of Audit (2006) for the assessment of the organs and tissues transplantation, donation and capture program, presented by the Resolution Number 562, of April 19, 2006.

The third group was made up of institutional documents of public or private nature useful in the analysis of health equity and policies on transplantation at the national and international levels. We included: a) data on the National Transplantation System, released by the Ministry of Health b) final report from the Working Group on Health Equity of the National Association of Post-Graduate Studies in Public Health - ABRASCO (2000); c) documents from the World Health Organization (WHO) on health policies, social health determinants and organs transplantation and d) texts of non-governmental organizations with expertise in the field of transplantation.

The documents were reviewed, seeking implementation of Tim May's social research perspective in documental sources (2004). May stressed the need to avoid any positivist emphasis and pointed out the importance to treat documents as reflections of reality, in other words, as a product of social interactions and, ultimately, as an expression of social power (MAY, 2004). Thus, the documents examined were not seen as neutral tools, but in a historical, political and social broader context, in particular with regard to the type of Brazilian Welfare State. This critical-analytical position (MAY, 2004) was considered necessary to increase the reliability and validity of the study. Despite the high presumption of legitimacy of the documents reviewed, provisions were taken to prevent assimilation of biases of interpretation perhaps contained in some of the documents and as a result of their selection process.

The four criteria suggested by John Scott (1990) were used to assess the quality of evidence obtained from documents: authenticity, credibility, representativeness and meaning.

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1 The external committee to investigate complaints related to interference on the waiting list of patients in need of bone marrow transplantation at the National Institute of Cancer served between March and June 2004. The parliamentary committee of inquiry which investigated the activities of criminal organizations in human organs traffic operated between August and November 2004.

The first two elements became evident by the very nature of the documents reviewed. Representativeness, associated with typical characteristics of the document, according to Scott (1990), was assisted by the inclusion of all relevant federal regulations in force (up to the level of ordinance). In the case of institutional reports, representation was strengthened by the selection of institutions directly involved with the implementation and control of the transplantation policy, in addition to obtaining the most updated reports. For example, a transcript of the II Transplantation Forum promoted by the Brazilian Federal Medical Council (CFM) proved to be essential to confirm findings on the use of criteria for organs allocation, in relationship to the lack of analysis produced by official bodies.

In regard to meaning, the three aspects mentioned by Scott were explored: the desired, the receipt and the contained. In other words, the meanings that the author wanted to produce, those received by the public in its various social situations and those explicitly contained in the text, allowing the identification of meanings not declared.

To capture these different meanings documents were analyzed in their historical contexts, even considering informations on replaced regulations. Moreover, the relationship between the various documents was emphasized. Thus, endorsing the qualitative emphasis employed in the study, placed in a theoretical structure, so that, through the efforts of reflection, the qualitative summary of the documents would allow their comprehension (MAY, 2004).

With regard to the practical aspects of the documents data collection, the identification of criteria for access to organs for transplantation in the SUS was prioritized, as well as the characteristics of those criteria with regard to equity in the distribution of organs. For criteria for access were understood both, those who regulate the inclusion of people in the transplantation program, as well as those related to the allocation of organs for those already subscribed.

During the assessment of the extensive and complex legislation on organ transplantation the need to group some related issues was recognized. Thus, legislation and its analysis were grouped as follows: social justice principles, mechanisms that influence the organs availability, transplantation program structuring, transparency of information on transplants and penalties related to the breach of the Transplantation Law (Law No 9434, 1997 – see appendix A), authority to regulate the transplantation policy and the principles of access to health services and actions (including specific criteria for organs transplantation). Equity was priority in each topic.

The National Health System (SUS) was characterized as a public free system, based on the universality of care and comprehensiveness of its services and actions; composed by the three spheres of government and the private network as complement. The transplantation policy was considered as a component of health policy. While this research has focused on the analysis of the federal normative component of the transplantation policy, it was understood that this was only one of the components of the policies to be considered, which, in turn, could not be considered outside a broader social policy context (MULLER and SUREL, 1998). The equity analysis considered the differences that are unnecessary, avoidable and socially unjust, as well as the fair opportunity to access (WHITEHEAD, 1992) in relationship to the regulations established for the operation of the SUS and our society context. Access to organs was assessed from the perspective of systemic capacity (*"capability")* to achieve a good health (SEN, 2006), not only through the view of mere distribution of health services.

3 ORGAN TRANSPLANTATION IN THE INTERNATIONAL CONTEXT

Organs transplantation success based on advances in immunology, molecular biology and the science of bio-materials resulted in a growing demand for transplantation services, particularly in countries with average and high income levels (CÂMARA DOS DEPUTADOS, 2004a). The transplantation organs shortage is an international phenomenon and has been related to the population's greater longevity and a larger incidence of chronic and degenerative diseases, which increase the demand for transplants (CÂMARA DOS DEPUTADOS, 2004a).

The development of organ transplantation programs required the drafting of national legislations that would allow the procedure and regulate the organs removal methods. In 1986, Belgium passed a law associated to the removal and transplantation of organs, adopting the presumed consent, by which citizens should explicitly oppose to their organs donation during their lives and in case they did not, donation was presumed (CÂMARA DOS DEPUTADOS, 2004a). Later, other countries introduced legal mechanisms related to transplantation. Despite differences present in those laws, they address the necessary aspects of the organ transplantation performance common to any country, such us definitions on the removal of organs after a brain death diagnosis and the organs allocation criteria, which will be discussed later in the Brazilian legislation analysis (Chapter 6).

Notwithstanding the technical aspects, distinctive of complex processes such as organs transplantation, ethical and humanitarian principles must be considered. For example, the European Community organ transplantation protocol anticipated the need to ensure equity in the access to transplantation services and organs allocation transparency, based on prominent medical criteria (CÂMARA DOS DEPUTADOS, 2004a). The World Health Organization (WHO), through Resolution WHA42.5, 1989, addressed the problem on human organs purchase and sale prevention, also dealt with in Resolution WHA57.18, 2004, which recognized the risk of renal living donors exploitation and recommended its member States to protect the poorest and most vulnerable groups from "transplantation tourism" and organs sale (WORLD HEALTH ORGANIZATION, 2007a).

The WHO resolution WHA44.25, 1991, emphasized the principles that should guide the implementation of organ transplantation programs. These principles emphasized voluntary donation, discouraged organs sale, the preference for cadaver to living person donations and the preference for genetically related to non-relatives donations. Donated organs availability should be based on principles of justice and equity, according to medical necessity, in other words, health care rather than with financial needs or other considerations (CÂMARA DOS DEPUTADOS, 2004a). Despite the existence of such principles of reference, there are those who advocate to some kind of organ commercialization, as a means to address the mentioned shortage. For example, Gary Becker and Julio Jorge Elías (2007) and Shaun Pattinson (2003), among others, supported further organs liberalization for transplantation trade.

The WHO identified among the problems related to transplantation: the lack of data and information on procedures performed, the lack of transplantation safety and efficiency for treatment documentation in different contexts and the insufficient organs supply from cadaver donors; due to deficiencies in health systems structure and by legal, religious and cultural resistance. It also found an excessive increase in the number of living donor organ donations, with ethical and safety implications for the donor's health; in addition to transplant tourism evidence from people who travel to countries of medium and low income to perform transplants, whose donors, generally belong to the poorest and most vulnerable population groups (CÂMARA DOS DEPUTADOS, 2004a).

According to the WHO, although the principles presented in resolution WHA44.25, 1991 have exercised great influence on the development of professional codes and national laws, they did not address issues of access, safety and efficiency (WORLD HEALTH ORGANIZATION, 2007th). These topics were discussed by the WHO in 2003, occasion in which discrepancy between the transplantation activities performed in different regions became explicit. For example, regarding renal transplantation, the U.S. performed 57 procedures per million persons (p.m.p.), while the European countries accounted for 27 p.m.p., almost a half. The difference was much greater in the case of Asia, which, despite its larger population, only carried out three renal transplants p.m.p. (WORLD HEALTH ORGANIZATION, 2003).

The WHO identified progressive increase in the use of living donors in Europe and the U.S., moreover, in 2001 the number of living donors overcame that of cadaver donors in the U.S. for the first time (WORLD HEALTH ORGANIZATION, 2003). Disparities between the Asian countries were also found. In India and Japan, livers and kidneys came almost exclusively from living donors, whereas in other countries such organs were usually obtained from cadavers and even from executed prisoners (WORLD HEALTH ORGANIZATION, 2003). The reasons for these discrepancies, both in the number of procedures, as in the source of organs, are complex, including: cadaver donations cultural resistance, regulations and local health policies and lack of intensive care units and human and material resources for establishing cadaver donation programs (WORLD HEALTH ORGANIZATION, 2003).

Among the consensual findings acknowledged by the WHO on the international context it is the recognition that organs transplantation is an effective procedure which should be seen as an globally available service and also the fact that in the last ten years the principles proposed by the WHA44.25, 1991 Resolution, were contradicted by many medical and social practices, including the increase in the use of living donors or non-relative donors who received some form of compensation (WORLD HEALTH ORGANIZATION, 2003). Facing the challenges highlighted by the WHO, the Spanish Health and Consumer Affairs Minister, Ana Pastor Julián, concluded that the most effective means to fight the human body parts trade is by providing quality treatment for people in all countries, considering equity and equality (WORLD HEALTH ORGANIZATION, 2003).

To appreciate the extent of a transplantation procedures throughout the world, estimates released by WHO's *Global Knowledge Base on Transplantation* (GKT) for the year 2004 (WORLD HEALTH ORGANIZATION, 2007b) are presented in Table 1. Considerable inequalities can be observed, since American and European countries perform transplants at levels far above from other regions, standing out the poor performance of Africa, which information regarding liver and heart transplantations was only available for one country.

On the outcome of transplants performed, the GKT discloses, for example, information on national renal transplantation programs, by which the procedure effectiveness is confirmed, even in countries with lower economic development. Data on the renal graft survival after one year showed good results for renal transplantation from living donors, as well as from the cadaver ones, though small higher rates are found in the first case (WORLD HEALTH ORGANIZATION, 2007b).

Table 1. Kidney, liver and heart transplantation estimates carried out in the administrative regions of WHO (2004).

Transplant indicators	WHO regions					
	Americas	Europe	East Mediterranean	West Pacific	South West Asia	Africa
Kidney Tx p.m.p.	30.13	27.34	13.17	5,45	2.15	1.34*
Kidney Tx living / cadaver donor rate	0.67	0.2	14.96	0.41	32.62	3.93
Liver Tx p.m.p.	11.15	13.83	1.18	1.73	0.22	0.17**
Liver Tx living / cadaver donor rate	0.075	0.06	1.38	0.54	5.5	-
Heart Tx p.m.p.	3.49	4.64	0.24	0.08	0.06	0.59**

Source: Global Knowledge Base on Transplantation (GKT), WHO.

Legends: p.m.p. = per million persons; Tx = transplants.

Notes: (*) data from five countries; (**) data from one country.

The *Eurotransplant International Foundation* annual report (2007), referring to the procedures in Austria, Belgium, Croatia, Germany, Luxembourg, Netherlands and Slovenia, indicated that in 2006, were conducted: 3,221 kidney transplants from cadaver donors and 898 from living donors, 1,273, liver transplants from cadaver donors and 116 from living. Considering all solid organ types, 6,970 transplants were performed in this region, which has a population of 120.1 millions, resulting in a rate of 58 solid organs transplants p.m.p.

In Spain, a country that stands out for its universal access transplantation program - the same principle used in the Brazilian program - and for having the world's highest rate of donors, 34.6 donors p.m.p. (an absolute number of about 1,600 donors), in 2006 were performed, 2,157 kidney, 274 heart, 169 lung, 94 pancreas, and 1,051 liver transplants (ORGANIZACIÓN NACINAL DE TRANSPLANTES, 2007).

The Spanish *Organización Nacional de Transplantes* (ONT) was selected by WHO to host the World Transplant Registry, which consists of information from 98 countries, a equivalent to 82% of the world's population, which in 2005 recorded about 95,000 solid organs transplants, of which 65,700 were for kidney, 21,000 liver, 6,000 heart and 1,800 lung transplants (GREGORI, 2007). The ONT prepared a comprehensive report (COUNCIL OF EUROPE, 2006) containing data on organ transplantation in various regions and world countries (Table 2).

The data in Table 2 show unequal access to various transplantation types. When compared, for example, the European Union with Latin American countries, the performance rate of these procedures is much higher among the first. In the case of renal transplants, the lowest rate in the use of living donors can be found in European countries, representing a greater success in drawing donors from cadavers, expanding the organs supply. It can also be observed that each country's context affects the performance of its transplantation program. The positive results obtained by Spain confirm the reputation of their system, supported by an organized structure that sponsors from reception of organs as well as various transplants procedures types. This structure allows greater efficiency to deal with people on the waiting list: the renal transplantation waiting line is an example.

The situation of the Brazilian transplantation program will be the object of the next chapter, however, from the indicators presented in Table 2 it can be observed a relative better performance of the Brazilian system in relation to those in Latin America, but still lower compared to those of the European Union countries or the U.S. At the same time, it should be noted that the number related to the Brazilian population used in the ONT report (COUNCIL OF EUROPE, 2006), of 211 million inhabitants, does not match with the estimates released by the Brazilian Institute of Geography and Statistics - IBGE (2007) – which for the year 2005, was of 184 million. This difference implies a reduction of an estimated 15% in the performance of Brazilian indicators, which, although worth the adjustment, do not affect the fundamental nature of the conclusions above.

Table 2. Indicators on 2005 organ transplantation procedures in the selected regions.

Transplantation indicators	Regions / Countries						
	European Union	United States	Canada	Italy	Spain	Latin America	Brazil
Population (millions)	453.7	298.2	32.2	56.9	44.1	531.1	211
Cadaver donor	8516	7593	414	1197	1546	2999	1688
(p.m.p.)	18.8	25.5	12.8	21	35.1	5.6	8
Kidney Tx.	16176	16477	1055	1772	2200	6807	3716
(p.m.p.)	35.6	55.2	32.6	31.1	49.9	12.8	17.6
Kidney Tx % with living donor	13.7	39.8	42.0	5.7	4.0	40.5	40.6
Kidney Tx Centers	-	250	21	40	42	-	-
(p.m.p.)	-	0.8	0.7	0.7	1.0	-	-
Kidney Tx waiting line by 12/2005	-	66757	2759	8688	4152	-	-
(p.m.p.)	-	223.9	87.7	152.7	94.1	-	-
Liver Tx	6095	6444	421	1081	1070	1386	872
(p.m.p.)	13.4	21.6	13	19.0	24.3	2.6	4.1
Heart Tx	2004	2160	6	344	287	401	236
(p.m.p.)	4.4	4.7	0.2	6.0	6.5	0.7	1.1
Pancreas Tx	720	1444	87	87	96	347	328
(p.m.p.)	1.6	4.8	2.7	1.5	2.2	0.6	1.6
Cornea Tx	-	-	-	4576	2758	-	-
(p.m.p.)	-	-	-	80.3	62.7	-	-
Bone marrow Tx	-	-	-	3956	1911	-	-
(p.m.p.)	-	-	-	69.5	43.3	-	-

Source: Modified version from International figures on organ donation and transplantation - 2005. COUNCIL OF EUROPE (2006).

Legends: p.m.p. = transplants per million persons rate; Tx = transplants; (-) = data not shown.

While the Unites States (U.S.) is the country that holds the larger number of organ transplants, the excess of demand also affects its system, resulting in growing waiting lines for various types of organs. In the case of renal transplants, Table 2 shows that countries with a lower number of transplants compared to that of the U.S., such as Spain, Italy and Canada, can keep a relatively smaller waiting list. According to information released by the Organ Procurement and Transplantation Network - OPTN (2007a), there were 97,515 applicants on the waiting list for an organ in the U.S. on September 30, 2007, 75% of which were for renal transplantation (73,466 candidates).[2] Between January and June 2007 14,224 transplants were performed, from 7,170 donors.

It is worth mentioning the abundance of data available to the U.S. society for control over transplantation program. For example, for the year 2006, it is known for kidney transplantations that: 10,659 transplants were performed from cadaver donors, 6,434 from living donors; there were 65,199 candidates on the list at the beginning of the year and 70,778 at the end, despite the performance of more than 17,000 transplants, because of 32,854 new candidates entry (US TRANSPLANT, 2007). Information about the results of the activities were also released, showing, in 2006, the renal transplant rate among the candidates on the list was 23% and mortality while waiting was 7% (U.S. TRANSPLANT, 2007). For liver and heart transplantation, in the same period, the rate of transplantation among the candidates on the list was 39% and 78% respectively; and mortality while waiting on the list was 13% and 16% (U.S. TRANSPLANT, 2007).

Consolidated per year figures are available for public consultation on the OPTN's web site. The 2006 annual report (OPTN, 2007b) showed that by the end of 2004 there were over 150 thousand people living with a functional organ transplant in the U.S. The report evidenced that the renal waiting list was the one that increased the most (8%) between 2004 and 2005 due to an excess on the demand. Meanwhile, in the same period, the heart, lung and lung-heart transplantation waiting lines fell by 8%, 18% and 18% respectively. Another sign of the system

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[2] The OPTN is a private nonprofit organization, created by the U.S. Congress in 1987, through the National Organ Transplant Act, consisting of all transplant centers, search organ organizations and histocompatibility laboratories of the U.S.

good performance was the new cadaver donations rate that achieved a 7%, followed by a fall in the number of living donors of 2% between 2004 and 2005 (OPTN, 2007b).

The 2006 OPTN report emphasized, however, the existence of geographical variations in the access to renal transplants in the United States. Important disparities among states became obvious, not just in the process of inclusion in the waiting lists, but also, once in the list, to renal transplantation access. Adjusted waiting list rates showed values ranging between 37% lower than the national average to 64% higher than the national average (OPTN, 2007b). Large variations among states were also detected with respect to the origin of the transplanted organ (living or cadaver donor).

Although the disparities in access between the states have been documented, the applied methodology failed to identify the related causes, even the influence of age, race, sex and cause of renal pathology have not been identified. The report concluded that these findings challenge those involved in transplantation to provide similar opportunities for people with similar disease diagnoses and stages of progression. Furthermore, it acknowledged that the data collected showed that this responsibility was not being properly handled (OPTN, 2007b).

Meanwhile, other studies on renal transplant access in the U.S., highlighted difficulties of access for blacks, women and poor (ALEXANDER; SEHGAL, 1998), due to difficulties in completing preparatory steps necessary for transplantation procedures (such as laboratory tests), as well as in the progression on the waiting list and in the achievement of the transplant itself. These authors concluded that efforts to allocate kidneys with equity must address each of the stages analyzed.

Inequalities in access to organ transplantation were also found in other countries, such as Scotland (ONISCU et al., 2003), where the assessment of a ten years period found less inclusion probability on the renal transplantation waiting list for women, elderly, people with diabetes, high socio-economic deprivation levels and treatment on health service without a transplantation unit. In France, differences in access were observed between residents of different regions of the country depending on the transplantation team experience, the activity of organs searching and the severity of the disease among those who were in the waiting list (ROUDOT-THORAVAL et al., 2003).

In the United Kingdom, regional variations were identified in waiting time for renal, liver and heart transplantation; in addition to variations in the organs donation rate (RUDGE et al., 2003). In Australia, geographical disparities in access to transplantation have been demonstrated, deepened in a 15 years period due to the increase in the size of the waiting lists in each state and the low rates of cadaver organ donations (CHAPMAN, Graeme, 2003). The authors stressed that the criteria for access to waiting lists differ from state to state. In Spain, differences were found in access to liver transplantation, identifying less waiting time for people with AB blood type, children, hepatic carcinoma patients and people living in the Valencia region, despite similar organ donation rates in all transplantation regions (MIRANDA et al., 2003).

As is pointed out, regional inequality of access to transplants is not only a poor countries phenomenon. Indeed, this issue has lead to intense debate in countries with greater economic development. According to David Meltzer (2003), concerns about the organs shortage in the U.S. and the mechanisms for its allocation were intensified in the 1980s, driven by the growth of waiting lists, which showed large regional variations. In 1990 the U.S. Congress required the OPTN to assist the *Organ Procurement Organization (OPO),* responsible for the allocation of organs at the local level, in promoting equity in the organs distribution at the national level (MELTZER, 2003). In 1994, the U.S. equivalent of the Ministry of Health, the *Health and Human Services (HHS),* proposed rules to facilitate the sharing of organs, reducing the local institutions control, emphasizing on the medical criteria to prioritize the most sick and those who would benefit the most from the transplantation (MELTZER, 2003).

The debate on these rules was intense in the 90s. Tom Koch (1999) highlighted the dispute between HHS and the of the *United Network for Organ Sharing* (UNOS) vision, in which the first stressed on greater equity at the national level and the second, more control of local organizations, allowing faster and more efficient use of available organs.[3] In 1998, the HHS sent a letter to U.S. Congress stating that changes in OPTN would be ordered, because equity in organ distribution was not achieved for people with the greatest medical needs, emphasizing on the big differences in the organ waiting lists (KOCH, 1999). On April 2, 1998 the HHS

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[3] The UNOS is a private non-lucrative organization that coordinates the national transplantation system in the U.S. by means of a contract with the OPTN.

regulations were issued determining the allocation of organs to a national level. Koch (1999) argued that both types of vision had similar goals and that inequalities would not be resolved if structural disparities in the U.S. health care system were not removed, such as the lack of access to health care for citizens who have no health-insurance.

The U.S. debate has not been isolated in the international context. There are coincidences in the implementation content and timing of alterations performed in transplantation programs by regulations of various countries. France modified its regulations on organs distribution in 1996, Germany drafted legislation on the subject in 1997 (BILLER-ANDORNO; ANDORNO, 2001) and Brazil passed a new law in 1997 (appendix A), which included concerns about the national scope of a unique waiting list.

Other useful elements can be drawn from the U.S. experience in approaching the Brazilian case, such as: the mentioned abundance of data available to the society on transplant procedures and the intense technical evidence-based debate about the criteria for organs allocation, even adopting computer based simulations (ZENIOS, WEIN e CHERTOW, 1999) and hierarchical organs allocation models (KOCH, 1996). Equally relevant to the Brazilian transplantation system debate was the discovery that the unequal access problem to transplantation organs is an international scope issue, ranging in its intensity according to the resources available in the different countries. The information presented on the performance of the national transplantation programs, and, particularly in those that have universal coverage public health systems (like Spain and Italy), will allow a better assessment on the Brazilian experience, the object of the next chapter.

4 ORGAN TRANSPLANTATION IN BRAZIL

4.1 BRAZILIAN WELFARE STATE AND NATIONAL UNIFIED HEALTH SYSTEM CONTEXTS

Article 196 of the 1988 Brazilian Constitution establishes that health is a right for all and a duty of the State, also asserts universal and equal access to actions and services for its promotion, protection and restoration (BRASIL, 1988). The National Unified Health System (SUS) was established as a network of actions and regionalized, hierarchical and organized services in accordance with the following guidelines: decentralization, with a unique head in each sphere of government; comprehensive attendance services, with priority to preventive actions, notwithstanding welfare services, and community involvement (Article 198). According to Article 194, health is component to social security together with welfare and social assistance, promoting social policies integration (BRASIL, 1988).

The Constitutional guidelines and principles of universality and “integrality” (comprehensiveness of care) grant the normative component of health policy a structuring role in strengthening the Brazilian Welfare State. Meanwhile, this legislation counteracted the economic and political thinking prevailing in central capitalist countries, which exhorted for a weakening of the Welfare State. Elaine Behring (2000) identified an adherence to neoliberalism in Latin America in the late 1980s, complying with political and economic characteristics of the region: political authoritarianism and poverty. The author agreed with Sonia Draibe, which suggested that in respect to social programs neoliberalism was based on the trinomial of focalization, decentralization and privatization, through cutbacks in social spending for the public sector financial balance (DRAIBE, 1988). According to Marcio Pochmann (2004), among the least developed capitalist countries and with less international influential power, the Welfare State did not completely develop, and yet, the small social apparatus built from the 1930s has been strongly questioned by the elite since the 1980s crisis.

In analyzing the Social Welfare Reform implications in the Brazilian Social Security, Ivanete Boschetti concluded that Social Security was not implemented as conceived in the 1988 Constitution, since the political trend was to fragment social policies and to threaten the conceptual and financial basis of social security, hindering its consolidation (BOSCHETTI, 2003). Consequently, the political components of Social Security, health among them, weakened, since they had to compete for the available resources, in opposition to the constitutional determination of integrated sharing of resources for the financing of each one of these components, by means of budgeting Social Security.[4] Nevertheless, health is one of the Social Security components in which major advances are observed in regard to compliance with the 1988 Constitution, in particular when compared with the situation of Social Assistances, many of the SUS problems have been attributed to the federal entities failure to fulfill with the constitutional financing. (CÂMARA DOS DEPUTADOS, 2007a).

In this challenging context, the SUS development and maintenance of a Welfare State faced obstacles, but also achieved significant successes. Data related to SUS activities developed in 2006 highlighted the production greatness of that system: 1.3 billion basic care procedures, 1.2 billion of specialized care procedures, 600 million consultations, 212 million dental treatments, 360 million laboratory tests, 11 million ultrasound, 11.8 million hospital admissions, 3.1 million surgeries (141 thousand heart), 150 million vaccinations, 23 million sanitary surveillance actions, 12 thousand transplants, among other procedures. (CÂMARA DOS DEPUTADOS, 2007a).

Renilson Souza (2002) admitted that before the creation of SUS medical hospital assistance provided to the population, then known as *indigente* (“beggar”), was provided by some municipalities and states, and, mainly, by philanthropic institutions, so that health care had more a charitable nature rather than one based on a citizenship right (SOUZA, 2002). Health care coverage sponsored by the Social Welfare Medical Assistance National Institute (*Instituto Nacional de Assistência Médica da Previdência Social* - Inamps) in this period was not universal, it only benefited the employees from the formal economy and its dependents (SOUZA, 2002). At the end of the 1980s, the Inamps adopted measures in the direction of universal coverage, such as the creation of the Decentralized Unified Health System (*Sistema Unificado e Descentralizado de Saúde* - SUDS), implemented through agreements between the Inamps and the states. For Souza (2002), health workers, universities and organized sectors of

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[4] Paragraph 2 of article 195 of the Federal Constitution provides that the proposed budget for social security will be elaborated in an integrated manner by the bodies responsible for health care, social welfare and social assistance, with the goals and priorities set by the budget guidelines laws, providing to each area the management of its own resources.

society mobilization established the Health Reform Movement (*Movimento da Reforma Sanitária*), which in such democratization context succeeded in introducing in the 1988 Constitution the previously mentioned rights.

The constitutional concepts of universal and comprehensive coverage, typical of a institutional and redistributive Welfare State type, faced great resistance from those who supported a more residual model (TITMUSS, 1974).[5] For example, Law No. 8,080, 1990, which regulates the SUS, was enacted just two years after the Constitution and with vetoes related to its financing, which were partially resolved, even in 1990, through Law No. 8,142.

Following several financial crisis of health actions and services in the 1990s, greater stability was obtained in 2000, with the introduction of Constitutional Amendment No 29, by which a minimum percentage was to be applied to health in municipalities and states and Union application continuation. As a result, an increase in the financial participation from municipalities and states was observed and a relative retraction on the Union part (FRENTE PARLAMENTAR DA SAÚDE, 2005). The battle around the concept of the welfare state represented by the SUS is once again exemplified by the current difficulty in approving the regulation of Constitutional Amendment No 29, through a Complementary Bill which defines the budget rate for the Union participation and clarifies the expenses types that should be considered for the calculation of minimum percentages in health expenditure.

The appointment of inadequate resources for financing the SUS, observed after its deployment, expressed the setback that the neo-liberal principles imposed on social policies in general. Although the SUS has been able to maintain its concepts at a legal level and has had some success in achieving social control over health policy, in practice, limitation in social expenditure imposed by successive governments since the 1990s, has hampered a proper decentralization of health actions and services (FRENTE PARLAMENTAR DA SAÚDE, 2005). The incomplete implementation of the SUS, due to its inadequate funding, affects the quality of service offered and its credibility. This may be perceived as a flaw in the system conception itself rather than a flaw in its realization. The crisis of confidence, in turn, could

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[5] In the institutional-redistributive model, the State seeks to redistribute wealth produced by society, ensuring to citizens, by means of institutionalized services, the necessary material conditions for them to act productively. In the residual model, the State must guarantee minimum conditions of freedom, security and stability so that citizenship seeks its own development, and consequently the society's.

make it even more difficult to get the necessary Congress support for the approval of measures to reverse the under-funding.

