



PAN AMERICAN HEALTH ORGANIZATION
WORLD HEALTH ORGANIZATION



144th SESSION OF THE EXECUTIVE COMMITTEE

Washington, D.C., USA, 22-26 June 2009

Provisional Agenda Item 4.10

CE144/15, Rev. 1 (Eng.)

20 May 2009

ORIGINAL: SPANISH

POLICY FRAMEWORK FOR HUMAN ORGAN DONATION AND TRANSPLANTATION

Introduction

1. Thanks to continuous improvements in medical technology, particularly in relation to tissue and organ rejection, there has been an increase in the demand for organs, despite a marked increase in organ donation from both deceased and living donors in recent years.

2. The shortage of organs has not only prompted many countries to develop procedures and systems to increase supply but has also stimulated commercial trafficking in human organs, particularly from living donors unrelated to the recipients. Moreover, the growing ease of international communication and travel has led many people to travel abroad to medical centers that advertise their ability to perform transplants and supply donated organs. In recent decades, the evidence of such commerce, along with the human trafficking that accompanies it, has become clearer.

Background

3. Over the past 50 years, human cell, tissue, and organ transplantation has become a useful therapeutic alternative for survival and, in many cases, the only one possible for improving the quality of life of patients with chronic diseases; thus, it is now a conventional procedure that has benefited hundreds of thousands of people. The Region of the Americas has been no stranger to this progress, and human cell, tissue, and organ transplantation is already part of medical practice in many countries.

4. In the 1990s, 20,800 kidney transplants were performed in Latin America, or 8.9% of the total worldwide. In 2007,¹ there were more than 8,200 kidney transplants, or over 12.5% of the total transplants worldwide, and more than 1,500 liver transplants, or 7.5% of the total worldwide. In the United States and Canada, 16,625 and 1,243 kidney and 6,493 and 488 liver transplants, respectively, were performed that year. In Latin America, 56% of these kidney transplants involved deceased donors and the remaining 44%, living donors, while in the United States and Canada, the percentage of living kidney transplant donors ranged from 36% to 38%. The past 29 years have witnessed a shift in the percentage of cadaveric organ transplantation: 18% in 1980, 34% in 1985, 42% in 1990, 47% in 2000, 50% in 2003, and 56% in 2008. This trend in the percentage of transplants of cadaveric origin is the result of more efficient organ donation policies; however, donation levels are still inadequate if we consider the situation in Europe, where countries such as Spain, France, Italy, and Portugal boast figures of over 90%. It is therefore very important to increase the donation of organs from cadavers in our Region and reach figures similar to those in the developed countries.

5. In 2006, a total of 44,120 patients were on waiting lists for a kidney transplant in nine Latin American countries (Argentina, Brazil, Costa Rica, Cuba, Ecuador, Mexico, Panama, Uruguay, and Venezuela); in Canada, the number was 4,195, and in the United States, 76,313.

6. There are not enough organs from cadaveric donors to meet the demand for kidney transplants, which has led to the use of living donors. One reason for this situation is the lack of effective incentives policies to encourage organ donation and transplantation in the majority of the countries. Although, in some countries a national or regional organization manages the donation-transplantation process, there are too few transplant coordinators in the hospitals, and most hospitals do not have them.

7. In mid-October 2005, the XV Ibero-American Summit of Heads of State and Government, held in Salamanca, Spain, ratified the proposal to create the Ibero-American Network/Council on Donation and Transplantation (RCIDT, for its Spanish acronym), presented in Grenada in September of that year. The Network/Council is the fruit of several years of Spanish technical cooperation with Ibero-America through the National Transplant Organization (ONT), which has trained transplant coordinators and held workshops and seminars. All the countries of Ibero-America are represented in the RCIDT by a transplantation expert or professional from the donation management systems appointed by the respective ministry of health. The mission of the RCIDT is to promote cooperation among its members in the areas of management, regulatory aspects, training of professionals in the ethical, and sociological aspects of cell, tissue, and organ

¹ International Figures on Organ Donation and Transplantation – 2007. Transplant Newsletter, Vol 13, No. 1, 2008. Available at:
<http://www.transplant-observatory.org/C5/News%20ONT/Document%20Library/newsletter2008.pdf>.

donation and transplantation. The Network considers the management aspects of transplantation for dealing with the organ shortage particularly important, together with country support for the application of the ethical principles governing cell, tissue, and organ donation and transplantation formulated by the World Health Organization, the Transplantation Society (TTS), and the other international scientific societies linked with the field of donation and transplantation.

