Pan American Health Organization
World Health Organization
REGIONAL OFFICE FOR THE Americas

57th DIRECTING COUNCIL

71st SESSION OF THE REGIONAL COMMITTEE OF WHO FOR THE AMERICAS

Washington, D.C., USA, 30 September-4 October 2019

Provisional Agenda Item 4.9

CD57/11
19 August 2019*
Original: Spanish

STRATEGY AND PLAN OF ACTION ON DONATION AND EQUITABLE ACCESS TO ORGAN, TISSUE, AND CELL TRANSPLANTS 2019-2030

Introduction

1. Organ, tissue, and cell transplants[1] have become global procedures that can prolong life and improve its quality. Advancements in ablation, conservation, transplantation, and immunosuppression techniques have increased the efficacy, cost-effectiveness, and cultural acceptability of transplants, with a consequent increase in the demand for these procedures. The ability to perform transplants within the Region's health systems varies, however. Notwithstanding the proven cost-effectiveness of kidney transplants for treating refractory chronic kidney disease, and of cornea replacements and liver transplants, these procedures are still not accessible to the entire population that needs them. Despite the marked increase in the donation of organs from both deceased and living donors in recent years, the supply and availability of donated cells, tissues, and especially, organs, are well below the demand *(1)*. Moreover, the lack of consolidated national programs and competent human resources and the high cost of transplants and maintenance therapies, coupled with inadequate financial coverage and protection, are barriers to equitable access to these procedures *(2)*.

2. Within the Policy Framework for Human Organ Donation and Transplantation of the Pan American Health Organization (PAHO), approved in 2009 (Resolution CD49.R18) *(3)*, and in response to the request of the PAHO Executive Committee in September 2017 *(4)*, the objective of this strategy and plan of action is to promote the gradual expansion of equitable and quality access to organ, tissue, and cell transplants in the Member States through voluntary donation, observing the Guiding Principles on transplants of the World

* This version contains editorial changes.

[1] For the purposes of this document, the term *transplant* generally refers to organ, tissue, and cell transplantation. Cell transplantation refers to the use of autologous, syngeneic, or allogeneic hematopoietic cells obtained from peripheral blood, bone marrow, or the umbilical cord, which have not been substantially modified and are used for the treatment of certain types of cancer or other blood disorders.

Health Organization (WHO) **(**Resolution WHA63.22) *(5)* (Annex A). This document presents options for meeting this objective and monitoring its implementation through four strategic lines of action, their expected outcomes, and a series of indicators. It thus provides a roadmap for addressing the Region's priorities with respect to increasing the supply of organs, tissues, and cells and strengthening the initiatives and capacities of the Member States, the Pan American Sanitary Bureau, and the relevant domestic and international organizations involved in this area.

Background

3. Transplant therapy should no longer be considered the prerogative of well-endowed health systems but an alternative of choice for the treatment of many diseases present in all Member States. PAHO's Member States have therefore adopted a series of mandates promoting access to comprehensive health services, chief among them the Strategy for Universal Access to Health and Universal Health Coverage (Document CD53/5 [2014]) *(6)*, the 2030 Agenda for Sustainable Development (Resolution A/RES/70/1 [2015]) *(7)*, and the Sustainable Health Agenda for the Americas 2018-2030 (Document CSP29/6, Rev. 3 [2017]) *(8)*. Moreover, resolutions such as those linked with the Plan of Action for the Prevention and Control of Noncommunicable Diseases (Resolution CD52.R9) *(9)*, Chronic Kidney Disease in Agricultural Communities in Central America (Resolution CD52.R10) *(10)*, and the policy on Access and Rational Use of Strategic and High-cost Medicines and Other Health Technologies (Resolution CD55.R12) *(11)*, stress the need to increase access to appropriate treatment and safeguard the sustainability of health systems. Promoting the use of transplants can contribute to the achievement of these objectives and to compliance with these and other related mandates.

4. WHO first expressed its concern about the trade in human organs in 1987, requesting that appropriate steps be taken to prevent the purchase and sale of organs (Resolutions WHA40.13 and WHA42.5) *(12, 13)* and adopting the Guiding Principles on Human Organ Transplantation in 1991 (Resolution WHA44.25) *(14)*, updated in 2010 (Resolution and Document A63/24) *(5, 15)*. These principles constitute a model for policies and laws to provide an orderly, ethical, and acceptable framework for organ, tissue, and cell procurement and transplantation for therapeutic purposes. Likewise, consensus has been reached on the definition and criteria for brain death and access to the organs of diseased donors *(16)*. WHO promoted the creation of the Global Observatory on Donation and Transplantation (GODT) to compile global data on transplant procedures (Resolution WHA57.18) *(17)*. The United Nations General Assembly (UN) recently adopted a resolution aimed at enhancing and promoting effective measures and international cooperation to prevent and combat human trafficking for the purpose of organ removal and human organ trafficking (Resolution A/RES/3/189) *(18)*. These resolutions constitute a milestone in the effort to put the issue of transplants on international public health agendas, representing consensus on an international framework for transplant practices, and facilitating the development of rules and optimal conditions for these interventions.

5. In 2009, the Region adopted Resolution CD49.R18 *(3),* approving the Policy Framework for Human Organ Donation and Transplantation, which proposed that the

countries have a policy framework for strengthening national capacity to effectively and efficiently address the issue of organ donation and transplants and achieve optimal use of the resources allocated for this purpose. The resolution urges the Member States to apply the WHO Guiding Principles; to promote equitable access to transplant services; to fight efforts to obtain economic gain or comparable advantages in transactions with human body parts, as well as organ trafficking and transplant tourism[2]; and to strengthen health authority stewardship and governance in this area *(13, 19)*. The resolution also seeks to increase the safety and efficacy of donation and transplants and encourage collaboration among the countries in data collection for adequate monitoring of the safety, quality, efficacy, epidemiology, and ethics of the procedures. In 2011, Argentina's *Instituto Nacional Central Único Coordinador de Ablación e Implante* (INCUCAI) launched the Donation and Transplantation Registry (DONASUR), created by the States Parties of the Southern Common Market (MERCOSUR) Agreement to obtain information on donation and transplants in these countries. In recent years, this registry has expanded to other countries in the Americas, and its participants now include Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Ecuador, Mexico, Panama, Paraguay, Peru, Uruguay, and Venezuela *(20)*.

Situation analysis

6. The world has witnessed the growing prevalence and incidence of noncommunicable chronic diseases, some of which can be successfully treated with organ, tissue, and cell transplants. Refractory chronic kidney disease and its main risk factors, diabetes and hypertension, have steadily increased and today are a global public health problem due to the medical, social, and economic consequences for individuals, families, communities, and health systems. Approximately 12% of Latin America's population suffers from this health problem *(21)*. In the Caribbean, diseases related to lifestyle, diabetes mellitus, and hypertension, are the main causes of chronic kidney disease, while in Central America, there has been a growing number of cases of chronic kidney disease from nontraditional causes, primarily among young men and, in lesser proportion, women, children, and adolescents *(22,23)*. At the same time, liver disease causes roughly two million deaths per year worldwide: cirrhosis is the 11th leading cause of death, and liver cancer, the 16th *(24, 25)*. Hepatitis C is the most common cause of liver disease in Latin America and the main indication for liver transplantation *(26)*. Similarly, according to WHO estimates, in 2010 the global prevalence of blindness, a visual disability that, like others, disproportionately affects the poor and elderly populations, was 39 million people *(27, 28)*. Some of these conditions can be successfully treated with transplants, and kidney and corneal transplantation are two examples of transplants yielding better results than other therapies in terms of survival, quality of life, and cost-effectiveness *(28, 29)*. Other types of transplantation, such as liver, heart, and skin transplants, and procedures involving the use of stem cells, are increasingly common and are used to save and improve the lives of people with debilitating or, in many cases, fatal, diseases *(2, 28)*.

[2] For the purposes of this document, the definitions of *organ trafficking* and *transplant tourism* are those of the Declaration of Istanbul 2018.

