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# **Human organ and tissue transplantation**

## **Report by the Director-General**

### **BACKGROUND**

1. In May 2010, the Sixty-third World Health Assembly adopted resolution WHA63.22,<sup>1</sup> in which it endorsed the updated WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation and provided strategic directions to support progress in human organ, tissue and cell donation with the aim of maximizing the benefits of transplantation, meeting the needs of recipients, protecting donors and ensuring the dignity of all involved. The present report aims to provide a comprehensive analysis of the current situation and facilitate a forward-looking discussion on actions for improving access to transplantation therapies. It is also submitted in response to decision WHA74(17) (2021)<sup>2</sup> in the context of the WHO governance reform process related to specifying end dates for reporting on governing bodies resolutions with unspecified reporting requirements and providing the governing bodies with an opportunity to decide on future reporting requirements.

### **CONTEXT**

2. The transplantation of human tissues, organs or cells is an established form of treatment that has been acknowledged as the best and very often only life-saving therapy for several serious and life-threatening congenital, inherited and acquired diseases and injuries.

3. **Human tissues for transplantation** include, but are not limited to, ocular (corneas and sclera), cutaneous (skin, dermis), musculoskeletal (bone, cartilage, ligaments), cardiovascular (heart valves, vascular conduits) and birth (chorion-amniotic membrane) tissues. The benefits of human tissue transplantation can be seen in both children and adults, including in survival rates following severe burn trauma, recovery of movement, closure of chronic wounds, rehabilitation of heart function and restoration of sight. Corneal disease (scarring or perforation) can be successfully addressed through transplantation in 80% of affected individuals.<sup>3</sup> Tissue transplantation allows many recipients to return to economically productive lives and promotes their independence.

4. While the development of xenografts (products of animal origin) and bioengineered alternatives is advancing, to date they cannot fully mimic or replace all human-sourced tissues on an equivalent basis. Where they are available, production costs and resourcing issues may be limiting factors to

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<sup>1</sup> See document WHA63/2010/REC/1, resolution WHA63.22 and Annex 8.

<sup>2</sup> See document WHA74/2021/REC/1, decision WHA74(17).

<sup>3</sup> Dunker SL, Armitage WJ, Armitage M, Brocato L, Figueiredo FC, Heemskerk MBA, et al. Outcomes of corneal transplantation in Europe: report by the European Cornea and Cell Transplantation Registry. *J Cataract Refract Surg.* 2021; 47(6): 780–85.

universal access. Thus, the availability of and access to human tissues for transplantation remains essential.

5. **Organ transplantation** is often the best, if not the only, treatment for acute and chronic organ failure. Noncommunicable diseases such as diabetes and arterial hypertension, combined with various social determinants (e.g. alcoholism, obesity), may lead to chronic kidney disease and liver cirrhosis, conditions that are among the top 10 causes of death worldwide. Kidney transplantation is a far more favourable treatment modality versus dialysis in terms of survival, quality of life and cost-effectiveness. For chronic or acute liver failure, as well as some cardiorespiratory conditions, the only alternative to transplantation is death.

6. **Haematopoietic stem cell transplants** have been performed in more than 1 500 000 patients (both autologous and allogeneic) to date.<sup>1</sup> Although haematological cancers remain the main indication, haematopoietic stem cell transplants are increasingly considered in the treatment of non-malignant disorders and genetic diseases such as haemoglobinopathies (sickle cell anaemia, thalassaemia) that can benefit greatly from this type of transplant. These inherited conditions previously had only limited treatment options available for disease modification with no possibility of a cure.

## WHO'S ACTIONS TO DATE

7. The following actions cover the period 2018–2021 (see also the Secretariat's previous progress reports submitted to the Sixty-seventh and Seventy-first World Health Assemblies),<sup>2</sup> during which significant organizational changes occurred as a result of implementation of the WHO transformation agenda, and the coronavirus disease (COVID-19) pandemic emerged, both of which have had an impact on the modalities and time frame of the Secretariat's work in this area.

8. In June 2018, the Secretariat established the WHO Task Force on Donation and Transplantation of Human Organs and Tissues as an advisory group composed of experts from all WHO regions. Its main objective is to advise and contribute to the development and implementation of WHO's activities on human organ and tissue transplantation. The Secretariat also established two transplantation working groups – one for organs and the other for tissues – with the objective of developing two global action frameworks for the period 2022–2030 to address the global and region-specific issues and challenges identified by the Task Force in its reports.