While an universal health care model, such as the Brazilian, faced financial drawbacks, already in the 1990s, the World Bank, through its then main economist, Philip Musgrove, acknowledged that a difficult choice would have to be made between equity and efficiency (MUSGROVE, 1999, p. 14). It was recommended that the public sector should finance: cost-effective public and semi-public goods for which the demand was inadequate; cost-effective interventions that preferentially benefit the poor and health care of catastrophic costs (MUSGROVE, 1999, p. 24). This view was clearly opposed to the universality and comprehensiveness of services offered to the public.

The difficulties in implementing the SUS seem to reflect a dissociation between its normative basis, universal and inclusive, and its visible results, which often expresses focus on specific populations (the poorest) and prioritization of catastrophic costs procedures, according to the neo-liberal recipe. In addition to success stories of SUS in some areas, such as the topic of this research, some less complex services are inadequately financed and have insufficient coverage and quality. Around 36 million Brazilians find themselves forced to use private health care plans, according to the Supplemental Health National Agency -*Agência Nacional de Saúde Suplementar*- (ANS, 2006), which supports Carlos Pereira thesis (1996) that the lack of quality in public services strengthens complementary private medicine.

The difficulties of access to SUS's health services and actions were recently explained by the current minister of health during a public hearing at the Chamber of Deputies Social Security and Family Standing Committee to discuss issues related to health financing (CÂMARA DOS DEPUTADOS, 2007b). The minister acknowledged discrepancies in the remuneration tables of the SUS and stressed that today there are 13 million hypertensive patients who are not being properly treated or monitored and 4.5 million diabetics in the same situation (CÂMARA DOS DEPUTADOS, 2007b). He also highlighted that: 25% of the population bearer of neglected diseases such as tuberculosis, malaria, leprosy, among others, have no regular access to the health system; 47% of pregnant women do not meet the minimum of seven pre-natal consultations and 90 thousand Brazilians diagnosed with cancer will be treated with chemotherapy and surgery, but will have no access to radiotherapy as a result of a deficient installed capacity (CÂMARA DOS DEPUTADOS, 2007b).

Furthermore, it is necessary to consider that inequalities in access to the SUS services are not evenly distributed among the Brazilian population, regional differences prevail. For example, Mariângela Cherchiglia et al. (2007) verified regional asymmetries in access to renal dialysis. In 2003, while the prevalence of people on dialysis in Southeast was 443 p.m.p., it was 140 in the North.

In spite of a perception of a reasonable quality standard in the provision of specific health services, such as transplants, there is inequity in the quality of other health services equally relevant, such as low and medium complexity actions. Thus, a situation of inefficiency is created in which the poorest component of the population suffers restriction of access to quality services (with regard to timing and resolution of care) essential in the prevention and in reducing the incidence of diseases that eventually will require more complex treatments, such as transplantation. This is the case of access to diabetes treatments and urinary infections and hypertension control to prevent renal failure. [6,7] On the other hand, access to high complexity services, with high costs and of reasonable quality, such as organ transplantation, are apparently available. Nevertheless, the poorest lead disadvantage in the use of more complex services, because they tend to enroll later in the waiting lists, a situation less satisfactory in the transplantation success.

In short, the SUS was conceived in the logic of the institutional-redistributive Welfare State, but by far, implemented in the residual logic. This ambiguity is reflected in the constant confrontation between the actors that conquered the inclusion of universality and comprehensiveness in the constitutional regulation (including health professionals and organized civil society sectors) and those who, in some way, promoted the limitation of those rights, giving

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[6] The prevention of renal disease is recognized with one of the most cost-effective approaches to population health, although may not completely eliminate the need for renal transplantations (WORLD HEALTH ORGANIZATION, 2003).

[7] Study carried out in Belo Horizonte which found that the causes of chronic renal failure, among those registered for renal transplantation between 2000 and 2005 were: glomerulonephritis (34.6%), hypertension (29.4%) and diabetes (15.3%) (MACHADO; ACÚRCIO; CHERCHIGLIA, 2007a).

more value to the country's macroeconomic stability, at the expense of limiting funding and imposing segmentation on a policy established as universal by the Federal Constitution.

The ambiguity of the health care model actually adopted that, in practice, combines universality for highly complex care services and those related to epidemiological and sanitary surveillance with selectivity for low and medium complexity health services, tends to keep a structure of inequality of access to health services. In the particular case of organ transplantation this situation can even increase the waiting lists and feeds a vicious circle of demand for resources, which it turns out to be perverse to those who depend on the public health system.

4.2 THE BRAZILIAN TRANSPLANTATION PROGRAM

The Ministry of Health established the Brazilian transplantation program, known as the National Transplantation System (*Sistema Nacional de Transplante* - SNT), in the 1990s aiming to: 1. deploy unique recipients lists; 2. encourage the creation of organs notification, extraction and distribution centrals (CNCDO) in the states; 3. create complementary regulations of the activity; 4. register and authorize services and specialized teams to promote tissues, organs and body parts withdrawal, transplants or graft; and 5. establish financing criteria (CÂMARA DOS DEPUTADOS, 2004a). The SNT is also composed by: a Technical Advisory Group (*Grupo Técnico de Assessoramento* **-** GAT), intra-hospital transplantation commissions, organ and tissue banks, National Registry of Donors (created in 2000) and the Bone Marrow Donors Registry-REDOME (CÂMARA DOS DEPUTADOS, 2004a).

The state CNCDO's are under the responsibility of the Health State Departments. Data disclosed by the SNT and updated July, 2007 showed the existence of 25 state CNCDO. There are no CNCDO in Roraima and Tocantins and only five regional central offices in Minas Gerais and two in the Paraná have been recorded (BRASIL, 2007a). According to the Ministry of Health, the Brazilian transplantation program is the second biggest public program of the world, surpassed only by the Spanish one (BRASIL, 2007b).

Table 3, displays data on 15,132 transplants registered by the SNT in 2006. The states that performed more transplants were São Paulo, Rio Grande do Sul and Minas Gerais. The most performed transplants were of cornea (9,948, 65.6% of total), kidney (2,904), bone marrow

(1,032), liver (930) and heart (147). It is important to remark that Table 3 shows information for 23 CNCDO, although there are 25 central states.

Table 3. Frequency of transplants performed in Brazil, by type of organ and state, 2006*.

	Type of transplant								
State	Heart	Cornea	Liver	Pancreas	Lung	Kidney	Kidney / Pancreas	Liver / Kidney	Total
Acre	0	0	0	0	0	2	0	0	2
Alagoas	0	18	0	0	0	25	0	0	43
Amazonas	0	68	0	0	0	23	0	0	91
Bahia	0	98	14	0	0	54	0	0	166
Ceara	12	210	46	0	0	109	0	0	377
Federal District	0	276	0	0	0	34	0	0	310
Espírito Santo	0	91	10	0	0	55	4	0	160
Goiás	2	795	0	0	0	72	0	0	869
Maranhão	0	58	0	0	0	30	0	0	88
Mato Grosso	0	39	0	0	0	1	0	0	40
Mato G. do Sul	0	90	0	0	0	49	0	0	139
Minas Gerais	14	632	50	17	2	282	22	2	1021
Pará	1	79	0	0	0	42	0	0	122
Paraíba	1	125	8	0	0	15	0	0	149
Paraná	26	615	54	1	0	226	9	0	931
Pernambuco	8	522	57	0	0	136	0	0	723
Piauí	0	39	0	0	0	36	0	0	75
Rio de Janeiro	2	77	97	0	4	220	0	0	400
Rio G. do Norte	4	125	0	0	0	36	0	0	165
Rio G. do Sul	13	805	99	2	21	274	20	2	1236
Santa Catarina	7	285	42	0	0	160	1	0	495
São Paulo	56	4756	453	65	26	1004	65	8	6433
Sergipe	1	45	0	0	0	19	0	0	65
Total	147	9848	930	85	53	2904	121	12	14,100

Source: CGSNT/DAE/SAS/MS (BRASIL, 2007a).
Note: (*) 1,032 bone marrow transplants are not included, bringing the number of transplants performed in 2006 to 15,132.

Among the resources available to support its activities, the SUS has 1,335 transplantation teams, 925 authorized hospitals to perform grafts and 170 hospitals fit to capture and make an active search of organs and tissues (BRASIL, 2007b). In addition, there are 58 laboratories able to conduct histocompatibility tests, 34 eye banks, six of musculoskeletal tissues, one of heart valves and one of skin (BRASIL, 2007b). In 2006, R$ 464.8 million were spent in transplants, of which R$ 278.5 million (60%) were for the acquisition of drugs to prevent rejection of transplanted organs (BRASIL, 2007b). There are 196 institutions authorized by the SNT to perform renal transplants, of which 31% are located in São Paulo (BRASIL, 2007a).

Despite the existing structure, it is noticed, through table 4, the inequality in access to transplantation between states and regions of Brazil, with regard to solid organs and cornea transplants. The simple fact that Rondônia, Roraima, Amapá and Tocantins, all from the Northern Region, are not present among the states that carry out these types of transplants is the first suggestion of that inequality. With respect to cornea transplantation, the region with a higher transplant rate is the Central-West (90 per million persons), depending on the performance of Goiás and the Federal District. The Northern Region has a 9 times inferior rate than the Central-West. With respect to solid organs transplantation, it is observed that, in general, its performance scale is well below cornea transplantation, almost by half. The Central-West Region presents levels similar to the Northeast. While the South holds 35 solid organ transplant p.m.p. and the Southeast, 31, the North holds only 5 p.m.p.

Table 5 and chart 1 show the evolution of the number of transplants performed between 2001 and 2006 for selected organs in Brazil. A progressive growth trend of cornea transplants is observed by 2005. For other transplants types the growing trend was until 2004 showing a later stability. In the case of heart and pancreas-renal transplants there was a decrease of 26.5% and 39.8% respectively, when years 2004 and 2006 are compared. In 2006, there were less of bone marrow transplants performed than in 2005.

According to the SNT, the total number of people enrolled in waiting lists for organs transplants in Brazil in June 2007 (see Table 6) was 69,053 (including "active" and "semi-active” inscriptions), being that São Paulo, Rio de Janeiro and Minas Gerais hold 46% of total subscribers (31,775). The waiting lists, with the largest numbers of members were those of: renal (49%), cornea (39%) and liver (10%).

Table 4. Cornea and solid organs transplantation rate, by region and federal unit, in Brazil, 2006.

Regions and States	Cornea Tx. (A)	Solid organs Tx. (*) (B)	Population[1] (C)	Cornea Tx. p.m.p.	Solid organs Tx. p.m.p.
Northern Region	**147**	**68**	**15,022,060**	**9.79**	**4.53**
Acre	0	2	686,652	0.00	2.91
Amazonas	68	23	3,311,026	20.54	6.95
Pará	79	43	7,110,465	11.11	6.05
Northeast Region	**1,240**	**611**	**51,609,027**	**24.03**	**11.84**
Maranhão	58	30	61,84,538	9.38	4.85
Piauí	39	36	3,036,290	12.84	11.86
Ceará	210	167	8,217,085	25.56	20.32
Rio Grande do Norte	125	40	3,043,760	41.07	13.14
Paraíba	125	24	3,623,215	34.50	6.62
Pernambuco	522	201	8,502,603	61.39	23.64
Alagoas	18	25	3,050,652	5.90	8.19
Sergipe	45	20	2,000,738	22.49	10.00
Bahia	98	68	13,950,146	7.03	4.87
Southeast Region	**5,556**	**2,458**	**79,561,095**	**69.83**	**30.89**
Minas Gerais	632	389	19,479,356	32.44	19.97
Espírito Santo	91	69	3,464,285	26.27	19.92
Rio de Janeiro	77	323	15,561,720	4.95	20.76
São Paulo	4,756	1,677	41,055,734	115.84	40.85
Southern Region	**1,705**	**957**	**27,308,863**	**62.43**	**35.04**
Paraná	615	316	10,387,378	59.21	30.42
Santa Catarina	285	210	5,958,266	47.83	35.25
Rio Grande do Sul	805	431	10,963,219	73.43	39.31
Central-West Region	**1,200**	**158**	**13,269,517**	**90.43**	**11.91**
Mato Grosso do Sul	90	49	2,297,981	39.16	21.32
Mato Grosso	39	1	2,856,999	13.65	0.35
Goiás	795	74	5,730,753	138.73	12.91
Federal District	276	34	2,383,784	115.78	14.26
Brazil	**9,848**	**4,252**	**186,770,562**	**52.73**	**22.77**

Source: CGSNT/DAE/SAS/MS (BRASIL, 2007a).

[1] Instituto Brasileiro de Geografia e Estatística.

Legend: (*) solid organs include heart, liver, lung, pancreas and kidney.
Tx .= transplants. p.m.p. = per million persons.

Table 5. Selected organs transplantation absolute frequency recorded by the Brazilian transplantation program (SNT) from 2001 to 2006.

Transplantation Type	Year					
	2001	2002	2003	2004	2005	2006
Heart	143	149	181	200	181	147
Cornea	6,193	6,556	7,556	8,394	9,970	9,848
Liver	542	654	794	914	939	930
Pancreas	39	57	53	94	112	85
Lung	25	36	43	39	42	53
Kidney	2,672	2,714	2,911	3,126	2,903	2,904
Kidney / Pancreas	105	161	203	201	108	121
Liver / Kidney	6	5	9	10	8	12
Bone marrow	703	871	972	1,197	1,307	1,032
Total	10,428	11,203	12,722	14,175	15,570	15,132

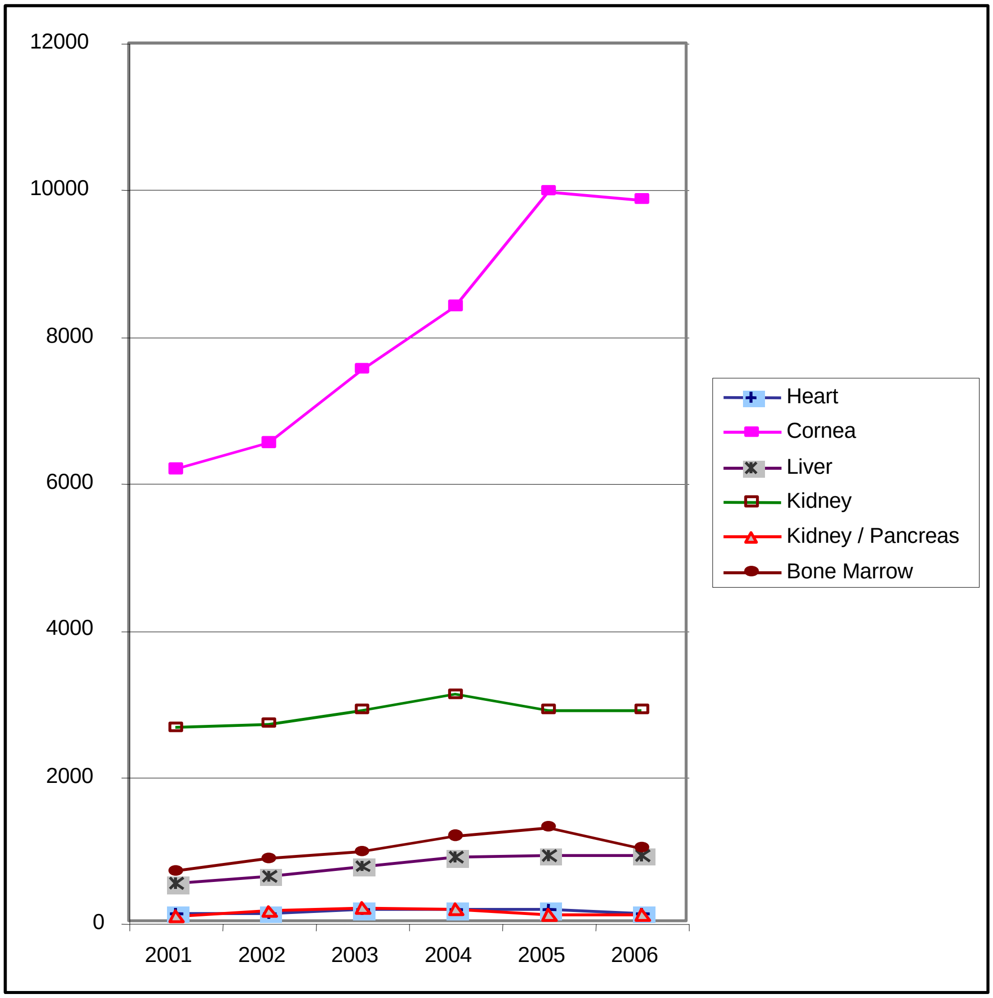
Source: Brazilian Ministry of Health - CGSNT/DAE/SAS/MS (BRASIL, 2007a).

More updated data, released by the Ministry of Health, at the September 2007 launch campaign for encouraging organ donation, indicate that between 2001 and June 2007 87,444 transplants were performed by the SUS and 71,152 people were in the donation waiting line (BRASIL, 2007b). According to the Ministry of Health 15,675 transplants were performed in 2006, highlighting: 10,382 cornea transplants, 2,961 kidney, 978 liver and to 155 heart (BRASIL, 2007b). Waiting lists, by June 2007 were composed of 42,282 people awaiting a solid organ transplant; 26,793, cornea, and 2,063, bone marrow (BRASIL, 2007b).

The number of transplants performed by the SUS is significant. The Parliamentary Investigatory Committee (CPI) report on human organs traffic emphasized that in 1996, before the creation of the SNT, 3,979 transplants were performed and that in 2003, this number reached 9,305 transplants paid by the SUS (CÂMARA DOS DEPUTADOS, 2004a). As mentioned, the currently annual total exceeded 15 thousand, indicating an increase of approximately four times in a short period of 10 years. The increased performance observed by the SNT in the first half of this decade supported the ambitious goals of the Ministry of Health for the sector. In 2003, for example, a target zero waiting list goal for 2006 was disclosed for cornea transplants (BRASIL, 2003). In the same period, it aimed to reduce the demand for bone marrow and solid organs at the following rate: 6% by the end of 2004, in a 9% at the end of 2005; and in 12% by the end of 2006 (BRASIL, 2003).

These objectives were not achieved; in contrast, a significant drop in the activity of some types of transplants was observed, as evidenced by data in Table 5. Thus, in 2007, the goals were reviewed by the Ministry of Health, so that now the disclosed objective for the number of transplants performed in the country is in at least a 20% annual rate growth (SANTA ROSA, 2007).

Chart 1. Selected organs transplantation absolute frequency recorded by the SNT from 2001 to 2006.



Source: Ministry of Health - CGSNT/DAE/SAS/MS (BRASIL, 2007a).

Table 6. Number of subscribers on the organ transplantation waiting lists, including semi-active and active subscriptions, by transplant central and type of organ. Brazil, June, 2007.

Transplant central (CNCDO)	Organ							
	Heart	Cornea	Liver	Pancreas	Lung	Kidney	Kidney / Pancreas	Total
Alagoas	02	313	--	--	--	564	--	879
Amazonas	--	571		--	--	341	--	912
Bahia	0	986	301	0	0	2,507	0	3,794
Ceará	11	1,457	169	--	--	383	--	2,020
Federal District *	03	1,279	0	0	0	529	0	1,811
Espírito Santo	03	435	21	--	--	909	03	1,371
Goiás	10	2,055	--	--	--	581	--	2,646
Maranhão	--	481	--	--	--	750	--	1,231
Mato Grosso	02	488	--	--	--	701	--	1,191
Mato G. do Sul	14	169	--	--	--	294	--	477
Minas Gerais	20	2,958	276	93	0	4,537	57	7,941
Pará	05	553	--	--	--	475	--	1,033
Paraíba **	01	97	17	0	0	501	0	616
Paraná	96	1,792	452	15		2,625	33	5,013
Pernambuco	02	3,472	377	--	--	2,334	--	6,185
Piauí	02	620	--	--	--	371	--	993
Rio de Janeiro	08	3,208	1195		05	35,41	28	7,985
Rio G. do Norte	07	456	--	--	--	761	--	1,224
Rio G. do Sul	21	1,474	390	23	72	1,829	54	3,863
Santa Catarina	10	1,043	70	--	--	299	--	1,422
São Paulo	117	2,536	3,768	36	58	8,998	336	15,849
Sergipe	--	350	--	--	--	247	--	597
Total	334	26,793	7,036	167	135	34,077	511	69,053

Source: CGSNT/DAE/SAS/MS (BRASIL, 2007a).

Notes: * Information regarding the month of April, 2007.
** Information regarding the month of May, 2007.

Another preoccupying number concerning the transplantation program is the donation performance rate in Brazil. In 1999, that rate was 3.9 p.m.p., growing to 7.3 in 2004 (GARCIA et al., 2007), but falling to 6.0 in 2006 (PICHONELLI, 2007). Variations in donation rates in the different regions of the country in 2006 were found: 9.7 p.m.p. donors in the South, 7.5 in the Southeast; 4.6 in the Northeast and Central-West and 1.4 in the North (CONSELHO FEDERAL DE MEDICINA , 2007a). These figures fall apart from rates found in countries like Canada, U.S. and Spain, where the numbers show 14, 23 and 35 donors p.m.p., respectively (PICHONELLI, 2007).

Among the Brazilian states, Santa Catarina stands out, with the highest organ donation rate - 12.8 p.m.p. - and Maranhão, with the lowest - 0.2 p.m.p. - (PICHONELLI, 2007). After the Transplantation Law reform held in 2001, which did away with the presumed donation, organ donation rates continued to grow with an 42.4% increase in the three following years, however, the index began to fall as from 2005, so the cause for the drop down cannot be related to family refusal (CARTA CAPITAL, 2007). The Ministry of Health reported that only 28.25% of families with brain death potential donors are against donation in Brazil (BRASIL, 2007b). Data from the COUNCIL OF EUROPE (2006) indicate that in Argentina and Uruguay this proportion is 49.8% and 22% respectively.

Is worth mentioning the unequal ability of the Brazilian states in collecting organs and performing transplants, exemplified by the fact that pancreas transplantation is not carried out by any state of the Northeast and that there was a 40% reduction of transplants in Pernambuco, being that the reduction was of 56% for corneas transplantation (CONSELHO FEDERAL DE MEDICINA, 2007a). In Rio de Janeiro, in three years the number of transplants fell a 25% and organ donation fell from 7.4 to 6.6 p.m.p. (CARTA CAPITAL, 2007).

Difficulties in preceding stages also produce inequities in access to transplantation in Brazil. For example, in Rio de Janeiro, difficulty was found in the transplant performance, even for members on the renal waiting list and with genetic compatibility (PAURA; REIS, 2007). Among the main problems highlighted was the lack or non re-validation of pre-transplant lab tests. Thus, those who rely on health insurance plans for carrying out lab tests become ready for transplantation more easily, while those who depend exclusively on SUS are more likely to enroll in the non-suitable list, even being registered on the waiting line (PAURA; REIS, 2007).

The situation described suggests difficulty in expanding the Brazilian transplantation program to meet a growing demand, which has been attributed to flaws in the organs donation and distribution system, including the poor performance of the in-hospital donation and transplantation committees. For example, in 2006, from an estimated 10 thousand brain deaths, only half were notified (CONSELHO FEDERAL DE MEDICINA, 2007a). Wagner Ratz (2006) found that logistical factors are relevant to the transplant non-realization after brain death were diagnosed in hospitals. In 2004, from 5,054 brain death reports, organ transplantation was completed in 28% of cases and the other were not effective because of: family refusal (25% of the total notifications), logistical problems (24%), cardio-respiratory complications (17%) and donor serology problems (6%) (RATZ, 2006).

Resources deficiencies exist to enable an increase in capacity of different surgical centers, to invest in organs donation and to buy the necessary equipment for brain death identification. Of the 18 states that have a heart and lung transplantation service, only five have aircraft to expedite the movement of those sensitive organs and other rely on private airline philanthropy (CONSELHO FEDERAL DE MEDICINA, 2007a). Despite the identified problems, it is possible to highlight cases of success, whose spread may broaden the Brazilian program efficiency. The mentioned Santa Catarina's success case in the organs capture was attributed to investment in hospitals (with an increase in number of accredited services), in transportation of removal and transplantation teams, in implementation of active organ search procedures and in professionals training (SECRETARIA DE SAÚDE DO ESTADO DE SANTA CATARINA, 2007).

The São Paulo state also stands out, because apart from holding the largest number of transplants in the country (40%), provides relevant information, such as the possibility for each waiting list subscriber to access to specific confidential information on his situation through the Internet, at the www.saude.sp.gov.br website. Technical analysis are also available through this website that show, for example, that most of the subscribers are from the state itself (93.2%), considering people from other states as well; being the largest number from Minas Gerais (1.1%) and Rio de Janeiro (0.6%), leaving a 5.1% for the other states. Survival analysis for many types of transplants are also provided (SECRETARIA DE SAÚDE DO ESTADO DE SÃO PAULO, 2007).

To complete the Brazilian Organ Transplantation Program presentation, the following topics present related information: program assessments (including official investigations, discussions held at the II Transplantation Forum and waiting lines evaluations) and the Brazilian situation in the international context.

4.2.1 Transplantation program assessments

In 2004 the Chamber of Deputies established two temporary commissions to investigate topics on organ transplantation: an external committee on abnormalities of the waiting line for bone marrow transplantation at the National Cancer Institute and a parliamentary investigatory committee on organs trafficking. The external committee investigated allegations of political intervention in the bone marrow transplantation line (characterized by interference in the laboratory tests orders required for transplant qualification) and health institution accreditations for bone marrow transplantation performances (CÂMARA DOS DEPUTADOS, 2004b). Although political intervention has not been proved, administrative gaps (in the directives for carrying out laboratory tests and in managing the waiting list for bone marrow transplants) were confirmed by this investigation, as well as from a Ministry of Health audit (CÂMARA DOS DEPUTADOS, 2004b).

The committee concluded that the lack of transparency in the registration of candidates for the bone marrow transplantation and insufficient standardization criteria for the bone marrow transplant waiting list, contrasted with the solid organs transplantations greater publicity and existing regulations (CÂMARA DOS DEPUTADOS, 2004b). They also found that the unique national recipients list was based on state lists integrations, so that the organs not used by state subscribers were made available for the national list. This model does not lay on an equal situation the recipients enrolled in states with different development stages to organs capture and transplantation performance (CÂMARA DOS DEPUTADOS, 2004b).

The referred external committee made suggestions to the Executive and the Legislative, recommending the drafting of legislation containing guidelines on the unique waiting transplantation list operation (CÂMARA DOS DEPUTADOS, 2004b). The administrative omission detected in organizing the technical records of bone marrow transplantation consisted in a threat to equity, even though regulation existed (Ministry of Health Ordinance No 1316,

2000) that mentioned the use of order criteria for inclusion on the waiting list. Later ordinances to the investigated events turn the requirements related to the bone marrow transplantation waiting list operation more specific and accurate (Ministry of Health Ordinance No 931, 2006 currently in force).

The parliamentary investigatory committee which investigated the activities of criminal organizations in the human organs trafficking submitted its report in November 2004. With regard to criminal organizations, the CPI report gave evidence of the case of Recife, which had already been investigated by the Federal Police, in which Brazilians traveled to South Africa to sell one of their kidneys (CÂMARA DOS DEPUTADOS, 2004a). The other cases related to: administrative inadequacies in the development of a local transplantation program, possible errors in the clinical conduction of organs donors and in the process of brain death diagnosing and the suspicion of corneas commercial imports (CÂMARA DOS DEPUTADOS, 2004a). On this last issue, it was considered that the Ministry of Health regulation regarding corneal transplantation were addressing the issue properly, because it was not explicit enough on the impossibility for the patient to pay for any costs characterized as trade, in addition to not ensuring compliance to waiting list order.

