

Resolution CM/Res(2017)1

on principles for the selection, evaluation, donation and follow-up of the non-resident living organ donors

*(Adopted by the Committee of Ministers on 14 June 2017
at the 1289th meeting of the Ministers' Deputies)*

The Committee of Ministers, in its composition restricted to the representatives of States Parties to the Convention on the Elaboration of a European Pharmacopoeia (ETS No. 50),¹

Considering that the aim of the Council of Europe is to achieve greater unity between its member States and that this aim may be pursued, *inter alia*, by the adoption of common action in the health field;

Having regard to Resolution Res(78)29 on the harmonisation of legislation of member States related to removal, grafting and transplantation of human substances and the final text of the 3rd Conference of European Health Ministers (Paris, 16-17 November 1987);

Having regard to the Convention on Human Rights and Biomedicine (ETS No. 164) and in particular to Articles 19 and 20 thereof;

Having regard to the Additional Protocol to the Convention on Human Rights and Biomedicine concerning the Transplantation of Organs and Tissues of Human Origin (ETS No. 186) and the Explanatory Report thereof, in particular Chapter III – Organ and tissue removal from living persons, Article 9 – General rule;

Having regard to the Convention on Action against Trafficking in Human Beings (CETS No. 197);

Having regard to the Convention against Trafficking in Human Organs (CETS No. 216);

Having regard to the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108) and its Additional Protocol on Supervisory Authorities and Transborder Data Flows (ETS No. 181);

Recalling Recommendation Rec(2004)7 on organ trafficking;

Recalling its Resolution CM/Res(2008)4 on adult-to-adult living donor liver transplantation;

Recalling its Resolution CM/Res(2008)6 on transplantation of kidneys from living donors who are not genetically related to the recipient and in particular the principles and measures laid down in its Appendix;

Recalling its Resolution CM/Res(2013)56 on the development and optimisation of live kidney donation programmes;

Recalling its Resolution CM/Res(2015)11 on establishing harmonised national living donor registries with a view to facilitating international data sharing;

Taking into account the Directive 2010/53/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation, in particular Article 15;

¹ Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Republic of Moldova, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey, Ukraine and United Kingdom.

Taking into account Regulation (EU) 2016/679 of the European Parliament and the Council of 27 April 2016 *on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)*, and in particular Article 9 points (h) and (i), which contain provisions allowing for processing of health data “for the purposes of preventive or occupational medicine, [...] medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services [...]” and “for reasons of public interest in the area of public health [...] or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy”;²

Taking into account the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation adopted by the World Health Assembly in May 2010;³

Taking into account the Declaration of Istanbul on Organ Trafficking and Transplant Tourism, adopted in 2008;⁴

Taking into account the consensus statements made by the Amsterdam Forum on the Care of the Live Kidney Donor^{5,6} and by the Vancouver Forum on the Live Lung, Liver, Pancreas, and Intestine Donor;^{7,8}

Taking into account the consensus statements on living organ donation made by an executive group representing the American Societies of Transplantation, Transplant Surgeons and Nephrology, and the National Kidney Foundation;⁹

Taking into account the position paper of the European Committee on Organ Transplantation (CD-P-TO) on the long-term outcome of living kidney donation, with the endorsement of the European Society for Organ Transplantation (ESOT), the International Society of Nephrology (ISN) and The Transplantation Society (TTS);¹⁰

Taking into account the Council of Europe *Guide on the Quality and Safety of Organs for Transplantation*, in particular its chapter on living donation;¹¹

Considering the large deficit of organs for transplantation compared to demand at present and in the foreseeable future, even after developing deceased donation to its maximum therapeutic potential;

Considering that many countries are developing living donation programmes as a way to pursue self-sufficiency in transplantation;

Taking into account that live kidney donation is a safe procedure, if performed according to recognised international standards, in terms of donor evaluation, selection and donor care;

Considering that living donation carries risks and requires robust legislative and operational procedures in place to safeguard the health of the living donor;

² Available at: http://ec.europa.eu/justice/data-protection/reform/files/regulation_oj_en.pdf