7. The data currently show an increase in global and regional transplant activity. The GODT reported that 135,860 solid[3] organ transplants were performed in 2016, 53,345 of them in the Americas *(30)*. In 2016, the solid organ transplants most commonly performed in the Region were kidney transplants (33,378), followed by liver transplants (11,000). Globally, there was a 7.2% increase in the organ transplant rate per million population between 2015 and 2016; regionally, the rate increased by 6.8% during the same period. The percentage of transplants from living donors worldwide in 2016 was 35% of the total organ transplants, relatively higher than the 32.6% of the previous year; in the Region, the figure rose from 21.8% in 2015 to 25.5% in 2016 *(30-34)*. A comparison of transplant rates among the six WHO regions, expressed as transplants per million population, shows that the most active region is the Americas, with 53.3 transplants per million population, followed by Europe, with 46.9 per million *(30)*.

8. While these numbers are encouraging, a more in-depth analysis reveals unequal development of access to transplants in the countries of the Region, since the majority of the procedures are performed in just a few countries. In the Region, the United States reports the highest donation rate, followed by Canada. The United States has 31.7 donors per million population while Canada has 21.9. Similarly, the United States has the highest transplant rate, with 109.9 transplants per million population, followed by Canada[4] with 78.1 *(34)*. In Latin America, the average rate of cadaveric donation is 6.3 per million population, and only Argentina, Brazil, Colombia, Panama, and Uruguay have rates above this average *(35)*. The organ transplant rate ranges from less than 1 to 47 per million population.

9. Analysis of the data on kidney transplants, one of the most widespread procedures in the world and the procedure of choice for the treatment of refractory chronic kidney disease, offers a window on country transplant capacity and reveals the Region's unequal development in this area *(35, 36)*. Although transplants are increasingly used for renal replacement therapy in the Americas, the increase in the use of this procedure has still not caught up with the increase in patients on waiting lists, and hemodialysis remains the treatment of choice, even though it is less effective. Kidney transplant rates in several Central American countries are much lower than the regional average, and few countries in the non-Latin Caribbean report the use of this therapy *(37)*. The data from the Region indicate the need to create and expand active kidney transplant programs in every country and especially in Central America and the Caribbean *(38)*.

10. Information on legal and regulatory frameworks, institutions, infrastructure, and available resources is important for developing strategies to increase access to transplants.

[3] The data on solid organ transplantation correspond to kidney, liver, heart, lung, pancreas, and small intestine transplants.

[4] Spain remains the global leader in cadaveric donation, with a rate of 47 per million population. In Latin America, Uruguay leads, with 16.8 per million population, followed by Brazil (14.2) and Argentina (12). In 2016, 64% of all kidney transplants in the Americas were performed in the United States and Canada.

A 2013 study shows that some countries have comprehensive up-to-date legislation, while others do not have a specific or comprehensive regulatory framework covering both donation and transplants[5] *(39-41)*. The Pan American Network for Drug Regulatory Harmonization (PANDRH) recently noted the need to regulate cellular products and therapies. While cell and tissue transplants are effective therapies that save lives and improve the quality of life, cells and tissues are considered medical products or devices of biological origin and must be used under strict quality and safety rules *(42)*. Latin America currently has more than 220 human and animal tissue banks, but these banks display heterogenous donation rates measured per million population. More than 50% of these facilities specialize in eye tissue, followed by those specializing in musculoskeletal and skin tissue. Mexico (69), Brazil (56), and Argentina (29) have the greatest number of tissue banks *(35, 43)*.

11. The main barriers to the gradual expansion of transplant therapy in many countries are the lack of institutionality and consolidation of national programs, adequate infrastructure, and human resources with the necessary competencies and training *(1)*. While some countries have national or regional organizations that oversee the donation-transplant process,[6] others do not. The number of hospital transplant coordinators is inadequate, and the majority of hospitals in the Region do not have a designated coordinator for this function *(1, 35)*. A recent survey showed wide variability of the nephrology workforce relative to the population, with inverse proportions in low- and middle-income countries compared to high income countries *(36, 44)*.[7]

12. Other factors that limit access to transplants are the lack of financing and adequate financial protection *(2, 45, 46)*. The high cost of transplants and post-transplant immunosuppression therapy limits equitable access unless health systems provide financial coverage and protection for these treatments. Argentina, Brazil, Canada, Colombia, Costa Rica, Cuba, the United States, and Uruguay have coverage for the costs of transplants *(47, 48)* and this coverage is correlated with a greater transplant activity.

13. Several studies have demonstrated the cost-effectiveness of many transplants. Moreover, kidney transplants are not only cost-effective but cost-saving for the health

[5] In countries such as Argentina, Canada, Chile, Colombia, Ecuador, Panama, and the United States, the regulatory framework and supplementary rules cover most aspects of donation and transplants; in some cases, there are even regulations governing cell and tissue transplants. The 13 DONASUR member countries have a law regulating donation and transplant activity. However, the structure of their systems varies widely, from a hospital model with hospital donation coordinators (4 countries, 30.8%) to an out-of-hospital model (3 countries, 23.1%); the majority (6 countries, 46.1%) have a mixed model, with hospital, state, or regional coordination. Argentina, Brazil, and Uruguay have different models that can provide examples of good practices and outcomes.

[6] DONASUR mentions that there are 2,248 donation facilities, 2,201 transplant programs (1,024 of them active), and 157 tissue banks. With respect to national development of transplant programs, it was found that 11 of the 13 countries reporting have a specific government entity responsible for this issue, and two have two such programs or areas under the Ministry of Health.

[7] The availability of nephrologists in the Region varies widely, with rates ranging from 2.1 per million population in Honduras to 50.8 per million in Uruguay. This gap is also observed in the number of transplant coordinators. In recent years, efforts have been made to improve this situation. The Ibero-American Network/Council of Donation and Transplantation (RCIDT) has trained 350 coordinators to promote and coordinate the donation and transplant process in the Region of the Americas.

system *(29)*. As the data from studies in Argentina and Colombia show, kidney transplants are the best treatment alternative for patients with terminal chronic kidney disease and yield better outcomes in terms of survival, quality of life, and cost-effectiveness than renal replacement therapy with dialysis, in addition to increasing the sustainability of health systems *(49)*. The same holds true for corneal transplants, which are the world's most common type of transplant and are often the only means of restoring the vision of patients with damaged corneas. Several studies have shown that this intervention is considered cost-effective and results in a substantial improvement in quality of life *(2, 28, 50)*. One of the most important cost and cost-effectiveness variables is the price of immunosuppressants *(51)*, which varies widely in the Region. Joint procurement of these medicines can increase access to quality therapies at a lower cost. Procurement of immunosuppressants at up to 80% lower prices through PAHO's Regional Revolving Fund for Strategic Public Health Supplies (the Strategic Fund) is an important example of this strategy *(52, 53)*.

14. Even in countries that have developed national transplant capacities and programs, limited organ, tissue, and cell availability is a major barrier to timely access to these treatments. Currently, the organ supply is inadequate to meet the demand. In 2016, more than 182,000 people were on a waiting list for a kidney transplant, and less than 10% of the need for liver transplants is considered to be met in the Region *(1, 21, 26-28)*. Similarly, blindness from corneal deterioration remains a global health problem, largely due to the shortage of quality corneal grafts *(50)*. In the same vein, the design and administration of waiting lists and allocation criteria can maximize equity and the probability that the organ will function for a long time and prolong the recipient's life. There are geographical, socioeconomic, and other challenges related to the criteria and practices involved in the preparation of transplant candidate lists that can make it hard to develop fair and equitable criteria for organ allocation. Determination of these criteria should involve a transparent and participatory process and should be periodically reviewed *(54)*. Moreover, in order to increase the organ and tissue supply, countries should adopt effective policies that encourage donation among the population. Living donors can be used in the case of kidney and liver transplants, although donation should be regulated to prevent organ, tissue, and cell trafficking and guarantee that these procedures adhere to the strictest ethical standards. Organ donation by living donors should be performed so as to minimize physical, psychological, and social risks to the donor and ensure that public trust and the credibility of the transplant program are not jeopardized *(55)*.

