COMMITTEE OF MINISTERS
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MINISTERS' DEPUTIES Recommendations **CM/Rec(2020)6** 7 October 2020

Recommendation CM/Rec(2020)6[1] of the Committee of Ministers to member States on establishing harmonised measures for the protection of haematopoietic progenitor cell donors

(Adopted by the Committee of Ministers on 7 October 2020 at the 1385th meeting of the Ministers' Deputies)

The Committee of Ministers, under the terms of Article 15.b of the Statute of the Council of Europe,

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 harmonisation of legislations 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);

Having regard to the Convention on Human Rights and Biomedicine (ETS No. 164), in particular to Articles 19, 20 and 21 thereof, and its Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186), in particular Chapter III – Organ and tissue removal from living persons, Article 9, and Chapter VI – Prohibition of financial gain;

Having regard to the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108, as amended by Protocol CETS No. 223[2]) and its Additional Protocol regarding supervisory authorities and transborder data flows (ETS No. 181);

Recalling Recommendation CM/Rec(2019)2 of the Committee of Ministers to member States on the protection of health-related data which replaces Recommendation Rec(97)5 of the Committee of Ministers to member States on the protection of medical data;

Recalling Recommendation Rec(98)2 of the Committee of Ministers to member States on provision of haematopoietic progenitor cells;

Taking into account the latest available edition of the Council of Europe Guide to the Quality and safety of tissues and cells for human application, in particular the Chapters on "Recruitment of potential donors, identification and consent" and on "Haematopoietic progenitor cells from bone marrow and peripheral blood";

Taking into account the World Health Organization Guiding Principles on Human Cell, Tissue and Organ Transplantation as endorsed by the 63rd World Health Assembly in May 2010, in Resolution WHA63.22, and in particular Guiding Principles 10 and 11, which call for health authorities to oversee that transplant programmes ensure traceability and vigilance and to monitor outcomes of both living donation and transplantation;

Taking into account Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation,

[1] When adopting this recommendation, the Permanent Representative of Germany indicated that, in accordance with Article 10.2*c* of the Rules of Procedure for the meetings of the Ministers' Deputies, he reserved the right of his government to comply or not with the recommendation.
[2] The Protocol amending Convention No. 108 (CETS No. 223) was opened for signature on 10 October 2018 and the revised convention has yet to enter into force.

storage and distribution of human tissues and cells, and Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells;

Taking into account Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells, and in particular Article 5(1)(a) and Article 7;

Taking into account Regulation (EU) 2016/679 of the European Parliament and of 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 (General Data Protection Regulation), and in particular Article 9, paragraph 2, points (a), (h) and (i), which contain provisions permitting the processing of health data;

Considering the observation included in the Evaluation of the European Union legislation on blood, tissues and cells (SWD(2019) 376 final) Chapter 6, point iv, that there are insufficient provisions in place to protect haematopoietic progenitor cell donors;

Considering that haematopoietic progenitor cell transplantation represents one of the most widely used forms of cell therapy and haematopoietic progenitor cells are one of the most exchanged biological materials for transplantation;

Considering that the application of haematopoietic progenitor cells for the treatment of different haematological diseases has increased extensively in the past half-century in developed countries and that many low- and middle-income countries are now establishing autologous and allogeneic haematopoietic progenitor cell transplantation programmes;

Considering that all haematopoietic progenitor cell donors are living donors, either genetically related or genetically unrelated to their recipient and that, in many cases, unrelated donors are identified across national borders;

Considering that, in exceptional situations as defined in the Convention on Human Rights and Biomedicine, in some member States, minors can become related donors;

Considering that donation of haematopoietic progenitor cells carries certain risks, which require robust legislative and operational measures to be in place to safeguard the health and rights of donors;

Considering that, to protect the health of haematopoietic progenitor cell donors, an appropriate framework should include adequate selection criteria, from both the medical and psychosocial perspective, proper informed consent, guarantee of follow-up care, as well as the collection of data on the donor’s health status in the short and long term;

Considering, in particular, that the prohibition of financial gain or comparable advantage under the terms of the Convention on Human Rights and Biomedicine does not prevent compensation of living donors for loss of earnings and reimbursement of any other justifiable expenses related to the removal of organs, tissues or cells or to the related medical examinations, as well as compensation in case of undue damage (e.g. disability) resulting from the removal of organs, tissues or cells;