9. In 2018, AMRO/PAHO conducted a thorough evaluation of the status of transplantation in countries in Latin America for consideration by the Regional Committee for the Americas at its seventy-first session in October 2019. The Regional Committee subsequently adopted resolution CD57.R11 on the Strategy and Plan of Action on Donation and Equitable Access to Organ, Tissue and Cell Transplants 2019–2030. The main actions promoted in the strategy are directed towards overcoming the barriers to the gradual expansion of transplant therapy in many countries, namely lack of oversight and consolidation of national programmes and lack of adequate infrastructure and human resources with the necessary competencies and training.

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<sup>1</sup> Niederwieser D, Baldomero H, Atsuta Y, Aljurf M, Seber A, Greinix HT, et al. One and half million hematopoietic stem cell transplants (HSCT). Dissemination, trends and potential to improve activity by telemedicine from the Worldwide Network for Blood and Marrow Transplantation (WBMT). *Blood*. 2019; 134: 2035.

<sup>2</sup> Documents A67/40 and A71/41.

10. At its seventieth session in August 2020, the Regional Committee for Africa adopted a report on the status of human organ and tissue donation and transplantation in the WHO African Region.<sup>1</sup> The actions proposed in the report include the development of a regional strategy, plan of action and regulatory framework, the provision of support to Member States to strengthen their capacity, and the conduct of a large-scale ethnographic study to address socioeconomic beliefs pertaining to organ and tissue donation and transplantation.

11. In June 2021, the Secretariat collaborated with the Pontifical Academy of Sciences through co-sponsorship of an international workshop on the role of science in the development of international standards of organ donation and transplantation.<sup>2</sup> The workshop addressed key issues such as the evaluation of the burden of disease that results in organ failure and the need to include transplantation in universal health care packages as a cost-effective treatment option. Expert opinion and technical guidance were provided to strengthen regulatory capacity and oversight of practice.

## **COLLABORATION AND PARTNERSHIPS**

12. Data on human organ donation and transplantation continue to be collected and published on the website of the Global Observatory on Donation and Transplantation,<sup>3</sup> a collaborative project between the Secretariat and the National Transplant Organization of Spain (operating through the WHO Collaborating Centre on Donation and Transplantation). A review on the impact of the COVID-19 pandemic was undertaken in the year 2021 through a comparison of data between the years 2019 and 2020.

13. The NOTIFY Library,<sup>4</sup> jointly developed by the Secretariat and the Italian National Transplant Centre (operating through the WHO Collaborating Centre on Vigilance and Surveillance for Human Cells, Tissues and Organs), continues to collect data on the relevant serious adverse events and reactions related to human organ, tissue and cell transplantation, including more than 1700 didactic case studies, with an emphasis on emerging pathogens. The NOTIFY Booklet<sup>5</sup> was developed as a powerful learning tool for risk estimation, quality and safety improvement. The Secretariat has expanded the scope of the collaboration to include further reviews on the impact of emerging threats, such as the COVID-19 pandemic, on the safety and availability of all products of human origin in order to elaborate appropriate preparedness plans.

14. The Argentinian National Coordination Centre for Donation and Transplantation (operating through the WHO Collaborating Centre on Donation and Transplantation) has been tasked with supporting AMRO/PAHO in the implementation of the regional Strategy and Plan of Action on Donation and Equitable Access to Organ, Tissue and Cell Transplants 2019–2030 by reinforcing policies, enhancing training and developing donation and transplantation programmes in the Region of the Americas.

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<sup>1</sup> Document AFR/RC70/12.

<sup>2</sup> Proceedings of the workshop on the role of science in the development of international standards of organ donation and transplantation. Pontifical Academy of Sciences; 2021 ([https://www.pas.va/en/events/2021/organ\\_donation/final\\_statement.html](https://www.pas.va/en/events/2021/organ_donation/final_statement.html), accessed 8 March 2022).

<sup>3</sup> Available at: <http://www.transplant-observatory.org> (accessed 8 March 2022).

<sup>4</sup> See: <https://www.notifylibrary.org/content/notify-project> (accessed 8 March 2022).

<sup>5</sup> Available at: <https://www.notifylibrary.org/content/booklet-2018> (accessed 8 March 2022).

15. In response to United Nations General Assembly resolution 71/322 (2017) 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, the Secretariat has increased collaboration with the Inter-Agency Coordination Group against Trafficking in Persons, including UNODC and the Office of the High Commissioner for Human Rights (OHCHR). Some of the joint actions include co-sponsorship of an expert workshop<sup>1</sup> and contribution to an issue brief.<sup>2</sup>

16. Through its ongoing collaboration with non-State actors in official relations with the WHO (namely, The Transplantation Society, The Worldwide Network for Blood and Marrow Transplantation and the International Council for Commonality in Blood Banking Automation Inc.), the Secretariat has raised awareness of the issue among health care professionals and organized capacity-building and training activities, including workshops. Cooperation has been extended to other non-State actors that are not yet in official relations with WHO but are supporting the dissemination of the WHO Guiding Principles and the development of technical material (namely, the World Union of Tissue Banking Associations and the Global Alliance of Eye Bank Associations).