15. The ethical and legal standards governing the donation of organs from deceased patients are critically important and should include the diagnostic criteria for brain death and cardiac arrest, as well as the mechanism for obtaining consent for the donation. On this latter point, legal frameworks tend to be based on the principle of presumed consent or explicit consent *(56-58)*.[8] Countries that have opted for presumed consent models have a

[8] Presumed consent is based on the assumption that the majority of citizens have a positive attitude about donation; thus, in the absence of a formal expression of opposition, when a death occurs, the deceased is

donation index 25% to 30% higher than those with explicit consent models, although the long-term impact of these laws should be evaluated.[9] It should be pointed out that the countries that have enacted these laws have done so within the framework of broader strategies that tend to increase donation and, thus, their impact should not be considered in isolation *(59)*. In some cases, presumed consent laws have led to resistance in society, which, added to the high rates of family opposition to donation, underscores the importance of cultural acceptability and community participation in strategies to promote donation *(60, 61)*. Several organizations have offered recommendations for encouraging organ donation have been issued *(61-64)*. The explosion of social networks and successful examples of their use to promote donation make it necessary to incorporate these new strategies *(65)*.

16. Inequity, a high poverty index, and low educational levels predispose the Region to the risk of organ trafficking. Unfortunately, the global scarcity of organs for transplants has created incentives for the commercial trafficking of organs from deceased and living donors unrelated to the recipients, as well as "transplant tourism" *(66, 67)*. The development of legal instruments and practices for supervising the processes for donation and acquisition or procurement of organs and transplants, the definition of basic eligibility criteria for tissue and cell donors, the creation of ethics committees, and the adoption of measures to protect the poorest and most vulnerable groups are intended to counteract transplant tourism, the sale of tissues and organs, and the trafficking of organs and other transplant materials *(19)*.

Proposal

17. The general objective of this strategy and plan of action is to promote equitable access to organ, tissue, and cell transplants through voluntary donation, observing the Guiding Principles on transplants to meet the growing demand for these treatments, save lives, and improve the health of individuals and communities. The document focuses on two basic areas: promoting voluntary organ, tissue, and cell donation to ensure the availability of transplant material, and strengthening the governance, stewardship, and capacities of the health authorities to promote equitable access to quality transplants. The proposal is grounded in the principles and guidelines developed by PAHO, WHO, and other important actors, such as the Ibero-American Network/Council of Donation and Transplantation (RCIDT) and the United Nations system. It is expected that the proposal will be implemented considering the specific context of the health systems and the needs, vulnerabilities, and priorities of the Member States.

presumed to be a donor. Most legislation recognizes the family as the repository of the last will of the deceased. Explicit consent, in contrast, is a system that requires citizens, while still living, to state their desire to become a donor. In the absence of this formal statement, when a death occurs, the family can also make the decision.

[9] Five countries in Latin America have presumed consent laws governing organ donation: Argentina, Colombia, Chile, Ecuador, and Uruguay.

Strategic Lines of Action

18. The plan includes the following strategic lines of action:

a) Strengthen health authority governance and stewardship in cell, tissue, and organ donation and transplants, especially its oversight capacity.

b) Increase the availability of organs, tissues, and cells through voluntary non-remunerated donation.

c) Increase equitable access to organ, tissue, and cell transplants in health systems.

d) Improve information management, monitoring, surveillance, risk evaluation, and risk management activities related to organ, tissue, and cell donation and transplantation.

Strategic Line of Action 1: Strengthen health authority governance and stewardship in cell, tissue, and organ donation and transplants, especially its oversight capacity

19. Countries should have policies and legal frameworks in place for all aspects of donation, transplantation, and the fight against trafficking and transplant tourism, and they should strengthen their oversight capacity. Creating and strengthening national donation and transplant organizations will facilitate the promotion of voluntary altruistic donation and the creation and administration of the competent services for these treatments.

Objective	Indicator	Baseline	Target
1.1 Develop, implement, and oversee compliance with legal frameworks and strategies for the organization of donation and transplant services consistent with the Guiding Principles of WHO	**1.1.1** Number of countries and territories with a legal and regulatory framework for the donation, acquisition or procurement, and transplantation of organs, tissues, and cells that prevents trafficking and transplant tourism and is consistent with the Guiding Principles of WHO	16	27
	1.1.2 Number of countries and territories with an adequate budget to finance a national plan for strengthening donation and transplant activities	9	27
1.2 Create or strengthen a national donation and transplant program	**1.2.1** Number of countries and territories with a national donation and transplant program that has the structure, competencies, and financing to exercise the donation and transplant responsibilities established by law, in keeping with the context of the health system	16	27

Strategic Line of Action 2: Increase the availability of organs, tissues, and cells through voluntary non-remunerated donation

20. Lack of timely organ, tissue, and cell availability is a barrier to increasing access to transplants. Creating and strengthening a national transplant coordination entity and a national, regional (if appropriate), and hospital network will make donation and timely access possible.

21. Promoting voluntary altruistic donation through strategies of proven effectiveness in which cultural acceptability is a factor is one of the determinants of a greater supply of transplant material. Countries should ensure adequate monitoring of living donors, guaranteeing their comprehensive treatment and care, and promote civil society engagement and social partnerships to encourage voluntary donation.

Objective	Indicator	Baseline	Target
2.1 Promote organ, tissue, and cell donation to increase the availability of these materials and ensure timely access	**2.1.1** Number of countries and territories with a plan to promote voluntary altruistic organ, tissue, and cell donation that includes a communication and community awareness strategy	16	27
	2.1.2 Number of countries and territories that increase the number of real donors (people from whom at least one organ has been removed for transplant purposes) by 5% every two years	0	27
2.2 Organize and consolidate an efficient donation and transplant services network within the health services network to meet the needs of the national health system	**2.2.1** Number of countries and territories with operating procedures, scientific and technical guidelines, and registries for standardizing the process of donor evaluation, selection, definition, and care	16	27
	2.2.2 Number of countries and territories with an organized network of donation and transplant services at the national, subnational (if appropriate), and hospital level	12	27

Strategic Line of Action 3: Increase equitable access to organ, tissue, and cell transplants in health systems

22. Early detection of potential transplant recipients, the preparation of waiting lists, and the definition of allocation criteria improve equity and timely access to transplants. Human resources education and the definition of technical and scientific criteria for organ, tissue, and cell donation, processing, and allocation, promote quality and effectiveness in the services, the transparency of the system, and a gradual increase in access to transplants.

Objective	Indicator	Baseline	Target
3.1 Increase access to organ, tissue, and cell transplant services in health systems through early detection of potential recipients and their timely referral	**3.1.1** Number of countries and territories with documented procedures that apply technical and scientific criteria to the identification, referral, and placement of potential recipients on waiting list for organ, tissue, and cell transplants	16	27
	3.1.2 Number of countries and territories with a national registry of people with chronic kidney disease and dialysis patients	17	27
	3.1.3 Number of countries and territories with a waiting list for the entire health system (public and private), coordinated by the regulatory body	13	27
3.2 Develop human resource competencies and skills and adopt technical and scientific criteria and quality management procedures in all aspects of donation and transplantation	**3.2.1** Number of countries and territories with technical and scientific criteria for the donation, processing, allocation, and distribution of organs, tissues, and cells	9	27
	3.2.2 Number of countries and territories with a quality management system that includes standardization of its human organ, tissue, and cell coding systems in line with international criteria, standardized indicators for evaluating donation procedures and services, and registration and oversight of the programs, institutions, and activities involved	7	27
	3.2.3 Number of countries and territories with one transplant coordinator or transplant service per high-complexity hospital (intensive treatment and neurosurgery) open 24/7 for donations, and with training programs for the human resources involved in all aspects of acquisition or procurement, donation, and transplantation, taught or endorsed by the regulatory body	3	27

Objective	Indicator	Baseline	Target
3.3 Ensure comprehensive care for recipients, as well as post-transplant treatment and monitoring, including immunosuppressants	**3.3.1** Number of countries and territories with financing for pre-transplant and transplant activities, from acquisition or procurement to transplantation and subsequent treatment	8	27
	3.3.2 Number of countries and territories that ensure access to drugs for pre- and post-transplant treatment	9	27

Strategic Line of Action 4: Improve information management, monitoring, surveillance, risk evaluation, and risk management activities related to organ, tissue, and cell donation and transplantation

23. Monitoring donation and transplant outcomes is essential for ensuring access to quality transplants. By knowing and analyzing the available information on donation and transplant management, it is possible to prevent adverse events through the development of risk analysis and assessment protocols and guidelines, and to put measures in place for their control and monitoring. Overseeing the services ensures compliance with regulations and progress in quality improvement.

