



PAN AMERICAN HEALTH ORGANIZATION  
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### **STRENGTHENING OF NATIONAL PROGRAMS FOR ORGAN DONATIONS AND TRANSPLANTS**

Kidney, liver, bone marrow, cornea and other organ or tissue transplants are considered conventional medical procedures. Organ transplants have proven a useful therapeutic survival alternative and are often the only one to improve the quality of life of patients with chronic diseases. In recent years, advances in technology and, above all, better immunosuppressive drugs have made it possible to expand the donor base and considerably improve transplant outcomes.

In addition to their clinical impact, transplants have forced societies to ponder the need for regulating transplant decisions, taking ethical and legal considerations into account—especially decisions related to organ procurement and distribution.

The purpose of a national organ transplant program is to promote the recovery of patients' health, reducing the gap between the demand for organs and their availability, while at the same time protecting the rights of donors and their families. The development of national policies and strategies to promote and safeguard an adequate supply of organs and their availability, quality, safety, and appropriate, equitable use is therefore essential.

This document analyzes the organ donation and transplant situation in the Region, with special emphasis on kidney transplants. It proposes support in coordinating regional action for the planning of organ donation and transplant policies and the training of professionals as a line of cooperation for the Organization, thereby guaranteeing the quality and safety of therapies and offering citizens better, more efficient health care in this field.

## **Introduction**

1. Organ transplants in humans have been used as a medical treatment for roughly half a century. Although some therapy strategies are in the experimental stage, kidney, liver, bone marrow, cornea and other organ or tissue transplants are considered conventional medical procedures. Organ transplants have proven a useful therapeutic survival alternative and are often the only one for improving the quality of life of patients with chronic diseases. In general, it is estimated that the 10-year survival rate for transplant patients is greater than 50%.

2. In most cases, for patients with severe heart, liver, lung, or pancreatic failure, an organ transplant is their last hope. For patients with chronic renal insufficiency, dialysis is an alternative. However, it is a very risky, expensive, and long-term treatment. Thus, safer and more economical therapeutic alternatives must be found that will make greater coverage and better results possible for patients with chronic renal insufficiency.

3. The Region of the Americas has already had nearly 40 years of experience with kidney transplants. In recent years, advances in technology and, especially, better immunosuppressive drugs, have made it possible to broaden the donor base and considerably improve transplant outcomes, with 98% of patients surviving one year after the procedure and 85%, five years, and 75% of grafts surviving five years after the transplant and 55% 10 years afterward.

4. In order to develop a national organ transplant program it is essential to study the factors that contribute to the contracting and progression of the pathologies that lead to the need for organ transplants, the existence of effective measures and strategies for their prevention, and the capacity of health systems to offer early diagnosis and treatment of these pathologies and those for which transplants are clinically indicated. An integrated risk and disease prevention approach will result in lower demand for organs down the line. Informing the public, educating social groups, creating regulatory mechanisms, enforcing standards of ethics and quality, and adopting national organ distribution strategies will help to broaden the cadaverous and live donor base.

5. The purpose of the national organ transplant program is to promote the recovery of patients' health, reducing the gap between the demand for organs and their availability, while at the same time protecting the rights of donors and their families. In this regard, the development of national policies and strategies to promote and safeguard an adequate supply of organs and their availability, quality, safety, and appropriate, equitable use is essential.

### **Analysis of the Situation in the Region.**

6. Kidney donations and transplants will be taken as an example, given their prevalence and economic importance in the countries of the Region.

#### ***Magnitude of the Problem: Prevalence and Incidence of Chronic Renal Insufficiency (CRI).***

7. The *prevalence* of treatment for terminal or extreme cases of CRI stood at 129 patients per million inhabitants (pmi) in 2001 and 349 patients pmi in 2001, rising to nearly 400 patient pmi in 2003. Although these are averages, it should be noted that in countries such as Puerto Rico, Uruguay, Chile, and Argentina the figures are around 1,000, 800, 650, and 570 patients pmi, respectively, which would indicate significant under-diagnosis in several Latin American countries. In 2001, of the 349 patients pmi who had received treatment, 277 patients pmi (79.4%) were on dialysis and the rest had received a kidney transplant.

8. The *incidence* of CRI treatment in 2001 was 91 patients pmi, ranging from 120 to 130 patients pmi in the developed countries and some Latin American nations (Puerto Rico and Uruguay). If the factors that determine the incidence of treatment have not changed in the past three years, the number of new cases annually in the Region is around 49,000. The difference in country rates may be attributable to differences in the incidence of the underlying pathologies in the general population and in the capacity of national health systems to diagnose and treat CRI.

