Commentary

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

Carlo Petrini1 and Walter Ricciardi2

1 Bioethics Unit, Office of the President, Istituto Superiore di Sanità, Rome, Italy
2 President, Istituto Superiore di Sanità, Rome, Italy

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.

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 heterogeneous-
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) and 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 justifi-
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.

Accepted on 5 June 2018.

REFERENCES