Objective	Indicator	Baseline	Target
4.1 Improve the supervision, control, and monitoring of donation and transplant activity through traceability, and strengthen monitoring and reporting of donation and transplant outcomes	**4.1.1** Number of countries and territories with standards and mechanisms to verify oversight that address trafficking and transplant tourism and the control and monitoring of donation and transplant services and tissue banks in their health systems	7	27
	4.1.2 Number of countries and territories with an audit and inspection plan for donation and transplant services	7	27
4.2 Develop mechanisms for the identification and management of adverse events associated with organ, tissue, and cell donation and transplants	**4.2.1** Number of countries and territories with a biovigilance system aligned with the patient safety strategy and implemented and coordinated by the competent authority that permits the reporting, recording, surveillance, analysis, and management of adverse events	1	27

Objective	Indicator	Baseline	Target
4.3 Improve the management, analysis, and monitoring of information on donation and transplant activities	**4.3.1** Number of countries and territories with a national information system for recording donation and transplant activity for the entire health system, both public and private, overseen by the regulatory body, focused on traceability, and publicly reporting on the program's performance	9	27
	4.3.2 Number of countries and territories that report information to official international information systems (DONASUR, for example)	17	27

Monitoring and evaluation

24. The strategy and plan of action will contribute to implementation of the Strategic Plan of the Pan American Health Organization 2020-2025, as well as the Sustainable Health Agenda for the Americas 2030. The strategic lines of action will be operationalized through PAHO programs and budgets. Progress toward meeting the targets of the strategy and plan of action will be evaluated through two progress reports to the Governing Bodies of PAHO, one in 2023 and the other in 2027. A final report with more in-depth information on the progress made will be submitted in 2031.

25. The Pan American Health Organization will also provide advisory services and technical assistance for the plan's implementation and will conduct monitoring and evaluation. For this purpose, there may be collaboration with subregional entities linked with donation and transplants, such as the Intergovernmental Commission on Donation and Transplants of MERCOSUR and the Meeting of Ministers of Health of Central America (COMISCA), and regional entities, such as the Ibero-American Network/Council of Donation and Transplantation (RDCIT).

Financial impact

26. The total estimated cost of execution over the lifespan of this strategy and plan of action (2019-2030) is US$ 1,898,750. Investments from the Member States are expected for proper and comprehensive implementation of this plan at the country level, but this document does not provide estimates in this regard.

Action by the Directing Council

27. The Directing Council is invited to review the Strategy and Plan of Action on Donation and Equitable Access to Organ, Tissue, and Cell Transplants 2019-2030, issue the pertinent recommendations, and consider adopting the proposed resolution found in Annex B.

Annexes

References

1. Pan American Health Organization. Policy Framework for Human Organ Donation and Transplantation [Internet]. 49th Directing Council of PAHO, 61st Session of the Regional Committee of WHO for the Americas, 2009 Sep 28-Oct 2; Washington, DC. Washington, DC: PAHO; 2009 (Document CD49/14 [cited 2018 Dec 14]. Available from: http://www1.paho.org/hq/dmdocuments/2009/CD49-14-e.pdf.

2. Canadian Blood Services. Cost Benefit Analysis: Cornea Transplantation [Internet] 2011 April [cited 2018 Dec 10]; 1:8. Available from: https://professionaleducation.blood.ca/sites/msi/files/1.cost-benefit-analysis_cornea-transplantation-may-3_-3012.pdf.

3. Pan American Health Organization. Policy Framework for Human Organ Donation and Transplantation [Internet]. 49th Directing Council of PAHO, 61st Session of the Regional Committee of WHO for the Americas, 2009 Sep 28-Oct 2; Washington, DC. Washington, DC: PAHO; 2009 (Resolution CD49.R18) [cited 2018 Dec 14]. Available from: http://www1.paho.org/hq/dmdocuments/2009/CD49.R18%20(Eng.).pdf.

4. Pan American Health Organization. Final Report. 161st Session of the Executive Committee; 2017 Sep 29; Washington, DC. Washington DC: PAHO; 2017 (Document CE161/FR) [cited 2019 May 3]. Available from: https://www.paho.org/hq/index.php?option=com_docman&view=download&category_slug=29-en-9249&alias=43244-ce161-fr-e-244&Itemid=270&lang=en.

5. World Health Organization. Human organ and tissue transplantation [Internet]. 63rd World Health Assembly; 2010 May 17-21; Geneva. Geneva: WHO; 2010 (Resolution WHA63.22) [cited 2018 November 23]. Available from: http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_R22-en.pdf?ua=1.

6. Pan American Health Organization. Strategy for Universal Access to Health and Universal Health Coverage [Internet]. 53rd Directing Council of PAHO, 66th Session of the Regional Committee of WHO for the Americas; 2014 Sep 29-Oct 3; Washington, DC. Washington, DC: PAHO; 2014 (Document CD53/5, Rev. 2) [cited 2017 Jun 10]. Available from: https://www.paho.org/hq/dmdocuments/2014/CD53-5-e.pdf.

7. United Nations. Transforming our world: the 2030 Agenda for Sustainable Development [Internet]. Seventieth session of the United Nations General Assembly; 2015 Sep 15 – 2016 Sep 12; New York. New York: United Nations; 2015 (Resolution A/RES/70/1) [cited 2017 Jul 12]. Available from: https://undocs.org/en/A/RES/70/1.

8. Pan American Health Organization. Sustainable Health Agenda for the Americas: A Call to Action for Health and Well-being in the Region [Internet]. 29th Pan American Sanitary Conference, 69th Session of the Regional Committee of WHO for the Americas; 2017 Sep 25-29; Washington, DC. Washington, DC: PAHO; 2017 (Document CSP29/6, Rev. 3) [cited 2018 Jan 15]. Available from: https://www.paho.org/hq/index.php?option=com_docman&view=download&category_slug=29-en-9249&alias=41946-csp29-6-e-946&Itemid=270&lang=en.

9. Pan American Health Organization. Plan of Action for the Prevention and Control of Noncommunicable Diseases [Internet]. 52nd Directing Council of PAHO, 65th Session of the Regional Committee of WHO for the Americas, 2013 Sep 30-Oct 4; Washington, DC. Washington: PAHO; 2013 (Resolution CD52.R9) [cited 2018 Dec 4]. Available from: https://www.paho.org/hq/dmdocuments/2013/CD52-R9-e.pdf.

10. Pan American Health Organization. Chronic Kidney Disease in Agricultural Communities in Central America [Internet]. 52nd Directing Council of PAHO, 65th Session of the Regional Committee of WHO for the Americas, 2013 Sep 30-Oct 4; Washington, DC. Washington: PAHO; 2013 (Resolution CD52.R10) [cited 2018 Dec 14]. Available from: https://www.paho.org/hq/dmdocuments/2013/CD52-R10-e.pdf.

11. Pan American Health Organization. Access and Rational Use of Strategic and High-cost Medicines and Other Health Technologies [Internet]. 55th Directing Council of PAHO, 68th Session of the Regional Committee of WHO for the Americas, 2016 Sep 26-30; Washington, DC. Washington: PAHO; 2016 (Resolution CD55.R12) [cited 2018 Nov 14]. Available from: https://www.paho.org/hq/dmdocuments/2016/CD55-R12-e.pdf.

12. World Health Organization. Development of guiding principles for human organ transplants [Internet]. 40th World Health Assembly; 1987 May 4-15; Geneva,: Geneva: WHO; 1987 (Resolution WHA40.13) [cited 2018 Nov 14]. Available from: https://www.who.int/transplantation/en/WHA40.13.pdf?ua=1.

13. World Health Organization. Preventing the purchase and sale of human organs [Internet]. 42nd World Health Assembly; 1989 May 8-19 (Resolution WHA42.5) [cited 2018 November 14]. Available from: http://digicollection.org/hss/documents/s15558e/s15558e.pdf.

14. World Health Organization. Human organ transplantation [Internet]. 44th World Health Assembly; 1991 May 6-16; Geneva. Geneva: WHO; 1991 (Resolution WHA44.25) [cited 2018 Nov 23]. Available from: http://web.ont.es/SiteCollectionDocuments/wha44resen.pdf.

15. World Health Organization. Human organ and tissue transplantation. 63rd World Health Assembly; 2010 May 17-21; Geneva. Geneva: WHO; 2010 (Document A63/24) [cited 2018 Nov 23]. Available from: http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_24-en.pdf.