This committee recommended to the Executive: a) the revocation of Article 14 Decree No. 2268, 1997, which became incompatible with the reforms promoted in the Transplantation Law of 2001, regarding transplantation authorization; b) strengthening the SNT structure, through the implementation of in-hospital committees in all the services were transplants are performed; c) more transparent disclosure of the transplantation waiting list; d) adjustment of its corneas import rules to the requirements of the Federal Constitution and the Transplantation Law; and e) reviewing and condensing the complex transplants legislation responsibility of the Executive, including clear rules for the use of rejected organs by certain organ reporting and collection centrals (CÂMARA DOS DEPUTADOS, 2004a).

On the official investigations related to transplants, it is worth mentioning the information disclosed by the National Audit System of the Ministry of Health about the inspection held in November 2005 on the transplant program performance in the Federal District (DF). By that time it was estimated that due to the small number of surgeries performed it would take 31 years to assist everyone in the DF list. Problems related to the lack of surgical materials, professionals and physical space, as well as failures in the organs capture, difficulties in diagnosing brain death and to identify potential donors, were also detected (BRASIL, 2006b).

Another relevant official investigation was the Brazilian Court of Audit operational inspection (TCU 2006) of the organs and tissues donation, capture and transplantation program. Its statement was presented by Ruling No 562, of April 19, 2006, reported by Minister Marcos Vinicio Vilaça, and identified situations of equity threat in the organs distribution. The audit, which used data collected between 2004 and 2005, had three areas of inquiry: the SNT process of operational management, the technical procedures quality and updates adopted by health teams in relation to organs transplantation and the timing and equity in the of care the targeted audience.

The TCU concluded that the information systems in use at the SNT and the routines planned for their use are not fraud safe, nor allow the tracking of changes made, recommending: the development of an information technology plan, elaboration of an operational procedures manual and systems control. It also indicated that access to transplantation has not been equitable and that efficient mechanisms to reduce the difficulties that especially have impact on the population living away from the transplant centers were not identified. According to TCU, the SNT has not been able to ensure full compliance with the criteria established for organs distribution, as reported by transplantation teams and notification centrals, which mentioned cases of transplantation teams not full time available and that do not perform simultaneous procedures (TRIBUNAL DE CONTAS DA UNIÃO, 2006).

It was also pointed out that there is no unique national list as there are several information systems in simultaneous use by the CNCDO, that have no communication between each other, without the existence of effective mechanisms which would enable a central data consolidation, making unfeasible the production of management information necessary for decision-making (TRIBUNAL DE CONTAS DA UNIÃO, 2006). Moreover, great heterogeneous distribution of transplantation teams throughout Brazilian states was found, which are concentrated in the Southeast, in addition to reports on the difficulties to complete the pre-transplantation tests by the SUS and suspension of some transplantation public services due to lack of material resources in hospitals. From this context the result would be an unequal access to transplants between residents of different federation states, by the different local capacities of health services and between those with access to private health services and those who entirely rely on the SUS, mainly by differential access to pre-transplantation tests (TRIBUNAL DE CONTAS DA UNIÃO, 2006).

Among other actions, were recommended: the National Audit Department of the SUS (Denasus) investigation in order to prove the occurrence of disregards to the unique list; the institution of communication to people on the waiting list on changes in their *status*, with justifications on the lists' order alterations; monitoring the laboratory tests performances and drawing up regulations on claims submitted by medical transplantation teams that may be accepted as a justification for refusal to perform surgery, at the time the organ is offered (BRASIL, 2006a).

In response to the TCU audit, the Ministry of Health, through note released on April 28, 2006 (BRASIL, 2006a), reaffirmed its commitment to people who were in the transplantation waiting line, explaining that it strictly meets criteria of unquestionable health, like, for example, genetic compatibility, age and weight of donor and recipient. Furthermore, it mentioned that it is "irresponsible to say that the organs waiting list is a fiction" (BRASIL, 2006a, p. 1) and stressed that the increase in donations and transplants resulted from the population raising sensibility, from the performance of teams and institutions authorized by SNT and from actions such us the annual advertising campaigns to encourage donation, which confer credibility to "the largest public transplantation system of the world" (BRASIL, 2006a, p. 1).

Many of the problems identified by the official investigations were also observed in the II Transplantation Forum of the CFM (2007b), held on August 29, 2007. The Ministry of Health representative highlighted the following problems perceived in SNT: a) institutional isolation; b) outdated standards, including prioritization and organizational criteria; c) SNT loss of regulation ability, for instance, against the National Health Surveillance Agency (Anvisa); d) failure in convoking technical chambers, e) concerns about the alleged sale in the kidneys inter-living donation; e) lack of monitoring and results evaluation at the national level; f) notarial renewal of transplantation teams permits; and g) the need to expand organs capture and to increase the volume and quality of transplants, through clarification campaigns to society and with incentives to professionals teams responsible for the capture process.

Representatives of the medical community, using data from the Brazilian Transplantation Registry collected since 2000, confirmed the reduction in the national donation rate and in the some types of transplants performance situation already described. It was also highlighted that: a) the SNT already accumulated more than 100 thousand transplants performed; b) the seven years period increase in transplants was largely due to corneas transplantation and the activity of Southeast and South regions; c) the 125 renal transplantation teams could achieve nine thousand transplants, but currently hold around three thousand; d) there are few patients on the heart waiting list and the number of transplants is declining; e) in the case of renal transplantation, a greater proportion in the use of cadaver donor was not maintained, which had been achieved in 2004; and f) active training of professionals involved with brain death diagnosis can promote the process of organ capture (CONSELHO FEDERAL DE MEDICINA, 2007b).

Among the causes for donations not becoming effective in cases of brain death, were described problems with: the identification and maintenance of the potential donor, the brain death diagnosis, the family interview and logistics and organs removal (CONSELHO FEDERAL DE MEDICINA, 2007b) .

In regard to the criteria for organs allocation, it was noticed that: a) they are included in the SNT information system, which assigns points according to each person's situation in the waiting list; b) in the case of renal transplantation, São Paulo state uses its own criteria, where the age is considered, benefiting children; c) in the case of liver transplantation, the implementation of a severity criteria reduced the number of premature entries in the waiting list, the post-transplant survival was not altered, but mortality on the waiting list was not reduced; d) the allocation of cornea no longer uses weighed criteria, since it is based only on waiting time, however the SNT information system reduced the transparency of the process by hindering doctors and those subscribed to the waiting list to obtain information; e) the corneas transplantation registry in São Paulo has particularities in relation to other states (CONSELHO FEDERAL DE MEDICINA 2007b).

Some problems were highlighted with the potential to create inequalities between the Brazilian states, such as: a) criteria differences by which transplantation teams accept or not the allocated organs; b) criteria differences in admission and transplantation waiting list; c) large price variations of immunosuppressive drugs; d) absence of an enrollment system for the transplantation of heart valves and skin; e) inadequate geographical distribution of transplantation centers and existence of inoperative centers; and f) the need to establish services to monitor the health of living donors (CONSELHO FEDERAL DE MEDICINA 2007b).

Other identified challenges were: a) the need to increase the in-hospital commissions and the state CNCDO integration; b) the provision of funding for monitoring the complications that may occur after the transplantation; c) to provide greater clarity for waiting lists subscribers on the scoring criteria in the organs allocation; d) the revision of the prioritization criteria for liver allocation; and e) increase the agility in the distribution of corneas (CONSELHO FEDERAL DE MEDICINA, 2007b).

Evidence was given for the necessity of effective implementation of a policy for the transplantation sector, which would clarify system components' responsibilities, that respects the SUS principles of regionalization and decentralization, which is sufficiently financed, that has the support of analysis based on evidence and that has transparent organs allocation and a planning that offers clear goals for the SNT members (CONSELHO FEDERAL DE MEDICINA 2007b).

The discussion on the complex Brazilian organ transplantation program could not dispense information on the logistics employed by SNT, particularly with regard to the transplantation waiting list management. It is worth mentioning that Ratz (2006) investigation indicated that there are no systematic logistical measures implemented for the measurement and monitoring of the SNT processes. Marinho (2004, 2006, 2007) conducted studies on the SUS transplantation lines.

Since there was no official data regarding the waiting time for transplants in the SUS, Marinho applied the Markovian / Markovian single model (based on the use of time intervals between the subscribers arrival and the procedure performance) to calculate the waiting times, using data on the size of the lines observed in 2004 and the number of transplants performed in 2003. He verified rather high waiting time for all kinds of organs, ranging from 1.6 years for heart, 8.8 years for liver and up to 11 years for kidney. With a 10% increase in the number of transplants offered the author estimated that the lines would be drastically reduced and, even, the goal of a zero line for cornea transplantation in four years would be feasible (MARINHO 2004, 2006).

Marinho and Cardoso (2007) performed an exploratory evaluation of the SNT efficiency from 1995 to 2003, using the non-parametric method of data envelopment analysis. Surgery expenditure, associated procedures and medications were considered as resources. The number of transplants were considered as results. The authors observed a decrease in efficiency over the study period, with a perceptible recovery from 2001 until 2003. Efficiency increase for liver transplants was verified, but a trend for renal transplantations was not clearly detected.

The authors also compared the waiting time (measured in years) to various organs in the U.S., United Kingdom and the SUS. In the case of the heart, that time would be approximately 0.5, 0.4 and 0.8 years respectively. For the liver, would be between 2 and 3, 0.2 and 4.4 years respectively. For kidney, would be between 3 and 5, 2 and 5 and 5, respectively. Noted that in Brazil, although the waiting list is unique and in order of arrival for most organs (with exception to liver), a division of activities between state centrals still exists (MARINHO; CARDOSO, 2007). The authors also stressed in the fact that the indirect costs of not carrying out transplants are high, since only in the case of kidneys, the renal substitutive therapy (dialysis), which can in many cases be replaced by transplants, cost to the public sector in 2005 more than a billion Reais (MARINHO; CARDOSO, 2007).

Marinho (2006) recognized the exceptional position occupied by Brazil in relation to organ transplantation, but stressed the lack of official data, in contrast to the U.S. where data is updated continuously over the Internet. He recommended the production and publication of detailed and systematic data and indicators on the country's transplants, so that the scientific community can understand, enhance and improve the SNT. These informations should include, at least, data segmentation by gender, age, case severity and service providers characteristics, to prevent any possible discrimination of people in lines, with an obvious harm to the system's equity (Marinho 2004, 2006). Corroborating this perception, at the moment, data from the SNT Internet portal on the waiting list and transplantation performances have at least three months discrepancy (BRASIL, 2007a).[8]

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[8] Furthermore, data from SNT on the organs waiting list in the portal area dedicated to citizenship, were not available in attempts made on September 5 and October 2 and 15, 2007.

4.2.2 The Brazilian transplantation program situation in the international context

Despite the current difficulties, the Brazilian system of transplants occupies a prominent position in the international scene. It has already been mentioned, however, that the Brazilian performance is lower than in European Union countries and the U.S. for many indicators. However, due to the complexity of the transplantation types and the specificities of each country, comparisons between them should be made with caution. For example, Brazil, with 54.1 p.m.p. cornea transplants in 2005, showed similar relative performance to that of Spain, which showed a rate of 62.7 p.m.p. (Tables 2 and 7).

Table 7 presents Latin America indicators on transplants performed in 2005. For Brazil, ONT estimates were included, plus a column with information from national institutions. There was discrepancy between these data which, although it did not cause major changes in the indicators, needs to be clarified.[9]

Among the countries presented in Table 7, Mexico has the least favorable indicators. Brazil, Argentina, Chile and Uruguay had favorable performance in a number of analyzed indicators. Brazil obtained the greater performance level of pancreas transplantation. Uruguay stands out for renal transplantation rate, with a low proportion of live donors use (2.5%). In Brazil, data from the ONT on the use of live donors in renal transplants was 40.6%. A study carried out in Belo Horizonte detected a 56.4% use of living donors between 2000 and 2005 (MACHADO; ACÚRCIO; CHERCHIGLIA, 2007b). Argentina displayed the highest rates of liver and heart transplantation performances and many of the results of Chile are comparable to those of Brazil. Data on bone marrow transplantation were not available in the ONT report for the mentioned countries, except from Brazil. Meanwhile, the Brazilian rate of 7.1 p.m.p. (Table 7) is well below from that of Spain, 43.3 p.m.p. (Table 2).

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[9] In the previous chapter we already mentioned that the ONT report (COUNCIL OF EUROPE, 2006) used a different estimate of the Brazilian population than the IBGE, causing a reduction of 15% in the results of Brazil.

Table 7. Organ transplantation performances indicators in 2005 in selected Latin American countries.

Transplantation indicators	Regions / Countries						
	Latin America*	Brazil*	Brazil**	Argentina*	Chile*	Uruguay*	Mexico*
Population (millions)	531.1	211	184.2***	38.6	15.5	3.2	106.1
Cadaver donor	2,999	1,688	-	407	129	64	141
(p.m.p.)	5.6	8	-	10.5	8.3	20	1.3
Kidney Tx.	6,807	3,716	2,903	823	233	119	773
(p.m.p.)	12.8	17.6	15.8	21.3	15	37.2	7.3
Kidney Tx % with live donor	40.5	40.6	-	26.2	-	2.5	63.9
Kidney Tx centers	-	-	196	55	-	4	-
(p.m.p.)	-	-	1.1	1.4	-	1.3	-
Kidney waiting line by 12/2005	-	-	-	4,657	-	506	-
(p.m.p.)	-	-	-	120.6	-	158.1	-
Liver Tx	1,386	872	947	251	62	1	57
(p.m.p.)	2.6	4.1	5.1	6.5	4	0.3	0.5
Heart Tx	401	236	181	87	17	7	14
(p.m.p.)	0.7	1.1	1.0	2.2	1.1	2.2	0.1
Pancreas Tx	347	328	220	6	2	2	3
(p.m.p.)	0.6	1.6	1.2	0.2	0.1	0.6	0.02
Cornea Tx	-	-	9,970	-	-	-	-
(p.m.p.)	-	-	54.1	-	-	-	-
Bone marrow Tx	-	-	1,307	-	-	-	-
(p.m.p.)	-	-	7.1	-	-	-	-

Source: (*) COUNCIL OF EUROPE (2006). (**) CGSNT/DAE/SAS/MS (BRASIL, 2007a).
(***) Instituto Brasileiro de Geografia e Estatística (2007).

Legends: p.m.p. = transplant rate per million persons; Tx = transplant; (-) = Data not shown.

The data presented in this chapter suggests that the SNT has considerably evolved since its foundation in 1997 (mainly due to a strong growth in the corneas transplantation, but progress achieved in solid organs transplants cannot be minimized, providing relevant services to Brazilian society and around 100 thousand transplanted people).[10] Meanwhile, the expansion of its activities found difficulties after 2004, so that the institutions involved in its continuous improvement, have collaborated to diagnose problems and suggested solutions so that the success course is resumed. The transplantation program improvement is seen as one of the essential factors to the achievement of greater equity in access to transplantation organs in Brazil. The concept of equity will be discussed in the following chapter.

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[10] More complex by its own nature, because they oftenly require of organs that need to be removed with the donor's heart still in operation, unlike the cornea, which can be withdrawn up to 6 hours after cardiac failure(BRASIL, 2004a).

5 HEALTH EQUITY AND ACCESS TO ORGANS FOR TRANSPLANTATION

Prior to the analysis of the contribution of legal criteria to equity in the access to donated organs for transplantation within the SUS it is essential to consider the concepts of equity and health equity. The first item of this chapter approaches theoretical aspects of these concepts and the following one discusses their application in organs allocation.

5.1 EQUITY AND HEALTH EQUITY CONCEPTS

The concepts of equity and health equity have been widely used by organizations that work in the area of public policy, as shown in documents of the WHO (WORLD HEALTH ORGANIZATION, 2007c), the World Bank (MUSGROVE, 1999) and the Inter-American Development Bank (BANCO INTERAMERICANO DE DESARROLLO, 2004). Meanwhile, conceptualizing equity is not a trivial task. For example, the WHO's work program for the period 2006-2015 pointed out the need to address social injustice and its effects on health and to clear up the health equity concept so it could be used as a guiding principle and promote health related human rights (WORLD HEALTH ORGANIZATION, 2006).

The term "equity" (from Greek, *epieikeia*) is used since ancient times, but its meaning has varied since then. In meditating on justice and equity, Aristotle (1979) looked up to equity because it would be fair, but not fair in the terms of law, rather a corrective for legal justice. In this context, equity would be an aid when the Law's generalities were not applicable to individual cases. In Biblical texts, *epieikeia* was used to show compassionate or merciful treatment.[11] The relationship of equity to a notion of justice seems to have inspired the creation of the “Courts of Law” and “Courts of Equity” in the English system. The Courts of Equity appeared in England in the fourteenth century, from vassals´ complaints and aimed to rectify injustices arising from the application of common law (GILLEN, 2006). This type of court

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[11] The use of the expression “equity” may be observed in many biblical texts such as: Psalm 98:9, Proverbs 2:9, Isaiah 11:3-5 and Malachi 2:6.

existed in England until 1873 and had much influence over the law systems in many English speaking countries (GUILLEN, 2006).

Equity has also been the object of economic analysis, especially, concerning the population’s distribution of taxes collection. At the beginning of the Twentieth century, Edwin Seligman (1908) was concerned about the study of progressive taxation theory and practice. In this type of analysis reference to two types of equities are common: horizontal and vertical. Horizontal equity is the principle by which people who are in similar circumstances should pay similar amounts of taxes, while in vertical equity, those who are in different circumstances must be treated differently, so that those with greater economic capacity pay more taxes (ELKINS, 2006). That economic logic has been adapted for use in other areas, such as health. According to the European Observatory on Health Systems and Policies glossary (EOHSP, 2006), equity is the principle of being fair to all, with reference to a defined and recognized set of values. The same glossary also presents complementary definitions, including the concepts of horizontal and vertical equity.

Célia Almeida discussed the concept of equity, indicating that its notion is dependent (ALMEIDA, 2002, p. 30) of a historical course that is tied to the idea of equality; in agreement with the theoretical concepts of Norberto Bobbio (2000, 2002). Even being this association undeniable, the conceptual dependency of equity to equality may overshadow the concept of equity own features and hinder the consideration of situations in which absolute equality can be unfair, depending on the social context. Almeida (2002) suggested that the connotation of the word equity varied over time in different societies, reason why the difficulty in reaching a consensus on a definition. She emphasized that, for the State, in the role of welfare services provider and financial supporter, equity was perceived as an equal opportunity of access to resources, according to necessities (ALMEIDA, 2002). The author recognized the need of defining coherent and consistent principles of justice, including the political aspect, according to the “degree of inequality (and conflict) that a society is willing to (or may) tolerate” (ALMEIDA, 2002, p. 35).

Since the principles of justice are fundamental to the concept of equity and also of health equity, the absence of such principles would reduce these concepts to mere verifications of inequalities. Not that this verification type is irrelevant, but it is necessary to bear in mind that inequalities detection is a stage prior to equity analysis. For example, a 1980 disclosure, the Black Report, identified health inequalities among the United Kingdom population (WORLD HEALTH ORGANIZATION, 2007c), which supported further discussions on equity and health equity.

Considering the application of principles of distributive justice in the practice of social policies, Marcelo Medeiros and Debora Diniz (2007) analyzed the equality and equity paradigms. The first is based on the equal treatment of individuals and the second considers the "inequality among individuals to define allocations and determines that the objective of a public allocation is to revert unfair inequalities if they may exist and to treat everyone equally when there is no inequality" (MEDEIROS and DINIZ, 2007, p. 4). The authors linked the equality paradigm to morality rights, exemplified in the basis of the French and the United States Revolutions (MEDEIROS and DINIZ, 2007). The equity paradigm was exemplified by John Rawls' theory and Karl Marx's notion of distributive justice, who proposed the rule "from each according to their ability, to each according to their need" (MEDEIROS and DINIZ, 2007, P. 4).

In our context, equity is related to the principles of justice appreciated by liberal and democratic societies. Silvia Porto (1995) identified three approaches to social justice in the liberal thought: Rousseau's contractualism, classical utilitarianism and Rawls' justice theory. Rawls approach intended to identify universal principles in the values of justice common to democratic societies in their various contexts. This approach proposed principles of social justice with Kantian basis, in which equity was considered, reason why was prioritized for analysis.

Rawls' theory (1997, 2000, 2003) is based on moral obligations, rationally justified by principles on which it is brought to agree, provided that the assumptions made are accepted. Moral fair procedures would be applied to the institutions of society. Rawls inferred principles of justice that could be accepted by society members in the agreement on the way of operation of their institutions - the basic structure - in a liberal and democratic context. His theory follows a tradition of contractualism, assuming that the fair functioning of institutions encourages equity in the distribution of society resources.

The author outlined two principles of justice, which interact and constitute "justice as fairness". The first principle addresses basic freedoms that should be equally available. For Rawls (1997, 2003), basic freedoms are considered crucial for the individual in exercising its role in society seeking its own means of development. The second principle, hierarchically inferior to the first, deals with economic inequality and equal opportunities. According to that principle, social and economic inequalities must satisfy two conditions: being linked to posts and positions available to all in conditions of fair equality and opportunity and to lead to the greater benefit of the less privileged members of society (RAWLS, 1997, 2003).

The society resources, social contract objects, are called primary goods, which are related to things that every rational man presumably wants and include: income and wealth, basic freedoms, freedom of movement and choice of occupation, powers and prerogatives of office and positions of responsibility and the social bases of self-respect (RAWLS, 2003). The admission of inequalities in favor of the less privileged is called the “difference principle” (RAWLS, 1997), a mechanism to mitigate inequalities. It is assumed that the theory accepted inequality as something natural and unavoidable and that, therefore, is necessary to provide mechanisms to improve the situation of the least advantaged.

The principles of justice proposed by Rawls have high appeal for the modern democratic societies as they provide elements to the discussion of equitable collective resources distribution independent of moral doctrines, allowing the integration of various ideologies members in the construction of a society project. Moreover, they address economic inequality, structural feature of capitalist societies and that require mechanisms for the less privileged to be treated in a certain way in order to promote their position in society. Rawls considered that the two principles of justice were not related to the moral notions of right and purpose, vehemently denying association with classical utilitarianism, which he considered to be a teleological theory, since it prioritizes a purpose: the welfare of the majority (Rawls, 1997).

The work of Rawls and his critics have contributed to the expansion of debate on justice and equity (NOZIK, 1991; SANDEL, 1984; DWORKIN, 2005; KYMLICKA, 2006; SEN, 1995). Robert Nozik (1991) defended the principle of distributive justice based on the right to fair possession, practical and historically established. That right would be established by the principles of acquisition and transfer of goods and, if necessary, the correction principle should be used to remedy injustice in the application of the mentioned principles. He considered that Rawls’ theory is unable to produce this type of notion, as it focuses on distribution final results and does not consider the historical process.

Michael Sandel (1984), from a Hegelian Communitarism point of view, which values the ethical systems that seek for a substantive good, and thus, the society's system of values, directed strong criticism to Rawls' principles of justice, which try to avoid moral values in the consideration of what is fair. For Sandel (1984), Rawls' individual moral concept is utilitarian and Rawls criticism of utilitarianism is limited to the implementation of its maximization principle over a collectivity.

Ronald Dworkin (2005) agreed with Rawls about the need for the fair operation of institutions to promote equity in the distribution of resources in society. He presented the thesis that equality of resources is more objective than the welfare one, allowing the comparison between patterns of resources distribution. His abstract model of equalitarian auction values individual's freedom of choice, but unlike Rawls difference principle , adds individual responsibility for the consequences of choices and provides compensation for natural inequalities, through corrections in the initial distribution of resources (DWORKIN, 2005).

According Will Kymlicka (2006), Rawls theory was one of the first alternatives to utilitarianism and its first principle of justice is the object of consensus, because the notion "that civil and political rights should be priority is widely shared in our society" (KYMLICKA, 2006, p. 68). Meanwhile, he criticized the fact that the difference principle is applied to compensate social inequalities (checked by means of primary goods), but does not offer the same treatment for the case of natural talents inequality, such as physical disabilities, becoming inadequate to the problem of undeserved inequalities (KYMLICKA, 2006). He also emphasized that the difference principle does not distinguish between chosen and not chosen inequalities, leaving aside the individual's responsibility approach and, in this case, established as an excessive reaction to undeserved inequalities (KYMLICKA, 2006).

Among Rawls theory critics, but yet inserted within the liberal and democratic context, Amartya Sen must be brought into consideration, who while acknowledging the relevance of Rawls' theory of justice and with no objection to its first principle of justice, criticized the difference principle in an equality context discussion (SEN, 1995). Initially, Sen warned about the need to specify the theoretical space when approaching the equality discussion. Each theory that deals with equality emphasizes a given space which it is considered crucial. Libertarians value the equality of rights and utilitarians, of individual interests (utilities) (SEN, 1995). Rawls' theory values the equality of basic freedoms and of primary goods distribution and Dworkin's, equality of resources (SEN, 1995). Other theories may consider the equality of rights, needs, rent, etc. Sen stated that equality in a given space tends to walk with inequality in another (for example, the libertarian equality principles, may coexist with income inequalities); so theories can explain the inequality through equality (SEN, 1995).

Sen acknowledged that Rawls transformed the way of thinking about inequality, which previously valued results, considering opportunities and freedoms (SEN, 1995). However, he observed that the difference principle , while limited to primary goods distribution, focused on the means to freedom instead of the actual freedom. Even among people who possess similar resources (primary goods), some may have more freedom than others to achieve their goals (SEN, 1995).

As a solution, he proposed an assessment of inequality in terms of achievements and freedoms. Thus, instead of assessing individuals through primary goods they would be evaluated by their ability to function in society, therefore, to achieve their welfare. This capability would derive from a set of functionings (situations of existence and desired activities, which are the welfare constitutive elements) that the person would have the effective freedom to choose for carrying out his plan of life (SEN, 1995). According to Sen, the functionings can vary from elementary situations, such us being well nourished or free of avoidable morbidity and premature mortality, to even complex achievements as self-respect, happiness and community life participation (SEN, 1995). In this approach, the dimension of resources or primary goods would be an imperfect indicator to assess the degree of freedom that the person really has to do or to be something (SEN, 1995). Hence, the informational base derived from de difference principle was considered inadequate by Sen, because it hardly informs about the means to obtain freedom, being necessary to advance towards the consideration of capacities, through the assessment of effective freedoms. This allows an interpersonal variation consideration in the transformation of primary goods in abilities to pursue our goals (SEN, 1995).

As observed by Álvaro de Vita (1999), Sen used Rawls theory's normative and ideological structure to build a conception of distributive justice, without, however, the scope of a theory of justice(VITA, 1999). Nevertheless, Sen established a minimum resources platform to be distributed among the society members, which promoted the individuals capacity to function, showing concern for the substantive character of his own proposition (SEN, 1995).

Within the health equity concept specific discussion the challenges of the general conception of equity remains. The “Associação Nacional de Pós-Graduação em Saúde Coletiva” (2000, p. 1) emphasized that “a lack of precise concepts and empirical evidence exists on health equity” and that “broad and comprehensive definitions have implicit ethical values and moral principles that are not given a priori, nor are easy to operate with.” However, in order to implement equitable health systems clearness is necessary in regard to the health equity concept being used.

Showing his concern in linking theoretical concepts to practical considerations, Sen (2006) also analyzed the health equity concept. For the author, this concept is core to social justice understanding, since any conception that acknowledges the need of a fair distribution and an efficient formation of human capacities cannot ignore the role of health in human life and in the opportunities that people have in achieving a good health (Sen, 2006).

Using elements of his reflection on equality, Sen considered health equity as a multidimensional concept, which includes aspects of health “achievement” and of the “capability” for obtaining a good health, not just the distribution of health (SEN, 2006). He emphasized that the concept also includes justice in institutional procedures, like, for example, when giving importance to non-discrimination in the delivery of health care. Moreover, he stated that the concept should be integrated “with broader aspects of social justice and total equity, giving adequate attention to the versatility of resources and the range and impact of different social arrangements” (SEN, 2006, p.31).

