

Increasing availability, ethical access and oversight of transplantation of human cells, tissues and organs

Draft decision proposed by Argentina, Brazil, China, the European Union and its 27 Member States, Peru and Qatar

The Executive Board, having considered the report by the Director-General,¹

Decided to recommend to the Seventy-seventh World Health Assembly the adoption of the following resolution:

The Seventy-seventh World Health Assembly,

(PP1) Having considered the report by the Director-General;

(PP2) Recalling Health Assembly resolutions WHA40.13 (1987) on development of guiding principles for human organ transplants,² WHA42.5 (1989) on preventing the purchase and sale of human organs³ and WHA44.25 (1991) on human organ transplantation,⁴ WHA57.18 (2004) on human organ and tissue transplantation⁵ and WHA63.22 (2010) on human organ and tissue transplantation (updated WHO Guiding Principles);⁶

(PP3) Noting initiatives by WHO regions in advancing the implementation of current resolutions on transplantation, including decisions taken by the WHO Regional Committee for the Americas⁷ and the WHO Regional Committee for Africa;⁸

¹ Document EB154/7.

² Resolution WHA40.13.

³ Resolution WHA42.5.

⁴ Resolution WHA44.25.

⁵ Resolution WHA57.18.

⁶ In resolution WHA63.22, the Health Assembly endorsed the updated WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation. See resolution WHA63.22 (accessed 26 December 2023).

⁷ See document CD57.R11 and resolution CD57.R11 (accessed 26 December 2023).

⁸ See document AFR/RC70/12 (accessed 26 December 2023).

(PP4) Noting the report by the Secretariat on principles on the donation and management of blood, blood components and other medical products of human origin, that promotes respect for human dignity, availability and safety, and good governance;¹

(PP5) Welcoming the United Nations General Assembly resolution 77/236 on 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;²

(PP6) Noting the Madrid resolution on organ donation and transplantation (2011),³ an outcome of the Third WHO Global Consultation on Organ Donation and Transplantation (2010) that provides recommendations for countries to progress towards meeting the transplant needs of patients;

(PP7) Aware that transplantation is currently the preferred, if not the only, therapeutic alternative for patients with end-stage organ failure and that many other diseases benefit from the clinical application of human cells and tissues, and that such treatments depend on the altruistic donation of cells, tissues and organs;

(PP8) Conscious that, despite the priority given by many Member States to prevention strategies, the burden of noncommunicable diseases treatable through transplantation continues to grow, as does the commensurate need for transplantation of human cells, tissues and organs;

(PP9) Mindful that facilitating access to transplantation of human cells, tissues and organs can reduce the premature mortality associated with noncommunicable and other diseases, improve the quality of life of thousands of patients throughout the world, and help communities to diminish the high costs of alternative treatment modalities;

(PP10) Noting that expanded access to transplant therapies might contribute to the achievement of the United Nations Sustainable Development Goals, in particular, targets 3.4 (reduction of premature mortality from noncommunicable diseases) and 3.8 (access to universal health care);⁴

(PP11) Aware that, despite the progress made over the past two decades, transplantation is not fully developed in all Member States, making access to these therapies neither universal nor equitable, a problem that impacts countries regardless of their level of development;⁵

¹ Document A70/19 (accessed 26 December 2023).

² See resolution A/RES/77/236 (accessed 26 December 2023).

³ The Madrid resolution on organ donation and transplantation: national responsibility in meeting the needs of patients, guided by the WHO principles. *Transplantation*. 2011; 91: S29–S31. doi: 10.1097/01.tp.0000399131.74618.a5.

⁴ Domínguez-Gil B, Ascher NL, Fadhil RAS, et al. The reality of inadequate patient care and the need for a global action framework in organ donation and transplantation. *Transplantation*. 2022 1;106(11):2111-2117.

⁵ See document A75/41 (accessed 26 December 2023).