16. World Health Organization. Clinical criteria for the determination of death [Internet]. Geneva: WHO; 2017 [cited 2019 Jan 29]. Available from: http://www.who.int/iris/handle/10665/254737.

17. World Health Organization. Human organ and tissue transplantation [Internet]. 57th World Health Assembly; 2004 May 17-22; Geneva. Geneva: WHO; 2004 (Resolution WHA57.18) [cited 2018 Nov 23]. Available from: http://apps.who.int/gb/ebwha/pdf_files/WHA57/A57_R18-en.pdf.

18. United Nations. Strengthening and promoting effective measures and international cooperation on organ donation and transplantation to prevent and combat trafficking in persons for the purpose of organ removal and trafficking in human organs. Seventy-third Session of the United Nations General Assembly; 2018 Sep 19-2019 Sep 16; New York. New York: UN; 2018 (Resolution A/RES/73/189) [cited 2019 May 6]. Available from: https://undocs.org/en/A/RES/73/189.

19. Declaration of Istanbul Custodian Group. Declaration of Istanbul on Organ Trafficking and Transplant Tourism [Internet]. 27th International Congress of The Transplantation Society; 2018 Jun 30-Jul 5; Madrid, Spain. Montreal: The Transplantation Society; 2018 [cited 2018 Nov 10]. Available from: http://www.multivu.prnewswire.com/mnr/transplantationsociety/33914/docs/33914-Declaration_of_Istanbul-Lancet.pdf.

20. INCUCAI [Internet]. Buenos Aires: Ministerio de Salud y Desarrollo Social. Ámbitos de Integración Regional; [cited 2018 Nov 20]. Available from: https://www.incucai.gov.ar/index.php/institucional/integracion-regional/ambitos-de-integracion-regional.

21. Bello AK, Levin A, Tonelli M, Okpechi IG, Feehally J, Harris D, Jindal K, Salako BL, Rateb A, Osman MA, Qarni B, Saad S, Lunney M, Wiebe N, Ye F, Johnson DW. Global Kidney Health Atlas: A report by the International Society of Nephrology on the current state of organization and structures for kidney care across the globe [Internet]. Brussels: International Society of Nephrology; 2017 [cited 2018 Dec 4]. Available from: https://www.theisn.org/images/ISN_advocacy/GKHAtlas_Linked_Compressed1.pdf.

22. Soyibo AK, Barton EN. Chronic renal failure from the English-speaking Caribbean. West Indian Med J [Internet]. 2009 [cited 2019 May 6];58:596-600. Available from: https://www.mona.uwi.edu/fms/wimj/system/files/article_pdfs/dr_soyibo_special_issue_december.qxd_.pdf.

23. Pan American Health Organization. Epidemic of Chronic Kidney Disease in Agricultural Communities in Central America: Case definitions, methodological basis and approaches for public health surveillance. Washington, DC: PAHO; 2017. Available from: http://iris.paho.org/xmlui/handle/123456789/34132.

24. Marcellin P, Kutala BK. Liver diseases: A major, neglected global public health problem requiring urgent actions and large-scale screening. Liver Int [Internet]. 2018 [cited 2019 May 6];38(Suppl. 1):2-6. Available from: https://doi.org/10.1111/liv.13682.

25. Asrani SK, Devarbhavi H, Eaton J, Kamath PS. Burden of liver diseases in the world. J Hepatoly [Internet]. 2019 [cited 2019 May 6];70(1):151-171. Available from: https://doi.org/10.1016/j.jhep.2018.09.014.

26. Salvalaggio PR, Caicedo JC, de Albuquerque LC, Contreras A, Garcia VD, Felga GE, et al. Liver transplantation in Latin America: the state-of-the-art and future trends. Transplantation [Internet]. 2014 [cited 2019 May 6];98(3):241-6. Available from: https://journals.lww.com/transplantjournal/fulltext/2014/08150/Liver_Transplantation_in_Latin_America___The.3.aspx.

27. World Health Organization. Global Data On Visual Impairments 2010. [Internet]. Geneva: WHO; 2012 [cited 2018 Aug 20]. Available from: https://www.who.int/blindness/GLOBALDATAFINALforweb.pdf.

28. Gain P, Jullienne R, He Z, Aldossary M, Acquart S, Cognasse F, Thuret G. Global Survey of Corneal Transplantation and Eye Banking. JAMA Opht [Internet]. 2016 Feb [cited 2018 Oct 10];134(2):167-173. Available from: https://jamanetwork.com/journals/jamaophthalmology/fullarticle/2474372.

29. Rosselli D, Rueda JD, Diaz CE. Cost-Effectiveness of Kidney Transplantation Compared with Chronic Dialysis in End-Stage Renal Disease. Saudi J Kidney Dis Transpl [Internet]. 2015 July [cited 2018 Oct 20];26(4):733-738. Available from: http://www.sjkdt.org/article.asp?issn=1319-2442;year=2015;volume=26;issue=4;spage=733;epage=738;aulast=Rosselli.

30. Global Observatory on Donation and Transplantation. Organ Donation and Transplantation Activities. 2016 [Internet]. Organización Nacional de Trasplantes/ World Health Organization; 2018 [cited 2019 May 6]. Available from: http://www.transplant-observatory.org/download/2016-activity-data-report/.

31. Council of Europe; Organización Nacional de Trasplantes; European Directorate for the Quality of Medicines and Health Care. Newsletter transplant: International figures on donation and transplantation 2015 [Internet]. Strasbourg: EDQM; 2016 [cited 2018 Dec 12];21:1-65. Available from: http://www.ont.es/publicaciones/documents/newsletter%202016%20nipo.pdf.

32. Council of Europe; Organización Nacional de Trasplantes; European Directorate for the Quality of Medicines and Health Care. Newsletter transplant: International figures on donation and transplantation 2017 [Internet]. Strasbourg: EDQM; 2018 [cited 2018 Dec 12];23:1-86. Available from: https://www.organdonation.dk/siteassets/tal/nogletal-europa/nogletal-2018newsletter/newsletter-transplan-2017-volume-23-2018.pdf.

33. Global Observatory on Donation and Transplantation. Organ Donation and Transplantation Activities: 2015 Report. [Internet]. Organización Nacional de Trasplantes/World Health Organization; 2017 [cited 2018 Oct 18]. Available from: http://www.transplant-observatory.org/download/organ-donation-transplantation-activities-2015-report-2/.

34. Newsletter trasplante Iberoamérica [Internet]. Toledo, Spain: Organización Nacional de Trasplantes. Vol. 11, núm. 1, 2017 Dec [cited 2018 Nov10]. Available from: http://www.ont.es/publicaciones/Documents/NEWSLETTER%20IBEROAMERICA-2017_baja.pdf.

35. DONASUR. Primer informe regional del registro de donación y trasplante: Periodo 2014 al 2016 [Internet]. Buenos Aires: DONASUR; 2017 [cited 2018 Dec 10]. Available from: http://www2.congreso.gob.pe/sicr/cendocbib/con5_uibd.nsf/C5561E9EC1082B0A0525831900602C17/$FILE/Informe_regional_DONASUR_2014-2016.pdf.

36. Levin A. Improving Global Kidney Health: International Society of Nephrology Initiatives and the Global Kidney Health Atlas. Ann Nutr Metab [Internet]. 2018 [cited 2018 Oct 10];72(suppl 2):28-32. Available from: https://www.karger.com/Article/FullText/488123.

37. Gonzalez-Bedat MC, Rosa-Diez G, Ferreiro A. El Registro Latinoamericano de Diálisis y Trasplante Renal: la importancia del desarrollo de los registros nacionales en Latinoamérica. Nefrol Latinoam [Internet]. 2017 Mar [cited 2018 October 16];14(1): 1-46. Available from: http://www.elsevier.es/es-revista-nefrologia-latinoamericana-265-articulo-el-registro-latinoamericano-dialisis-trasplante-S2444903216300051.

38. Soyibo AK, Barton EN. Report from the Caribbean Renal Registry, 2006. West Indian Med J. 2007;56(4):355-363.

39. Glazier KA. Organ Donation and the Principles of Gift Law Clin J Am Soc Nephrol [Internet]. 2018 [cited 2019 May 6];13:1283-1284. Available from: https://doi.org/10.2215/CJN.03740318.