Sen stressed that health equity violations cannot be judged simply by observation of health inequalities, as the verification extent of the inequality may not offer proper information for that assessment. To be materially relevant, more than revealing differences in the distribution of health services, the violation needs to be associated to avoidable and unfair causes, such us flaws in allocation policies of resources for health (SEN, 2006). Thus, health equity cannot be restricted to the isolated observation of health or of services distribution (SEN, 2006). Is not that the general and inclusive structure defense of the concept means contempt to the use of specific criteria for certain purposes, since they are helpful to the clarification of equity specific and concrete matters. His objective was to oppose the excessive valorization of specific criteria, present in operational concepts, since more comprehensive criteria are also necessary, in particular for establishing the relationships with total equity (SEN, 2006). For Sen, health equity is a broad concept and the recognition of that comprehensiveness has to precede any limitation by specific criteria, associated to contingency purposes (SEN, 2006).

Other researchers and institutions that work with health policies developed definitions on health equity, being their analysis useful for the verification of associated principles. Margaret Whitehead presented, in March 1990, as a result of the WHO's European Office Health Equity Program discussions revision, a definition for health iniquity, which refers to differences that are unnecessary and avoidable, apart from being considered socially unfair (WHITEHEAD, 1992, p. 431). While this definition addresses the social justice issue, it must be emphasized that the expression "unnecessary differences" implies the acceptance of "necessary differences". Strangely, that is the definition generally disclosed in discussions on health equity. Meanwhile, Whitehead also offered a working definition for health equity, which implies that, ideally, everyone should have a fair opportunity to attain a full health potential, and more programmatically, that no one should be disadvantaged from achieving this potential, if it can be avoided (WHITEHEAD, 1992, P. 433).

The European Observatory on Health Systems and Policies (EOHSP, 2006) introduces a similar concept, adding that everyone should have geographical and financial access to the available resources for health. This concept gives value to the principle of fair opportunity resources access, not necessarily based on absolute equality of conditions. It also highlights the relational nature of equity, since its determination relies on the resources distribution fairness according to the socio-economic characteristics of individuals. Both Whitehead definition (1992, p.433) as for EOHSP's are close to Sen's vision regarding individual capacities promotion to develop the full health potential.

In June 2007, the Knowledge Network on Health System report of the Commission on Social Determinants of Health (OMS) indicated that the health equity definition includes the concept of fair distribution of health results in the population, as well as a fair distribution of health services and payment levels (WORLD HEALTH ORGANIZATION, 2007). Moreover, it was highlighted the inclusion of the redistribution of power notion for decision making that affect health and health care (WORLD HEALTH ORGANIZATION, 2007). This definition incorporated elements of individual capacity promotion to obtain the health present in Sen’s conception, apart from avoiding the restriction to health services access criteria and moved forward on the importance of political action. Nevertheless, this concept still seems to be health system centered, reducing the emphasis of the relationships with other public policies necessary to the individuals capacities development, although many of these relationships have been mentioned throughout the referred report.

For the National Association of Post-Graduate Studies in Public Health - ABRASCO (2000) two dimensions of health equity must be considered: equity in living conditions and populations’ health and equity in the access to health services consumption. Such a distinction is necessary, since several studies have shown that the use of health services is not the only factor to health preservation, where other variables, such us the epidemiological panorama, the age structure, biological heritage, life style, are also relevant (ABRASCO, 2000). The consideration of an equity dimension, not only in the area of health care delivery, widens the concept scope, allowing to consider the interactions of sectorial health policies with the economic, social and political context in which is inserted. Notwithstanding, those equity dimensions may be included on Sen’s comprehensive and systemic concept, this proposes, as mentioned, a multidimensional conception. Thus, other dimensions, such us justice in procedures, non-discrimination and total equity relationships should also be considered.

For the International Society for Equity in Health (ISEH, 2006), health equity is the absence of systematic differences and potentially remediable in one or more health aspects between populations or population groups socially, economically, demographically or geographically defined. This definition opted for addressing equity by contrast of what it is not, avoiding to explicit subjective values of justice. However, the absence of a principle of justice may highlight health inequalities but without consideration of the broader picture of total equity and social justice, thus, moving away from Sen's comprehensive conception. A systemic approach, as Sen's, allows the identification and action, by means of inter sectorial public policies, in health inequalities relevant causes. Otherwise, less effective and efficient action over inequalities that hardly reflect the end of a cause-effect chain may be prioritized.

This type of action can be exemplified when considering the necessary steps to ensure that the Brazilian transplantation program overcome the issues addressed in the previous chapter. The adoption of a restricted concept of health equity may indicate a focus in measures which hardly relate to an efficiency increase in organs capture and in transplant performances, which, although necessary, may not be enough to achieve equity. A systemic vision would care for the financing of social policies and implementation of prevention and disease control measures to avoid the need for transplantation. Moreover, it would consider the relationships with the SUS in general, as the subscribers to the transplantation waiting list depend on lab tests performed by the SUS to be fit as organ receptors.

In addition, attention should be stressed in the case in which relatives of potential organ donors would make the donation effective in a greater proportion, given that they perceived that their relative, in the tentative to recover his health, was treated in the best way possible within the SUS. On the other hand, donation may be hampered if the patient waited too much for appropriate emergency health care, his condition worsened and only when found in a brain death situation derived to a intensive care unit for having his organs preserved.

The next item considers the application of principles of justice and equity in the allocation of organs for transplantation.

5.2 EQUITY AND CRITERIA FOR ORGANS ALLOCATION

The allocation of organs for transplantation is often associated with shortage, representing a limit situation for the application of the principles of distributive justice and the concept of health equity. Moreover, the consequences of such decision evoke a more direct association - than in other situations - with life and death (KOCH, 2002). Tom Koch (2002) mentioned the "lifeboat ethics" to illustrate situations in which decisions provide the opportunity for some to be saved and others not to.

International institutions recommend that only medical needs, of health situations, should be taken into consideration in organs allocation (CÂMARA DOS DEPUTADOS, 2004a). As a result, for example, the principle of equity cannot be directly applied and allocate organs based solely on the social situation of those less advantage within a given population. The area of equal opportunity that intends to be promoted needs to be well characterized and, at first, be associated to health needs. Notwithstanding, health needs show gradation levels, not always objective, that require intermediation of ethical principles for the promotion of organs allocation justice. Thus, in addition to principles of justice and equity, adoption of ethical principles must be taken into consideration.

Carlos Ribeiro and Fermin Schramm (2006) identified two strategies for allocation of transplantation organs: equalitarian and utilitarian. The equalitarian strategies offer equal opportunities for all, as in the case of registration orders in waiting lists and raffle. The utilitarian could be: medical and social. The medical utilitarian strategy uses criteria related to health needs and the procedure success probability. The social utility relates to allocation criteria based in social characteristics such as gender, race, age, life style and supporting social structure (RIBERO; SCHRAMM, 2006). The subjectivity of the social utilitarian criteria demands attention so that discriminatory criteria are avoided.

Nikola Biller-Andorno and Roberto Andorno (2001) identified four ethical principles that could be used in organs allocation. The first one is equal opportunity, similar to Ribeiro and Schramm's equalitarian strategy (2006). It was considered one of the simplest, based in the idea that all criteria would be arbitrary, then all subscribers to the waiting lists have the same right to receive organs, regardless any additional criteria (BILLER-ANDORNO, 2001). The authors indicated that the exclusive adopting of this principle is indefensible, because it does not consider the particular situation of people.

The second is the principle of compensatory justice, by which those who suffered the most or sacrificed more for others would have more rights to receive an organ. The third is the principle of efficient distribution, which stipulates that those who are more likely to achieve a better result would be preferred for organ reception. This can cause discrimination if there is no concern about justice, race, culture and gender issues (BILLER-ANDORNO; ANDORNO, 2001). The fourth principle is compassion, sometimes called urgency criteria, that states that those who need more the organ for survival should be selected, such as the case of imminent death. This principle, in general, conflicts with the efficient distribution one (BILLER-ANDORNO; ANDORNO, 2001).

Biller-Andorno and Andorno (2001) recognized that integration of those principles is not always simple and that the maintenance of a complete objectivity in the criteria for allocation is not feasible. They recommended the maintenance of a high level of attention upon the implicit difficulties in the transplantation organs allocation process, besides the continued effort to find the best possible solution, for each particular person and for the society (BILLER-ANDORNO; ANDORNO, 2001). They also suggested attention to non-discrimination, for transparency and for the combined used of medical necessity and not medical criteria, such as waiting time (BILLER-ANDORNO; ANDORNO, 2001). They highlighted the allocation principles present in the German and French legislation.

The German law, passed in 1997, mixed principles of compassion and efficient distribution. In that country, transplantation centers are compelled to decide on the inclusion of persons in the waiting list considering the state of scientific knowledge, in particular, urgency and transplant success probability (BILLER-ANDORNO; ANDORNO, 2001). The principle of compensatory justice was even discussed, but was rejected for its discriminatory nature. The equality principle was considered inadequate as the different pre-existent positions are not considered, which could reinforce prior inequalities (BILLER-ANDORNO; ANDORNO, 2001). This situation is a good example that the adoption of equalitarian criteria, without the intermediation of an equitable principle may not be acceptable by the society.

In France, Law No. 94-654, of July 29, 1994, established general principles on organ transplantation (BILLER-ANDORNO; ANDORNO, 2001). An institution for the management of the national waiting list and for establishing allocation criteria was created, ratified by the Ministry of Health. The report of a national committee, submitted in July 1996, proposed the harmonization of the existing national level protocols and a better geographical allocation of organs. The French government modified its regulations in 1996, establishing rules for different organs and four distribution stages -local, inter-regional, national and international. Priority in favor of those who are in imminent death, those with small chances to find another compatible organ and children was established. The right of non-resident foreigners to be included in the waiting list was recognized (BILLER-ANDORNO; ANDORNO, 2001).

Also in the U.S. a combination of principles for organs allocation was used. According to Robert Veatch (1998), the U.S. Organs Transplantation Act of 1984 demanded a combination of the principles of equity and of efficiency in the criteria of organ allocation, being UNOS' responsibility for the specification of the exact formula to be used in the allocation process.

As noted from the information presented, each country adopted a particular combination of ethical principles, according to its context and social values, providing orientation to organs allocation, which pretends to be equitable. The determination of the relative weight of each principle and of the prioritization needs (as the case of children) is a task that lies in each country to decide with transparency. Given the variety of possible combinations, it is perceived that ethical and distributive justice principles need to be integrated so to produce an equitable result.

Rawls' theory has relevant contribution to offer in what procedure justice of the responsible institution for organs distribution is referred; which should guarantee equal opportunities to all who show the same condition and apply allocation criteria agreed by the society and prescribed by regulations. Meanwhile, due to their political conception, focused on the society's basic structure operation, that theory has the limitation of not being designed to solve the specific problems of distribution. Nevertheless, Veatch (1998) questioned whether Rawls' difference principle may justify direct organ donation to specific social groups within a transplantation program based on a waiting line. Sen's health equity concept, for its social non-discrimination concern, may exclude direct donation in a waiting list system, since this donation type is viewed as discriminatory.

The most substantive character of Sen's contribution can offer other grants to the complex task of allocating organs. His systemic approach, for example, demands that the organ allocation criteria should be considered in the light of the health system context and the effective capacity of individuals to have access to transplantation organs. Thereby, so that the set of allocation criteria promote equity, the health system needs to offer equal opportunity of access to general health services, not only transplantation services. In this way inequalities would be avoided in the prevention and treatment of illnesses that may demand organs transplantation and that place the less privilege in a disadvantage situation. Koch (2002) pointed out the need that public policies should prevent artificial shortage of organs, shortage produced by inadequate decisions and resources allocation, which could have been avoided so to reduce privation levels to minimum.

In the case of specific access to transplantation services, Sen’s capacities approach gives support so that all subscribers to waiting lists have a real opportunity to be transplanted. For example, considering a universal public health system, the existence of allocation criteria in a formal level would not be admitted if the necessary means for their application were not accessible to all. Therefore, it would not be equitable the requirement of laboratory tests for enabling the transplant if they were not accessible for all the subscribers to the waiting lines, because the result would be unfair inequality (in advantage of those who have access to such tests by other means and by the displacement of the less privilege to “inactive” lists, extending their waiting time). Certainly, the test requirement could not be abolished, in benefit of their own candidates for transplant, but their access should be widened.

The approach on capabilities promotion would also demand a homogeneous geographic distribution of the transplantation centers and transplant centrals, apart from special arrangements of organ distribution to meet the needs of population groups with difficulties in the access in their places of residence (for example, through regional level distribution of waiting lists). In sum, the removal of barriers that restrict the effective freedom to fully develop the health potential of individuals.

In concluding this theoretical chapter, it is emphasized that the equity concept is related to a notion of justice, which would be primarily responsible for the changes in the equity meaning over time. Meanwhile, the basic outline of the equity concept, based on the Greek classical vision of justice of treating different people differently (BROWN, 1991, p. 491), has remained stable. The relationship of equity with the equality and inequality discussion is, therefore, indivisible. Based on Sen’s discussion, it is perceived that equality demanded spaces are plural and that a perception of different conceptions of justice grounded in different demands for equality are possible, and that may be associated to, or even justify inequalities in other spaces.

The principles of justice developed by Rawls have reasonable consensus among liberals, especially, with regard to the protection of basic individual freedoms and of procedure justice of the society’s institutions. These characteristics are useful for this study, since we find ourselves in a liberal and democratic context. Much of the disagreement to the Rawls theory concerns the distribution of primary goods through the difference principle . Although the theory promotes freedom, equal opportunities and inequalities reduction, it is not clear about the level of satisfaction among primary goods. Health is not even introduced as a primary good (RAWLS, 2003). Although the difference principle admits greater range compensations, such us equitable measures associated to the Welfare State, the fact of not introducing minimum requirements, may justify distributions that apparently represent major advantage for the less privileged, but that in practice, for its insufficiency to promote capabilities, result in the maintenance of a social inequality structure.

The criticism of Sen about the difference principle focus on the means to conquer freedom rather than freedom itself, brought concern on the interpersonal variability in the ability to transform primary goods into results. Sen established a difference between means and effective freedom to achieve welfare (with choice possibility). Even though the measurement of inequalities in capabilities is not methodologically simple, that approach expanded the possibilities of Rawls theory practical use. In the case of health, Sen's equity concept allowed a connection with total equity and social justice topics, moving away from the restriction of only analyzing inequality indicators at health and health care services level.

Of the set of concepts on health equity analyzed, which made reference to a principle of justice, we find predominance in the use of the principle of fair opportunity and support to the adjustment of unnecessary inequalities. This pattern is compatible with a principle of liberal justice, as proposed by Rawls. Theoretical advances contained in Sen's proposal, related to the development of individual capabilities to conquer health, are observed. Meanwhile, to guide the implementation o equitable health systems it is still necessary to highlight these operational concepts: the associated principle of justice, the multidimensional character of health equity and its relationships with total equity and social justice, in accordance with Sen's systemic vision. Regarding Rawls and Sen's theory application to the process of organ allocation for transplant, the need of integration with ethical principles accepted by the society was verified. So that such a combination results in an equitable access, the existence of formal allocation criteria and procedures justice is not enough, but also focuses on effective freedom to mobilize the means that may grant the individual a fair access to the transplantation program.

The next chapter presents an analysis of the organ transplants regulation in Brazil, using the theoretical support presented here.

6 ANALYSIS OF BRAZILIAN FEDERAL LAW ON ORGAN TRANSPLANTATION

The analysis of Brazilian regulation on access to organs for transplantation demanded the examination of the federal normative component of that public policy, contained in laws (Federal Constitution, Health Organic Law and Transplantation Law), decrees, ordinances from the Ministry of Health and resolutions. Appendix B details the characteristics of these laws and regulations, which are the basis of the following analysis.

A description of the evolution of that legislation can be found in the same Appendix, prioritizing recurrent topics and that have influenced the transplantation organs availability, such us: *post mortem* organ donation consent, death proof criteria, organ donation between living persons, free access to donated organs and organs allocation criteria. It is worth emphasizing that the Brazilian legislative drafting in the area of transplantation started in 1963 and followed the technological evolution of the sector, becoming increasingly complex. The 1988 Federal Constitution represents a landmark, as it forbids organs commercialization and demanded the drafting of a specific law. Before 1988, Law No. 4,280, 1963, and Law No. 5,479, 1968, were drafted. After the Constitution, and within the SUS context, Law No. 8,489, 1992, and the current Transplantation Law, No. 9,434, 1997 (appendix A), were put forward. This last one was modified in 2001 by Law No. 10,211 and, more recently, by Law No. 11,521, 2007.

Decree No. 2,268, 1997, which regulated the Transplantation Law, has not been updated in accordance with the law revisions, so it encloses outdated mechanisms. That Decree outlined the single national list of receivers operation. Ordinance No. 3,407, 1998 from the Ministry of Health (MS), through its annexed regulation, detailed the operation of the single list system (including the allocation criteria), composted of state lists, by organ type. The regulation developed between 1997 and 1998 promoted the Brazilian transplantation program growth. After 1998, a trend was observed by which each transplantation type is regulated through a specific ordinance from the Ministry of Health, resulting in excessive fragmentation of regulation.

To analyze that complex legislation, relevant topical groups for equity discussion were applied. The most directly related topics to the object of study were the principles of social justice and of access to health actions and services (including transplant organs access specific criteria). Due to the use of a systemic approach for the consideration of health equity, there were also included contextual topics, such as: transplantation program structuring, mechanisms that have influence on organs availability, sanctions related to breaches of the Transplantation Law, jurisdictions for transplantation policy regulation and transplant information transparency.

6.1 PRINCIPLES OF SOCIAL JUSTICE

The Federal Constitution text is filled with references to social justice, which serves as guide to public policies implementation. Already in the preamble, it is emphasized that our democratic State purpose is to ensure social and individual rights, including freedom, safety, welfare, development, equality and justice as society's supreme values. The concern with social justice is expressed among the fundamental objectives of our Republic: eradicating poverty and marginalization and to reduce social and regional inequalities (Article 3). The concern to equality is highlighted in the determination that all are equal before the law, without distinction of any kind, guaranteeing Brazilians and foreign residents, the inviolability of the right to life, freedom, equality, safety and to property (Article 5). The aversion to unequal treatment of Brazilians is expressed in the forbidding of the Union and those federated units that may create distinctions between Brazilians or preferences among themselves (Article 19).

The association between the principles of freedom, equality and social justice is found in the definition of which economic order is based on the valorization of human labor and free initiative, which aims to ensure a dignified existence for all, according to the dictates of social justice (Article 170). The same is observed in the case of social order, which is based on the supremacy of work and aims welfare and social justice (Article 193). For social security, where welfare, social assistance and health (including organs transplantation) policies are inserted, objectives were defined, among which stand out: universality of coverage and attendance; selectivity and distribution in the provision of services and equity in the ways to participate of costs (Article 194). It is worth mentioning that Article 194 is the only one of the Constitution that mentions the expression "equity", referring to solidarity in the financing of social security among the federal entities.

The Health Organic Law, Law No. 8,080, 1990, recognizing the existence of conditioning factors and health determinants[12], considered the multiple dimensions of health equity in a liberal social context, which reveals the use of a concept of health equity similar to that adopted by Sen (2006). More specifically, the concern with equity in organs distribution was outlined in the preamble of the Ministry of Health Ordinance No. 3,407, 1998, which introduced the technical regulation on transplantation, which was repeated in several subsequent ordinances related to organs transplantation.

In considering the constitutional principles and SUS guidelines, such as universality and comprehensiveness of actions, Porto (2003, p.2) inferred that “equality in opportunity of access to actions and health services which legislation advocates to, falls conceptually in Sen’s conception of justice”. Given the presented evidence, it is obvious that the equitable access to health services is a demand agreed by the Brazilian society, that must be obeyed by basic structure institutions, as its expressed in our Constitution, SUS rules and, consequently, in the organs transplantation policy. Legislation oriented towards social justice and equity favors the application of Rawls’ principles of justice and Sen’s approach for the analysis of legal criteria for the access to transplantation organs.

6.2 PRINCIPLES OF ACCESS TO HEALTH SERVICES AND ACTIONS

According to the Constitution, health is a right for all and duty of the State and it shall be ensured by means of social and economic policies aimed at reducing the risk of disease and other disorders and the universal and equal access to services and actions for its promotion, protection and recovery (Article 196). The constitutional right to health is a foundation that promotes equity. The final report of the Knowledge Network on Health Systems of the Commission on Social Determinants of Health of the WHO (World Health Organization, 2007c) established that

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[12] Article 3 of Law No. 8,080, 1990 identified as determinants of health conditions: food, housing, basic sanitation, environment, labour, income, education, transport, leisure and access to goods and essential services.

health systems matter as factors that can determine inequities in health, drawing attention to the fact that their failure may be associated to geographical or financial access barriers for the less advantaged groups of the population. Therefore, the legal criteria for access to SUS should seek for such barriers to be avoided and suppressed.

It is observed in the Constitution special attention given to priority access to a series of rights of children and adolescents, among which we find health (Article 227). The priority of children´s health can be detected in specific aspects of the transplantation regulation, as there are ordinances that grant them with the priority in organs allocation (as in the case of liver and bone marrow).

The Congress Representatives indicated that access to a wide range of actions and public health services would be provided through a regionalized and hierarchical network, structuring a single system (Article 198), which has among its organization guidelines: decentralization, with a single direction in each sphere of government; integral assistance, with priority to preventive actions, notwithstanding assistance services and community evolvement. According to these principles, access to complex services such as organs transplants must also be supplied to the population.

The organization of the SUS in increasing complexity levels and political-administrative decentralization, with one single direction in each sphere of government, with emphasis on the provision of services by municipalities, complement the framework of principles and guidelines related to health care access provided by the SUS approved in the Constitution and the Health Organic Law. These principles aim to provide rationality of access to the SUS, avoiding duplication efforts and waste of resources. The SUS free services, as described in the Health Organic Law, are another relevant principle of access that puts the Brazilian system in evidence.

The Health Organic Law also referred to equality without prejudice or privileges of any kind in health care, so that it values the procedural aspect in the delivery of services, elements that evoke the equal opportunity offered by institutions of the society’s basic structure, defended by Rawls, and concern with the non-discrimination in the delivery of health services outlined by Sen (2006). This Law also mentions the responsibility of individuals, family, business and society in the attention to health, strengthening the liberal character of our legal system and adopting a principle that is not explicit in Rawls theory (2003), but it was supported by Dworkin (2005).

Considering specifically the access to transplantation organs, is curious to note that in Article 199 of the Constitution, dedicated to health care provided by private initiatives, determinations in the specific interest to organs transplantation have been included. Paragraph 4 of that article stated that a law would regulate on conditions and requirements to facilitate organs, tissues and human substances removal for the purpose of transplantation, research and treatment, denying any type of commercialization. Forbidding organs trade made possible a system in which access to transplantation organs is based on a solidarity principle: organs donation. This represents a significant achievement for our society, because hinders economic exploitation of a socially vulnerable population.[13]

Brazilian legislation enhances public access to organs. The Transplantation Law of 1997 (appendix A) discouraged attempts to individualize the access, even considering a crime the public disclosure of appeals to obtain treatment for certain person. The law also established the conducting of clarification campaigns to encourage donation, which is the basis of public access to organs.[14] Meanwhile, the federal law also allows a more individual access, because, apart from the *post-mortem* donation related to the public system of waiting list, donations from a living person in benefit of a specific patient are allowed under certain restricted conditions.

About living donors, the Transplantation Law, intended to promote the safety in the procedure for the donor and for the organ receiver, in addition to trying to prevent the abuse represented by the trade of organs, because this type of donation does not follow the dynamics of the waiting lines. The criteria for donation between living persons were updated in the revision of the Law in 2001. New levels of relationships between donor and recipient were admitted (until

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[13] Concerned about the trade issue, a parliamentary investigatory committee on organ trafficking (2004a) recommended the revision of the Ministry of Health Ordinance No. 937, 1999, which allows the import of corneas, due to insufficient reference to the issue of non-commercialization of that human tissue. However, the Ordinance still remains in force with no alterations.

[14] It must be considered that clarification campaigns stimulus must be accompanied by measures that make effective the capture and use of organs, to avoid frustration in the donor's families.

the fourth grade) and non-relatives donations with a court order were allowed. In the original wording of 1997 there was no mention of such restrictions. Interestingly, the law in force in 1992 was more rigorous than the current: it limited relationship to the second grade and a court order was required for donation between non-related people. At present, there is concern about the current criteria, because there has been observed no reduction in the proportion of living kidney donors for transplants performed throughout the country; a reverse tendency in the transplantation programs of Europe and, more recently, the U.S.

As for donation from a cadaver donor, the Transplantation Law made no mention in 1997, to the waiting list, although the Decree No. 2,268, 1997, which regulated it, did. In 2001, the requirement of a waiting list was included in the text of the Law. The legislation, however, did not make explicit the criteria, only in a broadly manner, for inclusion of people in the list, nor of organs distribution for its subscribers. Thus, there was only the concern to set an organ distribution system based on single waiting lists; an application of the equality principle, as in the typology of Biller-Andorno and Andorno (2001).

It is assumed that the intended meaning with the inclusion in the Transplantation Law of the term "single list" was of a "single list system" (term used in Ordinance No. 3,407, 1998). That denomination and actual practice of the SNT implantation existed since 1998 and as a principle, since 1997, as Decree No. 2,268, 1997, had already outlined a system in which access to various types of organs is effectively controlled at a state level, as detailed in Ordinance No. 3,407, 1998. The Decree No. 2,268, 1997, gave the SNT managing responsibilities for the "recipients single national list" and the term used in the Transplantation Law from 2001 was "single waiting list" ("*lista única de espera*") **.**[15,16]

The mentioned Decree offered the first point of reference on the waiting list operation, as it clarified the roles of the CNCDO; but also as it was the first normative source to mention any

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[15] The Decree was drafted at a time in which several countries, such as France and USA, discussed regional access differences and sought for greater equity in the national level.

[16] Given the operational experience of the transplantation centrals, it is emphasized that the ambiguity of the term "single list" could have been resolved in the process of revising the law in 2001, through the use of the term "single list system."

registration order in the waiting list. Thus, Decree No. 2,268, 1997, assembled a system consisting of the collection of state's lists, classified by different organs types, respecting the entry order and the biological compatibility between donor and recipient and with national coverage, to the extent that the organs not used at a state level should become available for the national list.

About the single list entry, Ordinance No. 3,407, 1998, determined that is to be done by the CNCDO related to de receiver's place of residence. This Ordinance introduced flexibility on the place of residence criterion, following the determination of Decree No. 2,268, 1997, allowing the receiver to choose in case of dual enrolment. Furthermore, it is possible for patients with resources to transfer residence to other states with lower waiting times to have a more easy access to organs. There may also be unequal access if the criteria for inclusion in different states vary, in favor of individuals who anticipate their entry on a list and then transfer the waiting time to another state (which is allowed by the Ordinance) where the inhabitants face stricter criteria for inclusion .

Ordinance No. 3,407, 1998, established that the single list system, for each organ, body part or tissue, has three expressed integration levels: national, state and regional lists. However, a better organization of the national list of receivers, explicitly seeking equity, took place from 2000 onwards. Ordinance No. 901, 2000, created the national central, which was regulated by Ordinance No. 91, 2001, which organized the states into four regions and indicated the order of attendance at the various levels of integration, granting priority to the state level and the region to which the state belongs to. An important gap can be seen between the first time the single national list was mentioned in 1997 and its entry into effect in 2001, at least at the official level.

Regarding organs allocation criteria, Decree No. 2,268, 1997, gave the SNT a crucial role as coordinator and defining judge for the specific criteria to organs access, since no higher law sets specific criteria for the distribution of organs. As organs access criteria the Decree established: therapeutic need, compliance with the exclusion lists sent by the SNT, the dependence to laboratory tests to check for donor and recipient compatibility and obedience to the entry order of the state's CNCDO. Indications of organs allocation would be given by the CNCDO. There were only two exceptions to alterations in registration order, related to operational issues (distance and shipping conditions) and the recipient's health condition (imminence of death).

