COMMITTEE OF MINISTERS
COMITÉ DES MINISTRES

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

MINISTERS' DEPUTIES | Resolutions | CM/Res(2017)2 | 14 June 2017

Resolution CM/Res(2017)2

on establishing procedures for the management of patients having received an organ transplant abroad upon return to their home country to receive follow-up care

(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 the 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(2013)55 on establishing procedures for the collection and dissemination of data on transplantation activities outside a domestic transplantation system;

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;

Taking into account Commission Implementing Directive 2012/25/EU of 9 October 2012 laying down information procedures for the exchange, between member States, of human organs intended for transplantation;[2]

[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.

[2] Available at: http://ec.europa.eu/health/blood_tissues_organs/docs/organs_impl_directive_2012_en.pdf

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";*[3]

Taking into account the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation adopted by the World Health Assembly in May 2010,[4] and in particular Guiding Principles 10 and 11, which call for health authorities to ensure traceability and vigilance and to monitor results of both living donation and transplantation;

Aware that, in exceptional circumstances, some patients may be properly referred for transplantation abroad by their treating physicians for medical, organisational (e.g. co-operation agreements between countries) or social reasons (e.g. to facilitate family support);

Aware that organ shortage, or lack of access to a deceased donor programme, have also encouraged organ trafficking and human trafficking for the purpose of organ removal, often involving patients seeking to receive an organ transplant abroad;

Taking into account the Declaration of Istanbul on Organ Trafficking and Transplant Tourism, adopted in 2008,[5] which defines that travel for transplantation becomes transplant tourism – and ethically unacceptable – if it involves organ trafficking, human trafficking for the purpose of organ removal or if the resources devoted to providing transplants to patients from outside a country (may they be organs, professionals, and transplant centres) undermine the country's ability to provide transplant services for its own population;

Taking into account the Declaration of Istanbul Custodian Group guidelines on ethical travel for transplantation;

Taking into account the Resolution of Madrid,[6] calling for all States to strive towards self-sufficiency in organ transplantation;

Taking into account the Statement of the Pontifical Academy of Sciences Summit on Organ Trafficking and Transplant Tourism;[7]

Considering that patients having received an organ transplant abroad, should it have been through proper travel for transplantation or through transplant tourism, typically return to their country of origin shortly after the transplantation procedure to receive post-transplantation care;

Considering that patients having received an organ transplant abroad as a result of transplant tourism are much more likely to suffer serious complications or life-threatening conditions, particularly infections caused by opportunistic pathogens, microorganisms not previously seen in their home country or multidrug resistant organisms which entail a risk not only to themselves but to public health;

Aware that systematic and appropriate registration of patients who undergo organ transplantation within a jurisdiction allows traceability of organs from donors to recipients and *vice versa*, as well as vigilance and surveillance, and enables the evaluation of the long-term outcomes of transplantation, the minimisation of public health risks and the detection of cases that may raise ethical and/or criminal concerns;

---

[3] Available at: http://ec.europa.eu/justice/data-protection/reform/files/regulation_oj_en.pdf
[4] Available at: http://www.who.int/transplantation/TxGP08-en.pdf
[5] 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
[6] The Madrid resolution on organ donation and transplantation, Transplantation, 2011, vol. 91 (pg. S29-31)
[7] Available at: http://www.pas.va/content/accademia/en/events/2017/organ_trafficking/statement.html

Considering that the principles of transparency, traceability and continuity of care are desirable not only for patients having received an organ transplant domestically but also for those having received a transplant abroad;

Considering that the quality of care provided to patients having received an organ transplant abroad would be enhanced upon registration in national transplant registries and by ensuring connection between traceability and biovigilance systems which would allow to have up-to-date epidemiological information and to provide personalised care depending on the country where the patient has received the organ transplant;

Considering that currently patients who receive a transplant abroad are not systematically recorded in national registries in most member States and that their care is circumscribed to the attention that may be provided by their treating physician upon return home;

Considering that the international exchange of information about patients who receive a transplant abroad will help to better understand and analyse the phenomenon of travel for transplantation and to identify possible hotspots of transplant tourism that deserve careful investigation by the concerned countries;

Aware that procedures established for the management of patients who receive an organ transplant abroad, similarly to those procedures established for the management of patients who receive an organ transplant domestically, should respect the professional obligations of healthcare professionals towards patients and be in conformity with national and international data protection rules and other applicable national legislation, especially national transplantation law;

Aware that information collected from patients who receive a transplant abroad in circumstances that may be consistent with organ trafficking and/or human trafficking for the purpose of organ removal can provide the basis to initiate and/or co-operate in criminal investigations and help to detain and combat illicit practices;

Recommends to the governments of States Parties to the Convention on the Elaboration of a European Pharmacopoeia:

i. to provide the resources and the means to progress towards self-sufficiency in transplantation at a national level – with regional co-operation as appropriate – by reducing the need for transplants through preventive measures and improving access to national transplant programmes in an ethical and regulated manner;

ii. to ensure that patients having received an organ transplant abroad are promptly referred for evaluation at a transplant centre, where the best available expertise and knowledge will be available to guarantee appropriate screening and care of these patients;

iii. to ensure that specific guidelines and training for the evaluation and management of patients who have received an organ transplant abroad, particularly addressing infectious diseases, is provided to healthcare professionals at transplant centres;

iv. to ensure that patients having received an organ transplant abroad receive the necessary medical care upon their return to their home country, which should be the same as that provided to any other patient having received an organ transplant domestically;

v. to ensure that the same data routinely collected by healthcare professionals and recorded in national transplant registries on patients having received an organ transplant domestically, including long-term follow-up information, are also routinely collected for patients having received an organ transplant abroad;

vi. to support and promote communication and collaboration between transplantation centres, and where relevant, health authorities from the country where the transplantation procedure took place and where the patient returns to receive follow-up care. While respecting the privacy of the patient and professional obligations to patients, in conformity with national and international data protection rules and other applicable legislation, the data to be shared should include at least the date of the procedure, city and hospital where the procedure took place and type of organ transplanted. This exchange would ensure transparency of practices, the establishment of links between the traceability and biovigilance systems of both countries and guarantee the best possible care is provided to the patient and, as relevant, to the living donor or to the recipients of other organs and tissues from the same deceased donor;

vii. to increase awareness among healthcare professionals on organ trafficking and/or human trafficking for the purpose of organ removal and support the development of clear protocols to identify patients who may have received an organ transplant abroad in circumstances consistent with organ trafficking and/or human trafficking for the purpose of organ removal;

viii. to develop a framework for healthcare and other professionals to communicate information about suspected or confirmed events of organ trafficking and/or human trafficking for the purpose of organ removal to the appropriate national authorities, while respecting their professional obligations to patients. The decision in a member State may range from developing legislation and mechanism that provide for a (voluntary or mandatory) non-anonymised reporting of detected or suspicious events to the appropriate national authorities, to a (voluntary or mandatory) reporting of anonymised data that reveals information on entities, hospital or professional engaged in illegitimate transplantation but not the identities of the patients concerned;

ix. to take the necessary steps to ensure that national healthcare systems and/or insurance providers do not cover the costs of transplant procedures performed abroad involving organ trafficking and/or human trafficking for the purpose of organ removal;

x. to facilitate a comprehensive international collection of information by regularly reporting anonymised activity data on patients having received an organ transplant abroad to the Secretariat of the European Committee on Organ Transplantation (CD-P-TO) of the Council of Europe with a view to analysing and discussing such results within the CD-P-TO and informing member States.