(PP12) Noting with concern that the COVID-19 pandemic had a profound, negative effect on donation and transplantation activities,¹ revealing the need to consider including transplant therapies in approaches designed to strengthen the resilience of health care systems;

(PP13) Convinced that insufficient access to transplantation therapies is one of the root causes of trafficking in persons for the purpose of organ removal and trafficking in human organs, practices that undermine human rights and pose serious risks to public health;

(PP14) Alarmed that armed conflicts, natural disasters and humanitarian emergencies are fuelling migration, particularly among disadvantaged populations and those in the most vulnerable situations, thereby increasing the risk of trafficking in persons for the purpose of organ removal and trafficking in human organs, and exacerbating inequities in access to therapies based on human cells, tissues and organs;

(PP15) Noting with concern the lack of full implementation of the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation,² particularly regarding transparent data reporting and health authority oversight of transplant practices;

(PP16) Aware that technological innovations applicable to human cells, tissues, and organs are increasingly enabling therapies that, given the unique origin of these novel treatments, require specific regulations with a particular focus on ethical considerations,³

(OP)1. URGES Member States, in accordance with their national context:

- (1) to implement or strengthen existing preventive strategies targeted at reducing the burden of noncommunicable and other diseases treatable with transplantation;
- (2) to integrate donation, transplantation and transplant follow-up activities into health care systems, so deceased donation is routinely considered as an option at the end of life and transplantation is incorporated in the continuum of care of patients with noncommunicable and other diseases or conditions that may benefit from this therapy, by pursuing policies that support universal health coverage and eliminate financial barriers to access quality, safe, effective, affordable and essential health services;⁴
- (3) to protect living donors by requiring informed consent and appropriate medical and psychosocial evaluation, as well as by providing proper follow-up care;
- (4) to increase the availability of human cells, tissues and organs for transplantation with special attention to developing deceased donation to its maximum therapeutic potential, including donation after the neurological determination of death and, where appropriate,

¹ Aubert O, Yoo D, Zielinski D, et al. COVID-19 pandemic and worldwide organ transplantation: a population-based study. *Lancet Public Health*. 2021;6(10):e709-e719. doi: 10.1016/S2468-2667(21)00200-0.

² See document A63/24 (accessed 30 December 2023), annex adopted by reference in resolution WHA63.22.

³ WHO Expert Committee on Biological Standardization: seventy-seventh report. Geneva: World Health Organization; 2023 (WHO Technical Report Series, No. 1048) (<https://iris.who.int/bitstream/handle/10665/373128/9789240078116-eng.pdf?sequence=1>, accessed 30 December 2023).

⁴ United Nations General Assembly resolution 78/4 . Political Declaration of the high-level meeting on universal health coverage.

donation after the circulatory determination of death, and in line with the relevant WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation;

(5) to establish, where appropriate, official international cooperation for the exchange of human cells, tissues and organs or transplant services, based on the principles of reciprocity and solidarity, as a means to facilitate universal access to transplantation therapies;

(6) to develop and implement regulatory frameworks aligned with the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation, in particular by encouraging donation as an altruistic, voluntary and non-remunerated act and by promoting equitable access to transplantation therapies;

(7) to designate authorities and improve capacities to provide governance and implementation of donation and transplantation activities in their jurisdictions;

(8) to promote that donation and transplantation activities take place in centres specifically authorized, accredited or registered and establish control measures, such as periodic or risk-based inspections and the collection and timely reporting of data on every donation and transplant procedure, including transplants carried out on residents in other jurisdictions;

(9) to promote the safety and efficacy of transplantation by collecting data on the outcomes of recipients and living donors, conducting biovigilance and relevant surveillance, ensuring capacity to trace cells, tissues and organs from donor to recipient, and vice versa, and encouraging the use of global consistent coding systems for human cells, tissues and organs;

(10) to consider including donation and transplantation in national and regional preparedness plans designed to increase the resilience of health care systems and to facilitate an effective response to transplant needs in the event of crisis;

(11) to take measures to prevent and combat trafficking in persons for the purpose of organ removal and trafficking in human organs and to protect victims and survivors of these crimes by strengthening legislative frameworks, enforcing clinical protocols for the psychosocial evaluation of prospective living donors, engaging health care professionals, governments and other stakeholders in reporting suspected or confirmed cases of trafficking to law enforcement agencies, promoting international cooperation,¹ and collecting data and conducting research on the trends in both crimes;²

¹ World Medical Assembly statement on measures for the prevention and fight against transplant-related crimes. Seventy-first WMA General Assembly. Cordoba; 2020 (<https://www.wma.net/policies-post/wma-statement-on-measures-for-the-prevention-and-fight-against-transplant-related-crimes/#:~:text=The%20WMA%20emphasises%20the%20responsibility,assisting%20international%20organisations%2C%20medical%20associations> (accessed 26 December 2023)).