³ Available at <http://www.who.int/transplantation/TxGP08-en.pdf>

⁴ Adopted at the International Summit on Transplant Tourism and Organ Trafficking organised by the Transplantation Society and the International Society of Nephrology, Istanbul, Turkey, 30 April - 2 May 2008. Available at http://www.edqm.eu/medias/fichiers/The_Declaration_of_Istanbul.pdf

⁵ The Ethics Committee of the Transplantation Society: The Consensus Statement of the Amsterdam Forum on the Care of the Live Kidney Donor. *Transplantation* 78(4):491-92, 2004. Available at: http://journals.lww.com/transplantjournal/Fulltext/2004/08270/The_Consensus_Statement_of_the_Amsterdam_Forum_on.1.aspx

⁶ Report from the Amsterdam Forum On the Care of the Live Kidney Donor: Data and Medical Guidelines. Council of the Transplantation Society. *Transplantation* 79(6):S53-66, 2005. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/15785361>

⁷ Report of the Vancouver Forum on the Care of the Live Organ Donor: Lung, Liver, Pancreas, and Intestine Data and Medical Guidelines.

Barr ML, Belghiti J, Villamil FG, Pomfret EA, Sutherland DS, Gruessner RW. Available at: <https://www.livingdonorassistance.org/documents/Report%20of%20Vancouver%20Forum.pdf>

⁸ The Ethics Statement of the Vancouver Forum on the Live Lung, Liver, Pancreas, and Intestine Donor. *Transplantation* 81(10):1386-7, 2006. Available at: <https://www.livingdonorassistance.org/documents/Ethics%20Statement%20of%20Vancouver%20Forum.pdf>

⁹ Abecassis et al.: Consensus statement on the live organ donor. *JAMA* 284(22):2219-26, 2000

¹⁰ Available at https://www.edqm.eu/sites/default/files/position_paper_long_term_outcome_of_living_kidney_donation_2015.pdf

¹¹ Available at <https://go.edqm.eu/OTg>

Aware that organ shortages, or lack of access to a deceased donor programme, have also encouraged organ trafficking, often involving patients seeking potential donors abroad;

Aware that many countries are accepting organ donation from non-resident living donors with or without a genetic or emotional link to the recipient who come lawfully (with a visa or other authorisation) to the country and wish to become living organ donors;

Considering that for a number of reasons – economic, emotional, cultural or physical – the detection of possible cases of human trafficking for the purpose of organ removal and/or trafficking in human organs may be particularly difficult when evaluating and accepting non-resident living donors;

Recognising that countries accepting non-resident living donors should ensure rigorous donor selection, evaluation and follow-up;

Considering that the non-resident living donor who travels from another country to donate is particularly vulnerable and that additional measures are needed to ensure their protection and care;

Considering that non-resident living donors, especially those from developing countries, may have limited resources or access to health care to ensure appropriate post-donation long term follow-up;

Recommends that the governments of States Parties to the Convention on the Elaboration of a European Pharmacopoeia take the necessary measures for the care and safeguard of the non-resident living donor, in accordance with the principles and practices set out in the appendix to this resolution.

Appendix to Resolution CM/Res(2017)1

Introduction

As a way to pursue self-sufficiency in transplantation, many countries are developing and optimising living donor programmes to complement the limited availability of organs from deceased donors, or as the only source of organs.

However a lack of or delay in access to a suitable donor has encouraged human and organ trafficking. There are growing reports of donors being coerced to consent to donation; or who are offered financial or equivalent inducements to be an organ donor. Living donors also have a greater potential to develop medical and psychosocial conditions in the short and the longer term without adequate follow-up. This has prompted the development of international recommendations and standards for the care and protection of the living donor to encourage countries to develop their own national legislation, better regulatory oversight and any necessary changes to policy and operational protocols.

Non-resident donors may be particularly vulnerable and assessing the validity of their consent to donation – which must be free, specific and informed – is vital but can be especially challenging. The donor, in exchange for some form of financial inducement to give consent, may have been given inadequate or insufficient information about the donation procedure, risks and potential consequences or they may have been subject to coercion to agree to donation. The donor may be presented falsely as having a genetic or emotional relationship with the recipient. They may be given poor or no post-operative care and long term follow-up. In spite of these risks, specific international recommendations on how to safeguard the non-resident living donor have not been developed.