Decree No. 2,268, 1997, established a combination of several principles of ethics and equity for organs allocation related to therapeutical need. Among the ethical principles in the decree quoted by Biller-Andorno and Andorno (2001) we find: equality (subscription order), efficient distribution (biological compatibility and state level distribution privilege, to avoid organs loss, which may occur with displacement delays) and the principle of compassion (imminence of death). In addition to these ethical principles, principle of equity was used, expressed in the possibility of benefiting from organs not used in a state according to a national list.

Imminence of death could be regarded as an extreme application of a severity criterion; however, the Decree stated only the first situation, in a typical reference to a principle of compassion. Ordinance No. 3,407, 1998, whose annexed regulation detailed the single list system operation and organ allocation criteria, specified the situations of imminent death but made no reference to a severity criterion. Still, the severity criterion (not related to death imminence) has been adopted by SNT through ordinances (hierarchically inferior to decrees).[17]

In the case of the new infra-legal regulation concerning liver allocation criteria for transplantation, the Ministry of Health decided its amendment through Ordinance No. 1,160, 2006, introducing the clinical status severity criterion.[18] That criterion was based on the Model

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[17] Ordinance No. 3,407, 1998, considered urgent the cornea transplant in children, where there is no imminent death threat but the seriousness of the situation, because the neurological development of the vision is completed during childhood. In the case of liver allocation criteria, in 2006 (Ordinance No. 1,160, 2006) there was explicit reference to the severity criteria. Prioritization through severity can be also found in the bone marrow transplantation regulation (Ordinance No. 1,316, 2000).

[18] The modification was preceded by intense debate among experts. For example, in 2005, the Technical Council of the Department of Health Care of São Paulo State took position against any change in the proposition, criticizing the SNT's decision to alter the list order, arguing that any change in the organization of the line of chronological order to severity order could generate waste of available organs, due to the high rate of postoperative mortality among those with more severe disease (ESCOBAR, 2005). Data from the Department of Health Care of São Paulo showed that mortality in the waiting list was approximately 60% and that mortality of the liver transplanted within one year after surgery was 35%, with a survival rate of 65% (ESCOBAR, 2005). The Aliança Brasileira pela Doação de Órgãos e Tecidos – ADOTE (2007) believes that the adoption of this criterion diverts the focus of the central discussion that would be the organs for transplantation shortage of and that more important than setting a criterion of severity would be to concentrate efforts in increasing capture.

for End-stage Liver Disease (MELD) and Pediatric End-stage Liver Disease (PELD) systems, developed at Mayo Clinic and modified by the United Network for Organ Sharion - UNOS, a mathematical model that estimates the risk of death of a person with terminal liver disease based on routine laboratory tests (ALIANÇA BRASILEIRA PELA DOAÇÃO DE ÓRGÃOS E TECIDOS, 2007). [19,20] In both cases, the listing time is used as tie criterion. In Brazil, the PELD is multiplied by a 3 correction factor, which does not exist in the United States, giving priority to children (CONSELHO FEDERAL DE MEDICINA, 2007b).

After the adoption of the new liver allocating criteria, published reports suggest: reduction in the number of entries and waiting list; quicker transplantation response for the most severe cases, even if newly registered; no changes in the survival rates of the transplanted; priority to children care, which rose from 10% to 18%, and people with cancer, which rose from 3.4% to 33.5% of the transplants total and destination of a third of grafts to serious cases (RAIA, 2007). Data on mortality in the waiting line is still controversial, but no sign of important reduction in mortality is shown. It is interesting to note that, regardless of the debate on the technical merit of the severity criterion based on the MELD and the PELD, object of discussion in other countries, the main arguments that justified its introduction, reduction of mortality on the waiting list and higher proportion attendance of the most serious cases, did not stand out in the initial results since its adoption.[21] Apparently, other criteria, which were also included in the legislation amendment, but did not receive much attention in public debate, may have been more decisive (as the prioritization of children and patients with liver tumors).

Favourable opinions to criterion change for the liver distribution for transplantations, even in 2005, argued that the existing chronological rule may tend to exterminate all the seriously ill and those who remain still would not have a transplant indication (BARROS; SETTE JR., 2005).

[19] The MELD is a numerical value, ranging from 6 (less severity) to 40 (more severe), used to quantify the urgency of liver transplantation in the candidates aged 12 or more years, consisting of a death risk estimate if the transplant is not performed within the next three months, whose value is calculated by a formula that considers the result of three laboratory tests: bilirubin, creatinine and prothrombin activity (ALIANÇA BRASILEIRA PELA DOAÇÃO DE ÓRGÃOS E TECIDOS, 2007).

20 The PELD is also a numeric value, applied to children under the age of 12, which takes into consideration the outcome of the tests: bilirubin, albumin and prothrombin activity (ALIANÇA BRASILEIRA PELA DOAÇÃO DE ÓRGÃOS E TECIDOS, 2007).

[21] In the case of countries members of the Eurotransplant (2007), the MELD was adopted from 01 January 2007.

Judgments are not made about the SNT's attributions to amend the Decree; however, the body may have exceeded its jurisdiction when including exception criteria in the waiting order, by means of hierarchically lower norms (ordinances) that set these criteria (decree). Regardless the technical merit, the situation of a regulatory process inadequacy may threaten equity, by threatening the regulatory system hierarchies and, consequently, the fairness of procedures. Thus, a review would be fit, at least at the decree level, in order to deal with the irregularities in the normative hierarchy.

Another problem related to the application of the organs allocation criteria refers to the incomplete regulation regarding the effective application of those criteria. It is a fact that criteria for specific precedence determination of allocation for each type of organ, part and tissue collected were establish by Ordinance No. 3,407, 1998. In the technical regulation of 1998, annexed to the Ordinance, excluding and classification criteria exist. Waiting time is present as one of the classification criteria for all type of organs. On the other hand, weights related to each criterion were not assigned. The Ordinance mentioned that a "decision tree" would be regulated by an ordinance, nevertheless, classificatory algorithms were hardly found in ordinances for the bone marrow and liver transplantations cases.[22]

For cases of kidney and pancreas combined transplantations and of pancreas isolated transplants, Ordinance No. 935, 1999, from the Ministry of Health fails to describe a prior and thorough decision-making system for recipients selection, as in the case of a greater number of receivers in relation to pancreas donors, in which the SNT Coordination should be informed for the establishment of the minimum criteria for distribution.

Apparently, a computerized information system has the classification algorithms used for the selection of recipients, whose publication in the ordinance was not detected. Ordinance No. 783, 2006, established the compulsory use of the information systems developed by the SNT for feeding information regarding donation and transplantation and for waiting lists management for organs transplantations throughout the national territory. The system manual is not available on the SNT Internet site. Thus, the weights assigned to each criterion for organs allocation are

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[22] In the case of bone marrow, there are urgency and curability criteria quantified in table that specify various pathologies.

subject to change by simple alterations in a computer program, authorized by SNT, without the publicity provided by ordinances.

Furthermore, not all states are using the same information system as expected. For example, in the case of kidney and cornea transplantations, the São Paulo State uses its own system with some different criteria (CONSELHO FEDERAL DE MEDICINA, 2007b). This situation may affect uniformity in the application of the allocation criteria throughout the states. It is true that the Ordinance No. 3,407, 1998, requires copy of the single list system's state criteria, assuming, therefore, that there are no homogeneous criteria among the CNCDO. Moreover, article 37 of the technical annex to this Ordinance allows establishing state supplementary criteria for organs distribution, provided they do not exceed those of SNT. If this state competency is not strictly observed, the ability of SNT to establish such criteria, as endorsed by hierarchically superior norms, will be breached.

Due to inadequate national level disclosure of the organs allocation criteria used in different states, we cannot assess the effect of this difference on the equity of access to transplantation organs. Given the available information, it is not easy to say that any state may be using criteria surpassing those of the SNT. Moreover, analysis or official statements on the matter are unavailable. The actual situation of public ignorance is a threat to equity itself, as it makes difficult social control.

There is also need for regulation on inclusion criteria of people on waiting lists, which were not specified in the annexes of Ordinance No. 3,407, 1998. The omission has been resolved in a fragmented way for each type of organ, as was in the case of the liver waiting list. In 2002, Ordinance No. 541, approved criteria for registration of candidates as liver recipients (cadaver donor) in the single list of CNCDO. Some of the technical transplant councils created from 2004 to advise the SNT were granted with the attribution to suggest criteria for waiting lists inclusion, but many organs still remain without criteria, published in ordinance, for candidates' inclusion in the waiting lines. It turned out also that there is no standard criterion to give orientation to transplantation teams of how to proceed in situations where the available organ is not ideal for one transplant case, but may benefit any other subscriber. That situation may generate organs waste.

6.3 STRUCTURING THE TRANSPLANTATION PROGRAM

The SNT is an institution incorporated to the SUS, that if adequately structured will offer fair opportunity and equal treatments to all citizens; what is necessary for the equitable application of access criteria to transplantation organs. The proper functioning of the SNT may also reduce the organs shortage levels available for transplants by means of increasing the donation levels.

The structuring of the SNT was addressed by legislation since 1997 by the Transplantation Law, completing the fundamental omission of previous laws. Law No. 9,434, 1997, established the need of SNT authorization to operate for transplantation teams and for institutions where transplants are performed. Decree No. 2,268, 1997, detailed the SNT structure and its jurisdictions, highlighting the management function of the single national receivers list. Ordinance No. 3,407, 1998, addressed administrative issues, such as the creation of technical advisory groups and the operation of the state transplantation coordinations; and technical issues, through the approval of the technical regulation on transplantation.

This legal framework determined a strong centralization of the transplantation program management in the hands of the Ministry of Health, through the national coordination of the SNT. Much of the administrative effort is spent on authorization activities of specialized teams and public or private health care institutions throughout the country, often in a bureaucratic way (CONSELHO FEDERAL DE MEDICINA, 2007b), while data disclosure activities, analysis and system assessment indicators show obvious shortcomings. (MARINHO, 2004, 2006). For example, the Ministry of Health issued 2,395 ordinances containing the word “transplant” from 1988 to August 2007. [23] Many of these ordinances deal with administrative issues, such as those related to transplantation teams (1,044 ordinances), as well as logistical and financial aspects o the SNT’s structuring and maintenance.

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[23] Search held at the Saúde Legis website of the Ministry of Health (http://portal.saude.gov.br/saudelegis/leg_norma_pesq_consulta.cfm).

In the SNT structure, several technical councils to support the normative definition process were created by ordinance from 2004. The first technical councils dealt with organs whose allocation provoked more controversy, such as: liver, bone marrow and cornea. Meanwhile, during two years other councils were established, such us: tissue, lung, kidney, histocompatibility, pancreas and intestine. Also in that process, fragmentation is perceived, since some of the councils have a more objective indication of their purpose, such as the production of criteria for waiting line inclusion and organ distribution, while many others were only granted with their composition and meetings frequency. Reports regarding the operation of the technical councils are not available in the SNT website. Thus, there is difficulty in analyzing the effective role of that SNT's structures, although signs existed that the councils as a whole were not working as they should (CONSELHO FEDERAL DE MEDICINA, 2007b). However, there are examples of relevant performance, such as the work of the technical council for liver transplants, which resulted in considerable changes in related activities.

CNCDO regulation, particularly state related, was fundamental for the SNT structuring, as these institutions are responsible for the management of the single list system at a state level, which represents the first effective level of organ distribution. It is worth mentioning that the original text of article 12 Law No. 9,434, 1997, which addressed transplantation centrals organization in the states, was vetoed by the Executive, claiming to be unconstitutional, since it interfered in the jurisdiction of that Power in organizing its structure.[24] Despite of the inadequate approach, the legislature's concern was not unfounded, since even today two states without transplantation centrals still exist. Nevertheless, the operation of the transplantation centrals was regulated by Decree No. 2,268, 1997 and detailed in Ordinance 3,407, 1998.

Intra-hospital transplantation committees, based on the Spanish system performance model, represent another SNT structure with great potential to increase organs capture. Ministry of Health Ordinance No. 1,752, September, 23 2005, established that hospitals with more than 80 beds should create such committees. Unfortunately, their development has been uneven across

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[24] The concern to preserve the jurisdiction of other federal entities was not observed when federal ordinances (of inferior hierarchical level to laws and decrees) determined, rather than establishing operational principles, the creation of structures in other federal units, with specified timing, as was the case of the creation of state's liver technical councils.

several states and integration with state transplantation coordinations shows difficulties (CONSELHO FEDERAL DE MEDICINA, 2007b).

It may be observe, then, that regulation on SNT structure and operation is comprehensive, detailed, fragmented, promoter of centralization at a federal level and concerned with the provision of financial resources to support the procedures that are technically regulated. However, not always the instruments created by regulations to increase the system's efficiency work as intended.

It has to be emphasized that problems resulting from weaknesses on the SNT and SUS structure may affect the proper application of the organs allocation criteria. For example, Ordinance No. 1,160, 2006, established validity periods for the lab tests used in the MELD and PELD calculations, ranging from seven days to twelve months, so that any delay in the performance of these tests would undermine the situation of the waiting list subscriber and may become source of inequality. Ordinance No. 935, 1999, mentioned that laboratory tests availability of the leukocyte antigens may have influence on the organ distribution criteria, because the criteria should be reassessed when the 90% of the patients entered in the kidney and kidney-pancreas waiting lists are identified in relation to the Human Leukocyte Antigen –HLA. Differences in the resources of the state's health care systems can cause differences in the operation of waiting lists, resulting in a burden to the equity of access.

6.4 MECHANISMS WHICH AFFECT ORGANS AVAILABILITY

Certainly, an adequate SNT structure, discussed in the previous item, has influence on the transplantation organs availability, but it is possible to highlight mechanisms directly aimed to reducing the organs shortage and increasing the equity of access to them.

Law No. 9,434, 1997, intended to expand the quantity of available organs for transplantation through the adoption of the presumed donation consent of all the deceased Brazilians. That goal was so desired that the Transplantation Law was known as "the presumed consent law" in a document elaborated by the Ministry of Health (BRASIL, 2004). Meanwhile, the society's rejection of the presumed consent made this mechanism to be suppressed through the edition of several Provisional Measures and, finally, abolished by Law No. 10,211, 2001; prevailing family authorization in the decision of organs donation.

This reaction was so extreme that excluded from the text of the Law the express wishes of the donor manifested in life, possibility outlined in previous laws, such us Law No. 8,489, 1992, Law No. 5,479, 1968 and Law 4,280, 1963. Due to modifications made in 2001, article 14 of Decree No. 2,268, 1997, that deals with presumed organ donation, cannot be applied, indicating the need for revision.

The *Registro Nacional de Doadores de Órgãos e Tecidos* (National Registry of Organs and Tissue Donors), created by the Ministry of Health Ordinance No. 1,183, October 25, 2000, and dedicated to registering the citizen's desire of organs donation after death, would become an indispensable tool in a presumed consent context, but currently serves as aid for a future decision of the families regarding donation, and is therefore, in line with the changes effective in 2001.

The unsuccessful attempt of the presumed consent deployment suggests that legal provisions are not enough to ensure relevant modifications in implementing a public policy and that laws need to be in accordance to the wishes of the society. In the specific case, there is evidence of insufficient public debate in the law elaboration process, since the society's reaction did not appear at the time of its approval but in its further implementation.

One relevant instrument to increase organs capture was introduced by law in 1992 and kept in the Transplantation Law: brain death notification by health care services, since timely diagnosis is crucial for organ availability (CÂMARA DOS DEPUTADOS, 2004a). Meanwhile, technical issues, related to training of professionals who carry out these diagnoses, and operational issues, related to necessary resources for complementary tests performances and maintenance of potential donors in intensive care units, still need to be overcome so that this mechanism could be employed with greater efficiency in Brazil.

The Transplantation Law assigned the responsibility for regulating the brain death diagnosis to the *Conselho Federal de Medicina* (CMF - Federal Council of

Medicine). CFM Resolution No. 1,480, 08 August 1997, established a methodology for the brain death diagnosis, through the performance of clinical and complementary tests. CFM Resolution No. 1,752, 08 September 2004, addressed the ethical authorization for removal, after birth, of organs and tissues for transplantation from anencephalus, depending on prior parental authorization. Meanwhile, Ministry of Health Ordinance No. 487, 02 March 2007, established that organs and tissue removal from anencephalus should be preceded by an irreversible cardiac failure diagnosis and stressed that its breach constitutes a violation of the Transplantation Law terms.

Another specific action with organs supply expansion potential was the permission granted by the Ministry of Health Ordinance 3,407, 1998, by which eyeball withdrawal is performed by trained technicians, under the responsibility of an authorized medical ophthalmologist. This mechanism would be one of the available devices to overcome the theoretically unjustifiable existence of a cornea transplantation waiting list (of an estimated 30 thousand people), in a country that registers near a million deaths per year and considering that corneas can be withdrawn within 6 hours after cardiac failure (CÂMARA DOS DEPUTADOS, 2004a).

6.5 SANCTIONS

Criminal and administrative sanctions represent the means to prevent conduct deviations, to punish crimes and to prevent unfair procedures, contrary to those agreed for the operation of public institutions.

The Transplantation Law gives provision for several crimes, including the performance of transplants or grafts in breach of what established by article 10, which regulates the waiting list and the receiver’s consent. The penalty intended for this type of crime is imprisonment of six months to two years. Strangely, the administrative sanctions provided by this Law do not apply to institutions involved in this type of crime.

It is relevant the verification that crimes related to breaches on the waiting list and organs trade, among others, are likely to specific punishment. The parliamentary investigatory committee on human organs traffic discovered the value of those mechanisms in processes against suspected to promote the sale of kidneys from residents of Recife to South Africa (CÂMARA DOS DEPUTADOS, 2004a).

6.6 REGULATION COMPETENCES

According to Rawls (2003), justice in legal procedures at the society's basic structure, provided by the respect to the law is relevant to guarantee a fair and equal treatment of citizenship. In the specific case of this study, clear definitions on attributions to regulate organs transplantation became evident. The Constitution granted the Union with a legislative prerogative on general principles of health actions and services. It also ensured the jurisdiction of ministers to regulate these matters. The Health Organic Law (No. 8,080, 1990) foresaw that national level regulations, through technical rules, would establish standards and regulate the relationships between the SUS components. That Law acknowledged the supplementary legislative jurisdiction of the states and complementary jurisdiction of the municipalities. Decree No. 2,268, 1997, specifically assigned the SNT with the function of dispatching norms and technical regulations to give a framework to procedures and authorized the Ministry of Health to dispatch instructions and regulations necessary to the Decree implementation. This capability is crucial when considering that each type of organ needs specific distribution criteria.

Technical regulation introduced by Ordinance No. 3,407, 1998, recognized among the competencies of the *Grupo Técnico de Assessoramento* (GTA – Technical Advisory Group): the development of transplants and grafts policy guidelines, the proposal of complementary regulation topics and the identification of quality standards for the sector. However, no official document on the GTA's activities was found.

The state level was granted with the jurisdiction to develop additional complementary rules, of state scope, by means of the *Coordenações Estaduais de Transplante* (state transplantation coordinations) and to adopt additional criteria to the single list system, supplementary in character, so as not to surpass those defined by the SNT. As showed in item

6.2., this competence has been used, highlighting the São Paulo case. Regarding regulation of criteria for registration of candidates for liver reception, in other words, the waiting list subscription, Ministry of Health Ordinance No. 541, 2002, banned the establishment of CNCDO's own criteria, limiting the state competency.

The SNT power to regulate has been intensely exercised by the Ministry of Health, determined by the very centralized management structure. Overall, the regulations on technical requirements and resources needed to perform the various and complex types of transplants is comprehensive and is present at the ordinance level. In ordinances put forward from 1999, we find a rule fragmentation trend, since instead of introducing changes in the technical regulation of transplants of 1998 (which would be easier to monitor), specific ordinances on the different types of transplants just multiplied. The fragmentation trend makes it necessary to follow up each issued ordinance in order to compose the legal framework of the sector. This fragmentation could be minimized with changes in specific items of a smaller number of technical regulations.

It is also perceived in transplantation regulation, that some sectors, specially eye and bone marrow banks and the organs imports, are regulated by ordinances of the Ministry of Health, related to the SNT, and by resolutions issued by the National Sanitary Surveillance Agency (Anvisa). For example, the Anvisa Resolution RDC No. 154, 2004, (republished on May 31, 2006) deals with the inscription at the CNCDO to perform a kidney transplant from a person assisted in a dialysis service. Thus, jurisdiction conflict is possible in the development of rules, having the Ministry of Health the responsibility to coordinate and integrate this process. Likewise, the Ministry of Health is required to verify whether the competence for supplementary regulation of states is being applied in accordance to the criteria established by the SNT, in order not to provoke regional inequalities.

Despite the abundance of ordinances, relevant deficiencies in regulation were detected. For example, Decree No. 2,268, 1997, shows several mechanisms related to presumed consent and the process of donation between living, which are outdated since 2001. The Chamber of Deputies recommended a revision of Ordinance from the Ministry of Health No. 937, 1999, which allows cornea imports; in the meantime, this ordinance is in force without modification (CÂMARA DOS DEPUTADOS, 2004a). Also need revision and new ruling, as outlined in item

6.2: the adoption of severity criteria in the distribution of some organs (already established by ordinance, but not provided in law or decree); the need to define the inclusion criteria in the waiting lists (existing gap for various organ types) and standards for organs rejections by transplantation teams.

6.7 TRANSPLANTATION INFORMATION TRANSPARENCY

It was already mentioned that Biller-Andorno and Andorno (2001) considered transparency as one of the associated elements to transplantation programs that seek equity. Transparency promotes social control over fairness of the procedures adopted by public institutions and should be expanded so that society is aware of the criteria effectively used in organs allocation, so that discriminatory situations could be avoided.

The Health Organic Law promoted, broadly speaking, the disclosure of informations regarding health care service potential and patient usage, which may be associated to a necessary transparency in waiting lists. The law also valued the proper use of informations, as it promotes the use of epidemiological information for establishing priorities, the allocation of resources and programmatic orientation, what is relevant to governmental action based on evidence.

Information transparency related to organ transplantation was also considered by the Transplantation Law, which established compulsory keeping of medical records for 5 years in the transplanting institution and for 20 years at the CNCDO. Ordinance No. 3,407, 1998, mentioned the annual delivery of the information from the State Transplant Coordinations to the SNT and conditioned the renewal of teams and institutions permissions to the systematic delivery of the requested data to the local and national organ of the SNT.

Brain death diagnosis transparency was promoted by the Transplantation Law by enabling the presence of a doctor designated by the donor’s family in that activity. For the organs recipient candidates, Ordinance 3,407, 1998, compelled the CNCDO to give proof of waiting list inclusion, as well as specific explanation on the criteria for organ or tissue distribution. The

Ordinance also addressed the SNT information system, recognizing its importance to the functioning of the structure.

Although federal legislation has been busy trying to give transparency to the transplantation program, it was still not enough so that people enrolled in waiting lists all over Brazil have access to the information about their situation on the list, as already happens for the São Paulo state residents. Apparently, the federal law major concern was more with transparency of documentation held by institutions. In the specific case of liver transplants, Ordinance from the Ministry of Health No. 1,160, 2006, stated that the procedure indication, as well as the keeping or exclusion of the subscriber in the list is responsibility of the transplantation team to which the candidate is related to. However, procedures to report the subscribers on their situation within the list were not specified.

The system's transparency could be increased if regulation fragmentation could be reduced, as it hinders understanding of the normative component by non-specialists and, consequently, to the social control required by the SUS. Transparency would be greater with more disclosures of the national level SNT operational analysis and the recommendations of the transplantation technical councils. In this respect, documental analysis confirmed the lack of assessment indicators on the transplantation program, reaffirming the requirement identified by Marinho (2006) that the SNT must expand the information disclosure. A program of the Brazilian size needs of profound and systematic assessments, accessible to the public and to the academic community in general, not just to those who study medical aspects of transplantations, since the quest for equity involves multidisciplinary issues.

One aspect that causes particular concern was already mentioned in item 6.2: the difficulty of access of doctors and waiting lists subscribers to the criteria (some unpublished in ordinances) used by the information systems in the process of organ allocation.

In the case of Ordinance 541, 2002, that approved registration criteria for liver transplantation candidates, was given considerable level of discretion for the state liver transplantation technical council, since it is responsible for the assessment and authorization for subscription in waiting line of persons of 70 years of age or older. That kind of responsibility needs to be transparent enough to allow social control.

The study’s conclusion, considering legislation analysis and other information obtained from this research are presented in the following chapter.

7 CONCLUSION

The documental analysis and scientific literature review, which validated this qualitative study, offered enough ground to analyze the contribution of legal criteria for equity of access of the Brazilian population to organs donated for transplantation within the SUS. The consideration of the selected documents as products of social interactions and expressions of the social power, placed in a historical, political and social broader context, propitiated the inclusion, in the analysis, of the organs allocation criteria within the context of the SUS and the Brazilian welfare state.

The documental analysis of the international context related to organ transplantation allowed to support the idea that organs shortage is common to various countries and results in the formation of waiting lines for transplant procedures. This problem is associated with an increase in the demand generated by the very development of the sector, as well as by structural restrictions in country's ability to increase organ capture. Consequently, each country's available resources for application to the respective transplantation programs establish the distinction among them, resulting in different transplantation access levels in the international arena.

The organs shortage situation has also become a matter of concern because of the social vulnerability of the poorest countries, whose population has been suffering from "transplant tourism", where people travel to those countries with the purpose of buying organs, such as kidneys. Data from the WHO and the ONT show a greater transplantation access in the United States and European countries in comparison to countries from Latin America, Asia and, mainly, Africa. It was also found that even in economically developed countries outstanding inequalities of regional access still exist (such us United States, Scotland, France, Great Britain, Australia and Spain), generally affecting the most vulnerable groups.

By the international context analysis it was found that Brazil has followed, in the transplant regulation field, the main debates and amendments of the legal criteria to organs access. For example, at the end of the 1990s European countries and especially the United States established laws that aimed to reduce inequities in the regional distribution of organs. In 1997, Brazil introduced a national dimension to the waiting list through a decree which regulated the

Transplantation Law. More recently, the United Stated included the MELD as liver allocation criteria, which was adopted by Brazil in 2006 and by the Eurotransplant in 2007.

Regarding the outcome of the transplantation program activities, it was noted that Brazil stands out internationally in some areas, such us cornea and pancreas transplants, meanwhile the overall performance is still inferior to that of the European countries and the United States. In absolute terms, our country holds a prominent position in Latin America, however, in relation to its population size, has similar performance to some South American countries.

The comparison of the transplantation programs performance between countries is a complex task due to the variety of procedures involved. In the case of Brazil, data related to the more complex transplants (solid organs and bone marrow) are generally released along with cornea transplants (easier tissue to capture), suggesting that we hold the world's second largest program. Whereas the 65.5% of the Brazilian transplants are of cornea, that type of analysis may disguise the observed fact that there has been an increase in cornea transplants, but a reduction in important transplantation types, such as heart (26.5% reduction) and combined kidney-pancreas transplants (39.8% reduction), in addition to some stabilization in the other categories. Furthermore, a reduction in the organs donation rate was verified from 2004.

Although it has not been object of this study to verify equity in the results of the operation of Brazilian transplantation program and despite the scarcity of official analysis, unequal access to transplant was detected among the states residents. That inequality was put into evidence by: the lack of organs centrals in two states, the existence of waiting line information for just 22 states, the differences in the organ donation rates between states, in addition to striking inequalities in the performance of solid organ and cornea transplants between Brazilian regions. In 2006, the cornea transplant performance rate for the Northern Region accounted for roughly 10% of the Central-West Region; for solid organs, the Northern Region showed a rate equivalent to the 13% of the Southern Region.

In spite of the recognition given to the Brazilian organ transplantation program because of its complexity and the results achieved by a public system (about 100 thousand transplanted people), and also due to the considerable resources it manages and the existence of a comprehensive regulatory framework, it was found that, currently, the program is facing difficulties to expand its operations. Official investigations from the Brazilian Chamber of Deputies and the Court of Audit, as well as academic studies on Brazilian transplantation waiting lines, confirm this situation. Transplantation related institutions suggested the necessity of a specific policy with clear goals for implementation of strategic activities.