8. Since its creation, the RDCIT has published documents with recommendations and consensus papers on the creation and characteristics of transplantation organizations, the profile and training of professionals in charge of organ and tissue donation (hospital coordinators), quality and safety systems for organ, tissue, and cell donation, the creation of (umbilical) cord blood banks, the diagnosis of brain death, and bioethical considerations in donation and transplantation, as well as a training plan for donation and transplantation professionals and a position statement on transplant tourism in Ibero-America, which has been important in promoting and strengthening national organ donation and transplantation programs in the Region.

9. The RCIDT has created a virtual platform,² where information about network activities can be found and multilateral communication can take place via videoconferences; it has also published two newsletters that list all the documents produced by the RCIDT and provide annual statistical data on donation and transplantation activity in Ibero-America, as well as information on other training and information-sharing activities. Thanks to the RCIDT training plan, over 180 transplant coordinators from all the Ibero-American countries have been trained at hospitals in the 17 Autonomous Communities of Spain through the Master Alliance in Organ, Tissue, and Cell Donation and Transplantation; these coordinators are now working in their respective countries, often holding positions of responsibility in the national systems.

10. This activity has significantly boosted the donation rate in several countries, notably Argentina with an increase of 11%; Colombia with 60%; Chile with 22%; Cuba with 30%; Uruguay with 20%; and Venezuela with 27%. Uruguay is a case in point: by 2006, it ranked third on the global donation index, behind only Spain and the United States.

11. The Caribbean, specifically Bahamas, Barbados, Guadeloupe, Jamaica, and Trinidad and Tobago, has kidney transplant programs in different stages of development that need to be strengthened. Given the situation in the subregion, to ensure the feasibility and sustainability of this type of program, it is important to consider the possibility of developing subregional kidney health and transplantation services with the participation of the centers already in development.

² Red/Consejo Iberoamericano de donación y Trasplante (RCIDT). Available at: <http://rcidt.ont.es/>.

12. In 1991, through Resolution WHA44.25, WHO adopted the Guiding Principles on Human Cell, Tissue, and Organ Transplantation, which have influenced the legislation of many Member States, as well as professional codes and practices. Since then, commentaries have been added to these principles, and major fundamental progress has been made in cell, tissue, and organ donation and transplantation. Resolution WHA57.18 requested the Director-General of WHO to examine and reformulate the Guiding Principles, which were recently updated and submitted to the WHO Executive Board.

13. The new Guiding Principles, presented at the Executive Board in January 2009,³ serve as a framework to support advances in cell, tissue, and organ transplantation that will make it possible to obtain the maximum benefit from transplants, meeting the needs of recipients, protecting donors, and guaranteeing the dignity of all parties involved. The Principles represent a model for national policies and laws that promote transplantation, while discouraging organ trafficking.

Proposal

14. At the World Health Assembly in May 2004, the World Health Organization adopted resolution WHA57.18 recommending specific measures for the promotion and development of donation and transplantation programs that will reduce current disparities, provide an appropriate legal and organizational framework, guarantee the quality and safety of these therapeutic procedures, and offer citizens better, more efficient health care in this area.

15. The countries with the most successful donation programs have demonstrated the advantages of having strong national organizations that can promote, coordinate, and regulate organ donation and transplantation. These organizations educate the population about the importance of maintaining a community resource that relies on voluntary unpaid organ, tissue, and cell donations to which everyone has equitable access and not on the exploitation inherent in organ trafficking.

16. The Guiding Principles contain essential points that should be borne in mind concerning the ethical and legal considerations that should form part of the policy framework for cell, tissue, and organ donation and transplantation:

- (a) *Universal access to transplantation*, so that all the inhabitants of the Region have the same opportunity to receive a transplant, bearing in mind the basic principles of bioethics;

³ World Health Organization, Document EB124/15, Human Organ and Tissue Transplantation. Report of the Secretariat. 124th Session of the Executive Board, 20 November 2008. Available at: http://apps.who.int/gb/ebwha/pdf_files/EB124/B124_15-en.pdf