Although many countries allow non-resident living donation, there are recognised variations in approach, such as the data collected, the screening and consent process, the reimbursement of loss of earnings and justifiable expenses (such as travel and medical costs) related to the donation procedure, and access to post-operative follow-up care.

These concerns have prompted the European Committee on Organ Transplantation (CD-P-TO) of the Council of Europe, using as a basis the legal instruments and guidelines of the Council of Europe and other relevant organisations, to prepare guidance for member States on the principles and practices to safeguard the non-resident living donor. These measures should be put in place in conjunction with the existing national provisions to ensure the safety and well-being of living donors.

Work-up of the potential non-resident living donor before travel for donation

- The formal process of referral of the non-resident donor should be agreed between the transplant centre/hospital undertaking the donation and implantation procedure and the referring centre/hospital of the prospective living donor.
- Initial tests and evaluation to identify and rule out any obvious reasons that would contraindicate the donation should be performed preferably in the donor's own country. Exclusion criteria should include donor physical or mental health problems, social or behavioural issues or be based on ABO blood groups or Human Leukocyte Antigen (HLA) incompatibility between donor and recipient. These initial evaluations will reduce unnecessary travel or expenses if any obvious contraindications to donation are found.
- Arrangements for long-term follow-up once the living donor has returned home should be discussed to ensure that medical care is available. As recently stated in the CD-P-TO Position Paper on the long-term outcome of living kidney donation, if adequate long-term life-long follow-up cannot be guaranteed, the donor should not be accepted.¹²
- The process and level of reimbursement of justifiable expenses, including loss of income, incurred by the non-resident living donor should be discussed at an early stage to ensure the process is clear and cost-neutral for the donor. For the non-resident donor, reimbursement should include the initial assessment, testing and evaluation costs, travel, accommodation, loss of earnings, the cost of the donation procedure and the costs of any related treatment including that of complications as a result of the donation.¹³ It should be clear from whom the reimbursement will be made (e.g. insurance companies, State funders or social security schemes). Similarly, regimes for the protection and indemnification of the non-resident donor should be in place in the event of undue damage resulting from the donation on their territory, on equal conditions with resident donors.
- Unless such basic health-related and administrative requirements are satisfied, non-resident living donors should be discouraged from leaving their country of residence for the transplanting country.

Lawful entry of the non-resident living donor

- Clear procedures should be established with relevant agencies for the lawful entry of the potential non-resident living donor (or the potential non-resident donor and recipient) into the country and exit post donation. In countries where authorisation or a visa is required, transplant centres/hospitals may need to work with the potential donor, recipient and referring centre/hospital to provide any necessary documentation to help facilitate entry into the country for a sufficient period of time to enable the living donor procedure and related post-operative recovery.

Further work-up of the potential non-resident living donor once in the country where the donation is expected to take place

- The work-up for donation should continue in the country where the transplant will take place. Specific medical tests, particularly from the infectious disease point of view, may be needed according to the epidemiology of the country of residence of the non-resident living donor.¹⁴

¹² Long-term Outcome of Living Kidney Donation: Position Paper of the European Committee on Organ Transplantation, Council of Europe. Transplantation. 2016 Feb;100(2):270.

¹³ Recommendation No. S1 of 15 March 2012 concerning financial aspects of cross-border living organ donations. Available at: [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32012H0810\(01\)](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32012H0810(01))

¹⁴ Guide to the Quality and Safety of Organs for Transplantation, available at <https://go.edqm.eu/OTg>

