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STRATEGY AND PLAN OF ACTION ON DONATION AND EQUITABLE ACCESS TO ORGAN, TISSUE, AND CELL TRANSPLANTS 2019–2030: PROGRESS REPORT

Background

1. The purpose of this document is to inform the Governing Bodies of the Pan American Health Organization (PAHO) regarding progress made in the implementation of the Strategy and Plan of Action on Donation and Equitable Access to Organ, Tissue, and Cell Transplants 2019–2030 (Document CD57/11) (1), adopted by the 57th Directing Council of PAHO in 2019, through Resolution CD57.R11 (2). The goal of the strategy and plan of action is to promote equitable access to organ, tissue, and cell transplants, based on voluntary donation and on the World Health Organization (WHO) guiding principles on transplantation, in order to meet the growing demand for these treatments, save lives, and improve the health and conditions of individuals and communities (3). The strategic lines of action in this document, together with its objectives and indicators, provide a roadmap to address priorities in the Region of the Americas, namely: improving the availability of organs, tissues, and cells; and strengthening the initiatives and capacities of Member States, the Pan American Sanitary Bureau, and relevant national and international organizations in this field.

2. The COVID-19 pandemic has profoundly affected health systems in the Region, and its donation and transplant systems were no exception, with the closure of programs, reduction of activities, and setbacks in previously achieved results. These impacts were worsened by access barriers to transplantation such as the lack of institutional consolidation of national programs; inadequate infrastructure and lack of human resources with adequate skills and training; lack of funding and financial protection; and failure to recognize transplants as a cost-effective option (4). This situation reduced the capacity to perform transplants in the different health systems of the Region and to advance in the progressive expansion of transplant therapy. The number of deceased donors and the number of transplants also declined, and there were delays in the admission of patients to waiting lists (5). The time patients remain on waiting lists to receive an organ also increased. As the COVID-19 pandemic led to reduced donation and transplantation rates—and in some countries, to a complete cessation of activities (6),—there was a negative impact on progress towards meeting the indicators of the strategy and plan of action.

Analysis of Progress Achieved

3. In coordination and cooperation with PAHO/WHO collaborating centers such as Spain's National Transplant Organization (ONT) and Argentina's *Instituto Nacional Central Único Coordinador de Ablación e Implante* [national institute for excision and implants] (Incucaí), technical cooperation was provided for Member States to implement the strategy and plan of action, and address the COVID-19 pandemic. This progress report is based on the report of the Global Observatory on Donation and Transplantation (GODT) (7); the DONASUR regional report (8); the Latin American Dialysis and Transplant Registry (9); the results of progress evaluation meetings within the framework of the Ibero-American Network/Council on Donation and Transplantation (RCIDT) (10), which is led by the ONT; subregional meetings; and reports from country delegates.

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

4. All countries and territories in Central and South America have a legal framework for donation and transplants, and Caribbean countries have made progress on this indicator. The COVID-19 pandemic altered the provision of budgets to fund national donation and transplant plans; however, some countries are improving this situation by promoting the need to recover donation rates. Outstanding challenges include the need to update regulatory frameworks in accordance with internationally recognized practices, advance in the development and financing of national donation and transplant plans, and improve system coordination by strengthening national donation and transplant coordination structures and organized services networks that enable donation and timely access.

Objective 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	
Indicator, baseline, and target	Status
<p>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</p> <p>Baseline (2019): 16 Target (2031): 27</p>	<p>Nineteen countries and territories have a legal and regulatory framework. Some of them are making progress in updating their laws.</p>
<p>1.1.2 Number of countries and territories with an adequate budget to finance a national plan for strengthening donation and transplant activities</p> <p>Baseline (2019): 9 Target (2031): 27</p>	<p>Eight countries and territories reported compliance with this indicator. The COVID-19 pandemic affected the budgets of donation and transplant services.</p>

Objective 1.2: Create or strengthen a national donation and transplant program	
Indicator, baseline, and target	Status
<p>1.2.1 Number of countries and territories that have 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</p> <p>Baseline (2019): 16 Target (2031): 27</p>	Seventeen countries and territories have a national donation and transplant program with structure, competencies, and financing.

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

5. The availability of organs, tissues, and cells is based on voluntary altruistic donation and on the development of an organized network of donation and transplantation services that facilitate access to transplants. Due to the COVID-19 pandemic, progress was not made toward the objectives and indicators of this strategic line, given the disruptions to donation and transplant services in hospitals as care shifted to infected patients. Donation and transplant rates declined, and in some countries activities ceased altogether. It is necessary to encourage the participation of civil society, build social partnerships to increase voluntary altruistic donation, and reactivate and strengthen donation and transplant services. These actions are necessary to consolidate deceased donor programs and to recover donation and transplant rates.