² Global Report on Trafficking in Persons, in accordance with the provisions set out in General Assembly resolution 70/179 of 17 December 2015.

(12) to promote research and innovation to maximize the use and optimize the outcomes of transplantation of human cells, tissues and organs, as well as enable development of alternative therapies to those based on the clinical use of human cells, tissues and organs;

(13) to implement regulatory frameworks applicable to innovative therapies developed from substantially manipulated cells, tissues and organs that ensure the protection of donors and recipients, and that pursue equity in access to these novel therapies and sustainable health care systems;

(14) to participate in consultations organized by WHO to develop a global strategy on donation and transplantation; and

(15) to consider providing appropriate support to WHO in implementing this resolution;

(OP)2. REQUESTS the Director-General:

(1) to provide Member States, upon request, with technical assistance for developing national legislation and regulations aligned with the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation,¹ assessing transplantation needs, establishing or strengthening national authorities, improving capacities to increase the availability of cells, tissues and organs, and implementing ethical, effective and safe transplant programmes;

(2) to assist Member States, upon request, to strengthen their regulatory capacity to effectively oversee donation and transplantation practices, including through monitoring and evaluating transplantation programme performance and donor and recipient outcomes;

(3) to continue collecting, analysing and making available to Member States global data on the legislation, regulations, practices, safety, quality, effectiveness, epidemiology and ethics of donation and transplantation of human cells, tissues and organs;

(4) to revise the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation to incorporate additional principles that address new ethical challenges posed by scientific advancements in the field, in particular principles to safeguard the intrinsic value of novel products and treatments that are developed from human cells, tissues and organs;

(5) to continue and strengthen cooperation with United Nations agencies, including the United Nations Office on Drugs and Crime, interagency mechanisms, Member State ministries and other relevant stakeholders to improve country, regional and global capacity to respond to identified cases of trafficking in persons for the purpose of organ removal and of trafficking in human organs;

(6) to provide, in cooperation with key international professional associations and other relevant stakeholders, reference guidance to Member States on the diagnosis of death by neurological and by circulatory criteria;

¹ In resolution WHA63.22, the Health Assembly endorsed the updated WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation. See resolution WHA63.22 (accessed 26 December 2023).

(7) to develop, in consultation with Member States, nongovernmental organizations and other relevant stakeholders in accordance with the Framework of Engagement with Non-State Actors and within existing resources, a global strategy on donation and transplantation, for consideration by the Seventy-ninth World Health Assembly, through the Executive Board at its 158th session, that supports Member States to integrate donation and transplantation into health care systems and promotes the implementation of the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation;

(8) to further explore, as part of the global strategy referred to in OP2(7), and in accordance with the current framework for world health days, the feasibility and potential impact of establishing a World Donor Day to raise public awareness and enhance understanding on the need for altruistic donation of human cells, tissues and organs and propel global action by Member States to structure appropriate donation and transplantation systems, taking into consideration the existence of other relevant events either observed by WHO or established by other international entities;

(9) to establish an expert committee in accordance with the Regulations for Expert Advisory Panels and Committees,¹ to assist the Secretariat in developing the proposed global strategy on donation and transplantation and support its implementation;

(10) to provide a consolidated report on progress in the implementation of this resolution in 2026 to the Seventy-ninth World Health Assembly, through the Executive Board at its 158th session, as well as on progress in the implementation of resolution WHA63.22 on human organ and tissue transplantation.

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¹ Regulations for Expert Advisory Panels and Committees. Geneva: World Health Organization; 2022 (<https://apps.who.int/gb/bd/PDF/bd47/EN/regu-for-expert-en.pdf>, accessed 30 December 2023)