- Specific psychosocial evaluation pre-donation, intended to prevent donation from non-resident donors with significant risk of developing mental health disorders or psychological/social problems, and to avoid worsening their quality of life, should also be undertaken. The psychosocial evaluation should be aimed at: the assessment of the donor-recipient relationship; competency; knowledge and understanding of donation risks and benefits; psychological functioning, motivations and expectations; and social support.
- Procedures should be in place to verify the claimed relationship between the potential donor and the recipient, and, where it cannot be proven, the donation should not proceed. Such checks should include official documents (e.g. birth certificates or marriage certificates) and affidavits by embassies or consulates, as needed. If the genetic relationship is not conclusively established after evaluating the documentary evidence, HLA testing should be performed. National legislations should clearly establish which relationships are acceptable and, in the case of non-resident living donors, they should preferentially be limited to first- or second-degree genetic relatives or spouses (or equivalent). In exceptional cases, other relationships may be accepted when they can be unequivocally verified and in accordance with national legislations.
- Consent (free, specific and informed) should be given and fully recorded. It should be made clear to the potential donor that consent may be withdrawn at any time before donation with no need for a specific formal procedure. Authorisation of the donation by an independent body should take place in line with the clinical and regulatory framework in place in the country where the transplant procedure will take place.
- Living donors should be provided with detailed information on the short and long-term medical and psychological risks for their own health and well-being; the potential risks and complications for the intended recipient; alternative treatments for the intended recipient; any information about contraindications that might prevent donation; and information about the possible use of the organ if it is procured but cannot be used for the intended recipient (e.g. transplant of the organ into another patient on the waiting list).
- Information about the donation procedure should be provided in a manner able to be fully understood by the potential non-resident living donor, relying on interpreters and culturally competent advocates where required, to ensure that any outstanding issue or concern is thoroughly addressed. Should an interpreter be required, the services should not be provided or arranged by the donor, the recipient or anyone in their entourage.
- Countries should ensure that living donor programmes include procedures for living donor assessment or advocacy, independent of the transplant team. This is particularly important for the non-resident donor. The living donor advocate should be an independent medical, psychosocial and legal counsellor, with neither time constraints nor interests shared with any party. Donor advocacy has the dual purpose of supporting the potential donor and ensuring the legal safeguards are followed, for example by assessing the donor's motivation to donate. This will help confirm that the donor is giving free, specific and informed consent; ensuring that they fully understand the process and the risks; confirming that they are not being pressurised – emotionally, physically or economically – into consent for donation; and that the donor, or a third party, has not been offered or received any financial gain or comparable advantage for the donation. To undertake the assessment, the potential donor and recipient should be interviewed together and separately by a trained assessor independent of the transplant team, taking into account any language and cultural requirements.
- National protocols should specify the action(s) to be taken, in addition to deferral of donation, should a suspicion of organ trafficking or trafficking in human beings for the purpose of organ removal arise. This could include reporting the case to the national regulator and/or the law enforcement authority. Official international data sharing may prevent further attempts to perform the illicit organ procurement from the same donor or from a different unsuitable organ donor for the same recipient or by the same criminal network for a different donor-recipient pair at a different location.

Organ procurement from the non-resident living donor and follow-up

- The initial follow-up of the non-resident living donor – both medical and psychosocial – should be undertaken by the transplant centre/hospital as part of the post-surgery rehabilitation. Arrangements for long-term follow-up should have been discussed as part of the initial work-up and consent process, to ensure that medical care is available once the living donor has returned home.
- The non-resident living donor should be provided complete medical records to ensure continuity of care once they return to their country of residence.

Recording the donation

- National Living Donor Registries should be established in all countries to enable transparency, traceability, data analysis and improvement to clinical practice. These registries should include data on the donor and recipient, the hospital(s) involved, the surgical procedure and the follow-up of the donor.^{15,16} All donation procedures, including those involving non-resident living donors, should be recorded in such Living Donor Registries.
- For the non-resident living donor, donor information from the transplant centre/hospital that has performed the donation or from the Living Donor Registry of the country where the procedure took place should be shared with the country of origin of the non-resident living donor, for example, with the healthcare professional or hospital continuing the follow-up care of the non-resident living donor, the referring hospital, the national transplant organisation, the Ministry of Health and/or with the national Living Donor Registry. This data sharing, which should be done in conformity with national and international data protection rules and other applicable legislation, will ensure connection between traceability and biovigilance systems of both countries and continuity of care for the donor.

¹⁵ Council of Europe Committee of Ministers' Resolution CM/Res(2015)11 on establishing harmonised national living donor registries with a view to facilitating international data sharing.

¹⁶ EU Directive 2010/53/EU obliges member States to have a national living donor registry.