Objective 2.1: Promote organ, tissue, and cell donation to increase the availability of these materials and ensure timely access	
Indicator, baseline, and target	Status
<p>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</p> <p>Baseline (2019): 16 Target (2031): 27</p>	Seventeen countries and territories have a plan to promote voluntary altruistic organ, tissue, and cell donation.
<p>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</p> <p>Baseline (2019): 0 Target (2013): 27</p>	Three countries and territories increased the number of real deceased donors by 5%. This indicator was calculated considering information from GODT for 2018 and 2021; 2020 was not included due to the major impact of the COVID-19 pandemic on donation rates.

Objective 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	
Indicator, baseline, and target	Status
<p>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</p> <p>Baseline (2019): 16 Target (2031): 27</p>	Fifteen countries and territories have operating procedures, scientific and technical guidelines, and registries.
<p>2.2.2 Number of countries and territories with an organized network of donation and transplant services at the national, subnational (if applicable), and hospital level</p> <p>Baseline (2019): 12¹ Target (2031): 27</p>	Thirteen countries and territories have an organized network of donation and transplant services at the national, subnational, and hospital level. Reactivation of services is the basis for recovering donation and transplant rates.

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

6. Improving access to transplants depends on several factors: *a)* early identification of potential recipients; *b)* establishing waiting lists; *c)* establishing technical and scientific criteria for donation; *d)* processing and allocating organs, tissues, and cells; and *e)* training health personnel. Progress was made in the development of technical and scientific and quality criteria. Some countries increased access to transplant services through early identification of potential recipients and timely referral. There are persistent challenges to maintaining a national waiting list, using chronic kidney disease and dialysis registries, and ensuring that all stages of transplantation are included in financing and coverage mechanisms for transplants and access to immunosuppressants.

Objective 3.1: Increase access to organ, tissue, and cell transplant services in health systems through early detection of potential recipients and their timely referral	
Indicator, baseline, and target	Status
<p>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</p> <p>Baseline (2019): 16 Target (2031): 27</p>	Seventeen countries and territories have technical and scientific criteria for identifying, referring, and placing recipients on waiting lists for organ, tissue, and cell transplants.

¹ One country was counted twice—the adjusted number is 11.

Objective 3.1: Increase access to organ, tissue, and cell transplant services in health systems through early detection of potential recipients and their timely referral	
Indicator, baseline, and target	Status
<p>3.1.2 Number of countries and territories with a national registry of people with chronic kidney disease and dialysis patients</p> <p>Baseline (2019): 17 Target (2031): 27</p>	<p>Eighteen countries and territories have a national registry of people with chronic kidney disease and dialysis patients.</p>
<p>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</p> <p>Baseline (2019): 13 Target (2031): 27</p>	<p>Fifteen countries and territories have a waiting list for the entire health system (public and private), coordinated by the regulatory body</p>
Objective 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	
Indicator, baseline, and target	Status
<p>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</p> <p>Baseline (2019): 9 Target (2031): 27</p>	<p>Fifteen countries and territories have technical and scientific criteria for the donation, processing, allocation, and distribution of organs, tissues, and cells</p>
<p>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</p> <p>Baseline (2019): 7 Target (2031): 27</p>	<p>Ten countries and territories have a quality management system.</p>

Objective 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	
Indicator, baseline, and target	Status
<p>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</p> <p>Baseline (2019): 3 Target (2031): 27</p>	<p>Twelve countries and territories have one transplant coordinator or transplant service per high-complexity hospital (intensive treatment and neurosurgery) for donations.</p>
Objective 3.3: Ensure comprehensive care for recipients, as well as post-transplant treatment and monitoring, including immunosuppressants	
Indicator, baseline, and target	Status
<p>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</p> <p>Baseline (2019): 8 Target (2031): 27</p>	<p>Thirteen countries and territories have financing for pre-transplant and transplant activities, from acquisition or procurement to transplantation and subsequent treatment</p>
<p>3.3.2 Number of countries and territories that ensure access to drugs for pre- and post-transplant treatment</p> <p>Baseline (2019): 9 Target (2031): 27</p>	<p>Fourteen countries and territories ensure access to medicines for pre- and post-transplant treatment.</p>

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

7. Stewardship of the donation and transplant system includes monitoring the outcomes of donation (living and deceased), transplantation into the recipient, and oversight of services. The COVID-19 pandemic directly affected this strategic line as well since many services stopped functioning. Some countries made progress in developing registries of information on national activities and in recording and analyzing adverse events. There was very significant progress in the number of countries reporting to GODT and DONASUR as official international information systems. This allowed progress in the transparency and monitoring of regional activity. It is necessary to implement quality audit programs to monitor the indicators of improvement in donation and transplantation activities. It is also necessary to involve the health or regulatory authority in order to advance in the registration, authorization, and surveillance of services.