Recognising that, in enabling transplantation of haematopoietic progenitor cells in the interest of patients in Europe, there is a need to protect individual rights and freedoms and to prevent the commercialisation of haematopoietic progenitor cells;

Considering that eligibility criteria for related donors (adults and minors) are less stringent and established compared to eligibility criteria for unrelated donors in most of the member States;

Considering that few member States have taken action to ensure insurance coverage of related donors at the same level as unrelated donors, especially when the related donor is a non-resident;

Considering that the technique for the collection of haematopoietic progenitor cells is the same irrespective of whether the donor is related or unrelated, and that the vast majority of donors need to undergo mobilisation of haematopoietic progenitor cells with growth factors (peripheral blood stem cell donation), whereas others require general anaesthesia (bone marrow donation), and thus an inherent risk of complications associated with the donation does exist and potential donors should be duly informed;

Considering that the requirements for the follow-up of haematopoietic progenitor cell donors and the registration of data also differ significantly between member States, and that donor outcome data for both related and unrelated haematopoietic progenitor cell donors (adults and minors), including their health status and short-, medium- and long-term complications (e.g. malignancies, autoimmune disorders, thromboembolic disorders), should be collected, notified to health authorities and managed to help prevent these risks in the future;

Considering that the management of related and unrelated haematopoietic progenitor cell donors, including selection criteria and follow-up, should guarantee an equal level of donor safety and protection;

Considering that only through compilation of harmonised data on the outcome of haematopoietic progenitor cell donors (related and unrelated, adults and minors) by health authorities or other officially designated bodies will it be possible to obtain sufficient information to define and secure the proper follow-up of haematopoietic progenitor cell donors, to document prognoses (safety/morbidity) of these donors, to investigate causal relationships between pre-donation comorbidities and the incidence of complications during and after the donation process, and advise on possible preventive measures, and to inform future haematopoietic progenitor cell donors on the risks related to the donation process,

Recommends the governments of member States establish harmonised haematopoietic progenitor cell donor protection measures, which should be identical irrespective of the type of donor (related or unrelated, adult or minor), including the following:

i. to develop recommendations for the assessment of donor medical suitability and on eligibility criteria for haematopoietic progenitor cell donation, as set out in Appendix 1 to this resolution;

ii. to ensure that, before consent, donors (related and unrelated) receive appropriate information on the type(s) of tissues or cells to be donated, the collection procedures, the consequences and possible side-effects of donation and the purpose or final use of the donated cells to ensure a free and informed decision, including the right to withdraw consent at any time;

iii. to ensure that no haematopoietic progenitor cell donation is carried out on a person who does not have the capacity to consent. Exceptionally, and depending on the age and the degree of maturity, a minor may become a family donor only in very specific circumstances and provided they do not object to the donation and with the support of an advocate. The authorisation of a representative, authority or person or body provided for by law should be given specifically and in writing and with the approval of the competent body;

iv. to ensure that donors (related and unrelated, adults and minors) having donated haematopoietic progenitor cells are offered both appropriate psychological support in the event of post-donation difficulties, and medical care, including, short- and long-term follow-up that takes into account the actual health status and possible complications related to donation;

v. to set up procedures and methods for the collection of a minimum set of data on all haematopoietic progenitor cell donors (related and unrelated, adults and minors; peripheral blood stem cells and bone marrow) as specified in Appendix 2;

vi. to ensure that haematopoietic progenitor cell donors (related and unrelated) receive financial compensation for loss of earnings and reimbursement of any justifiable expenses associated with the donation and related medical examinations, as well as in the event of undue damage as a direct result of the donation;

Agrees that the Council of Europe European Committee on Organ Transplantation or, if necessary, a subordinate body, may revise the appendices of this recommendation in the future in keeping with developments in the field.

