COMMITTEE OF MINISTERS
COMITÉ DES MINISTRES

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

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

(Adopted by the Committee of Ministers on 15 September 2015 at the 1235th 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,[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 field of healthcare;

Taking into account Resolution Res(78)29 on the harmonisation of legislation of member States relating 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);

Taking into account EU Directive 2010/53/EU, Article 15.4;

Having regard to the Convention on Human Rights and Biomedicine (ETS No. 164) and, in particular, to Article 19 (General rule) and Article 20 (Protection of persons not able to consent to organ removal) 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);

Recalling Recommendation Rec(2004)7 on organ trafficking;

Recalling its Resolution CM/Res(2008)4 of 12 March 2008 on adult-to-adult living donor liver transplantation;

Recalling its Resolution CM/Res(2008)6 of 26 March 2008 on transplantation of kidneys from living donors who are not genetically related to the recipient;

Recalling its Resolution CM/Res(2013)55 of 11 December 2013 on establishing procedures for the collection and dissemination of data on transplantation activities outside a domestic transplantation system;

Recalling its Resolution CM/Res(2013)56 of 11 December 2013 on the development and optimisation of live kidney donation programmes;

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;[2]

Taking into account the Declaration of Istanbul on Organ Trafficking and Transplant Tourism, adopted in 2008;[3]

Taking into account the consensus statements made by the International (Amsterdam) Forum on the Care of the Live Kidney Donor;[4]

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[1] States concerned: Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, 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] Abecassis et al.: Consensus statement on the live organ donor. JAMA 284(22):2219-26, 2000.
[3] 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 (last accessed 22/07/2015).
[4] 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.

Considering that there is a large discrepancy between the need for human transplants in Europe and the availability of suitable organs, and that many countries are trying to expand the living donor pool;

Being of the opinion that there is great potential for improving the supply of transplantable human organs and that the proper utilisation of these organs will improve patient life expectancy and quality;

Recognising that, in facilitating the transplantation of organs in the interest of patients in Europe, there is a need to protect individual rights and freedoms and to prevent the commercialisation of parts of the human body involved in organ procurement, exchange and allocation activities;

Considering that the safety of living donation is crucial, and even more so with liver donors;

Considering that to protect the donor's health and safety, an appropriate framework of donor care should be established. Such a framework should include proper selection, both physical and psychological, a proper informed consent procedure and a possibility to follow a donor's health by collecting both short- and long-term data;

Considering that living donor registries are needed for transparency of practices, to facilitate evaluation of the consequences of donating an organ and for the generation of evidence;

Considering that the living donor registry should meet privacy requirements, as regulated by each country's data security legislation and guidelines;

Considering that the number of living donations performed among Council of Europe member States varies enormously, as does medical eligibility, screening and after-care of the donors (including social cover);

Considering that the follow-up and data registration protocols of living donors also differ significantly between member States. Some countries have a national living donor registry, but most do not;

Considering that only by compiling harmonised data from the various countries with living donor programmes will it be possible to obtain sufficient information to:

- define and secure proper follow-up of living donors;

- document living donor prognoses (safety/morbidity);

- investigate causal relationships between pre-donation risk factors (body mass index, estimated kidney/liver function, mild hypertension, etc.) and future prospects, including cardiovascular events, kidney/liver failure and death;

Considering that significant developments in IT solutions will help to decentralise data input and that technical developments will support data exchange between countries/regions;

Considering that (inter)national initiatives are compatible with the work developed in the EU Joint Action entitled 'Achieving Comprehensive Co-ordination in Organ Donation throughout the European Union', particularly with the recommendations produced for the design and management of national and supranational living donor registries;

Recommends the governments of States Parties to the Convention to develop and maintain harmonised national living donor registries, according to the general guidelines presented in the appendix to this Resolution (and the detailed list of parameters shown in the Explanatory Memorandum), with a view to facilitating international data sharing.

The parameters detailed in the data set, outlined in the Explanatory Memorandum, may be revised in the future in keeping with developments in the field.

With the aim of facilitating and harmonising the collection of living donor baseline and follow-up data, this appendix provides the characteristics and general guidelines for the construction of national/international living donor registries.

These are:

1. The infrastructure of a national/international database and its interaction with currently existing data systems should have the following attributes:

    i. interoperability with currently existing transplant databases, including linkage with corresponding transplant recipient registries, to facilitate data exchange and meta-analyses;

    ii. English as the common language.

2. The procedures and infrastructures of existing living donor registries within Europe should be designed in such a way that they may form the basis for identifying the variables to be collected in a common international living donor registry (Registry of Registries), taking into account the following:

    i. there should be designed templates for a 'National Registry' and a 'Registry of Registries';

    ii. there should be separate sections for living 'Kidney donation' and 'Liver donation';

    iii. the registry should contain a mandatory (minimal) data set and an extensive data set with additional, optional parameters;

    iv. the chosen mandatory variables should be defined and standardised.

3. Any living donor registry, be it national or a Registry of Registries and covering kidney and/or liver, should contain the following donor information:

    i. donor demographic information;
    ii. pre-donation data;
    iii. peri- and post-operative data;
    iv. follow-up data.

4. Follow-up: Duration/intervals:

    i. long-term follow-up (preferably life-long) is essential to obtain comprehensive data and for the security of the individual donor;

    ii. the transplantation centres should provide and guarantee proper donor follow-up, as part of the authorisation requirements;

    iii. owing to restrictive capacity or national regulations, mandatory follow-up data collection may have to be limited to a specified timeframe.

5. Data security/legislation:

    i. national and international data protection rules must be adhered to. Overall data security has to be attained and assured in the country hosting the database;

    ii. owing to more restrictive data security legislation in recent years, additional measures are required in most countries, e.g. informed consent for storage of personal donor data and separate, national permission for this kind of storage (according to national legislation).

6. Access/publication of data:

    i. each transplant centre should have full access to all data pertaining to their own donors/patients;

    ii. simple, unidentifiable, summary reports on all donors/patients in the living donor registry should be made available to everyone and presented in annual reports;

iii. more extensive analyses, intended for publication, should be regulated by a protocol.

An additional Explanatory Memorandum to this resolution provides a detailed list of parameters intended for inclusion in any national living donor registry, defining a mandatory data set and an expanded set of variables, as well as those to be included in a ‘Registry of Registries’ aimed at international data sharing. It also contains a glossary of terms intended to provide clarity on the way each parameter should be measured or collected and to facilitate harmonised international data sharing.