Objective 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	
Indicator, baseline, and target	Status
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 Baseline (2019): 7 Target (2031): 27	Ten countries and territories have standards and mechanisms to verify oversight
4.1.2 Number of countries and territories with an audit and inspection plan for donation and transplant services Baseline (2019): 7 Target (2031): 27	Nine countries and territories have an audit and inspection plan for donation and transplant services
Objective 4.2: Develop mechanisms for the identification and management of adverse events associated with organ, tissue and cell donation and transplants	
Indicator, baseline, and target	Status
4.2.1 Number of countries and territories with a biosurveillance 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 Baseline (2019): 1 Target (2031): 27	Five countries and territories have a biosurveillance system aligned with the patient safety strategy.
Objective 4.3: Improve the management, analysis, and monitoring of information on donation and transplant activities	
Indicator, baseline, and target	Status
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 Baseline (2019): 9 Target (2031): 27	Fifteen countries and territories have a single national information system for the entire health system, led by the regulatory body.

Objective 4.3: Improve the management, analysis, and monitoring of information on donation and transplant activities	
Indicator, baseline, and target	Status
<p>4.3.2 Number of countries and territories that report information to official international information systems (e.g., DONASUR)</p> <p>Baseline (2019): 17 Target (2031): 27</p>	<p>Twenty-three countries and territories report information to official international information systems.</p>

Lessons Learned

8. The following are some of the lessons learned and good practices in the implementation of the strategy and plan of action:

- a) Donation and transplant programs reflect the development of health systems. Donation and transplant services play an essential role in health systems, saving or improving the quality of lives of many patients.
- b) The COVID-19 pandemic impacted the objectives of the strategy and plan of action. The increasing number of infected patients who required hospitalization led to reduced donation and transplant activities, a decrease in the number of deceased donors and transplants, and delays in joining waiting lists. This compromised the health and lives of patients.
- c) The health crisis caused by the COVID-19 pandemic complicated decision-making aimed at reactivating donation and transplant services without compromising the availability of organs, tissues, and cells, and ensuring access to safe procedures. This experience must be considered when dealing with similar events in the future.
- d) Increased availability of organs and tissues, and improved access to transplants, should be based on donations by deceased people. For this, it is necessary to promote voluntary altruistic donation in the community. The donation of organs by living donors should complement donations by deceased persons and should be used in specific cases, according to national legislation, with technical criteria defined at the national level to ensure proper monitoring and comprehensive care.

Action Needed to Improve the Situation

9. In light of the achievements and challenges presented in this report, the following actions are proposed for consideration by the Member States:

- a) Increase the governance and stewardship of donation and transplant programs to strengthen the management of national programs, efficient organization of services, and oversight of activities.

- b) Strengthen and expand financial support for the adoption of national action plans for donation and transplantation, and advance health system coverage at all stages of the donation and transplant process in order to progressively expand access to transplants.
- c) Recognize transplantation as an essential service of national health systems and prioritize the networking of these services to reduce the risk of morbidity and mortality from chronic diseases associated with transplants.
- d) Increase donation rates, strengthening deceased donor programs as the main source of organs and tissues for transplants and promoting voluntary altruistic donation through strategies of proven effectiveness, training of donation coordinators, and appropriate regulations that promote this.
- e) Strengthen the development and use of national registries of chronic kidney disease and dialysis, as well as national waiting lists for patients requiring a transplant; and develop technical and scientific criteria for the donation, processing, and allocation of organs, tissues, and cells as a mechanism to ensure equitable access to transplants.
- f) Expand continuous access by transplant patients to immunosuppressive medicines, considering procurement mechanisms such as PAHO's Strategic Fund.
- g) Advance the development of information systems aimed at collecting, analyzing, and monitoring information related to donation activities, transplant patients, living donors, and reporting of adverse events in order to improve decision-making.
- h) Analyze information from official registries coordinated by PAHO/WHO collaborating centers to monitor the progress of donation and transplant policies, and improve the transparency of the system.
- i) Consider international reference documents and regional recommendations established by RCIDT and PAHO to update legal frameworks, documents, and technical criteria.
- j) Continue joint work among Member States, PAHO, and two PAHO/WHO collaborating centers (ONT and Incucaí) to achieve the objectives of the Strategy and Plan of Action for Donation and Equitable Access to Organ, Tissue, and Cell Transplants.

Action by the Directing Council

10. The Directing Council is invited to take note of this report and provide any comments it deems pertinent.

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