- (b) *Express prohibition in the legal texts on organ trafficking.* At a recent meeting in Istanbul in May 2008, it was declared that: “Travel for transplantation becomes transplant tourism if it involves organ trafficking and/or transplant commercialism or if the resources (organs, professionals and transplant centers) devoted to providing transplants to patients from outside a country undermine the country’s ability to provide transplant services for its own population.”⁴ The RCIDT made a similar pronouncement in its document *Bioethics Considerations in Organ, Tissue, and Cell Donation and Transplantation*, and at its 2008 meeting in Mexico, “expresses its opposition and disapproval of this practice, which had been publicly and unanimously condemned by the International Community and competent agencies, and calls on the governments of member states, strongly recommending that they oppose and/or introduce measures in their legislation to control and impose sanctions to discourage the promotion and advertising of transplantation services for people traveling to a foreign territory for sole purpose of receiving an organ transplant (transplant tourism) from local or foreign donors, as such practices promote inequity, exclusion, and social injustice, and violate the human rights of national recipients.”⁵
- (c) *The diagnostic criteria for brain death and the procedures for obtaining consent for the donation;*
- (d) *Organ donation from living donors* must be performed so as to minimize the physical, psychological, and social risks to the donor and ensure that public confidence and the credibility of the transplant program are not undermined;
- (e) *Follow-up of donation and transplantation outcomes* is essential for guaranteeing good quality services and detecting problems that will make early warnings possible in the case of adverse events; and
- (f) *Organizational structure* is absolutely necessary in donation and transplantation policies to guarantee success in donation and transplantation; thus, each country should search for the optimum structure that will enable it to obtain the best outcomes with the resources at its disposal, taking three basic elements into account: the transplant recipient and the donor; the competent transplant team; and, a public coordination and follow-up system that guarantees the ethics, equity, quality, safety, and efficiency of the processes.

⁴ The Declaration of Istanbul on Organ Trafficking and Transplant Tourism. Available at: http://www.prnewswire.com/mnr/transplantationsociety/33914/docs/33914-Declaration_of_Istanbul-Lancet.pdf

⁵ Declaration against Transplant Tourism in Latin America. Available at: http://www.grupopuntacana.org/materiales_consejo/declaraturismotraspla.pdf

17. The complexity of donation and transplantation processes and the multitude of agents, professionals, and institutions involved makes it necessary to expand participation to other civil society organizations and entities that can be influential and make a contribution. In addition to the RDCIT and the ONT, these regional and global actors include the Transplantation Society of Latin America and the Caribbean (STALYC), the Latin American Society of Transplant Coordinators (Punta Cana Group), the Latin American Nephrology and Hypertension Society (SLANH), and the Transplantation Society, among others.

Action by the Executive Committee

18. The Executive Committee is requested to review this document and issue comments and observations regarding organ donation and transplantation in the Region and to promote the application of the new Guiding Principles developed by WHO for the formulation and enforcement of policies, laws, and regulations on the acquisition, donation, and transplantation of human cells, tissues, and organs to guarantee the quality, safety, and efficacy of the procedures.

Annexes



PAN AMERICAN HEALTH ORGANIZATION
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Annex A

ANALYTICAL FORM TO LINK AGENDA ITEM WITH ORGANIZATIONAL AREAS

1. Agenda item: 4.10. Policy Framework for Human Organ Donation and Transplantation.

2. Responsible unit: THR

3. Preparing officer: José Luis Di Fabio, Manager THR

4. List of collaborating centers and national institutions linked to this Agenda item:

National Transplantation Organization of Spain, national organ donation and transplantation coordinators of the countries, national transplantation offices, etc.

5. Link between this Agenda item and the Health Agenda for the Americas 2008-2017:

The national health authority, as regulator, should guarantee that drugs, technologies, and medical supplies be of the requisite quality, safety, and efficacy. At the same time, it should promote the rational use of these products.

6. Link between the Agenda item and Strategic Plan 2008-2012:

RER 12.3: Member States supported through technical cooperation to implement evidence-based policies to promote scientifically sound and cost-effective use of medical products and technologies by health workers and consumers.

7. Best practices in this area and examples of countries within the Region of the Americas:

The Ibero-American Network/Council on Donation and Transplantation (RDCIT) has made significant contributions to the development and strengthening of national organ donation and transplantation programs in the Region. Thanks to this activity, a very significant increase can be seen in the donation rates of several countries, especially Colombia (60%), Cuba (30%), Venezuela (27%), Chile (22%), Uruguay (20%), and Argentina (11%). In 2006, Uruguay already ranked third in the world on the donation index, behind only Spain and the United States.

8. Financial implications of this Agenda item:

The funding required to support the annual meetings of the Network/Council, facilitate information exchange among countries (maintenance of a web page); strengthen the national organ donation and transplantation coordination offices; train national coordinators in the promotion of organ donation. Estimated cost: US\$ 300,000 per biennium.