9. Since the population on chronic dialysis is increasing at a faster rate than the general population, which is growing at 1.5% per year, it is estimated that by the end of 2004 the Region had 98,500 patients on hemodialysis, 41,000 patients on peritoneal dialysis, and 39,500 patients who underwent a transplant to receive a functional kidney. That leaves many patients without proper care and diagnosis of chronic renal insufficiency; furthermore, the proportion of identified patients who receive transplants is extremely low, which translates into longer waiting lists, with adverse medical, social, and economic consequences.

#### ***Kidney Transplants***

10. In the 1990s, 20,800 kidney transplants were performed in Latin America, or 8.9% of the total transplants worldwide, and since the beginning of the present decade, there have been 63,618, or 12.7% of the world's total kidney transplants.

11. In 47% percent of transplants in Latin America, the kidney is from a cadaverous donor; in 53%, it is from a live donor. The past 23 years have witnessed an increase in the percentage of cadaverous transplants: 18% in 1980, 34% in 1985, 42% in 1990, 47% in 2000, and 50% in the 2003. In other words, the number of cadaverous transplants has progressively risen, with the figure currently holding stable at around 50%. This is indicative of more efficient donation policies. However, these policies are still not enough when the situation in Europe, where the figure in countries such as Spain, France, Italy, and Portugal exceeds 90%, and the benefits of using a cadaverous donor over a live donor are considered. The number of kidney transplants performed exceeds the supply of organs from cadaverous donors which means that live donors are resorted to worldwide.

12. Despite the organ shortfall, kidney transplant rates in Latin America have gradually risen in recent years, growing from 3.8 pmi in 1988 to 13.6 in 2000 and 17.3 pmi in 2003, although the numbers vary widely from country to country, ranging from 1 to 25 cadaverous transplants pmi.

### ***Organ Donation in Latin America and the World.***

13. There is no doubt that organ donation is a complex issue with multiple causes that generate to significant differences worldwide. Reviewing the situation in the different continents, we have North America, with 20.7 donors pmi, Latin America and the Caribbean with 4.5, Africa with 2.6, Oceania with 10.4, Europe with 17.2, and Asia with 1.1. In all instances, organ donation rates are lower than CRI treatment incidence rates.

14. Reviewing the situation in Latin America, we observe that in this Region, the Southern Cone has achieved donation rates of 7 pmi, with substantial growth in recent years, while in other countries the donation rate is less than 2 pmi. It should be noted that Uruguay had a donation rate similar to the European average of 14.1 pmi in 2002, 16.1 in 2003, and 19.3 in 2004, bringing it closer to the donation rate of the United States, 22 pmi, and higher than the European average.

15. The outcomes and donation potential clearly indicate that organ donation should be strengthened in the Americas. The donation potential of a country is calculated at 30 to 40 donors pmi, according to international data and the experience in countries such as Spain, which has already managed to meet this target.

16. Organ donation is not a simple issue. A clear indication of this is the fact that, in the past 10 years, donation rates in some developed nations have fallen, even though they have considerable resources, spend a significant proportion of their Gross Domestic Product on health, and have a high income per capita. That is to say, the factors that determine the availability of organs and, hence, the effectiveness of kidney transplant programs, go beyond health expenditure to include the organization of the organ

procurement system, human resources and their training, and the population's degree of education about this particular issue.

17. Although transplants save thousands of lives each year, the organ supply is insufficient to cover all the people on the waiting list. Latin America and the Caribbean today have a high number of patients on chronic dialysis, 20% of whom are on the waiting list, with only 10% having the opportunity for a transplant.

18. As a result of this high demand and the shortage of cadaverous donors, many countries with little organizational capacity for organ donation are forced to promote transplants from live donors as a solution to this dramatic problem. This is viewed with a great deal of concern, since in countries with little regulation, growing numbers of people are willing to donate a kidney, even though there is no blood relationship with the recipient, in exchange for compensation. It is very important, therefore, to increase cadaverous donation in our Region and achieve the donation figures of the developed countries.

#### **Legal and Ethical Considerations.**

19. The possibility of replacing sick organs with healthy ones revolutionized medicine in the mid-20th century after the success of the first kidney transplant performed between identical twins by Murria and Bent in 1954. In addition to its clinical impact, this event forced society to ponder the need for regulating transplant decisions, taking ethical and legal considerations into account--especially decisions related to organ procurement and distribution.