The verification of such a context became relevant for the study as it revealed an organ shortage worsening situation, which requires more of legal allocation criteria, to provide equal opportunities and so that unfair situations can be avoided. Moreover, it was confirmed that the transplantation program, in spite of being one of the Brazilian's public policy success examples, cannot be separated from the SUS situation, in particular regarding its inadequate financing. Likewise, the SUS cannot be separated from the situation of our Welfare State, characterized by macroeconomic predominance over the population social needs, in contradiction to constitutional determinations.

The dissociation between what the Constitution prescribes for health care (universal and integral assistance) and what is actually deployed by the SUS (top quality services for situations of catastrophic expenses and for epidemiological and sanitary surveillance actions, but of lower quality for medium-complexity services) may create a situation of inefficiency. The inadequate access to services of low and medium complexity (simpler and less expensive with potential to avoid diseases treated by organ transplantations) can increase the total costs of the health system and also the organ shortage.

The organs allocation legal criteria analysis and their contribution to equity of access were preceded by a meditation of the equity concept and its application in the health area. It was verified that this concept has changed over time, but has been applied since Antiquity. The notion of treating equally the equal and unequally the unequal has remained stable, but the definition of what is fair to justify the unequal treatment, is susceptible to changes, according to each society's values.

Currently, Rawls theory stands out for providing a set of political principles of justice to be adopted by institutions from the society's basic structure, in a liberal and democratic context, in order to provide fair distribution of resources and equal opportunities to citizenship. That theory emphasizes the justice of procedures and the respect to society's agreements expressed in laws, so that, in the case of this study, supports regulation of the organs allocation criteria through laws, decrees and ordinances, as necessary conditions for the operation of an equitable system.

However, due to the political nature of Rawls' principles of justice, they are not intended to resolve specific distributive matters and so cannot be directly applied to solve the organs allocation problem. Despite the indication offered by the difference principle that primary goods distribution should favor the less privileged from society, we must consider that Rawls did not explicitly defined health as a primary good. On that point, Sen's reflection provided progress for Rawls' theory application, because in respect of distributive justice, rather than focusing on primary goods equality, Sen defended the equal capacity to carry out different life projects, which explicitly includes health. The individual's equality of freedom to effectively be and do considers, in Sen's perspective, individual variations in the ability to transform primary goods into welfare results. For this study, such vision indicates that the organs allocation criteria need to be considered in conjunction with the means offered by the health system, so that everyone has equal opportunity of access to organs.

Sen applied his equality and inequality reflection to the health context and produced a multidimensional concept of health equity, which values not just access issues, but also the relationship with social justice and total equity (e.g., in the resources sharing among the society) and the non-discrimination in the delivery of health services. That systemic approach has been incorporated to heath equity concepts used by health institutions, although it is still needed greater emphasis on systemic relationships and clarity on the principles of justice that underlie those concepts.

The application of Sen's systemic approach to the problem of equitable organs allocation is useful to highlight that allocation criteria cannot be conceived in a purely formal way, without considering the effective ability to enable people as organs recipients. For example, the existence of apparently fair formal criteria, but not aided by access to pre-transplantation laboratory tests for all, may outline a non-equitable system The same can be expressed of a system that does not promote organs distribution considering regional inequalities of access. In spite of that theoretical contribution, for organs allocation at the individual level makes necessary the integration of principles of justice and equity with ethical principles, as those quoted by Biller-Andorno and Andorno.

In the transplantation programs practice it is observed that each country follows a set of ethical principles aimed at achieving equity. Generally, an equality principle (waiting list order) is used associated with a compassion (death imminence) and an efficient distribution criterion (better expected result in accordance with the severity of disease and health need). In special situations priorities are offered, such as the case of children. The importance that each principle receives in the organs allocation process varies in each society, but once expressed in regulations, needs to be applied with impartiality and transparency to ensure justice in the procedures and equal opportunity.

From Rawls' theoretical framework (on justice principles), Sen's (on health equity) and Biller-Andorno and Andorno's (on the ethical principles of organs allocation), we proceeded to the analysis of the Brazilian federal legislation on organs transplantation. Greater emphasis was placed in the verification of existence of legal access criteria which could threatened SUS's organs allocation equity. Respect to legislation hierarchies was also considered. It is necessary to emphasize that the existence of equitable legal criteria, although being considered a necessary condition, it does not represent a guarantee of equity on the overall health system equity results, since other factors intervene.

The Brazilian transplant regulation, which began in 1963, is complex, comprehensive, fragmented and includes relevant contributions from the Constitution of 1988. Expansion on transplantation activity occurred from 1997 with the introduction of the regulations of the Transplantation Law, which still in force. Whereas an equity analysis cannot be considered independently from the principles of justice involved, it was verified that the constitutional principles and SUS guidelines value the equal access opportunity to actions and health services and make explicit reference to social justice. Consequently, the organs transplantation policy must be determined by the quest for equity, which makes it suitable for analysis in accordance with the principles of justice developed by Rawls and the approach of health equity proposed by Sen.

On the principles of access to health services within Brazilian legislation, stands out the constitutional right to health by means of free services provided by the SUS. Services should be available to everyone and covering the whole of the population's health needs, including complex ones, such as transplantation. The Health Organic Law also made reference to equality in health care attention without prejudice of any kind, as supported by Sen. Regarding transplantation access, 1988 Constitution did away with any possibility of legal access through organ commercialization or trade, so that organ access can only occur by donation, a solidarity principle. Donation can be from a living donor and be targeted to a specific receiver, regardless the waiting line. In that specific case, the Transplantation Law provides for kinship limitations, but accepted non-related donations, through court authorization. Such a measure, however, was not enough, for example, to reduce the proportion of kidney transplantation from living donors performed in the country, in opposition to the trend of increasing rates of cadaver donation, experienced by more effective transplantation programs.

In the case of *post mortem* organ donation, organs must be distributed according to the single list. The meaning of the expression "single list", which was incorporated in the Transplantation Law in 2001, may be interpreted by non-specialists in different ways. However, the purpose was to designate a "single list system", since regulations clearly specified the existence of single waiting lists in each state, by organ type, and also allowed the use of surplus organs at regional and national levels. That was an example that the meaning of documental evidence may vary, even dealing with laws, which wording are supposed to be objective.

In fact, our legislation complied, since 1998, a system consisting of a set of state lists, classified by different organ types, honoring the subscription order and the biological compatibility between donor and recipient and with national coverage, making available state surplus organs to the national list (it is important to note that the national transplantation central has been regulated only since 2001). The inscription to waiting lists occurs at a state level; changes between transplantation centrals are allowed, keeping the accumulative waiting time. In a context of great inequality in the ability of Brazilian states to offer transplantation services, individuals with more resources may move to other states to have a differential access to transplants.

The organs allocation criteria were defined by the Ministry of Health through ordinances, that must be guided by the Transplantation Law and by the Decree No. 2,268, 1997. That Decree admitted only two exceptions to the subscription order, related to operational issues (distance and shipping conditions) and recipient health condition (death imminence). Meanwhile, the severity criterion (not death imminence related) surmounted the inscription order in some situations, prominently in the case of liver allocation, through amendments introduced by ordinances (hierarchically inferior regulations in relation to decrees). It is worth mentioning that the greatest aspiration in the implementation of the severity criterion in liver allocation was to broaden the selection of people with more severe disease, but early analysis shows that certain mechanisms contained in the regulation also would have benefited people in other situations, such as children and liver tumor patients. In the face of alterations of such high level of consequences for the waiting lines subscribers, the maintenance of a procedural rigidity guarantees full discussion among the interested sectors of society.

That situation demands a revision, at least at a decree level, for, in any case, make the severity criterion available for the allocation of other organ types and to address the deficiency in the regulation hierarchy and, consequently, the threat to justice of procedures. Such a revision is also necessary in the Transplantation Law updates, related to the exclusion of presumed donation and requirements for donations from a living person.

Regarding the organ allocation criteria, our legislation provides for a combination of the following ethical principles: equality (subscription order), efficient distribution (biological compatibility and state level privilege in the distribution, to avoid organs loss, which may happen with the delay in displacements) and compassion (death imminence). Those ethical principles were fully integrated to an equity principle at the national level, expressed by the possibility of benefiting from surplus organs from one state according to a national list.

Despite the existence of allocation criteria for the various organ types, it was detected the need for complementary legislation for the following cases: organs allocation criteria weights definition, which in general are not available in the form of ordinances for all organs, but only in computer information systems, decreasing the system's transparency and undermining social control; standardize the use of allocation criteria in the different states, in order not to surpass those established by the SNT; definition of the inclusion criteria in the waiting lists for all organ types and definition of standards for rejection of available transplantation organs by transplantation teams.

The adoption of Sen's systemic approach to analyze health equity, allowed integration of the mentioned allocation criteria to legal mechanisms related to the SNT structuring. The proper transplantation program operation is associated with a reduction in organs shortage, in addition to encourage fair opportunity and equal treatment of citizenship, necessary for an equitable application of the access criteria to organs.

It was verified that the Transplantation Law determined a centralized role of the Ministry of Health in authorization activities of specialized teams and of health care institutions throughout the country, resulting in a high amount of administrative work on the part of the SNT in those activities. On the other hand, it was detected lack of disclosure of analysis, program's assessments, activities reports from technical councils created to support the SNT, as well as reports about the performance of intra-hospital transplantation commissions.

It was also verified that the regulations on the functioning and structure of the SNT is comprehensive, detailed and concerned in providing the financial resources to support the procedures that are technically regulated. However, not always legal instruments designed to increase the system efficiency have worked as intended, as was the case: of the presumed organs donation consent (that was included in the Transplantation Law of 1997, and was received with reluctance by the society and ended abolished by a law in 2001); of the mandatory notification of brain death (also provided in the Transplantation Law, but has not been adequately supported by measures in the performance of such a diagnosis) and of the permission for eyeball withdrawal by supervised technicians (mechanism provided by ordinance, that needs to be integrated to a broader strategy to deal with a line of 30 thousand people, in a country where there are plenty of potential donors, since near a million people die every year in Brazil).

Another striking feature of the federal legislation, perceived in ordinances drafted from 1999, is a fragmentation trend, because instead of introducing amendments in the technical regulation of transplants of 1998, which would be easier to monitor, specific ordinances for the different types of transplants have multiplied. It was also found that specific sectors such as eye bank, bone marrow, and organ imports are regulated by ordinances from the Ministry of Health and by Anvisa's resolutions, which may creates conflict of interests.

The mechanisms of the SNT also received support from criminal sanctions (including those related to disrespect of the waiting list) and administrative penalties provided in the Transplantation Law. Those sanctions represent the means to inhibit unfair procedures, contrary to what was agreed for the operation of public institutions. That Law also dealt with transparency of transplantation activities, mainly related to documentation keeping. Other measures that may promote social control over the public institutions procedures fairness were not specified in the regulation. For example, the SNT does not provide information regarding the situation of those subscribed to the waiting list, as already happens for the citizens of the São Paulo State. In that area, it was already mentioned an important restriction to transparency represented by the difficulty of access to the weights of the organ allocation criteria (some unpublished in ordinances), used by the computerized information systems.

From the documental evidence analyzed it is concluded that, in general, the allocation criteria present in the federal legislation and in its regulation are directed towards seeking equity of access to the Brazilian population to donated organs for transplantation purposes within the SUS. It can be identified in transplant legislation a set of principles that value justice of procedures, equality, efficiency, compassion and solidarity in organ donation. The combined use of those principles seems appropriate enough for a system that seeks equity, according to our society's leading values. At the same time in which the waiting order is honored, as a general scheme, the consideration of more urgent and serious cases is allowed, apart from the predominant search of efficiency, based in therapeutical indications and a greater compatibility between donor and recipient.

It was confirmed, however, the hypothesis that imprecisions in the Transplantation Law regarding the principles that must be used in organs allocation (it hardly mentions the non-commercialization and the respect to a “single list”), allows the drafting of regulations with potential to threaten organs allocation equity. Although infra-legal regulations have predominantly conceived allocation criteria based in a principle of justice that values equity, few were found, but relevant situations, strictly related to regulation drafting, that may threaten it.

One of them was the introduction of the severity criteria, overcoming the waiting order, by means of an ordinance, without consideration of the limitations specified in a hierarchically superior legislation. Regardless the technical merit, the justice of procedures was threatened. Another threat detected was the non-regulating by ordinance of the weights used to apply allocation criteria for all types of organs, with damage to procedures transparency. The existence of such definitions in computer programs, of difficult access and complex by nature, does not allow adequate social control.

Considering Sen’s systemic approach of health equity, it was verified, that in spite of the organ allocation criteria that exists in the federal law providing, in general, equity of access to organs, it is also necessary to consider other measures that promote equal access to transplantation organs for everyone. Thus, in addition to revisions and eventual corrections of normative omissions, a more equitable result of the Brazilian transplantation program will only occur with a more adequate implementation of its activities, based on improved management, strategic planning, a greater transparency of information (in order to allow greater collaboration from the academic community and social control) and, mainly, by the consideration that the SNT is a program which is a part of the SUS. It cannot act isolated, so it relies on the proper functioning of this to reduce access inequities and better serve the population.

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APPENDIX A – BRAZILILIAN TRANSPLANTATION LAW

This is not an official translation.
Text in red were part of the original law, but were replaced by other laws.
Translated by Pablo Regino and reviewed by Fabio Gomes.
09-26-2008.

Law No. 9434, February 4, 1997.

Provides on the removal of organs, tissues and human body parts for the purpose of transplant and treatment among other provisions.

THE PRESIDENT OF THE REPUBLIC I hereby let it be known that the National Congress decrees and I sanction the following Law:

CHAPTER I

GENERAL PROVISIONS

Art. 1 The free provision of tissues, organs and human body parts, in life or post mortem, for transplantation and treatment purposes, is permitted under the terms of this Law**.**

Sole paragraph. For the purposes of this Law, blood, sperm and ovule are not included among the tissues to which this article references.

Art. 2 Transplant or graft of tissues, organs or human body parts will only be performed by health entities, public or private, and by removal and transplantation medical-surgical teams previously authorized by the national management entity of the Unified Health System**.**

Sole paragraph. The performance of grafts or transplants of tissues, organs and human body parts is authorized provided that all screening tests for infection and infestation diagnosis required in blood screening for donation, are performed over the donor, pursuant to dispositions in Law No. 7.649, January25, 1988, and regulatory acts of the Executive Power.

“Sole paragraph. The performance of grafts or transplants of tissues, organs and human body parts is authorized provided that all screening tests for infection and infestation diagnosis required in blood screening for donation, are performed over the donor, pursuant to regulatory standard requirements established by the Ministry of Health (Writing amended by Law No. 10,211, 23.3.2001)

CHAPTER II

OF THE POST-MORTEM PROVISION OF TISSUES, ORGANS AND HUMAN BODY PARTS FOR THE PURPOSES OF TRANSPLANTATION

Art. 3 The removal of post-mortem tissues, organs or human body parts for the purpose of transplantation or treatment should be preceded by a diagnosis of brain death, verified and recorded by two medical physicians neither of whom should be a member of the team of medical practitioners participating in the removal nor transplantation, using clinical and technological criteria defined by resolutions of the Federal Council of Medicine.

§ 1 Medical records, containing the results or reports of examinations regarding brain death diagnosis and copies of documents mentioned in arts. 2, sole paragraph; 4 and its paragraphs, 5, 7, 9, §§ 2, 4, 6 and 8, and 10, when applicable, and detailing surgical acts regarding transplants and grafts, shall be kept in the files of the entities referred to in art. 2 for a period of no less than five years.

§ 2 Institutions referred to in art. 2 shall submit an annual report containing the names of the receptor patients to the state level management entity of the Unified Health System.

§ 3 The presence of a medical practitioner whom the family of the decedent trusts shall be admitted upon proof and attestation of brain death.

Art. 4 Unless otherwise stated, in terms of this Law, authorization over the donation of tissues, organs or body human parts, for purposes of post-mortem transplantation or therapy shall be presumed.

Art. 4 The removal of tissues, organs and body parts from deceased persons for transplantation or other therapeutic purpose, will rely on the authorization of spouse or relative, of legal age, privileged succession line, ordinary or collateral, up to the second degree, in writing and signed by the two witnesses present on death verification. (Writing amended by Law No. 10,211, 23.3.2001)

Sole paragraph. (VETOED) (Included by Law No. 10,211, 23.3.2001)

§ 1. The expression "non-donor of organs and tissues" should be recorded, in permanent and inviolable manner in the Civil Identity Card and Driver's License of the person who has chosen this condition. (Revoked by Law No. 10,211, 23.3.2001)

§ 2. The recording referred to in this article shall be compulsory throughout the National territory to all organs of civil identification and driver’s services departments, within thirty days from the publication of this Law. (Revoked by Law No. 10,211, of 23.3.2001)

§ 3. The bearer of a Civil Identity Card or Driver's License issued by the date referred to in the preceding paragraph may express his desire not to donate tissues, organs or body parts after death, attending to the official organ of civil identification or driver's services department and proceeding to the recording of the term "non-donor of organs and tissues." (Revoked by Law No. 10,211, 23.3.2001)

§ 4. The expression of will made in the Civil Identity Card or Driver's License can be altered at any time, by making the new statement registered on the proper document. (Revoked by Law No. 10,211, 23.3.2001)

§ 5. In the case where two or more legally valid documents express different options, on the condition of donor or not of the deceased, that of the latest issue will prevail. (Revoked by Law No. 10,211, 23.3.2001)

Art. 5 The post-mortem removal of tissues, organs or body parts from legally incapable person may be made as long as explicitly permitted by both parents, or legal guardians.

Art. 6 The removal of post-mortem tissues, organs or body parts of unidentified persons is forbidden.

Art. 7 (VETOED)

Sole paragraph. In the case of death without medical assistance, death due to non-defined causes or other situations in which any indication of verifying the medical cause of death may exist, the removal of tissues, organs or parts of corpses for transplant or therapy may only be held after authorized by the death verification service pathologist responsible for the investigation and quoted in the autopsy report.

Art. 8 After the body parts retrieval, the corpse will be dingily restored and handled to the relatives of the deceased or his legal guardians for burial.

Art. 8 If assumptions in sole paragraph article 7 are met, after the retrieval of tissues, organs and parts, the corpse shall be immediately necropsied, and in any case, dingily restored and handled to the relatives of the deceased or his legal guardians for burial. (Writing amended by Law No. 10,211, 23.3.2001)

CHAPTER III

OF THE PROVISION OF TISSUES, ORGANS AND HUMAN BODY PARTS FROM LIVING PERSONS FOR THE PURPOSES OF TRANSPLANTATION OR TREATMENT

Art. 9 Any legally capable person may freely dispose tissues, organs or parts of his living body for transplantation or therapeutic purposes.

Art. 9 Any legally capable person may freely dispose tissues, organs or parts of his living body, for therapeutic purposes or transplantation in spouse or consanguineous relatives until the fourth grade, including in the form of the § 4 of this article, or in any other person, by means of judicial authorization, requirement waived in relation to bone marrow. (Writing amended by Law No. 10,211, 23.3.2001)

§ 1 (VETOED)

§ 2 (VETOED)

§ 3 Subject to and in accordance with this article, donation is only allowed when it comes to double organs, parts of organs, tissues or body parts which retrieval shall not impede the donor to continue living without risk to his integrity and shall not represent serious commitment to his vital skills and mental health and shall not cause an unacceptable mutilation or deformation, and responds to a proven need of therapy crucial to the receptor person.

§ 4 The donor must authorize, preferably in writing and in the presence of witnesses, which tissue, organ or body part will be object of retrieval.

§ 5 The donation could be revoked by the donor or legal guardian at any time before its completion.

§ 6 A legally incapable individual, with proven immunological compatibility, may donate in cases of bone marrow transplantation, provided that, both parents or his legal guardians consent and judicial authorization exists while this action does not offer risk to his health.

§ 7 It is forbidden to a pregnant women to donate tissues, organs or parts of her own living body, except in the case of donation of tissue for use in bone marrow transplantation while this act shall not offer risk to her own health or the fetus.

§ 8 Autotransplantation relies only on the consent of the individual itself, registered in his medical records, or if legally incapable, on one of his parents or legal guardians.

Art. 9A Every woman is guaranteed with access to information on the opportunities and benefits of voluntary donation of umbilical cord and placenta blood during the prenatal medical appointments and upon delivery. (Included by Law No. 11,633, 2007)

CHAPTER IV

OF THE COMPLEMENTARY PROVISIONS

Art. 10 The transplant or graft will be only done with the express consent of the recipient, after advised on exceptions and on the risks of the procedure.

Art. 10 The transplant or graft will be done only with the express consent of the recipient, properly placed in the unique waiting list, after advised on exceptions and on the risks of the procedure. (Amended by Law No. 10,211, 23.3.2001)

§ 1 In cases where the recipient is legally incapable or whose health condition hinder or undermine any valid expression of his will, the consent referred to in this article shall be given by one of his parents or legal guardians. (Paragraph included by Law No 10,211, 23.3.2001)

§ 2 Inscription on the unique waiting list shall not give the alleged recipient or to his family subjective right to compensation, if the transplant did not take place due to change in the status of organs, tissues and parts, intended to him, caused by accident or incident in their transport. (Paragraph included in Law No. 10,211, 23.3.2001)

Sole paragraph. In cases where the recipient is legally incapable or whose health condition hinder or undermine any valid expression of his will, the consent referred to in this article shall be given by one of his parents or legal guardians. (Paragraph included by Law No 10,211, 23.3.2001)

Art. 11. It is hereby forbidden to run, through any form of media advertising, which may configure:

a) advertising of entities authorized to perform transplants and grafts, related to these activities;

b) public appeal for the donation of tissue, organ or human body part for a certain identified or unidentified person, with exception of that mentioned in the sole paragraph;

c) public appeal for the collection of funds for the financing of transplant or graft in benefit of individuals.

Sole paragraph. The national, regional and local management departments of the Unified Health System shall held periodically, by the appropriate means of social communication media, public enlightenment campaigns on the benefits expected from this law and to encourage organ donation.

Art. 12. (VETOED)

Art. 13. It is mandatory, for all health establishments to report, to the organ notification, collection and distribution centers of the proper federated unit, brain death diagnosis in patients treated by them.

Sole paragraph. After the notification mentioned in the caput of this article, healthcare entities not authorized to remove tissues, organs or human body parts for transplantation or treatment should enable the immediate transference of the patient or make their facilities available and provide all operational support needed to medical-surgical removal and transplantation teams, in which case compensation according to the law may be obtained. (Included in Law No. 11,521, 2007)

CHAPTER V

OF THE PENAL AND ADMINISTRATIVE SANCTIONS

SECTION I

Of Crimes

Art. 14 Remove tissues, organs or body parts of a dead body or person, in violation of the provisions of this Law:

Penalty – imprisonment, from two to six years, and a fine, of 100 to 360 day-fine.

§ 1. If crime is committed expecting payments or promises of reward or some other vile reason:

Penalty – imprisonment, from three to eight years, and a fine, of 100 to 150 day-fine.

§ 2. If the crime is committed on a living person, and results for the offended:

I - the inability to deal with normal occupations, for more than thirty days;

II - danger of life;

III - permanent weakness of member, sense or function;

IV - premature delivery:

Penalty – imprisonment, from three to ten years, and a fine, of 100 to 200 day-fine

§ 3 If the crime is committed on a living person, and results for the offended:

I - inability to work;

II - incurable illness;

III - loss or uselessness of member, sense or function;

IV - permanent deformity;

V - abortion:

Penalty – imprisonment, from four to twelve years, and a fine, of 150 to 300 day-fine.

§ 4. If the crime is committed on a living person and death follows:

Penalty - imprisonment of from eight to twenty years, and a fine, of 200 to 360 day-fine.

Art. 15 Buy or sell tissues, organs or human body parts:

Penalty – imprisonment, from three to eight years, and a fine, of 200 to 360 day-fine.

Sole paragraph. It is liable to the same penalty that whom promotes, mediate, facilitate or receives any benefit from such a transaction.

Art. 16. Conducting transplant or graft using tissues, organs or parts of human body which are certain to have been obtained in breach of the provisions of this Law:

Penalty – imprisonment, from one to six years, and a fine, of 150 to 300 day-fine.

Art. 17 Collect, transport, store or distribute parts of the body which are certain to have been obtained in breach of the provisions of this Law:

Penalty – imprisonment, from six months to two years, and a fine, of 100 to 250 day-fine.

Art. 18. Conducting transplant or graft in breach of that establish in article. 10 of this Law and its sole paragraph:

Penalty – detention, from six months to two years.

Art. 19. Fail to restore the corpse, return him to a dignified state, for burial or fail to deliver or delay its delivery to family members or other interested:

Penalty – detention, from six months to two years.

Art. 20. Publish notice or public appeal in breach of provisions of art. 11:

Penalty – fine, from 100 to 200 day-fine.

Section II

Of Administrative Sanctions

Art. 21. In the case of crimes specified in the arts. 14, 15, 16 and 17, the health care entity and team of medical practitioners involved could be temporarily or permanently unauthorized by the competent authorities.

§ 1. If the entity is private, a competent authority shall establish a fine of 200 to 360 day-fine, and in case of recurrence, may have its activities suspended temporarily or permanently, without any right to indemnification or compensation from loss of investment .

§ 2. If the institution is private, it shall be forbidden to establish contracts or agreements with the Public Administration, as well as take advantage of credit from government related institutions or those in which the State is a shareholder, for the term of five years.

Art. 22. Entities that fail to keep on file records of transplants performed, according to art. 3. § 1, or fail to submit the reports mentioned in art. 3, §2 to the state board of the Unified Health System, are subject to a fine, of 100 to 200 day-fine.

§ 1. It is liable to the same penalty the health entity that would stop making the proper notifications expected from art. 13.

§ 1 It is liable to the same penalty the health entity that would stop making the proper notifications expected from art. 13. of this Law or forbids, obstructs or delays the assumptions set out in its sole paragraph. (Writing amended by Law No. 11,521, 2007)

§ 2. In case of recidivism, in addition to fines, the state board of the Unified Health System shall determine the temporary or permanently unauthorization of the health entity.

Art. 23. The social media company that may have distributed advertisements in breach of the provisions of art. 11 will be liable to penalties described in art. 59 Law No. 4117 August 27, 1962.

CHAPTER VI

OF FINAL PROVISIONS

Art. 24. (VETOED)

Art. 25. Opposed provisions are hereby revoked, mainly Law No. 8489, November 18, 1992, and Decree No. 879, July 22, 1993.

Brasilia, February 4, 1997, 176th Year of the Independence and 109th Year of the Republic.

Fernando Henrique Cardoso
Nelson A. Jobim
Carlos Cesar de Albuquerque

APPENDIX B – HISTORICAL EVOLUTION AND FEDERAL LEGISLATION FEATURES ON ORGANS TRANSPLANTATIONS IN BRAZIL.

Following, it will be presented a description of the historical evolution of the federal legislation on organs transplantation in Brazil, in addition to its features and regulations.[25] The aspects that contribute to transplantation organs access through the SUS and the hierarchical relationships between regulations were prioritized.

The introduction of each regulation will highlight relevant topics for the access analysis, addressing, as appropriate: principles of justice, jurisdictions for the execution of health services and competences to establish regulations, conditions that favor the access to transplantation organs, access criteria themselves, apart from the aspects related to information transparency about health services.

1 Evolution of transplants legislation in Brazil

The first regulation related to transplants in Brazil was Law No. 4,280, November 6, 1963 (BRASIL, 1963), that addressed organs or tissues removal from a deceased person for transplantation, provided that, previous to the cadaver organ withdrawal, the donor should have issued a written expressed consent, or there was no opposition from spouse or relatives to the second degree, or from religious or civil corporations regarding the destination of the remains.[26] That Law considered that the donor's expressed life will and the presumed consent was still subject to the determination of the family and specific institutions. In a technological context that, in general, allowed the use of corneas, arteries and bones, the issue of donation among living was not a matter of discussion, nor was brain death diagnosis, so there was no reference to a death proof criteria, being the only requirement that death was righteously proven and certified by the institution's director where the death took place or by his legal substitutes.

