

TOWARDS GLOBAL CONVERGENCE IN TRANSPLANTATION: SUFFICIENCY, TRANSPARENCY & OVERSIGHT

09-10/NOV/2023
High Level Meeting



SANTANDER STATEMENT

On 9 and 10 November 2023, the Organización Nacional de Trasplantes (ONT), under the Spanish Presidency of the Council of the European Union, convened in Santander a Global Summit entitled “Towards Global Convergence in Transplantation: Sufficiency, Transparency and Oversight”. The Summit was co-organised by the European Directorate for the Quality of Medicines and Healthcare (EDQM) of the Council of Europe, the European Society for Organ Transplantation (ESOT), and The Transplantation Society (TTS). The Summit was co-sponsored by the World Health Organization (WHO) and supported by the International Society of Nephrology (ISN).

The Summit’s objective was to pave the way for global action in transplantation for the next decade. In particular, the Summit aimed to critically review the current state of donation and transplantation of organs, tissues, and cells, identify key challenges, and shape the future direction of transplant activities worldwide to ensure that advances in this field benefit citizens across the globe.

The Summit, attended by 183 participants from 57 countries, international organisations and professional associations, concluded with the following set of recommendations targeted to national and regional governments, though acknowledging the role of other key stakeholders, including health authorities, relevant professional associations, healthcare professionals and institutions, law enforcement agencies, academic and research institutions, and civil society organisations. The Summit also called upon international organisations, in particular the European Union, the Council of Europe, and the WHO, to provide guidance and support States in taking effective measures to implement these recommendations to ensure that no one is left behind.

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RECOMMENDATIONS

Participants in the Global Convergence in Transplantation Summit urge governments to:

1. Improve patient care by

- implementing preventive strategies to reduce the burden of diseases that give rise to the need for transplantation;
- integrating donation and transplantation of organs, tissues, and cells into their healthcare systems, taking into account the resources available to address the population's health needs;
- prioritising transplant therapy when that is the most cost-beneficial treatment modality for patients;
- incorporating opportunities for donation of organs, tissues and cells into end-of-life care;
- working towards a unified concept of death, recognising that death can be defined as the permanent cessation of brain functions;
- supporting low-resource countries in developing and strengthening their transplant systems;
- making donation and transplant programs resilient by establishing emergency preparedness plans designed to ensure a timely and effective response to transplant needs in the event of crisis;
- identifying and relieving inequities in access to donation and transplantation and to Substances of Human Origin (SoHO)-based therapies.

2. Make progress towards sufficiency in transplantation by

- developing and expanding deceased donation to its maximum therapeutic potential, including donation after both the neurological and the circulatory determination of death;
- developing living donation programs, preferably as supplements to deceased donation, that ensure informed consent, optimal care of, and long-term follow-up for donors;
- removing financial disincentives for living and deceased donation, while prohibiting financial incentives, in order to ensure that donation is a financially neutral act.

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3. Ensure transparency and oversight of practices by

- designating health authorities at the national or regional level that are responsible for the authorisation and monitoring of donation and transplant activities;
- mandating the reporting of data on every donation and transplant procedure, as well as demographic, clinical, and outcome data of recipients and living donors to a registry established or recognized by the relevant health authority;
- establishing a biovigilance system and ensuring the traceability of organs, tissues, and cells from donors to recipients and vice versa;
- supporting data sharing, including by health authorities with relevant international bodies and registries, with due regard for the protection of patients' and donors' privacy.

4. Strengthen the prevention of human trafficking for the removal of SoHO and trafficking in SoHO by

- ensuring appropriate psychosocial evaluation of all prospective living donors;
- establishing a mechanism for the mandatory reporting of suspected or confirmed cases of trafficking, while respecting professional obligations towards patients and maintaining a human rights-based approach focusing on early identification and appropriate protection of victims;
- criminalising and prosecuting all illicit transplant-related activities within their jurisdiction, including by establishing extraterritorial jurisdiction over such activities of their residents in other countries;
- strengthening national and international cooperation in combatting transplant-related crimes.

5. Foster responsible innovation for the clinical use of SoHO by

- actively supporting and funding efforts to overcome the research and economic challenges in developing sustainable innovation;
- mandating the demonstration of quality, safety, and effectiveness of SoHO-based therapies before permitting them to be incorporated into healthcare systems;
- reinforcing the capacity of donation and transplant systems to oversee ethical conduct and clinical translation of research;
- ensuring that human organs, tissues and cells do not become marketable products and that necessary fees for services relating to SoHO and benefits from SoHO-derived products are proportionate and consistent with the altruistic nature of donation;
- ensuring transparency in costs, pricing, and profits from all SoHO-based therapies, and making such therapies affordable to patients;
- promoting social responsibility in public-private collaboration in the development of SoHO-based therapies.