40. Organización Panamericana de la Salud. Legislación sobre donación y trasplante de órganos, tejidos y células: compilación y análisis comparado [Internet]. Washington, DC: OPS; 2013 [cited 2018 Oct 16]. Available from: https://www.paho.org/hq/dmdocuments/2013/HSS-MT-Leg--donacion-trasplante-2013.pdf.

41. Ochoa MM, Merck B, Villar V, García D, Ciangherotti C. Estado de la cuestión, aspectos conceptuales y de regulación sobre el uso de la terapia celular en la Unión Europea y en los Estados miembros de la Red/Consejo Iberoamericano de Donación y Trasplante. NewsLetter Trasplante Iberoamérica [Internet]. 2017 [cited 2018 Oct 12];11(1):13-24. Available from: http://www.ont.es/publicaciones/Documents/NEWSLETTER%20IBEROAMERICA-2017_baja.pdf.

42. Organización Panamericana de la Salud. Estado actual de la regulación sobre los medicamentos de terapias avanzadas. Nota conceptual y recomendaciones. Washington, DC: OPS; 2018.

43. Kairiyama E, Martínez ME, Sánchez E, Otero I. Overview on radiation and tissue banking in Latin America. Cell Tissue Bank [Internet]. 2018 Jun [cited 2018 Nov 10];19(2):249-257. Available from: https://link.springer.com/article/10.1007%2Fs10561-018-9699-9.

44. Matesanz R, Soratti C, Pérez-Rosales MD. Regional Perspective: The Iberoamerican Network/Council on Donation and Transplantation. Available from: https://journals.lww.com/transplantjournal/Fulltext/2015/09000/Regional_Perspective___The_Iberoamerican.1.aspx.

45. Medina-Pestana JO, Duro-García V. Strategies for Establishing Organ Transplant Programs in Developing Countries: The Latin America and Caribbean Experience. Artif Organs [Internet]. 2006 [cited 2019 May 6];30(7)498-500. Available from: https://onlinelibrary.wiley.com/doi/epdf/10.1111/j.1525-1594.2006.00250.x.

46. DeFilippis EM, Vaduganathan, M, Machado S, Stehlik J, Mehra MR. Emerging Trends in Financing of Adult Heart Transplantation in the United States. JACC Heart Fail [Internet]. 2019 [cited 2019 May 6];7:56-62. Available from: https://www.sciencedirect.com/science/article/pii/S2213177918307583.

47. Hepp Kuschel J. Organización y financiamiento del trasplante hepático en Chile: ¿cómo debiera ser?. Medwave [Internet]. 2007 Ago [cited 2019 May 6];7 (7): e3328. Available from: http://www.medwave.cl/link.cgi/medwave/cursos/3328?ver=sindiseno.

48. Arrieta J. Evaluación económica del tratamiento sustitutivo renal (hemodiálisis, diálisis peritoneal y trasplante) en España. Nefrología [Internet]. 2010 Mar [cited 2018 Sep 28]; 1(1):37-47. Available from: http://www.revistanefrologia.com/es-pdf-X2013757510002348.

49. Organización Panamericana de la Salud. Estudio de costo efectividad comparativa entre trasplante renal y técnicas dialíticas como alternativas de tratamiento sustitutivo en enfermedad renal crónica terminal. Washington, DC: OPS; 2018.

50. World Health Organization. Towards universal eye health: a global action plan 2014-2019 [Internet]. 66th World Health Assembly; 2013 May 20-28; Geneva. Geneva: WHO; 2013 (Resolution WHA66.4) [cited 2018 Oct 10]. Available from: https://apps.who.int/iris/bitstream/handle/10665/151023/A66_R4-sp.pdf?sequence=1&isAllowed=y.

51. Mercado-Martínez FJ, Hernández-Ibarra E, Ascencio-Mera E, Díaz-Medina BA, Padilla-Altamira C, Kierans C. Viviendo con trasplante renal, sin protección social en salud: ¿Qué dicen los enfermos sobre las dificultades económicas que enfrentan y sus efectos? Cad Saúde Pública. 2014;30(10):2092-2100.

52. Fondo Estratégico: Apoyando el acceso y disponibilidad a Medicamentos e Insumos Estratégicos de Salud Pública. Newsletter transplante Iberoamerica [Internet]. 2016 [cited 2019 May 6];10(1):15-19. Available from: http://www.ont.es/publicaciones/Documents/NEWSLET.%20IBEROAMERICA-2016.pdf.

53. Pan American Health Organization [Internet]. Washingon, DC: PAHO. The Strategic Fund supports the MERCOSUR countries and Associate States in the procurement of immunosuppressant medicines at reduced prices; 2018 Nov 23 [cited 2019 May 6]. Available from: https://www.paho.org/hq/index.php?option=com_content&view=article&id=14843:the-strategic-fund-supports-the-mercosur-countries-and-associate-states-in-the-procurement-of-immunosuppressant-medicines-at-reduced-prices&Itemid=39594&lang=en.

54. González F, Rocca X. Un sistema de asignación de órganos para trasplante que no considere las edades de donante y receptor es inicuo. Rev Med Chile [Internet]. 2015 Nov [cited 2018 Sep 26];143(11):1419-1425. Available from: https://scielo.conicyt.cl/pdf/rmc/v143n11/art07.pdf.

55. Alberú-Gómez J, Baquero A, Delpín E, Tanús E, Reyes-Acevedo R, Matamoros M, et al. El Document de Aguascalientes. Rev de Inv Cli [Internet]. 2011 Apr [cited 2018 Sep 4];63(2):187-197. Available from: http://www.medigraphic.com/pdfs/revinvcli/nn-2011/nn112k.pdf.

56. Rithalia A, McDaid C, Suekarran S, Myers L, Sowden A. Impact of presumed consent for organ donation on donation rates: a systematic review. BMJ [Internet]. 2009 Jan 15 [cited 2018 December 16];338:a3162. Available from: https://www.bmj.com/content/338/bmj.a3162.

57. Boyarsky BJ, Hall EC, Deshpande NA, Ros RL, Montgomery RA, Steinwachs DM, Segev DL. Potential Limitations of Presumed Consent Legislation. Transplantation [Internet]. 2012 Jan [cited 2018 Oct 10]; 93(2):136-40. Available from: https://journals.lww.com/transplantjournal/fulltext/2012/01270/Potential_Limitations_of_Presumed_Consent.2.aspx.

58. Zúñiga-Fajuri A. Increasing organ donation by presumed consent and allocation priority: Chile. Bull World Health Org [Internet]. 2015 [cited 2018 Oct 4];93:199-202. Available from: https://www.who.int/bulletin/volumes/93/3/14-139535/en/.

59. Bustamante-Ubilla M, Villarreal-Navarrete P, Cisternas-Ramírez C. Percepción y disposición a donar órganos en Chile. Rev Adm Pública [Internet]. 2011;45(1):243-252. Available from: http://dx.doi.org/10.1590/S0034-76122011000100011.

60. Erbs Pessoa JL, Schirmer J, de Aguiar Roza B. Evaluation of the causes for family refusal to donate organs and tissue. Acta Paul Enferm [Internet]. 2013 [cited 2019 May 6];26(4):323-330. Available from: http://www.scielo.br/scielo.php?pid=S0103-21002013000400005&script=sci_arttext&tlng=en.

61. Molina MI, Toro PA, Manzi E, Dávalos D, Torres K, Aristizábal AM, et al. Principales causas de negativa familiar a la donación de órganos y tejidos: 10 años de experiencia en un centro latinoamericano. Nefrologia. 2018;38:225-227 Nefrología [Internet]. 2018 [cited 2019 May 6];38(2):220-228. Available from: https://www.revistanefrologia.com/en-main-causes-family-refusal-organ-articulo-S2013251418300117.

62. Red/Consejo Iberamericano de Donación y Trasplante. Recomendación Rec-CIDT-2006 (6) sobre solución a la escasez de donantes. Newsletter transplante Iberoamerica [Internet]. 2017 [cited 2019 May 6];1(1):23-38. Available from: http://www.ont.es/publicaciones/Documents/IberoamericaNEWSLETTER07.pdf.

63. Organ Procurement and Transplantation Network [Internet]. Washington, DC: U.S. Department of Health & Human Services. Ethical Principles in the Allocation of Human Organs [Internet]; 2015 June [cited 2018 Dec 2]. Available from: https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/.