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[25] The description of the historical development of legislation on organ transplantation was based on data from the CPI report on human organs trafficking (CÂMARA DOS DEPUTADOS, 2004a).

[26] Resulted from the Law Project No. 4,542, 1958, authored by congressman Adylio Martins Vianna.

In the absence of a public transplantation program, organ donation was made to a specific person or to an approved and recognized state level institution, being the directors of such establishments responsible for the weekly detailed reporting on donors and recipients to the Public Health Director. Expenses related to the organ withdrawal and transplantation were responsibility of the interested person or of the Ministry of Health, when the receiver was officially admittedly poor. The Law did not mention the gratuitousness of donation.

That Law was replaced by Law No. 5,479, August 10, 1968 (BRASIL, 1968), which made dispositions on tissues, organs and body parts withdrawal and transplantation for therapeutic and scientific purposes.[27] Besides transplantation, the use of cadavers for scientific purpose was regulated. Reflecting technological progress at that time, free *post mortem* body parts donation became explicit and donation among living allowed, for humanitarian and therapeutic purposes. The last one, however, was not associated to gratuitousness or requirement of kinship or court order, needing only the donor’s consent, limiting withdrawal to double organs or tissues that would not harm him and mediating proof of therapeutic need for the receiver.

On death verification, irrefutable death proof was required. The presumed consent was not accepted, being one of the following conditions demanded: express manifestation of the donor's will, being required a public instrument for the case of incapable or illiterate donors; written authorization of spouse, together with successive descendents, ascendants and collateral, or the religious or civil corporations responsible for the destiny of the remains and in absence of any other responsible person, permission from the director of the institution were the death took place, being even necessary this authorization in the previous conditions.

That Law allowed the allocation of the organ for a specific person, and, in case of incompatibility, the provision to another recipient at the discretion of the chief doctor of the institution, with prior administrative provision or authorization of who is granting rights. Organ removal with crime suspicion was forbidden and punishment and penalties were established, with imprisonment of one to three years. That Law was never regulated by the Executive Power, who also did not structure an organ transplantation program.

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[27] Resulted from Law Project No. 1,309, 1968, authored by Executive Power.

With the introduction of the 1998 Federal Constitution, its article 199, paragraph 4, granted the law the role of providing on the conditions and requirements that enable organ, tissues and human substances removal for transplant purposes, forbidding any kind of commercialization (BRASIL 1988). The law that regulated that constitutional mechanism was the Law No. 8,489, November 18, 1992, revoked, that addressed on tissues, organs and human body parts withdrawal, for therapeutic and scientific purposes (BRASIL, 1992). That Law replaced by amendment the use of the word "cadaver" by the expression "human body", stressing, thereby, that it also regulated donation among living, although the previous Law also regulated this donation type.[28] The statement that *post mortem* body parts donation should be free was maintained.

Following the constitutional determination, that Law also made explicit the issue on free donation among living for humanitarian and therapeutic purposes; limiting donation to grandparents, grandsons, parents, sons, brothers, uncles, nephews, cousins even to second degree, brother in law and spouses; requiring court authorization for donation to non related persons. Donor’s authorization over the withdrawal object, limitation withdrawal to double organs or tissues that may not harm the donor and proof of receiver's therapeutic need were kept.

Regarding the consent for benefiting from organs the rule admitted the express desire of the disposer manifested in life, through a personal or official document and in its absence, organs withdrawal procedure would be held if there were no expressions stating otherwise by spouse, ascendant or descendent. Thus, it considered the express donor’s living will and the presumed consent regulated by the determination of relatives, which, as noted earlier, it was already current in Law No. 4,280, 1963, and abolished in 1968.

The regulation required proficiency from the public or private transplantations institutions and registration at the Ministry of Health. Medical records detailing surgical acts should be kept filed in the institutions, and an annual report, containing the recipients names, should be sent to the Ministry of Health. Punishments for infractions were also provided with penalties of imprisonment from one to three years. It was included the compulsory notification for public and

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[28] Resulted from Law Project No. 1,169, 1988, authored by congressman Carlos Mosconi

private hospitals of all brain death proven cases. However, proof of death criteria were not mentioned. Lima, Magalhães and Nakamae (1997) noted that the presidential veto left the law without clear indications about brain death. There was also no reference to organs allocation criteria for cadaver withdrawals and the restriction of organ withdrawal in the case of crime suspicion was removed.

Decree No. 879, 22 July, 1993 (BRASIL, 1993), revoked, regulated, through its 33 articles, Law No. 8,489, 1992, filling out conceptual gaps which were not addressed by the Law, including references to brain death definitions by the Federal Medical Council (CFM) and financing through the SUS.

Law No. 9,434, February 4, 1997, the Transplantation Law in force, provides on organs, tissue, and human body parts removal for transplantation purposes and treatment (BRASIL, 1997A).[29] Its summary excluded the use of tissues for scientific purposes, though it is worth mentioning that a specific law addressing the use of not claimed cadavers for scientific purposes was already effective, Law No. 8,501, November 30, 1992.

The Transplantation Law was explicit in allowing free disposal of tissues, organs and human body parts, in life or *post mortem*, for transplantation and treatment purposes. Some provisions of Decree No. 879, 1993, where included in the Law, such us: the non-inclusion of blood, sperm and ovule between the tissues to which the Law refers to; the admittance of the presence of a doctor trusted by the family of the deceased in the act of brain death proof and certification; the permission so that a legally incapable individual, with proved immunological compatibility, can make a donation for the cases of bone marrow transplants; and the restrictions of donations from pregnant women.

That Law was amended by 32 Provisional Measures until the year 2001, because of the controversy on the presumed consent for organ donation (when no explicit expression of the contrary were made during the life of the donor).[30] Decree No. 2,268, June 30, 1997, still in

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[29] Resulted from the Senate bill of law No. 6, 1995, authored by senator Jose Eduardo Dutra.

[30] The first Provisional Measure was No. 1,718, October 6, 1998 and the last one was No. 2,083, February 22, 2001.

force, regulated Law No. 9,434, 1997, of which most important was the SNT creation and the introduction of the expression “recipients single national list" (BRASIL, 1997c). That expression was incorporated to the text of the Transplantation Law as “single waiting list” (without regional spheres distinctions) by Law No. 10,211, Mach 23, 2001, that also included amendments related to family authorization as an organ donation requirement. Recently, the Transplantation Law was amended by Law No. 11,521, September 18, 2007, to allow the withdrawal, within the SUS, of organs and tissues of donors who are in health institutions non-authorized to perform transplants. More details on current legislation will be presented in the next item.

2 1988 Federal Constitution

Considering the Constitution the highest regulation in the legal hierarchy, relevant general principles for an equitable access to health services will be detailed, through identifying: social justice principles, principles of access to actions and health services and of jurisdictions for execution and regulation of the health policy.

The 1988 Constitution of the Federal Republic of Brazil (BRASIL, 1988) displays principles of social justice that give orientation to public policies implementation throughout the country. Already in the preamble, it is emphasized that our democratic State purpose is to ensure social and individual rights, including freedom, safety, welfare, development, equality and justice as society’s supreme values. The concern with social justice is expressed in the fundamental objectives of our Republic: eradicate poverty and marginalization and to reduce social and regional inequalities (article 3, item III). The consideration of equality is highlighted in article 5, which establishes that all are equal before the law, without distinction of any kind, guaranteeing Brazilians and foreign residents, the inviolability of the right to life, freedom, equality, safety and to property. The reluctance to unequal treatment of Brazilian can be seen in the impossibility for the Union, the States, the Federal District and Municipalities to create distinctions between Brazilians or preferences among them (article 19, item III).

The association between the liberal principles of freedom and equality and social justice can be found in mechanisms that address the social and economic order. Article 170 establishes that economic order, based on the value of human labor and free initiative, has as purpose to assure everyone with a dignified existence, in accordance to the dictates of social justice. Article 193 indicates that social order is based on supremacy of work, and welfare and social justice as aims. The translation of these principles in the organization of the social policy is observed in article 194, which stipulates that social security comprehends a set of integrated actions of public policy and society initiatives, aimed at ensuring health rights, welfare and social assistance.

Social security, were the health policy is placed and, as a consequence, of organ transplantation, must be organized, according to the Constitution, based on seven objectives (article 194, sole paragraph), among which stand out: universality of coverage and assistance; the selectivity and distributive concern in the provision of benefits and services and equity in the way of costs contribution. It is worth mentioning that this is the only article of the Constitution that mentions the expression “equity”.

The Constitution also establishes principles of access to health services, related to social justice. Health is a right for all and duty of the State and it shall be ensured by means of social and economic policies aimed at reducing the risk of disease and other disorders and offering universal and equal access to services and actions for its promotion, protection and recovery (article 196). The Congress Representatives indicated that the access to a wide range of public health actions and public services would be promoted through a regionalized and hierarchical network, forming a single system (article 198), which has among its organizational guidelines: decentralization, with a single head in each sphere of government (item I); integral assistance, with priority to preventive actions, without prejudice of health services (item II); and community involvement (item III).

One way of access to health services, generally not available to the poorest is also regulated by the Constitution. Article 199 establishes that health care is open to private initiative. It is interesting to note that in this article, devoted to private initiative, specific determinations for the organ transplantation interest have been included. Paragraph 4 of article 199 specifies that the law will make provisions on the conditions and requirements that facilitate organs, tissues and human substances withdrawal for transplantation purposes, research and treatment, as well as the collection, possessing and transfusion of blood and its sub products, being prohibited any kind of commercialization. Besides the reference to the need of drafting a law that would facilitate organs transplantation, forbidding organs commerce complies a system in which access to transplantation organs is based on solidary donation.

Some constitutional mechanisms that prioritize access to health services to certain groups are worth mentioning. Article 227 states that is family, society and State's duty to ensure children and adolescents, with absolute priority, a series of rights, of which among them we find the right to health. This prioritization may happen through State's integral assistance health programs promotion for children and adolescents, admitting the involvement of non-governmental entities (article 227, paragraph 1). Item I of the referred paragraph determines the application rate of public resources to be destined to maternal and child health and assistance.

With regard to jurisdictions for the execution and regulation of the health policy, it is defined the joint jurisdiction of the Union, States, Federal District and Municipalities to look after health (article 23, item II), being the Municipalities responsible for providing the population with health services, with the technical and financial support of the Union and States (article 30, item VI). To perform that activity previsions were taken for the Union, States and Federal District jurisdictions to legislate concurrently on the protection and defense of health (article 24, item XII). Meanwhile, within the competitive legislation scope, Union's jurisdiction is limited to setting general standards, which does not exclude the supplementary jurisdictions of the States (article 24 item XII, paragraphs 1 and 2).

On regulatory jurisdictions of the Executive's members, are relevant the President of the Republic exclusive jurisdiction to sanction, promulgate and disclose laws, as well as to dispatch decrees and regulations for their accurate execution, in addition to the ability to veto bills partially or totally (article 84, items IV and V). The State Ministers received the authority to send instructions for the execution of laws, decrees and regulations (article 87, item II, sole paragraph). Regarding health policy regulation, article 197 states that is the public power that must regulate, inspect and control the SUS and article 200 makes references to the regulation by law of that system's jurisdiction.

3 Health Organic Law (Law No. 8,080, September 19, 1990)

Law No. 8,080, September 19, 1990, makes dispositions on the conditions for promotion, protection and recovery of health, the organization and functioning of the involved services and gives other providences, regulating the SUS. Also for this Law will be highlighted: social justice principles, principles of access to actions and health services and of jurisdictions for execution and regulation of the health policy.

Article 3 of Law No. 8,080, 1990, states that the population health levels express the social and economical organization of the Country and that health has decisive and conditioning factors, such us: food, housing, basic sanitation, environment, labor, income, education, transport, leisure and the access to essential goods and services. That Law also mentions, among the objectives of the SUS, the identification and disclosure of conditioning and determinant factors of health (article 5, item I). The association of health to conditioning and determining social and economic factors, exhibit the concern with social justice principles already identified in the Constitution.

Regarding the principles of access to health, following the Constitutional determination, that Law reaffirms the right to health, the duty of the State, the universal and equal access to health action services, stressing, however, that State’s duty does not exclude the obligation of persons, families, businesses and society (article 2, paragraph 2). As to the SUS's scope of action, it is included in its field of action, the execution of integral therapeutical assistances actions, including pharmaceutical, which refers to the “integrality” (comprehensiveness) of the access to health services (article 6, item I, line d).

The following access principles are stated (article 7): the universality of access to health services in all levels of assistance (item I); integral assistance, understood as a set of articulated and continued preventive and healing, individual and collective actions and services, demanded for each case in all levels of the system’s complexity (item II); equality in health assistance, without prejudices or privileges of any kind (item IV); disclosing the informations regarding the health services potential and their availability to the user (item V); the use of epidemiology for establishing priorities, the allocation of resources and programmatic orientation (item VII); the political-administrative decentralization, with a single head in each government sphere, stressing in the decentralization of services for municipalities and regionalization and hierarchization of the network of health services (item IX, line a and b).

The constitutional principle of the organization of the SUS in a regionalized and hierarchical way in increasing complexity levels is reaffirmed (article 8). An expression not mentioned in the Constitution, but of great importance to public services access, was included in article 43 of Law No. 8,080, 1990, which states that free health services actions are kept within the public services area, making exceptions on contracts and agreement clauses established with private entities.

Regarding the jurisdictions for the execution and regulation of the health policy, the Health Organic Law emphasizes the scope of the SUS national direction in the execution of the health policy, among which stand out some relevant to the transplantation policy: define and coordinate the systems of integrated networks of high complexity assistance; identify the state and municipal services of national reference for the establishment of technical patterns of health assistance; control and monitor procedures, products and substances for the interest of health and watch, control and asses the actions and health services, with observance of the state and municipal jurisdictions (article 16, items III, XI, XII and XVII).

Regarding regulation, article 15 sets among the common powers of the Union, States, Federal District and Municipalities, within their administrative area: the development of technical regulations and the establishing of quality standards and costs parameters that characterize health assistance (item V); the development of regulations to lead the activities of private health services, bearing in mind their public relevance (item XI) and the drafting of technical-scientific regulations of health promotion, protection and recovery (item XVI). It was established as jurisdiction of the SUS national head: drafting legislation to regulate the relationships between the National Unified Health System (SUS) and the private health assistance services hired (article 16, item XIV). For the case of the state management of the SUS it was established its jurisdiction for drafting regulations, complementary in character, for the control and assessment of the health services and actions (article 17, item XI). Regarding the municipal management of the SUS it was established jurisdiction to completely regulate the action and public health services with its scope of action (article 18, item XII).

4 Transplantation Law (Law No. 9,434, February 4, 1997)

Law No. 9,434, 1997 (shown in appendix A), modified by Law No. 10,211, March 23, 2001, and by Law No. 11,521, September 18, 2007, deals specifically with organ transplantation. In the light of such specificity, the topic groupings used in the analysis of those laws were modified to address: principles of access to transplantation organs, mechanisms that impact on availability of transplantation organs, the structuring of the transplantation program, information transparency on transplants and sanctions related to breaches to the Transplantation Law.

The Transplantation Law is clear in limiting the scope of its mechanisms not being applicable to blood, sperm or ovule. That inclusion is similar to international regulations, for example, the additional protocol of the Convention on Human Rights and Biomedicine regarding organs and human tissue transplants (COUNCIL OF EURPE, 2002) which states that reproductive organs, embryo and fetal tissues or blood and their derivates are not applicable. However, apart from solid organ transplants, the Transplantation Law resolutions include cornea and bone marrow transplants.

Within the scope of the principles of access to organs transplantation, following explicit constitutional determination, the Law reaffirms that the availability of tissues, organs and human body parts, living or post mortem for transplant and treatment purposes is free (article 1) and explains that it does not cover blood, sperm and ovule (article 1, sole paragraph). Article 9 allows a special condition of access, as it does not comprehend a waiting list. A legally capable person can make his own living body tissues, organs and parts freely available for therapeutic or transplant purposes to spouse or consanguineous relatives until fourth grade, through authorization on the donor's part (paragraph 4), or to any other person, through court order, excepting bone marrow. It is important to stress that before the changes made in 2001, the Law did not mention restrictions related to the kinship degree nor mentioned court authorization.

In article 9 mechanisms are found that: only admit organ donation whose withdrawal will not cause harm to the donor and respond to a therapeutic need proven indispensable for the receiver (paragraph 3), allows donation revocation at any time before its performance (paragraph 5), require especial procedures for the legally incapable donors (paragraph 6), forbid pregnant women to make available tissues, organs or parts of her living body, with exception of tissue to be used in bone marrow transplants and the act may not offer risk for her health or the fetus (paragraph 7) and recognizes that autologous transplant relies on the individual consent, documented in his medical record, or if legally incapable, of one of his parents or legal guardians (paragraph 8).

Organs access for transplantation through a waiting list is regulated in article 10 of Law 9,434, 1997, which states that the transplantation or graft will be only performed with the receiver's expressed consent, thus placed in single waiting list, and only after advice on exceptionalities and procedure risks. This article addresses the legally incapable receiver consent whose health conditions hinders or undermines a valid expression of his willingness, to allow that the consent can be given by one of the parents or legal guardians (paragraph 1). It also specifies that subscription to the single waiting list does not grant to the alleged receiver or his family subjective rights to compensation, if the transplantation is not performed due to alterations in the state of the organs, tissues or parts, which were assigned, caused by accident or incident in their transport (paragraph 1).

Some mechanisms of the Law promote public access and discourage attempts to particularize access. Article 11 forbid the circulation, through any mass social communication media any piece of announcement that may configure: (i) advertising from authorized institutions for performing transplants or grafts, related to these activities; (ii) public appeal for the donation of tissue, organ or body part for a certain person, identified or not, with the exceptions expressed in the sole paragraph; (iii) public appeal for fund collection for financing transplant or graft in benefit of private individuals. It is also indicated that national, regional and local management boards of the SUS will carry out regular public enlightenment campaigns regarding the benefits expected from the Law and stimulate organ donations (article 11, sole paragraph).

It is important to highlight aspects of that Law which, although not directly related to access principles, constitute mechanisms that have influence on transplantation organs availability. For example, article 4 from Law 9,434, 1997, addresses the removal of tissues, organs and body parts from deceased persons for transplantation or other therapeutic purposes, which will rely on the authorization of spouse or relative, of legal age, privileged succession line, ordinary or collateral, up to the second degree, in writing and signed by the two witnesses present on death verification. This mechanism, in a way, limits what was expected from the original article of 1997, which adopted the presumed donation consent by all deceased individuals, unless there was explicit indication of a non-donor condition, in order to increase transplantation organs availability.

Other mechanisms of Law No. 9,434, 1997, that regulate the *post mortem* removal of tissues, organs or body parts, establish that such withdrawal: can be made, in the case of a legally incapable person, as long as explicitly permitted by both parents, or legal guardians (article 5); is forbidden, for unidentified persons (article 6); that in case of death without medical assistance, death due to non-defined causes or other situations in which any indication of verifying the medical cause of death may exist, shall only be held after authorized by the death verification service pathologist responsible for the investigation and quoted in the autopsy report (article 7, sole paragraph).

Another determination that aims to expand the transplantation organs availability can be found in article 13, which requires for all health establishments to report, to the organs notification, collection and distribution centrals of the proper federated unit, brain death diagnosis in patients treated by them. Law No. 11,521, 2007, modified its article 13, so that, after brain death notification, health institutions not authorized to remove tissues, organs or human body parts bound for transplant or treatment should allow immediate dismissal or make their facilities available and provide for the necessary operational support for the transplantation removal medical surgical teams, in which case they will be compensated as provided by law.

As for the transplantation program structuring, some mechanisms related to logistic and human resources indispensable to their adequate operation stand out. The performance of transplant or graft of tissues, organs or human body parts will only be performed by health entities, public or private, and by removal and transplantation medical-surgical teams previously authorized by the national management board of the SUS. The performance of these procedures can be only authorized after the performance, on the donor, of all the screening test of infection and infestation diagnosis required in regulatory standards dispatched by the Ministry of Health (article 2, sole paragraph).

The removal of *post-mortem* tissues, organs or human body parts for the purpose of transplantation or treatment should be preceded by a brain death diagnosis, verified and recorded by two medical physicians neither of whom should be a member of the team of medical practitioners participating in the removal nor transplantation, using clinical and technological criteria defined by resolutions of the Federal Medical Council (article 3).

The Transplantation Law has mechanisms related to transplantation information transparency and disclosure of related activities. Medical records, containing the results or statements regarding brain death diagnosis and copies of specific documentation, such as those detailed in surgical acts regarding transplants and graft, should be kept in the files of the institutions for a minimum five year period (article 3, paragraph 1). Moreover, those institutions that perform transplants should submit an annual report containing the names of the recipient patients to the state management organ of the SUS (article 3, paragraph 2). The acceptance of the presence of a medical practitioner whom the family of the decedent trusts upon proof and attestation of brain death (article 3, paragraph 2) also promotes transparency to the process of organ capture for transplant.

Sanctions related to breaches of the Transplantation Law, receive special attention, since there are mechanisms that punish crimes related to the illegal access to transplantation organs, and those that affect the conditions of access and information transparency. The Law typifies crimes related to: the removal of tissues, organs or human body parts or cadaver (article 14); the purchase or selling of organs (article 15); the performance of transplant or graft using tissues, organs or human body parts obtained in breach of the Law (article 16); the collection, transport, storage or distribution of human body parts obtained in breach of the Law (article 17); and the performance of transplant or graft in breach of what stated in article 10 of the Law (article 18).

Apart from criminal sanctions administrative penalties were provided. In the case of crimes provided in articles 14 to 17, the health institution and the medical-surgical teams involved may be temporarily or permanently unauthorized by competent authorities (article 21). Another administrative sanction states that the institutions that fail to keep on file records of the performed transplants, according to article 3, paragraph 1, or that fail to submit the mentioned reports in article 3, paragraph 2, to the state management board of the SUS, are subject to fine, of 100 to 200 day-fine (article 22). It is liable to the same penalty the health establishment that would stop making the brain death notifications or forbids, hinder or delays the donor transference or the removal of organs procedures (article 22, paragraph 1) In the case of recurrence, in addition to fines, the state management board of the SUS may temporarily or permanently unauthorize the institution (article 22, paragraph 2). Article 23 states that the social media company that discloses an announcement in breach of article 11 will be subject to the penalties established in article 59 of Law 4,117, August 27, 1962.

5 Decree No. 2,268, June 30, 1997

Decree No. 2,268, June 30, 1997, regulated Law No. 9,434, February 4, 1997, and revoked Decree No. 879, July 22, 1993. Considering that it is an infra-legal regulation, it is guided by the already established principles in the previously analyzed regulations. In fact, most of its mechanism addresses the necessary conditions for the proper operation of the organs transplantation program, so that its analysis included topics related to the implementation of the transplantation policy, such us: structuring of the transplantation program, principles of access to organs transplant, regulation of the transplantation policy, mechanisms that influence on the transplantation organs availability, information transparency on transplants and sanctions related to breaches to the Transplantation Law.

The structuring of the transplantation program is treated with emphasis by Decree No. 2,268, 1997, which represents the milestone in the Brazilian transplantation policy, since it established the National Transplantation System - SNT, aiming to develop the process of capture and distribution of tissues, organs and parts removed of the human body for therapeutic purposes, including activities of brain death verification in any part of the national territory and the determination of the destiny of the tissues, organs and parts removed (article 2). The functions of the SNT central board were trusted to the Ministry of Health, to be exercised by means of its own unit. Article 4 expressed the attributions of that board, among which are highlighted: the drafting of standards and regulations (item II); the management of the recipient single national list (item III); the authorization of heath care institutions and specialized teams (item IV); and the accreditation of Organs Notification, Capture and Distribution Centrals – CNCDO (item VIII).

The jurisdictions of the CNCDOs are detailed in article 7 and include: the coordination of transplantation activities in the states scope; the inscription and classification of potential receptors; the communication with the SNT regarding the receivers national list; the receipt of brain death reports; the transport of transplantation tissues; the routing of annual reports to the SNT; the control and supervision of transplantation activities and application of penalties stipulated by law. That article also deals with the creation of regional centrals. The Municipality considered as administrative region pole may establish a CNCDO, that will be linked to the state CNCDO.

It is required the prior and expressed authorization from the Ministry of Health for specialized teams and health institutions, public or private for performing transplants (article 8). The authorization will have a two years validity, renewable for equal and successive periods, once verified the compliance with the requirements established by the Decree (article 8, item 5). The requirements for authorization, essential to the quality of the services offered, are detailed in articles 9 to 13. Articles 16 to 20 deal with the procedures on organs removal.

Article 24 states that the performance of transplants will only be authorized after the fulfillment, by the donor, of all the screening tests for infection and disease diagnosis, especially regarding blood, being observed, on this, including those required in the donation screening, according to Law 7,649, January 25, 1988 (on registration of blood donors and carrying out laboratory tests on the collected blood) an regulations of the Executive Power.

Article 33 of Decree No. 2,268, 1997, demonstrate concern with the viability of the execution of transplantation activities in providing remuneration of medical procedures through figures set in a table approved by the Ministry of Health. The single paragraph of this article also states that the brain death diagnosis procedures, the donor homeostatic support and of the withdrawal of tissues, organs or parts, performed by a private health institution, may, jointly or separately, be also financed, independently to the contract or agreement, through a receivers declaration, or, in the case of death, his family's, in the presence of CNCDO officials, that such services were not charged.

Principles of access to organs transplantation are addressed by Decree No. 2,268, 1997, by establishing as the SNT duty: the determination of the destination of tissues, organs and parts removed (article 2, sole paragraph), the management of the single national list of receivers, with all the indications necessary for the search, in all the national territory, of tissues, organs and parts compatible with the organic conditions (article 4, item III) and the Decree regulation (article 4, item II). The Decree also provided guidance on the operation of the single waiting list, since it clarified the roles of the CNCDO.

The CNCDO is responsible for the inscription of potential receivers in the state scope, with all the necessary indications for its rapid emplacement and the compatibility verification for the transplant or graft of tissues, organs and parts available, that requires (article 7, items I and II). The CNCDO must classify the receptors and group them according to organic compatibility for the transplant of tissues, organs or body parts that requires, in the order established by the subscription date, providing them with the necessary admission receipt (article 7, item III). The CNCDO is compelled to notify the central board of the SNT the entries carried out to organize the national list of receivers (article 7, item IV).

It was also included the notification to the SNT regarding the tissues, organs and parts not used between the recipients enrolled in its records, for use among those related to the national list (article 7, item VII). Receivers enrolled in the regional CNCDOs, whose data has been previously referred to the state CNCDOs, may receive tissues, organs and parts withdrawn within the scope of the regional board (article 7, paragraph 2). The criterion of therapeutic need was established, since transplants can only be performed in patients with progressive disease or disability, irremediable by other therapeutic techniques (article 23).

Article 24 states other access criteria: transplantation will not occur for tissues, organs and parts of bearers of diseases that appear on exclusion lists dispatched by the central board of the SNT (paragraph 2); the transplant will still depend on the necessary tests to verify blood compatibility and histocompatibility with the subscribed receptor, in the waiting lists of the CNCDO (paragraph 3); the CNCDO, according to the informations that will receive from the withdrawal team, will indicate the destination of tissues, organs and removed parts, in strict compliance with the order of the receivers enrolled, with compatibility to receive them (paragraph 4); the inscription order, as provided in the previous paragraph, may be abandoned, if, because of distance and transportation conditions, the estimated time for the selected receiver allocation becomes inaccessible for the transplantation of tissues, organs or parts removed or they may be required by someone in the situation of death imminence, according to the assessment of the CNCDO, observed the criteria establish by the central board of the SNT (paragraph 5).

Finally, the Decree introduced a series of mechanisms in order to unify the access to transplantation organs and compel the use of the single list in each central. Article 30 determines that from the validity of the Decree, tissues, organs or parts shall not be transplanted to a receiver which has not been designated by the CNCDOs. In the case of absence of CNCDO, the jurisdictions given by the Decree, may, for a maximum period of one year, be exercised by the Health Departments of the States and the Federal District. Inscriptions in more than one CNCDO as receptor of tissues, organs or parts is not allowed and if double entry verified, the central board of the SNT will notify the receiver to choose among one of them, within a fifteen days period, of which overdue, without reply, will be excluded of the latest list and will communicate the fact to the CNCDO, where the subscription took place, for equal precaution (article 31).