Appendix 1 to Recommendation CM/Rec(2020)6 of the Committee of Ministers to member States Recommendations for the medical suitability assessment and eligibility criteria for haematopoietic progenitor cell donors

The European Committee on Organ Transplantation (CD-P-TO) of the Council of Europe, using as a scientific basis the Council of Europe Guide to the quality and safety of tissues and cells for human application, has prepared these recommendations to guide the medical suitability assessment and eligibility criteria for haematopoietic progenitor cell donors (adults and, when applicable, minors):

1. during the recruitment/registration of related and unrelated haematopoietic progenitor cell donors, certain diseases and risk behaviours that pose a risk to the donor or the potential recipient should be identified through a dedicated questionnaire checking for:

   a. malignancy;
   b. cardiovascular disease;
   c. any chronic disease (immune-mediated, allergic, thrombo-embolic disease, etc.);
   d. risk of infectious diseases related to behaviour;
   e. inherited genetic disease;

2. during the selection stage for related and unrelated haematopoietic progenitor cell donors, potential contraindications for one of the two collection methods should be identified; information about potential transmissible diseases and any relevant issue should be provided to the transplant centre through:

a. history/questionnaire, updating the information from the previous stage, specifically with regard to:

   i. the risk of infectious diseases (e.g. risk behaviour, trips, planned invasive procedures);
   ii. any planned medical procedure;
   iii. serious psychosocial or psychiatric disease with impact on the capacity to undergo a donation procedure;
   iv. medication;
   v. non-prescription drug use;
   vi. height and weight;
   vii. blood pressure;
   viii. pregnancy or pregnancy planning and breastfeeding;

b. blood tests for infectious disease markers (depending on national laws and requirements [e.g. HIV, HBV, HCV, HTLV, syphilis, cytomegalovirus]);

3. prior to HLA typing (related donors), in order to save time and disappointment and before concluding that the related donor is the best match, information on all aspects highlighted above should be obtained to identify any contraindication to donation and consent to donation should be confirmed;

4. donor work-up should include:

   a. a full record of the donor's history, looking for any signs of undiagnosed diseases (including emerging diseases);
   b. complete physical examination;
   c. psychological evaluation by a trained professional (if appropriate);
   d. laboratory tests:

      i. infectious disease markers;
      ii. full blood count;
      iii. ABO and Rh typing;
      iv. biochemistry;
      v. chest X-ray (if appropriate);
      vi. electrocardiogram (if appropriate).

Appendix 2 to Recommendation CM/Rec (2020)6 of the Committee of Ministers to member States Recommendation for the collection of minimum data on all haematopoietic progenitor cell donors and donations

With the aim of facilitating harmonised data collection for haematopoietic progenitor cell donors and donations (related and unrelated; adult and minor; peripheral haematopoietic progenitor cells and bone marrow) and to ensure that all donors are offered the same medical care after donation, including follow-up according to professional standards that takes into account their actual health status and possible complications related to donation, this appendix includes the minimum data set that should be collected from each donor:

1. donor information:

    a. identification number;
    b. date of birth/age;
    c. gender;
    d. country of residence;

2. donation data:

    a. date of donation;
    b. donation centre;
    c. type of donor:

        i. related (HLA-identical/haplo-identical)/unrelated;
        ii. peripheral haematopoietic progenitor cell;
        iii. bone marrow;
        iv. unstimulated leukocytes;

    d. number of haematopoietic progenitor cell collection procedures in the donation cycle concerned;
    e. total number of procedures during the donor's lifetime;
    f. type of mobilising agents, doses and administration route, if appropriate;

3. post-donation/follow-up data:

    a. short-term follow-up;

        i. severe adverse reactions during and in the first 30 days after donation, related to:

            a. the collection procedure;
            b. haematopoietic progenitor cell mobilisation;

    b. long-term follow-up

The first long-term follow-up report should be submitted one year after the last haematopoietic progenitor cell donation and, subsequently, every two years up to 10 years after the last donation procedure.[3] These follow-up reports should contain the following:

    i. information about newly diagnosed diseases covering at a minimum:

        a) severe or systemic autoimmune disorders;
        b) malignancies (haematological, oncological);

    ii. new long-term medication prescriptions;

    iii. survival and, if applicable, cause of death.

[3] According to the recommendations of the European Society for Blood and Marrow Transplantation (EBMT), available at https://www.ebmt.org/sites/default/files/migration_legacy_files/document/Donor%20Outcome%20Manual.pdf [last accessed 25 June 2020]