64. Salim A, Malinoski D, Schulman D, Desai C, Navarro S, Ley EJ. The Combination of an Online Organ and Tissue Registry With a Public Education Campaign Can Increase the Number of Organs Available for Transplantation. J Trauma [Internet]. 2010 Aug [cited 2019 May 6];69(2):451-454. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2927713.

65. Cameron AM, Massie AB, Alexander CE, Stewart B, Montgomery RA, Benavides NR, Fleming GD, Segev DL. Social Media and Organ Donor Registration: The Facebook Effect. Am J Transplant [Internet]. 2013 [cited 2019 May 6];13:2059-2065. Available from: https://onlinelibrary.wiley.com/doi/epdf/10.1111/ajt.12312.

66. Delmonico FL. The Hazards of Transplant Tourism. Clin J Am Soc Nephrol [Internet]. 2009 [cited 2019 May 6];4:249-250. Available from: https://cjasn.asnjournals.org/content/4/2/249.long.

67. Lopez-Casas JG. La donación y el trasplante de componentes anatómicos en Colombia: siete décadas de logros. [Internet]. 2017 [cited 2019 May 6];37(2):1-2. Available from: https://www.revistabiomedica.org/index.php/biomedica/article/view/3909/3535.

Annex A

WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation[1]

1. Cells, tissues and organs may be removed from the bodies of deceased persons for the purpose of transplantation if: *a)* any consent required by law is obtained, and *b)* there is no reason to believe that the deceased person objected to such removal.

2. Physicians determining that a potential donor has died should not be directly involved in cell, tissue or organ removal from the donor or subsequent transplantation procedures; nor should they be responsible for the care of any intended recipient of such cells, tissues and organs.

3. Donation from deceased persons should be developed to its maximum therapeutic potential, but adult living persons may donate organs as permitted by domestic regulations. In general living donors should be genetically, legally or emotionally related to their recipients. Live donations are acceptable when the donor's informed and voluntary consent is obtained, when professional care of donors is ensured and follow-up is well organized, and when selection criteria for donors are scrupulously applied and monitored. Living donors should be informed of the probable risks, benefits and consequences of donation in a complete and understandable fashion; they should be legally competent and capable of weighing the information; and they should be acting willingly, free of any undue influence or coercion.

4. No cells, tissues or organs should be removed from the body of a living minor for the purpose of transplantation other than narrow exceptions allowed under national law. Specific measures should be in place to protect the minor and, wherever possible the minor's assent should be obtained before donation. What is applicable to minors also applies to any legally incompetent person.

5. Cells, tissues and organs should only be donated freely, without any monetary payment or other reward of monetary value. Purchasing, or offering to purchase, cells, tissues or organs for transplantation, or their sale by living persons or by the next of kin for deceased persons, should be banned. The prohibition on sale or purchase of cells, tissues and organs does not preclude reimbursing reasonable and verifiable expenses incurred by the donor, including loss of income, or paying the costs of recovering, processing, preserving and supplying human cells, tissues or organs for transplantation.

[1] Updated Guiding Principles, approved by the World Health Assembly in 2010. World Health Organization. Human organ and tissue transplantation. 63rd World Health Assembly; 2010 May 17-21; Geneva, Switzerland. Geneva (Switzerland): WHO; 2010 (Document A63/24) [cited 2018 Nov 23]. Available from: http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_24-en.pdf

6. Promotion of altruistic donation of human cells, tissues or organs by means of advertisement or public appeal may be undertaken in accordance with domestic regulation. Advertising the need for or availability of cells, tissues or organs, with a view to offering or seeking payment to individuals for their cells, tissues or organs, or, to the next of kin, where the individual is deceased, should be prohibited. Brokering that involves payment to such individuals or to third parties should also be prohibited.

7. Physicians and other health professionals should not engage in transplantation procedures, and health insurers and other payers should not cover such procedures, if the cells, tissues or organs concerned have been obtained through exploitation or coercion of, or payment to, the donor or the next of kin of a deceased donor.

8. All health-care facilities and professionals involved in cell, tissue or organ procurement and transplantation procedures should be prohibited from receiving any payment that exceeds the justifiable fee for the services rendered.

9. The allocation of organs, cells and tissues should be guided by clinical criteria and ethical norms, not financial or other considerations. Allocation rules, defined by appropriately constituted committees, should be equitable, externally justified, and transparent.

10. High-quality, safe and efficacious procedures are essential for donors and recipients alike. The long-term outcomes of cell, tissue and organ donation and transplantation should be assessed for the living donor as well as the recipient in order to document benefit and harm. The level of safety, efficacy and quality of human cells, tissues and organs for transplantation, as health products of an exceptional nature, must be maintained and optimized on an ongoing basis. This requires implementation of quality systems including traceability and vigilance, with adverse events and reactions reported, both nationally and for exported human products.

11. The organization and execution of donation and transplantation activities, as well as their clinical results, must be transparent and open to scrutiny, while ensuring that the personal anonymity and privacy of donors and recipients are always protected.

Pan American Health Organization
World Health Organization
REGIONAL OFFICE FOR THE Americas

57th DIRECTING COUNCIL

71st SESSION OF THE REGIONAL COMMITTEE OF WHO FOR THE AMERICAS

Washington, D.C., USA, 30 September-4 October 2019

CD57/11
Annex B
Original: Spanish

PROPOSED RESOLUTION

STRATEGY AND PLAN OF ACTION ON DONATION AND EQUITALBLE ACCESS TO ORGAN, TISSUE, AND CELL TRANSPLANTS 2019-2030

THE 57th DIRECTING COUNCIL,

(PP1) Having reviewed the *Strategy and Plan of Action on Donation and Equitable Access to Organ, Tissues, and Cell Transplants 2019-2030* (Document CD57/11);

(PP2) Taking into account that, in 2009, the Pan American Health Organization (PAHO) approved the Policy Framework for Human Organ Donation, and Transplants, through Resolution CD49.R18, and that in September 2017, the Executive Committee of PAHO called on the Director of the Pan American Sanitary Bureau to begin consultations for the preparation of a plan of action on human organ donation and transplants to advance more quickly down the path established in the policy;

(PP3) Considering that, in 2017, the 29th Pan American Sanitary Conference approved the Sustainable Health Agenda for the Americas 2018-2030, whose goals include promoting the expansion of equitable access to medicines, vaccines, and other priority and quality health technologies, based on the available scientific evidence, as an important step toward universal access to health and universal health coverage,

RESOLVES:

(OP)1. To approve and implement the *Strategy and Plan of Action on Donation and Equitable Access to Organ, Tissue, and Cell Transplants 2019-2030* (Document CD57/11);

(OP)2. To urge the Member States, bearing in mind the specific context of their national health systems and needs, vulnerabilities, and priorities, to:

a) promote implementation of the Strategy and Plan of Action on Donation and Equitable Access to Organ, Tissue, and Cell Transplants 2019-2030 to achieve the gradual expansion of and the equitable and quality access to organ, tissue, and cell transplants through voluntary altruistic donation, observing the Guiding Principles on transplantation of the World Health Organization;

b) report periodically on the progress of this strategy and the indicators included in the plan of action.

(OP)3. To request the Director to:

a) provide technical cooperation to the Member States for the preparation of updated national plans of action, and disseminate tools that facilitate the availability of organs, tissues, and cells and access to transplants;

b) strengthen and promote coordination among countries, including through South-South cooperation, and among United Nations agencies, other international organizations, and the main actors working on issues related to organ, tissue, and cell donation and transplant activities;

c) report periodically to the PAHO Governing Bodies on the progress made and challenges encountered in the implementation of the Strategy and Plan of Action.

Report on the Financial and Administrative Implications of the Proposed Resolution for PASB

1. Agenda item: 4.9 – Strategy and Plan of Action on Donation and Equitable Access to Organ, Tissue, and Cell Transplants 2019-2030

2. Linkage to Proposed PAHO Program Budget 2020-2021:*

Outcome 8: Increase in equitable access to safe, affordable, clinically effective, cost-effective, and quality-assured essential medicines, vaccines, and other health technologies, and in the rational use of medicines, with strengthened regulatory systems that contribute to the achievement of universal access to health and universal health coverage.