It is also established that subscription in a determined CNCDO will not prevent the receiver to undergo a transplant or graft in any authorized health institution if, by the list under the control of the central board of the SNT, states that she (he) is more suitable to receive tissues, organs or removed parts not used, from any source (article 31, paragraph 2). Finally, inscriptions made through the CNCDO or similar institutions, which were already working in the states of the Federation, were accepted if informed to the central board of the SNT and updated with the respective dates of inscription (article 32).

With respect to the special access represented by donation with living donor, article 15 states that any legally capable person may dispose tissues, organs and parts of his own body to be removed, in life, for transplantation or therapeutic purposes. Paragraph 4 of this article establishes that the donor will specify, in writing, and signed by two witnesses, which tissue, organ or part of his body is being donated for transplantation or graft and to which identified person, all of which should be properly identified, even through postal address. This document will be dispatched, in two ways, one of which will be to the board of the Public Ministry related to the donor's legal address, with receipt tracking in the other one, as condition to perform the donation (paragraph 5). Paragraph 3 of article 15 requires for kidney withdrawal, proof of, at least, four compatibilities regarding human leukocyte antigens (HLA), except between spouses and consanguineous, in straight or collateral line, including up to the third degree.

Decree No. 2,268, 1997, addresses the regulation of the transplantation policy, giving the SNT the duty of dispatching rules and technical regulation to standardize the procedures established by Decree (article No. 4, item II). That function is reaffirmed by the indication that the Ministry of Health is authorized to dispatch instructions and regulation necessary to the Decree’s implementation (article 28).

As for the mechanisms that impact on availability of transplantation organs, article 14 of the Decree deals with the presumed organs donation, however, with the legal amendments made in 2001 this type of donation was abolished, and this mechanism cannot be applied.

Among the mechanisms of Decree No. 2.268, 1997, related to transplants information transparency are the CNCDO annual reports to the central board of the SNT on the development of transplantation activities within their scope of action (article 7, item VIII) and the need that those records contain specific data of the dead or alive donor and the receiver (article 25). The records should be kept for five years in the institutions where procedures were performed and, expired that procedural term they may be confined to the responsibility of the state CNCDO head of the responsible institution for the alleged procedure, remaining available for a 20 years period, for any possible criminal investigation (article 26).

Regarding to sanctions related to breaches on the Transplantation Law, article 7 of the Decree provided for jurisdictions of the CNCDO related to sanctions enforcement, being them: application of administrative penalties for violation of provisions of Law No. 9,434, 1997 (item X); precautionary suspension, for a maximum period of sixty days, of institutions and specialized teams, before or during the course of the infraction investigation process, if, by the available evidence, there might be founded reasons of life risks or intolerable injury to people's health (item XI); communication of penalty enforcements to the central board of the SNT (item XII) and actions of the Public Ministry of the State and other public competent institutions, to restraint offenses whose investigations are not comprehended in their area of competence (item XIII).

6 Ordinance No. 3,407, August 5, 1988

Ordinance No. 3,407, 1998, from the Ministry of Health, approves the technical regulation on transplantation activities and provides on the National Coordination of Transplants. Its presentation will use the same topics covered in the previous item, excluding those related to sanctions. We must consider that this type of regulation is hierarchically inferior to decrees and laws.

Regarding the structuring of the transplantation program, the Ordinance established a period of 6 months to revalidate credentials and authorizations for the CNCDOs, specialized teams and health institutions according to the technical regulation annexed to the ordinance (article 4). That regulation established the Technical Advisory Group (*Grupo Técnico de Assessoramento* – GTA), composed of members and substitutes, appointed by the Health Assistance Secretary, for a period of two years, in order to give advice to the SNT (article 2). The GTA was granted jurisdiction to: develop guidelines; identify quality standards for the sector; analyze the reports with data on the SNT's activities and give opinion on authorization cancelation processes of institutions and teams for organs withdrawal and transplants or graft performance (article 2, paragraph 1).

The composition of the GTA was subject to modification by Ordinance No. 1,807, August 2, 2006, so that is currently composed by the National Transplantation System (SNT) General Coordination and representatives from: the Federal Medical Council *(Conselho Federal de Medicina)*; the Brazilian Medical Association *(Associação Médica Brasileira)*; Public Ministry *(Ministério Público)*; National Sanitary Surveillance Agency *(Agência Nacional de Vigilância Sanitária);* the Brazilian Society of Bioethics *(Sociedade Brasileira de Bioética)*; the National Commission of Ethics in Research *(Comissão Nacional de Ética em Pesquisa)*; the National Board of Health Departments *(Conselho Nacional de Secretários de Saúde)*; and the Organs Notification, Capture and Distribution Centrals *(Centrais de Notificação, Captação e Distribuição de Órgãos)* - selected by elective process among its equals.

Another relevant structure for the SNT was regulated by article 3 of the technical regulation annexed to Ordinance No. 3,407, 1998, which establishes that the Health Departments of the States and Federal District or equivalent bodies, integrated with the SNT, in accordance to dispositions of article 5 Decree No. 2,268, 1997, must include a State Transplantation Coordination *(Coordenação Estadual de Transplantes).* The State Transplantation Coordinations were granted with jurisdictions to (paragraph 1): draft complementary regulations; authorize the creation of regional CNCDOs; forward CNCDO's accreditation requests to the SNT; supervise the operation of the CNCDO in their area of competence; send annual reports to the SNT Coordination and designate the intra-hospital coordinators for organs, parts and tissue capture. The activities of the Transplantation State Coordination can be surrogated, in whole or part, to the CNCDO (paragraph 2).

Regarding the structuring of the CNCDOs, each Federated Unit may create a CNCDO provided that in its territory exist specialized teams and health institutions authorized to carry out brain death diagnosis, remove organs and perform transplants and grafts (article 4 of the technical regulation of the Ordinance). Only the States with a population exceeding six million people may create regional CNCDOs (article 4, paragraph 1). The area of competence of the

Regional CNCDO must have minimum population of three million inhabitants (article 4, paragraph 2).

Article 10 of the technical regulation, annexed to Ordinance No. 3,407, 1998, detailed the requirements for the performance of specialized teams, according to the organs to be transplanted: renal, liver, lung, heart, cornea, bone-fasciocutaneous-cartilage-muscular tissues and skin. It also makes general demands for new types of transplants or grafts. Articles 11 and 12 deal with the general conditions required for the approval of health institutions. Articles 13 and 14 describe the specific conditions in order to proceed with organs withdrawal. Article 15 specifies three classes of transplants, for the purposes of the requirements described in the Ordinance: I – of corneas and others not specified; II – heart valves, bone-fasciocutaneous-ligament tissue and skin; III – of kidney, liver, lung and heart.

Article 16 provides for specific requirements for health institutions in accordance to the referred transplantation types. It is observed that requirements are higher for class III and lower for class I. Article 17 states requirements of the conditions for the transplantation performance in each specified organ. Articles 18 and 32 deal with the routine of authorizations. It was stressed the need to revalidate the authorization of institutions and teams for withdrawal and transplantation of organs, parts and tissues every two years.

Regarding the principles of access to organs transplantation, is relevant, to the object of this study, verify that in the preamble of Ordinance No. 3,407, 1998, becomes explicit the consideration of the guarantee in the equity of distribution, for patients, of organs and tissues for transplant or graft. It is also recorded that within the requirement for the CNCDO accreditation is the requirement of copy of the criteria adopted for the single list system in relation to each type of organ part or tissue (article 5, paragraph 1, item II).

The technical regulation uses, for the first time, the expression “single list system”, specifying that it consists of the set of specific criteria for the distribution of each type of organ or tissue for recipients (article 33). There is an inaccuracy in this article, since it makes reference related to the list, referring to article 3 of the Ordinance, however the word list, does not appear in the text of the Ordinance, but in the article 5 of the technical regulation.

Article 34 of the technical regulation states that all organs or tissues obtained from a cadaver donor, and that for its allocation accounts for receptors in the waiting regime, must be distributed according to the single list system. Article 35 establishes that the subscription of patients within the single list system, as provided in items II and III of article 7 of Decree No. 2,668, 1997, will occur in the CNCDO with jurisdiction in the area of his residence by the health institution or by the team responsible for her (his) assistance.

The same article from the technical regulation indicates that the person's subscription date in the single list is the reference for the beginning of waiting time registration (article 5, paragraph 2). The inscription transference from one CNCDO to another one may happen through receiver's authorization, leaded by the institution or team that will be assisting her (him) (article 5 paragraph 3). Existing receiver's inscription transference, the previous subscription date will be considered for waiting times calculation (article 5, paragraph 4).

Article 36 of the regulation states that the single list system, for each type of organ, tissue or part, has three integration levels expressed in national, state and regional lists. The national lists will be conformed by the set of the state lists (paragraph 1). The state lists are composed by the set of the CNCDO lists under their jurisdiction (paragraph 2). Regional lists are made up by the patients subscribed to the regional CNCDO (paragraph 3). By means of cooperation mechanisms officialised between States, the state or regional lists may include patients from a whole other State or region within it (paragraph 4). For the formation of a list for a specific organ or tissue, the CNCDO must hold, in the territory of its jurisdiction, an authorized health institution and specialized team for the performance of the corresponding transplant or graft (paragraph 5).

The organs distribution criteria are addressed in article 37 of the technical regulation, which sets the operating mechanisms of the single list system for such distribution. The clinical data of the potential recipients enrolled in the system constitute the technical registry referred to each type of organ, part or tissue. For each organ, part or tissue available a correlation between the anthropometric and immunologic characteristics of the cadaver donor and the corresponding technical registry must be done, by means of specific criteria referred to each organ, part or tissue type, for recipient precedence ordering (article 37 paragraph 1). When the receiver needs various organs, the distribution criteria will be defined for the organ for higher demand within the single list system (article 37, paragraph 2). In the state scope, additional criteria may be adopted, complementary in character, so as not to surpass those referred in the first paragraph of article 37 (paragraph 3).

The precedence determination criteria specific to the distribution of each type of allocated organ, part and tissue are presented in article 39. Excluding and classification criteria for renal, lung and heart transplantations exist. Liver and cornea have classification criteria only. Waiting time is an element present in all classification criteria, sometimes mentioned in last place. Sole paragraph of article 39 states that the use of minimum criteria should be done through the established decision tree, regulated, in the national scope, by the Health Assistance Secretary, as addressed by article 29 of Decree No. 2,268, 1997.

The technical regulation addresses the situation of clinic urgency for transplants performance (article 38). In that case, the CNCDO must be informed for patient precedence indication in relation to the single list. The sole paragraph of this article states that urgency communications must be repeated and justified to the CNCDO, seventy two hours after the previous communication, with exception of kidney. The urgency criteria themselves are presented in article 40. Broadly, they are all serious clinical situations, with the exception for the item regarding the receptor aged under seven with bilateral corneal opacity.

Finally, the regulation highlights an operation issue on the kidneys recipients selection, by establishing that the CNCDO, which does not have eighty per cent of its patients enrolled in the renal receiver registry identified in relation to Human Leukocyte Antigens, will have twelve months time, estimated from the day of publication of this Regulation, to obey the classification criterion specified in article 39, which addresses HLA compatibility (article 44).

Regarding the transplantation policy regulation, the technical regulation implemented by Ordinance No. 3.407, 1998, acknowledges between the competencies of the Technical Advisory Group (article 2, paragraph 1): the development of guidelines for the transplantation and graft policy; the proposition of complementary regulation topics and the identification of quality indicators for the sector. The state level received jurisdiction to develop complementary regulation, of states cope, by means of the State Transplantation Coordinations (*Coordenações Estaduais de Transplante* – article 3, paragraph 1) and to adopt additional criteria to the single list system (article 37, paragraph 3), supplementary in character, so as not to surpass those defined by the SNT.

In regard to the mechanisms that have influence on transplantation organs availability, articles 8 and 9 of the regulation deal with the conditions for organ removal. Article 8 demands the performance by an authorized team and, in its sole paragraph, states that the eyeball removal, with the purpose of obtaining transplantation corneas, may be carried out by trained technicians, under the responsibility of an authorized medical ophthalmologist.

The following mechanisms that promote transplantation information transparency can be highlighted in the technical regulation: the annual transmission of information regarding the activities related to transplants by the Transplantation State Coordinations to the SNT Coordination (article 3, paragraph 1, item V); the authorization renewal condition dealt within the regulation of systematic reporting of the informations required by the local and national board of the SNT (article 32) and the requirement that the patient when enrolled in the single list system must receive from the health institution that forwarded his inscription, the receipt of his inclusion dispatched by the CNCDO, as well as the specific explanations on the organs or tissues distribution criteria to which she (he) relates as possible recipient (article 35, paragraph 1). Moreover, articles 41 and 43 deal with the system’s control and assessment through the SNT information system.

7 Other Ordinances of the Health Ministry and Resolutions

Following we will be presenting only the ordinances from the Ministry of Health considered more directly associated to organs criteria access, as well as resolutions from the Federal Council of Medicine on brain death and Anvisa’s resolutions related to organs transplantation.

Ordinance No. 935, July 22, 1999, that provides on the activities of renal and pancreas combined transplants and pancreas transplants, regulates the operation of teams and health institutions that claim to perform this type of transplants. It was established that patients with combined renal and pancreas transplantations indications have to be enrolled in the single list system, forming a subset of the technical registry for renal transplant (article 2). Patients already enrolled in the renal distribution list, if transferred to the renal-pancreas list, will retain the original subscription date. The pancreas and a kidney will be offered, preferably, to the recipient of a combined transplant, when the donor fills certain minimum criteria (article 3). In case de alleged donor is rejected by the renal and pancreas transplantation teams, both kidneys will be automatically allocated in the isolated renal transplantation line, following the established criteria.

The ordinance states excluding and classificatory criteria for the selection of patients in the distribution of the renal and pancreas combination from the same donor (article 4). It is stated that minimum criteria and the inclusion of complementary criteria considerations are given within the scope of the CNCDOs. The absence of a prior decision system is presumed by the indication that if, within the scope of a CNCDO, a greater number of receptors exist, in relation to the pancreas donors, the SNT Coordination must be informed for the definition of minimum distribution criteria (article 7, sole paragraph).

That ordinance also states that the distribution criteria must be revalidated when the 90% of the patients enrolled in the renal and combined renal pancreas transplantation waiting lists may be identified in relation to the Human Leukocyte Antigens – HLA (article 6).

Ordinance 937, July 22, 1999, indicates that cornea imports will be held, exclusively, by a patient enrolled in the proper state CNCDO waiting list and related to teams and transplantation centrals, registered in the SNT. It also determines: that the approval, made by the National Sanitary Surveillance Agency, to import corneas will be done in sight of the conclusive opinion of the respective state CNCDO; that costs related to the cornea import will be of exclusive patient responsibility and that the quality assessment of the imported cornea to be transplanted would be responsibility of the transplantation team.

Ordinance 901, August 16, 2000, creates, in the scope of the SNT, the Organs Notification, Capture and Distribution Centrals – CNCDO, considering the need to improve the management and control of state, regional and national recipients lists and ensure equity and transparency in organs and tissue transplantation and graft distribution. That ordinance was also justified by the need to establish mechanisms and criteria that may allow a proper organ capture and their subsequent distribution, especially when the latter is between states.

That regulation states that organ distribution among states must be made in accordance with the national receivers list, with the technical conditions of transport and distribution and other criteria established by the legislation in force, to ensure the best use of the available organs and allocation equity (article 1, paragraph 1, line d). Is jurisdiction of the Health Assistance Secretary (SAS) of the Ministry of Health to establish the regulation on operation and technical criteria to be used by the national central (article 2).

The mentioned regulation on the operation of the CNCDO occurs through Ordinance No. 91, January 23, 2001. It establishes the following regional organization for the distribution of organs by the national central: (i) Region I - Rio Grande do Sul, Santa Catarina and Paraná; (ii) Region II – Rio de Janeiro, Minas Gerais and Espírito Santo; (iii) Region III – São Paulo, Goiás, Mato Grosso do Sul, Mato Grosso, Distrito Federal, Tocantins, Amazonas, Pará, Acre, Roraima, Rondônia, Amapá; and, (iv) Region IV – Bahia, Sergipe, Alagoas, Pernambuco, Paraíba, Rio Grande do Norte, Ceará, Maranhão e Piauí (article 1).

The criteria for organ distribution are clarified for cases in which a donor exists whose organs are not allocated among the recipients enrolled in the state central registries (article 2), according to the contents of the technical regulation on the transplantation activities approved by Ordinance No. 3, 407, 1998. Not existing possibility of benefiting within the state from one or more organs, among the recipients enrolled in the regional or state central, they should compulsory have, to be notified to the national central, for which they will become available.

The national central will select the recipients for the available organs, through lists that should be rotated (article 3, item I, line b) through the adoption of criteria, presented in descending order of priority: 1st) the list of prioritized patients within the organ's capture region; 2nd) the list of prioritized patients in the rest of the regions; 3rd) the general recipients list designated by the state centrals where there are suitable transplantation teams, within the organ's capture region; and 4th) the general recipients list from the other regions.

Ordinance No. 1,183, October 25, 2000, established the National Organs and Tissues Donor Registry (*Registro Nacional de Doadores de Órgãos e Tecidos*). That regulation provided the structure to register the citizenship desire for after death organ donation, serving as death subsidy for a future decision from their families in regard to donation (ordinance preamble). The regulation was in consonance with the amendments that would be introduced by the Transplantation Law in 2001, in which the final decision on donation rests in the family.

Ordinance No. 2,115, November 20, 2001, revoked in 2004, created within the scope of the SNT, the Working Group with the aim of studying and suggesting the Ministry of Health the formulation, revision, update and improvement of regulations related with the inclusion criteria of candidate patients to liver transplants in the states single lists, as well as the distribution and allocation criteria of livers captured with transplantation purposes. The ordinance was justified by the need to optimize patients care enrolled in the single lists linked to these central, by the need to strengthen the implementation of single lists as instruments of technical and legal guarantee of justice in the organs distribution captured by the system, and so that this is accomplished within strict technical, ethical and moral criteria, and considering the need that these criteria are unified and valid in all the national territory, that are clear and objective, so as to allow an uniform assessment of patients both for their inclusion in the single lists as to the distribution of organs.

The Work Group was composed by representatives from SNT, medical entities, legislators, the Federal Public Ministry, the National Health Council, of professionals of notorious knowledge among hepatologists and liver transplanters in activity in the country.

Ordinance No. 541, March 14, 2002, approves enrolment criteria for liver recipient candidates - cadaver donor, in the technical registry of liver recipients - single list – of the CNCDO. The Ordinance forbids the establishment of own criteria by the CNCDO with the same purpose (article 2, paragraph 1). Thus, suppressing competence of complementary regulation establish by the technical regulation of 1988. The enrolment of all liver recipient candidates that have been enrolled in previous dates to the publication of the ordinance, with the respective subscription order was kept (article 2, paragraph 2).

It was determined that the State and Federal District Health Departments should create the Technical Board of Liver Transplant in the scope of their respective CNCDO where the liver transplants are performed, by act of the Health Department, within 30 days from the publication of the ordinance (article 3, paragraph 1)[31]. The Ordinance admitted that while the respective boards were not created, inscription requests on technical registry of liver recipients that depend on their approval should be assessed by the technical boards of the same CNCDO (article 3, paragraph 2).

The Ordinance annex details the patients' inclusion criteria by age groups. It was established, however, compulsory inscription approval of liver recipient candidates in the single list by the liver transplants technical boards in two situations. These situations are: for patients in which the criteria approved by the ordinance specifically determines the board appraisal and in the cases of inclusion request in the liver transplant single list, by the transplantation team, of patients who are not regarded within the inclusion criteria addressed by the ordinance (article 6). During the initial assessment of the inscription request by the technical board, the CNCDO Coordinator must keep secrecy about the patient's and team identity that is requesting the enrolment, assigning the process an identification number (article 6, item II, paragraph 3);

It is worth mentioning some principles that reveal the discretionary level of the operation of such boards: decisions taken by the boards may by object of reconsideration requests, with presentation to the same boards with the reasons that justify an eventual alteration of the decision previously made (article 6, item III, paragraph 7); the enrolment of patients aged 70 or more must be assessed and authorize by the Technical Board of the CNCDO (item X from the ordinance annex).

Ordinance No. 2,155, October 7, 2004, creates the National Liver Transplantation Technical Board (*Câmara Técnica Nacional de Transplante de Fígado*), considering the need to guarantee distribution equity for the liver transplantation patients. The technical board will be composed by the General Coordinator of the SNT, founding member, and by eight members representing health institutions (article 2); consultative in character, convoked by the SNT in accordance to the demand (article3) and pondering on its members consensus (article 4). This ordinance revoked the work group created by Ordinance No. 2,115, 2001. The National Liver Transplantation Technical Board did not receive so clear and deliberative attributions as the state ones, regulated two years before.

Ordinance No. 2,480, November 17, 2004, approves the Technical Regulation for Hematopoietic Stem Cells Transplantation, and gives other provisions, being justified by the need to organize the access with equity and optimize the application of resources for maintaining and updating the hematopoietic stem cells non-relative national registry of donors. The regulation granted the National Cancer Institute (*Instituto Nacional do Câncer* – INCA), the specific technical management for the search, at national or international level, of non-related donor of hematopoietic stem cells, originally a jurisdiction of the SNT (article 6). It was stated that a management software of the National Bone Marrow Registry (*Registro Nacional de Receptores de Medula Óssea* – REREME), was to be implemented in 60 day by the SUS´s Department of Informatics (*Departamento de Informática do SUS* – DATASUS), which would provide the organization of search flows and selection of related and non-related recipients for alogenic hematopoietic stem cells, as defined in the Technical Regulation annexed to the ordinance (article 9).

It was established the single registry for candidate patients to Hematopoietic Stem Cells Transplantation – TCTH alogenic – REREME, whose access to TCTH must consider prioritization criteria described in the annex I of the regulation for the allocation of beds in the hospitals for admission to the procedure by the regulatory agency of the National Transplantation System – SNT (article 10). That ordinance was revoked by Ordinance No. 931, May 2, 2006, that updated the addressed mechanisms and uses urgency and curability criteria with specific

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[31] The use of a “determination” expression for the creation of an administrative board (the technical boards) in another federated unit does not keep up with the constitutional principle of autonomy of those units. It is worth mentioning that the Nation Technical Board was created two years later (October 2004).

scores for each type of disease to define the prioritizing criteria in the list. There are also increments related to waiting time and extra scoring for children under the age of 13.

Ordinance 715, December 1st, 2004, creates the Cornea Transplantation National Technical Board (*Câmara Técnica Nacional de Transplante de Córnea*), also considering the need to guarantee equity in the distribution of donated eye tissues, for patients enrolled in the cornea transplantation waiting list. Other ordinances create specific technical boards for: tissues (No. 1, January 6, 2005), lung (No. 160, March 17, 2005), kidney and pancreas (No 161, March 17, 2005), pancreas (No. 508, September 30, 2005), histocompatibility (No. 508, September 30, 2005), intestine (No. 508, September 30, 2005) and tissue donation and capture (No. 565, August 8, 2006). Ordinance No. 297, March 2, 2006, created an advisory council for umbilical cord and placental blood.

Ordinance No. 2,692, December 23, 2004, regulates the ocular tissues banks within the SUS. Ordinance No. 1,752, September 23, 2005, determines the constitution of an intra-hospital commission of transplantation organs and tissues donation in all public, private and philanthropic hospitals with more than 80 beds.

Ordinance No. 783, April 12, 2006, states the compulsory use of the information systems developed by the SNT and by DATASUS for information feeding on donations and transplants and for the management of waiting lists for organs transplantations in all the national territory.

Ordinance No. 1,160, May 29, 2006, modifies the liver transplantation distribution criteria from cadaver donors, establishing the clinical severity criteria, considering the need to review and update the criteria for distribution of transplantation livers. To assess the clinical severity criteria the MELD - Model for End-stage Liver Disease / PELD Pediatric End-Stage Liver Disease system was adopted, valid throughout the national territory, both for already enrolled patients as for those subscribed after system deployment (article 1). Laboratory screening tests necessary for MELD calculations, for adults and adolescents over the age of 12, and the necessary for PELD calculations, for children under 12 years old, must be performed in laboratories recognized by the Brazilian Society of Clinical Pathology (*Sociedade Brasileira de*

Patologia Clínica - SBPC), or by hospital institutions authorized by the SNT for liver transplantations performance (article 2).

Liver distribution will be held by the CNCDO, using the waiting list management Computerized Program designated by the National Transplantation System (DATASUS SNT 5.0 or higher), established by Ordinance No. 783/GM, April 12, 2006 (article 2). Item 2.2.2 annexed to the Ordinance states that liver transplant indications not provided in the ordinance itself must be reported to the SNT General Coordination and assessed by the Liver Transplantation National Technical Board, which should give a conclusive opinion to the CNCDO related to the patient, in no more than a week. Item 4 annexed to the Ordinance presents validity periods for tests used in MELD and PELD calculations, which vary from seven days to twelve months, according to a scoring level, the higher the severity, the smaller is the validity period of the tests.

On brain death diagnosis, we must highlight CFM resolutions No. 1,480, August 8, 1997, that characterizes brain death, through the completion of clinical test during variable time intervals, characteristic of certain age groups and of No. 1,752, September 8, 2004, on ethical authorization on the use of anencephalic organs or tissues for transplantation, after birth, with prior authorization from the parents.

Ordinance 487, March 2, 2007, provides on anencephalic neonates organs or tissue removal for transplantation or treatment purposes. Considering technical meetings, it establishes that anencephalic neonates organs or tissue removal for transplantation or treatment purposes must be preceded with an irreversible cardiac failure diagnosis and stated that breaches to the Ordinance constitutes a violation under the terms of the Transplantation Law.

Resolutions related to transplantation organs have also been drafted by Anvisa. Resolution RDC No. 347, December 2, 2003, establishes technical regulations for the operation of eye banks, stating that the control of donations and distribution of corneas is CNCDO responsibility.

Resolution RDC No. 350, December 28, 2005, provides on the technical regulation of sanitary surveillance of imported goods. According to item 3.1.a., human cornea imports for transplantation will observe the technical advice of Anvisas' Blood, Tissues, Cells and Cells

General Management (*Gerência-Geral de Sangue, outros Tecidos, Células e Órgãos* - GGSTO), at its headquarters. Items 22 to 29 regulate cornea imports and item 30 to 34 give details on solid organs imports.

Resolution RDC No. 124, May 12, 2005, approves the timing table to be applied to documents related to Anvisa's activities, addressing item 246.7, the destination of organ and tissue imports license documents.

Resolution RDC No. 154, June 15, 2004 (republished May 31, 2006) establishes the technical regulation for the operation of dialysis services, providing for minimum requirements. The regulation establishes that in 90 days after the beginning of the dialysis treatment, the service must, necessarily, present the fit patient or his legal representative, the option to enroll in the local or reference CNCDO (item 4.6). Within the same period the person in treatment must, after explained, formalize his option or rejection in relation to his enrolment in the CNCDO for renal transplantation (item 4.6.1). The dialysis service must formally lead the patient, together with an updated medical record, to the institution and team chosen for the transplant performance, committed to report, quarterly, samples of the collected serum, in addition to inform the clinical situation and status within the waiting list (item 4.6.3). The refusal, impossibility or delay in the pre-transplantation assessment, by the transplantation or dialysis service, must be formally notified to the patient and a copy reported to the CNCDO, to take the appropriate provisions. (item 4.6.4). The HLA is, necessarily regulated by the CNCDO, both its authorization, as for the results reception (item 4.6.5).

Resolution RDC No. 101, June 6, 2006, regulates the physical environment, material resources, working conditions and activities and procedures related directly to the transplantation cycle of cells, tissues and organs, exercised by the CNCDO, which are subject to sanitary surveillance. Resolution RDC No. 220, December 27, 2006, provides for technical regulation for the operation of musculoskeletal tissue banks and human origin skin banks.