## CURRENT SITUATION AND CHALLENGES

17. Despite the range of activities developed by Member States, the Secretariat and other stakeholders during the 12 years since the adoption of resolution WHA63.22, there is still an apparent insufficient growth in and asymmetrical development of transplantation worldwide. Notwithstanding the differing capabilities and priorities of health care systems, common national and regional barriers persist as a result of:

- low organizational and political commitments, including lack of national strategies for transplantation and therefore lack of significant funding, human resources or infrastructure;
- lack of understanding of the burden of disease in order to escalate interventions for preventing end-stage organ failure;
- inadequate legislation, ethical frameworks, regulatory oversight and governance that may allow for illegal or unethical practices such as organ trafficking or tissue commercialization;
- limited community awareness and knowledge, as well as cultural resistance, regarding donation and the value of transplantation;
- deficiencies in deceased donor identification and donation management, including low awareness and engagement among the public and health care professionals;
- inadequate measures for the protection of living donors from coercion and exploitation;

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<sup>1</sup> Expert meeting on combating trafficking in human beings for the removal of organs. Organization for Security and Co-operation in Europe and United Nations Office of the High Commissioner for Human Rights; 2020 (<https://www.osce.org/cthb/473661>, accessed 8 March 2022).

<sup>2</sup> Issue brief on trafficking in persons for the purpose of organ removal. Inter-Agency Coordination Group against Trafficking in Persons; 2021 ([https://icat.un.org/sites/g/files/tmzbd1461/files/publications/icat\\_brief\\_tip\\_for\\_or\\_final.pdf](https://icat.un.org/sites/g/files/tmzbd1461/files/publications/icat_brief_tip_for_or_final.pdf), accessed 8 March 2022).

- deficient universal health coverage that excludes access to transplantation; and
- limited alternatives in cases of undersupply or emergencies.

18. **Human tissue donation, banking and transplantation** are at different stages of implementation or establishment at the regional level. The absence of, or reduced activity in, tissue transplantation indicates that its benefits have not yet been fully recognized or that issues surrounding availability have not been adequately addressed. The exact number of donors or recipients of available tissue products is difficult to establish or verify for a precise period or location. There are few existing databases and the definitions used are not consistent. National and regional data collection is not performed in a uniform manner to accurately capture donation, processing, distribution and use, and to monitor outcomes.

19. The ease with which human tissues can be transported across international borders facilitates their allocation from places of oversupply to areas of undersupply, often in a process motivated by financial gain. However, long-term or ongoing reliance on external sources can expose the “importing” national health system to an unpredictable supply in terms of quantity and quality and to commercialization, with imposed higher or unacceptable costs limiting access. Conversely, “exporting” countries may be underserving their own population of potential recipients by diminishing local availability.

20. Transplantation tissues, in particular eye tissues, can often be produced at a lower cost than industrially produced and imported tissues, especially in low- and middle-income countries. Moreover, tissue transplantation is not always integrated into the wider health care system or universally covered by insurance schemes. As a result, the out-of-pocket cost of tissue transplants and care becomes a barrier to those awaiting transplantation, which in turn exacerbates inequities in health care provision worldwide.

21. The most recent data collected by the Global Observatory on Donation and Transplantation<sup>1</sup> indicate that more than 150 000 **solid organ transplants** are performed worldwide annually, an increase of 52% compared with data collected in the year 2010. It is estimated, however, that this figure represents less than 10% of the global need. Furthermore, the disparity between supply and demand of human organs has been exacerbated by the COVID-19 pandemic, the impact of which has resulted in an 18% decline in the number of global transplants.<sup>2</sup>

22. According to the Global Observatory on Donation and Transplantation, more than 100 000 kidney transplants are performed worldwide each year,<sup>3</sup> compared with more than 5 million patients undergoing dialysis annually.<sup>4</sup> With a global prevalence of 9.1%, chronic kidney disease is estimated to cause 1.2 million deaths and result in 35.8 million disability-adjusted life years annually.<sup>5</sup> Cost and outcome

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<sup>1</sup> International report on organ donation and transplantation activities. Global Observatory on Donation and Transplantation; 2021 ([http://www.transplant-observatory.org/wp-content/uploads/2021/06/GODT2019-data\\_web\\_updated-June-2021.pdf](http://www.transplant-observatory.org/wp-content/uploads/2021/06/GODT2019-data_web_updated-June-2021.pdf), accessed 8 March 2022).