** The proposed PAHO Program Budget 2020-2021 was presented to the 13th Session of the Subcommittee on Program, Budget, and Administration and to the 164th Session of the Executive Committee. The 57th Directing Council will review the proposed Program Budget in September 2019. Therefore, the final version of the Program Budget may have some changes to the outcomes, which will be reflected in this Strategy and Plan of Action as well.*

3. Financial implications:

a) Total estimated cost for implementation over the lifecycle of the resolution (including staff and activities):

The total estimated cost of the strategy and plan of action is US$ 1,898,750. This estimate considers the total amount necessary for the activities of the Pan American Sanitary Bureau. However, the outcomes will be achieved only if the Member States also increase their strategic investments in donation, acquisition or procurement, and transplantation. Consequently, the total amount necessary for the key activities at the country level is not reflected in this estimate. The estimated amount for staffing (see the following table) includes the PAHO staff member currently assigned to program area 4.3 at the regional level. The estimated amounts for activities (training, consultants, travel and meetings, publications, and supplies) were calculated considering the regular funds and voluntary contributions that must be mobilized during the strategy and plan of action's implementation period.

Areas	Estimated cost (US$)
Staffing	708,750
Training	200,000
Consultants/service contracts	700,000
Travel and meetings	230,000
Publications	30,000
Supplies and other expenses	30,000
Total	1,898,750

b) Estimated cost for the 2020-2021 biennium (including staff and activities):

The estimated cost for the 2020-2021 biennium is US$ 388,381 (this is the cost of implementing the strategy and plan of action for the biennium, including October to December 2019).

c) Of the estimated cost noted in *b)*, what can be subsumed under existing programmed activities?

US$ 140,400.

4. Administrative implications:

a) Indicate the levels of the Organization at which the work will be undertaken:

All levels of the Organization will be involved, namely: regional, country, and subregional. The participation of the ministries of health of the Member States, as well as other sectors at the national and local level, will also be needed. The participation of other United Nations agencies, main actors and organizations, and subregional mechanisms will facilitate effective, harmonized implementation of the necessary multisectoral action.

b) Additional staffing requirements (indicate additional required technical staff full-time equivalents, noting necessary skills profile):

Implementation of the Strategy and Plan of Action on Donation and Equitable Access to Organ, Tissue, and Cell Transplants 2019-2030 will require the support of a consultant.

c) Time frames (indicate broad time frames for the implementation and evaluation):

Implementation will begin on approval of this strategy and plan of action by the Directing Council to guarantee its inclusion in the new Strategic Plan and Program Budget.

Three evaluations of this strategy and plan of action will be conducted to measure the progress made toward the goals and, if necessary, make adjustments. A final report will be submitted to the PAHO Governing Bodies in 2031.

CD57/11
Annex D

Analytical Form to Link Agenda Item with Organizational Mandates

1. Agenda item: 4.9 – Strategy and Plan of Action on Donation and Equitable Access to Organ, Tissue, and Cell Transplants 2019-2030

2. Responsible unit: Medicines and Health Technologies (MT)

3. Preparing officer: Dr. Analía Porrás

4. Link between Agenda item and Sustainable Health Agenda for the Americas 2018-2030:

The proposed strategy and plan of action are fully aligned with the principles and values of the Sustainable Health Agenda for the Americas 2018-2030, especially the right to the enjoyment of the highest attainable standard of health, the universality of equity in health, and social inclusion. The purpose of the strategy and plan of action is to make the vision of the Sustainable Health Agenda for the Americas 2018-2030, in terms of equitable access to organ, tissue, and cell transplants, a reality for all people in the Region of the Americas that need them.

The strategy and plan of action addresses the full scope of the Sustainable Health Agenda for the Americas 2018-2030 and emphasizes objectives 1, 2, 3, 4, 5, 6, 7, 9, and 11.

The strategy and plan of action is also expected to help meet most of the targets of the Sustainable Health Agenda for the Americas 2018-2030, emphasizing targets 1.1, 2.1, 2.2, 2.3, 3.2,4.2, 4.5, 5.7, 6.1, 6.2, 6.3, 7.1, 7.2, 9.1, 9.3 and 11.1.

5. Link between Agenda item and the Proposed Strategic Plan of the Pan American Health Organization 2020-2025:*

Outcome 8: Increase in equitable access to safe, affordable, clinically effective, cost-effective, and quality-assured essential medicines, vaccines, and other health technologies, and in the rational use of medicines, with strengthened regulatory systems that contribute to the achievement of universal access to health and universal health coverage.

** The proposed PAHO Strategic Plan 2020-2025 was presented to the 13th Session of the Subcommittee on Program, Budget and Administration and the 164th Session of the Executive Committee. The 57th Directing Council will review this proposal in September 2019. Thus, the final version of the Strategic Plan may contain certain changes in the outcomes, which will be reflected in this Strategy and Plan of Action as well.*

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

- In the case of the countries of the Region: ministries of health, social protection, and development; and national institutes of health.
- Instituto Nacional Central Único Coordinador de Ablación e Implante (INCUCAI) of Argentina. PAHO/WHO Collaborating Center
- Ibero-American Network/Council of Donation and Transplantation (RCIDT)
- Subregional initiatives: Southern Common Market (MERCOSUR), Andean Health Organization - Hipólito Unanue Agreement (ORAS-CONHU), Union of South American Nations (UNASUR), Meeting of Ministers of Health of Central America (COMISCA), Caribbean Community (CARICOM).
- United Nations and other agencies involved in transplantation activities.
- Declaration of Istanbul Custodian Group (DICG).
- United States Agency for International Development (USAID).
- Inter-American Development Bank (IDB).
- Other: civil society organizations and academic, scientific, and research institutions.

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

- In 2011, Instituto Nacional Central Único Coordinador de Ablación e Implante (INCUCAI), of Argentina created the Donation and Transplantation Registry (DONASUR) to obtain information on donation and transplants in the MERCOSUR countries. In recent years, this registry has been expanded to other countries in the Americas, with PAHO support. The current participants are Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Ecuador, Mexico, Panama, Paraguay, Peru, Uruguay, and Venezuela.
- The Commission of Ministers of Health of Central America and the Dominican Republic (COMISCA), through its endorsement of the Declaration of Antigua in 2011, committed its governments to including chronic kidney disease as a health priority within the context of the global mobilization to contain noncommunicable chronic diseases.
- The Intergovernmental Donation and Transplant Commission (CIDT) of MERCOSUR, comprised of the officials responsible for donation and transplantation in Argentina, Brazil, Paraguay, and Uruguay, as Permanent Members, and in other Latin American countries, as Associated States, works to promote cooperation in human resources education, conduct analyses of the economic aspects of transplants, and establish common quality and safety standards for the procurement, processing, preservation, distribution, transportation, and implantation of organs, tissues, and cells.
- The Regional Revolving Fund for Strategic Public Health Supplies (the Strategic Fund), as a technical cooperation mechanism for increasing access to strategic public health supplies and contributing to the strengthening and sustainability of health systems in the Region, facilitated the joint procurement of immunosuppressants by the MERCOSUR countries, resulting in savings of up to 80% of the costs incurred by national procurement mechanisms.

- The Ibero-American Network/Council of Donation and Transplantation (RCIDT), a permanent institution/organization, seeks to serve as the point of intersection for different initiatives linked with donation and organ, tissue, and cell transplants in the Ibero-American countries, Spain, and Portugal. This initiative was endorsed at the VII Ibero-American Conference of Ministers of Health and the Summit of Heads of State and Government, held respectively in the cities of Granada and Salamanca, Spain, in 2005. The RCIDT is comprised of ministerial representatives from 21 Spanish- and Portuguese-speaking countries in the Americas and Europe. The Pan American Health Organization (PAHO) has supported this initiative from the outset.

8. Financial implications of this Agenda item:

The total estimated cost of the strategy and plan of action is US$ 1,898,750. This estimate takes into account the total amount corresponding to the activities of the Pan American Sanitary Bureau, including regional capacity building and technical support to the Member States. The estimated cost for the 2020-2021 biennium is US$ 388,381 (this is the cost of implementing the strategy and plan of action for the biennium, including October to December 2019).

However, the results will be achieved only if the Member States also increase their strategic investments in donation, acquisition or procurement, and transplantation. Consequently, the total amount necessary for the key activities at the country level is not reflected in this estimate.

- - -