20. Several key points related to the ethical and legal aspects of organ donation and transplants should be borne in mind, namely:

- a) *The diagnostic criteria for brain death:* this is the first step in the donation and transplant process and thus, the different legislation in Latin America should clearly state these criteria.
- b) *The donation consent form:* once death has been pronounced, consent should be obtained for donation, and the countries have opted between:
  - Presumed consent—where the State considers donation a greater good for the community and declares that anyone who dies can be a donor, provided that he has not voiced objections to it in life. This is the “opting out” employed by most European countries; however the practical application of this model varies, and the majority of countries end up obtaining permission from the family.

- Informed consent: this system requires the family or the donor to give express consent (“opting in”), as in the United States, most Latin American countries, and the United Kingdom.
- c) *Laws that penalize organ trafficking.* It is important that the law expressly prohibit organ trafficking. The recommendations of international organizations state that physicians and health professionals should not perform transplants if they have reason to believe that the organs have been procured through a commercial transaction, and that no human organ should be donated for profit to an organ-sharing agency or organ bank. Universal access to transplants is the goal, so that all the inhabitants of the Region have the same opportunity to receive a transplant, in keeping with the basic principles of bioethics.
- d) It is recognized that *kidney donation from living people* must be performed in a way that will minimize physical, psychological, and social risks to the donor and not undermine public confidence and the credibility of the transplant program. The decision to donate should be made in an environment that allows the potential donor to decide in an autonomous but informed manner. The risks associated with kidney donation from living people are small but not inconsiderable.
- e) A system should be in place to guarantee the security of the organ for transplantation--security not only in terms of its ability to function in the recipient but of its traceability as well. Thus, registration, identification, monitoring, coding, and biosurveillance of both donor and recipient indicate a secure process that should be required through a specific regulation guaranteeing quality control in donation and transplants.

### **Considerations and Proposal for a Regional Framework for Work in this Area.**

21. Whereas:

- a) Chronic renal insufficiency is an established disease that is steadily on the rise and should be properly treated.
- b) Transplants are without a doubt the most economical therapy option and offer patients the best quality of life.
- c) To accomplish this, health policies should be established that increase organ donation and strengthen organizational systems that will facilitate an increase in organ donation in the different countries.
- d) All this is grounded in sound ethical principles and a legal framework that offers transparency and guarantees to the system and the population as a whole.

22. It is therefore important to organize the regional work into five clearly differentiated levels to analyze the chronic renal insufficiency, donation, and transplant situation:

- a) Determine the situation with respect to extreme chronic renal insufficiency and its treatment in Latin America and the Caribbean.
- b) Determine the organ donation and transplant situation in our Region (current legislation and organizational systems.)
- c) Determine the donation potential and the possibilities for enhancing it to offer solutions for our patients on the waiting list.
- d) Establish educational policies to provide training in prevention and organ donation for professionals and health teams in the countries.
- e) Maintain and increase the proper registration of donation and transplant activities and of current transplant centers and their activities.

23. This framework makes it possible to establish future lines of action that include the activities already commenced in the Region by the Punta Cana Group, the Latin American Transplant Society, and the Ministries of Health themselves, all of whom work to promote organ donation and transplants in their respective countries and whose activities have resulted in growing donation rates in recent years.

24. Within this framework, the Pan American Health Organization can improve this situation by supporting the creation of an Organ Donation and Transplant Committee to plan a regional transplant policy and issue recommendations for the different countries, in addition to offering technical assistance to implement the organ donation solutions that each country needs. The Committee would issue its recommendations and submit them to the respective Meetings of Ministers for consideration and approval. It would be a technical body that would issue recommendations for the different countries in this regard at biennial meetings, set up a training program for professionals in the countries, and assist in the planning of organ donation and transplant policies in countries that need it.

25. In organ donation and transplant policies, the organizational structure is absolutely key to success. Thus, each country should search for the structure that will enable it to attain the greatest success with the existing resources.

26. At the World Health Assembly in May 2004, the World Health Organization adopted a resolution recommending specific action to promote and develop organ donation and transplant programs to reduce the existing gaps, provide an appropriate legal and organizational framework, guarantee the quality and safety of therapies, and offer citizens better, more efficient health care in this field.

27. Thus, organization, education, training, and ethics are the pillars on which the success of an organ donation and transplant program should rest. It is the professionals of the Region themselves, who are familiar with the difficulties involved, who must find solutions to this public health problem that implies high costs for the health authorities.

**Action by the Subcommittee on Planning and Programming**

28. The Subcommittee on Planning and Programming is requested to formulate comments and observations on the general situation of organ donation and transplants in the Region, as well as suggestions for determining PAHO's support for regional coordination of the legal, ethical, safety, and quality aspects of the organ procurement, donation, and transplant processes.

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