<sup>2</sup> Aubert O, Yoo D, Zielinski D, Cozzi E, Cardillo M, Dürr M, et al. COVID-19 pandemic and worldwide organ transplantation: a population-based study. *Lancet Public Health*. 2021; 6(10):E709-19. doi: 10.1016/S2468-2667(21)00200-0.

<sup>3</sup> Executive summary of 2019 activity data. Global Observatory on Donation and Transplantation; 2021 (<http://www.transplant-observatory.org/reports/>, accessed 8 March 2022).

<sup>4</sup> Global burden of disease 2019. Institute for Health Metrics and Evaluation; 2020 (<http://www.healthdata.org/gbd/gbd-2019-resources>, accessed 8 March 2022).

<sup>5</sup> GBD Chronic Kidney Disease Collaboration. Global, regional, and national burden of chronic kidney disease, 1990–2017: a systematic analysis for the Global Burden of Disease Study 2017. *The Lancet*. 2020; 395(10225):709–33. doi: 10.1016/S0140-6736(20)30045-3.

studies indicate that kidney transplantation should be prioritized for renal failure. In all WHO regions, with the possible exception of the African Region, haemodialysis is more costly than maintaining a transplant.

23. Many countries do not have active kidney or liver transplant programmes and in some of those where such programmes do exist, there is no robust governmental support, the programmes are offered only by private for-profit institutions and they depend on living donors (with a potential for exploitation). Limitations in access to transplantation services are also evident in the number of available national heart programmes and lung programmes, where important disparities exist among WHO regions. For example, there is a huge gap between the African Region on the one hand, with one available heart centre per 285 million inhabitants and one available lung centre per 570 million inhabitants and the Region of the Americas on the other, with one available heart centre per 3.5 million inhabitants and one available lung centre per nine million inhabitants.<sup>1</sup> Differences in availability also exist among countries in the same Region (e.g. in the European Region, between eastern European countries and the countries of the European Union).

24. Less than 40% of Member States report on the existence of a functioning deceased donor programme,<sup>2</sup> which mainly exist in countries with a higher human development index. Huge gaps exist in donation rates and practices among countries, which is indicative of different organizational approaches and levels of resources dedicated to detection and management of donors and procurement of donated organs.

25. The shortage of donors, combined with the low availability of transplantation services, is the root cause of transplantation tourism and may lead people to obtain a transplant through illegal and unethical pathways, usually from poor and vulnerable populations who are trafficked as sources of organs. Even though national legal frameworks have been established to counter such practices, major issues related to oversight, reporting and investigation remain in both the countries of origin of the patients involved and the destination countries.

26. In summary, improving access to transplantation is contingent on a multitude of financial, governmental and societal factors. Lower-income countries lack the prerequisite transplant facilities, waiting lists, workforce, political will and publicly funded health care systems to facilitate increased access to transplantation, especially from deceased donors. High-income countries may also be faced with system-specific challenges concerning low public awareness and education. As a consequence, millions of potential recipients in all WHO regions, and in particular in low- and middle-income countries, continue to lack access to the profound benefits of medical procedures involving human tissue, organ or cell transplantation.

## **THE WAY FORWARD**

27. To address these challenges, the Secretariat is developing frameworks for improving access to tissue and organ transplantation, respectively. These frameworks will provide a proposed road map for the Secretariat's activities and will enable the exchange of best practices and technical expertise.

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<sup>1</sup> GBD Chronic Kidney Disease Collaboration. Global, regional, and national burden of chronic kidney disease, 1990–2017: a systematic analysis for the Global Burden of Disease Study 2017. *The Lancet*. 2020; 395(10225):709–33. doi: 10.1016/S0140-6736(20)30045-3.

<sup>2</sup> Executive summary of 2020 activity data. Global Observatory on Donation and Transplantation; 2021 (<http://www.transplant-observatory.org/reports/>, accessed 8 March 2022).

**ACTION BY THE HEALTH ASSEMBLY**

28. The Health Assembly is invited to note this report and to consider the following draft decision:

The Seventy-fifth World Health Assembly, having considered the report of the Director-General,<sup>1</sup>

Decided to request the Director-General to continue to report to the Health Assembly every two years until 2030 on progress made in the implementation of resolution WHA63.22 (2010).

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<sup>1</sup> Document A75/X.