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COMMENTARY
The Convention on Human Rights and Biomedicine twenty years later: a look at the past and a step towards the future

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Abstract
A document published by the Council of Europe provides practical indications for interpreting Article 21 of the Convention on Human Rights and Biomedicine, which asserts that "The human body and its parts shall not, as such, give rise to financial gain". In Italy the Istituto Superiore di Sanità (ISS, Italian National Institute of Health) is actively committed to comply fully with this imperative ethical requirement.

Key words
- bioethics
- blood
- human rights
- legislation
- organ transplantation

The "Convention for the protection of human rights and dignity of human beings with regards to the application of biology and medicine: Convention on human rights and biomedicine" [1] (hereinafter the Convention) of the Council of Europe is one of the most authoritative reference documents on the subject of bioethics.

This year sees the twentieth anniversary of the adoption of the Convention, which was opened for signature by Member States on 4th April 1997.

The Convention, which was opened for signature by Member States on 4th April 1997, comprises 14 chapters that address the basic issues of: consent (chapter 2), private life and right to information (chapter 3), human genome (chapter 4), scientific research (chapter 5), organ and tissue removal from living donors for transplantation purposes (chapter 6), prohibition of financial gain and disposal of a part of the human body (chapter 7).

Article 27 allows Member States to grant wider protection through legislation at national level: thus the Convention establishes the minimum indispensable standards.

Some of the principles affirmed in the Convention were subsequently supplemented by additional protocols addressing specific issues, such as: the prohibition of cloning human beings [2]; the transplantation of organs and tissues of human origin [3]; biomedical research [4]; genetic testing for health purposes [5].

The Convention was ratified in Italy by Law no.145 of 28th March 2001, but although the law was passed by the Italian Parliament it has not yet been filed by the Italian government with the General Secretariat of the Council of Europe. This final step in its legislative procedure has been solicited by various parties, including the Italian National Bioethics Committee, which on 24th February 2012 adopted a "Motion to complete the ratification procedure of the Oviedo Convention" [6].

Although the ratification procedure is not formally complete, the Convention is nonetheless quoted in Italian case-law and is an important point of reference for jurists and bioethicists. Indeed, it is listed among the reference documents that inspired the "Codice di Etica dell'Istituto Superiore di Sanità" (Code of Ethics of the Italian National Institute of Health [7]).

That the Convention contains instances of ambiguity is explicitly admitted in the Explanatory Report [8] and is borne out by the fact that Article 1 fails to provide a definition of a human being. The text refers both to "human beings" and to "everyone" (and in French to "être humain" and "toute personne").

One of the articles most susceptible to diverging interpretations is Article 21 ("Prohibition of financial gain"), which states that: "The human body and its parts shall not, as such, give rise to financial gain". In this case, though, potential differences in interpretation could arise less from any lack of clarity in the text, which is unequivocal, than from the multitude and heterogene-

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ity of situations involving the use of human cells, blood, tissues and organs.

The procedures involved in the collection, possible processing, storage and use of human biological material frequently incur considerable costs, and there is a need to ensure that legitimate refunds for expenses and the relative flows of money are not allowed to conceal mechanisms intended to generate any kind of financial gain. The principle underlying the prohibition of financial gain is intrinsically linked to the prohibition of trafficking in human cells, organs or tissues.

In order to prepare a proper interpretation of Article 21 of the Convention, the Council of Europe set up the *Ad hoc* Working Group on The prohibition of financial gain with the task of "preparing proposals for clarification of key notions with a view to facilitate the implementation of the principle in Article 21 of the Oviedo Convention", on which the Head of the Bioethics Unit of the Istituto Superiore di Sanità (ISS, Italian National Institute of Health), who is also co-author of the present paper, represented Italy.

The Working Group was installed on 22nd February 2016 and, after examining a number of legal instruments and reference documents relevant to the principle of the prohibition of financial gain and in-depth discussion of the issue, it produced a draft text: this was then discussed and amended and the final text was adopted on 11th October 2016 [9].

The text was then forwarded to the Committee on Bioethics (DH-BIO), which conducted an editorial revision on it in 2017, and subsequently adopted it on 4th December 2017. The guide was then sent to the European Committee on Organ Transplantation (CE-P-TO) an d the CD-P-TO and the European Committee on Blood Transfusion (CE-P-TS). The CD-P-TO adopted the guide on 11th January 2018 [9].

The *ad hoc* working group felt that it should focus its efforts on the issues surrounding donation and the prohibition of financial gain in relation to the human body and its parts, excluding the field of research.

The document offers "guidance on how to interpret the principle of the prohibition of financial gain with respect to the human body and its parts from living or deceased donors in order to define a common framework for its interpretation". It recognises that the aim of the principle is twofold. On the one hand it is intended to underscore the welfare and respect for the human rights of living donors, and on the other hand it aims to protect recipients by ensuring the safety and quality of the bodily materials donated.

The document also recognises that the prohibition of financial gain is compatible with ensuring financial neutrality for living donors and, therefore, that the prohibition of financial gain does not preclude:

- "compensation of living donors for loss of earnings and reimbursement of any other justifiable expenses caused by the removal or by the related medical examinations;
- compensation in case of undue damage resulting from the removal of organs, tissues or cells".

The document also notes that the prohibition of financial gain does not preclude the payment of "a justifiable fee for medical or related technical services rendered in connection with donation". Throughout the document the term "reimbursement" is used in relation to expenses such as travel and other outlays incurred in connection with a donation, while the term "compensation" is used in relation to any loss of income or earnings connected with a donation.