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Annex B
ORIGINAL: SPANISH

PROPOSED RESOLUTION

POLICY FRAMEWORK FOR HUMAN ORGAN DONATION AND TRANSPLANTATION

THE 144th SESSION OF THE EXECUTIVE COMMITTEE,

Having reviewed the document, *Policy Framework for Human Organ Donation, and Transplantation* (Document CE144/15)

RESOLVES:

To recommend that the Directing Council adopt a resolution written as follows:

POLICY FRAMEWORK FOR HUMAN ORGAN DONATION AND TRANSPLANTATION

The 49th DIRECTING COUNCIL,

Having reviewed the report of the Director, *Policy Framework for Human Organ Donation and Transplantation* (Document CD49/__), which proposes that Member States have a policy framework that will facilitate the strengthening of national capacity to effectively and efficiently address the problem of cell, tissue, and organ donation and transplantation and achieve optimal utilization of the resources allocated for this purpose;

Recognizing the valuable contributions of the Ibero-American Network/Council on Donation and Transplantation (RDCIT) to the promotion and strengthening of national organ donation and transplantation programs in the Region;

Aware of the growing magnitude and usefulness of human cell, tissue, and organs for a wide range of disorders in high- and low-income countries alike;

Committed to the principles of human dignity and solidarity, which condemn the purchase of human body parts for transplantation and the exploitation of the poorest and most vulnerable populations, as well as the human trafficking stemming from such practices;

Convinced that voluntary, unpaid donation of organs, cells, and tissues from deceased or living donors helps guarantee the continued presence of a vital community resource; and

Sensitive to the need for monitoring reactions and adverse events associated with the donation, processing, and transplantation of human cells, tissues and organs as such, and for ensuring that this information is disseminated internationally to optimize the safety and efficacy of transplants,

RESOLVES:

1. To urge Member States to:

- (a) apply the Guiding Principles on Human Cell, Tissue, and Organ Transplantation in the formulation and execution of their policies, laws, and regulations on human cell, tissue, and organ donation and transplantation, as the case may be;
- (b) promote equitable access to transplantation services, as national capabilities permit, that serve as the foundation for public support and voluntary donations;
- (c) fight efforts to obtain economic gain or comparable advantages in transactions with human body parts, organ trafficking, and transplant tourism, and even to encourage health professionals to notify the proper authorities when they have knowledge of such practices, in accordance with national capabilities and national law;
- (d) strengthen national public authorities and capabilities, providing them with support to guarantee the supervision, organization, and coordination of donation and transplantation activities, with special attention to ensuring that, insofar as possible, they use donations of organs from deceased people and protect the health and well-being of living donors;
- (e) improve the safety and efficacy of donation and transplantation by promoting international best practices;

- (f) collaborate in the collection of data, especially on adverse reactions and events related to the practices, safety, quality, efficacy, epidemiology, and ethics of donation and transplantation; and
 - (g) stay actively involved in the RDCIT and incorporate the guidelines and recommendations of this Network/Council in their policies, laws, regulations, and practices related to cell, tissue, and organ donation and transplantation.
2. Request the Director to:
- (a) disseminate the updated Guiding Principles on human cell, tissue, and organ transplantation as widely as possible to all stakeholders;
 - (b) support Member States and nongovernmental organizations in matters related to the prohibition of trafficking in materials of human origin and transplant tourism;
 - (c) continue to gather and analyze regional data on practices, safety, quality, efficacy, epidemiology, and ethics in human cell, tissue, and organ donation and transplantation;
 - (d) provide technical assistance to the Member States that request it in the drafting of national laws and regulations on human cell, tissue, and organ donation and transplantation and to set up appropriate systems for this purpose, facilitating international cooperation in particular;
 - (e) facilitate Member States' access to appropriate information on the donation, processing, and transplantation of human cells, tissues, and organs, especially data on severe reactions and adverse events; and
 - (f) provide technical assistance to the English-speaking Caribbean countries to promote or improve their kidney transplant programs and propose a subregional kidney health services and transplantation system that would ensure the sustainability and viability of this type of program.



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Annex C

**Financial and Administrative Implications for the Secretariat of
the Resolution Proposed for Adoption**

1. Agenda item: 4.10. Policy Framework for Human Organ Donation and Transplantation.
2. Linkage to program budget: (a) Area of work: SO12: To ensure improved access, quality and use of medical products and technologies (b) Expected result: RER 12.3: Member States supported through technical cooperation to implement evidence-based policies to promote scientifically sound and cost-effective use of medical products and technologies by health workers and consumers.
3. Financial implications (a) Total estimated cost of implementation over the lifecycle of the resolution (estimated to the nearest US\$ 10,000, including staff and activities) US\$ 150,000 (b) Estimated cost for the biennium 2008-2009 (estimated to the nearest US\$ 10,000, including staff and activities): US\$ 300,000. (c) Of the estimated cost noted in section (b), what part can be subsumed under existing programmed activities?: US\$ 30,000 per biennium
4. Administrative implications (a) Indicate the levels of the Organization at which the work will be undertaken): Global, regional, and national level. (b) Additional staffing requirements (indicate additional required staff full-time equivalents, noting necessary skills profile): These are processes to assist the countries and promote horizontal cooperation. Extra staff are not needed. (c) Time frames (indicate broad time frames for implementation and evaluation):