Parliamentary Assembly
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COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Recommendation 2173 (2020)[1]

Combating trafficking in human tissues and cells

Parliamentary Assembly

1. Advances in technology in human tissue and cell transplantation can save lives, restore essential bodily functions, improve the quality of life and help individuals to become parents. Today, human substances, ranging from musculoskeletal, cardiovascular and ocular tissues to many types of cells and gametes, are used routinely for medical purposes, therapy and research. Within the European Union alone, over 2 million human tissue and cell units were distributed for medical use in 2016. At the same time, the use of substances of human origin for transplantation and research raises many ethical and legal questions.

2. The Council of Europe Convention on Human Rights and Biomedicine (Oviedo Convention, ETS No. 164) stipulates that the "human body and its parts shall not, as such, give rise to financial gain", that an "intervention in the health field may only be carried out after the person concerned has given free and informed consent to it" and that the "interests and welfare of the human being shall prevail over the sole interest of society or science." Today, these principles are in danger of being bypassed and watered down.

3. In contrast to the field of organs, limited attention has been paid to illicit and unethical activities associated with the procurement, processing and clinical use of human tissues and cells. This is perhaps because society is less familiar with tissue and cell transplantation compared with organ transplantation, although the latter happens far less often.

4. When illicit and unethical activities involve donors, they frequently relate to recently deceased persons. Illicitly obtained tissues from one deceased person can reach up to 90 recipients. Various ethical and safety-related scandals have been reported, such as procurement without consent or authorisation, inadequate testing, inaccurate or false donor files, irresponsible allocation and illegal trade. Hearings, lawsuits, resignations and closures of tissue establishments have followed. However, knowledge about the true extent of these illicit activities remains limited. Little information is available from official sources.

5. Furthermore, there are activities that, in addition to their illicit and unethical component, could seriously jeopardise the quality and safety of tissues and cells, and thus the recipients' health.

6. When illicit and unethical practices occur in the form of financial inducement to donors (or their families), there may be a risk of potential living donors not adequately considering the risks related to the donation procedure or the families of deceased donors not disclosing relevant medical or behavioural information that would, under normal circumstances, preclude donation. This can also motivate intermediaries to withhold information for fear of losing fees.

7. Excessive compensation for donation may endanger the health of vulnerable donors, who may be enticed to donate driven by financial need. This may be of particular concern in the case of oocyte donors, where financial inducements can prompt women to provide multiple donations in different clinics without proper follow-up and medical care, and thus with risks for their health and fertility. The risk of excessive donation is increased in the case of cross-border donations, where financial disparities between countries may transform originally appropriate compensation in one jurisdiction into real inducements for donation for donors from less affluent countries.

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1. *Assembly debate* on 31 January 2020 (9th Sitting) (see Doc. 15022, report of the Committee on Social Affairs, Health and Sustainable Development, rapporteur: Ms Reina de Bruijn-Wezeman). *Text adopted by the Assembly* on 31 January 2020 (9th Sitting).

8. Desperation may also lead patients to search for alternative therapies for various diseases, including cell-based experimental treatments promoted without clinically demonstrated safety and efficacy.

9. Illicit and unethical practices undermine public trust and support. Scandals related to such practices cause a drop in confidence in all types of donor-derived substances and result in reluctance among the general population to donate bodily materials. Ultimately, this will affect the availability of tissue and cell grafts, and may jeopardise the availability of organ and blood donors as well.

10. The existing international legal framework – developed by the World Health Organization, the European Union and the Council of Europe – includes ample provisions to ensure the quality and safety of tissues and cells, by specifying the principles of consent, prohibition of financial gain and authorisation requirements. These principles, however, are not fully implemented and violations of them are not systematically prosecuted. The prohibition of financial gain, which is a universally accepted principle for such donations, is not always easy to uphold. Income disparities between and within different countries, together with the fact that tissues and cells can be easily stored and shipped, create opportunities for profit-making and abuse.

11. Most importantly, the absence of an internationally agreed definition of what constitutes trafficking in tissues and cells on the one hand, and the diversity of legal provisions within the European Union, Council of Europe member States and third countries, on the other hand, make it difficult to prosecute illicit and unethical activities.

12. The Assembly recalls that in its Recommendation 2009 (2013) "Towards a Council of Europe convention to combat trafficking in organs, tissues and cells of human origin", it suggested that the issue of trafficking in human tissues and cells was different from trafficking in human organs, and that the two issues had to be addressed through two distinct legal instruments. The Assembly thus called upon the Committee of Ministers to decide on a road map for the preparation of an additional protocol on trafficking of human tissues and cells to the proposed Convention against Trafficking in Human Organs.

13. Since then, the Council of Europe Convention against Trafficking in Human Organs (CETS No. 216) has been opened for signature and ratification. It has been ratified by nine countries and signed (but not yet ratified) by 15 further countries. It entered into force in 2018. The committee of the parties will be convened following the 10th ratification. As foreseen, this convention does not address the issue of tissues and cells.

14. With respect to the trafficking in human cells and tissues, the Assembly welcomes the work of the European Committee on Organ Transplantation, and in particular its report "Illicit and unethical activities with human tissues and cells: addressing the need for the elaboration of an international legal instrument to protect donors and recipients" prepared in 2018. The report identified gaps in international legal frameworks, reiterated the committee's concern with respect to lack of agreement on what constituted illicit activities in this area and stressed the need for a new legal instrument to address such activities.

15. The Assembly takes note of the progress made so far, as well as of the remaining challenges. It is convinced that stronger action is needed in this area on the part of the Council of Europe member States.

16. In the light of the above, the Assembly recommends that the Committee of Ministers:

16.1. initiate the drafting of a legally binding Council of Europe instrument against trafficking in human tissues and cells, possibly in the form of an additional protocol to the Convention against Trafficking in Human Organs;

16.2. ensure that such a legal instrument:

16.2.1. provides a definition of illicit activities in this area, and is based on a comprehensive approach covering crime prevention and repression, victim protection, promotion of appropriate policies, as well as national and international co-operation;

16.2.2. includes mechanisms for regular data collection and analysis on trafficking in human cells and tissues, in compliance with democratic governance structures, as well as transparent, authoritative and effective monitoring and implementation;

16.3. call on the Council of Europe member States that have not yet ratified the treaties related to this area, such as the Convention on Human Rights and Biomedicine, the Convention on Action against Trafficking in Human Beings (CETS No. 197) and the Convention against Trafficking in Human Organs, to do so as a matter of priority, and as a contribution to the United Nations Agenda for Sustainable Development Goal 3: Good health and well-being and Goal 16: Promote peace, justice and strong institutions.