In the matter of the reimbursement of justifiable expenses and compensation for loss of earnings for living donors the document notes that this is permitted by the requisite of financial neutrality for the living donor. When the costs incurred are of a kind for which the donor is able to produce receipts, such as travel tickets, the fact that the cost is justifiable – and therefore acceptable – is apparent.

Other costs, such as lost earnings, costs related to the care of dependants or to follow-up visits, are less straightforward to determine. The dominant principle should be that the act of donation should not give rise either to a financial loss or to a financial gain for the donor. In order to ensure that they are properly compensated for losses or expenses actually incurred, donors should provide evidence that compensation is indeed appropriate.

The document recognises that, in exceptional circumstances, Member States may opt to provide compensation in the form of a fixed-rated scheme. In this case the conditions of "implementation must be provided for under national law, including the setting of an upper limit for compensation. If the upper limit is not specified by law, it should be established by an independent body set up in accordance with national law".

A key element is that any reimbursement or compensation should be disbursed in relation to living donations in so far as it is the donor whose losses are being reimbursed or compensated for. Reimbursement or compensation should never be connected to the donation as such.

The document then addresses the issue of payment for the provision of legitimate medical or related technical services. In this regard, the "Additional Protocol to the Convention on Human Rights and Biomedicine on transplantation of organs and tissues of human origin" explicitly allows for the payment of a justifiable fee for legitimate medical or related technical services rendered in connection with transplantations [3]. The Explanatory Report specifies that this could include "costs of retrieval, transport, preparation, preservation and storage (…), which may legitimately give rise to reasonable remuneration" [8]. The Report also describes some of the technical processes that may legitimately give rise to justifiable costs, such as "sampling, testing, pasteurisation, fractionation, purification, storage, culture and transport of related items".

The Convention permits the sale of a medical device that incorporates human tissue that has undergone a manufacturing process provided the tissue used as the original material is not sold.

The issue of prohibiting financial gain also calls for clarification as to what constitutes a justifiable fee for the medical teams and processing services involved.

On this subject the Convention enjoins Member States to ensure that any arrangements for remuneration

or bonus payments envisaged in hospitals or donation centres in relation to medical services in connection with the donation of parts of the human body from both living and deceased donors are comparable to those envisaged for other services provided by the medical team in the same hospital or donation facility or in similar institutions throughout that member state. This means that while overtime payments are permitted, bonus payments for work performed in relation to obtaining consent to donation from individuals or their families are not.

In the matter of processing fees for technical services connected with the donation of parts of the human body from either living or deceased donors, Member States are expected to ensure that these do not exceed the operational costs and are comparable among different technical facilities, regardless of their legal status within a member state. Such fees may include the costs of procuring, testing, processing, storing and distributing human body parts, as well as costs related to the personnel involved in these procedures, transportation, infrastructure and administration, and the need to invest in state-of-the-art equipment and processes to ensure the sustainability in the long term of all the procedures and services involved, among others.

It is thus essential that great care be taken to ensure that donations of human cells, tissues and organs are voluntary and unpaid for and that legitimate forms of reimbursement or compensation do not translate into surreptitious forms of payment.

However, donations require the intervention of third parties, particularly of healthcare professionals, and the use of appropriate procedures, all of which can and must be paid for at the proper price. Here, too, there is a need for transparent regulations in order to prevent any form of financial gain.

The ISS attributes the greatest importance to these issues, particularly in consideration of the fact that it houses both the National Blood Centre and the National Transplant Centre, two technical facilities of the Ministry of Health responsible respectively for the coordination and technical-scientific control of all transfusion medicine issues regulated by Italian and European legislation and for the organisation and management of the procedures for organ donation, procurement and transplants throughout Italy.

On the twentieth anniversary of the Convention the ISS is pleased to contribute to improving the implementation of one of its key underlying principles. The human body and its parts should never be reduced to the level of traded goods: this would reveal a lack of the respect due to the person and violate his dignity.

CP is a member of the "*Ad hoc* working group on the prohibition of making a financial gain from the human body" of the Council of Europe.

Conflict of interest statement

None to declare.

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REFERENCES

1. Council of Europe. Convention for the protection of human rights and dignity of human being with regards to the application of biology and medicine: Convention on human rights and biomedicine. Oviedo, 4 April 1997. Available from: www.coe.int/en/web/conventions/full-list/-/conventions/rms/090000168007cf98.
2. Council of Europe. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings. Paris, 12 January 1998. www.coe.int/en/web/conventions/full-list/-/conventions/treaty/168.
3. Council of Europe. Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin. Strasbourg, 24 January 2002. Available from: www.coe.int/en/web/conventions/full-list/-/conventions/treaty/186.
4. Council of Europe. Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research. Strasbourg, 25 January 2005. Available from: www.coe.int/en/web/conventions/full-list/-/conventions/treaty/195.
5. Council of Europe. Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes. Strasbourg, 27 November 2008. Available from: www.coe.int/en/web/conventions/full-list/-/conventions/treaty/203.
6. Comitato Nazionale per la Bioetica (Italian National Bioethics Committee). Motion to complete the ratification procedure of the Oviedo Convention. 24 February 2012. Available from: http://presidenza.governo.it/bioetica/eng/motion/motion_completion_ratificationprocess_oviedo_convention240212.pdf
7. Comitato Etico dell'Istituto Superiore di Sanità. Codice di etica dell'Istituto Superiore di Sanità. Versione 1. 13 gennaio 2015. Available from: www.iss.it/coet/.
8. Council of Europe. Explanatory Report to the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. 4 April 1997. Available from: http://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=09000016800ccde5.
9. Council of Europe. Guide for the implementation of the principle of prohibition of financial gain with respect to the human body and its parts from living or deceased donors. 2018. Available from: https://rm.coe.int/guide-financial-gain/16807bfc9a.