Ann Ist Super Sanità 2013 | Vol. 49, No. 4: 412-416
DOI 10.4415/ANN_13_04_16

Between altruism and commercialisation: some ethical aspects of blood donation

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Abstract
Numerous documents (declarations, codes, recommendations, guidelines) issued by eminent institutions recommend that the donation of blood should be voluntary and unremunerated. This does not preclude the possibility: 1) that donors receive some form of reimbursement; 2) that subsequent procedures, which inevitably incur costs, may involve considerable financial activity; 3) that legislation in some nations may allow trade in certain types of human biological material; 4) that voluntarily donated human blood be used to derive products that are subsequently marketed. The present article highlights some of the contradictions generated by these considerations and affirms that they do not undermine the primary duty to uphold the voluntary nature of donation.

Key words
- bioethics
- blood
- informed consent
- legislation
- plasma-derived medicinal products

THE BAN ON COMMERCIALISATION OF THE HUMAN BODY OR ITS PARTS

The principle that the human body should be neither commercialised nor a source of gain is enshrined in numerous respected documents.

The World Health Organisation's *Guiding Principles on human cell, tissue and organ transplantation* (Resolution WHA 63.22) states that "Cells, tissues and organs should only be donated freely, without any monetary payment or other reward of monetary value. Purchasing, or offering to purchase, cells, tissues or organs for transplantation, or their sale by living persons or by the next of kin for deceased persons, should be banned" [1].

For Council of Europe member countries 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* [2] published by the Council in 1997, is a key document and an essential reference for bioethics and biolaw. Under the heading "Prohibition of financial gain", Article 21 of the Convention states: "The human body and its parts shall not, as such, give rise to financial gain". Article 22 ("Disposal of a removed part of the human body") rules that "When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures". The Explanatory Report [3] annexed to the Convention clarifies that the words "body parts" include "organs and tissues proper, including blood" but not products such as "hair and nails, which are discarded tissues, and the sale of which is not an affront to human dignity". Blood is thus explicitly included in Articles 21 and 22 of the Convention [2].

Within the European Union this concept is echoed in European Directive 2004/23/EC, which uses the term "donor" to designate "every human source, whether living or deceased, of human cells or tissues" [4].

Other documents that adopt the principle that the human body and its parts (including blood [5]) should not be a source of gain have been issued by the United Nations Educational, Scientific and Cultural Organisation (UNESCO), notably the *Universal Declaration on the Human Genome and Human Rights* [6], the *International Declaration on Human Genetic Data* [7] and the *Universal Declaration on Bioethics and Human Rights* [8].

Table 1 lists some of the key documents that affirm this principle of non-commercialisation of the human body or its parts. Many of those listed also address such topics as: different procedures for donating blood or other human biological material; the requisites for informed consent; the rights involved.

The Table is not exhaustive, but indicates some examples of the different types of document that, albeit in different contexts, affirm this principle that the human body or its parts should not be a source of gain.

Of the various considerations generated by these documents, two are of interest here and are addressed below (in the following two paragraphs):

1) Regulations allowing various forms of buying and selling of human biological material are in force in sev-

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eral countries that are also signatories to documents affirming the non-commercialisation of the human body. 2) Forms of reimbursement to donors of biological material, particularly blood, are recognised as legitimate – and even in some cases encouraged – in several documents published by national institutions and by some legislative frameworks.

ON THE TRADE IN HUMAN BIOLOGICAL MATERIAL ENVISAGED IN NATIONAL LAWS

The statute books of several nations that have signed documents such as the *Convention on Human Rights and Biomedicine* [4] mentioned above allow various forms of trade in buman body parts [9].

In Belgium, for instance, the "Arrêté ministeriel fixant le prix du matériel corporel humain" of 14 October 2009 contains a detailed list of the cost (in euros) of different parts of the human body [10].

In Germany biological material taken from the human body can be subject to ownership and there are no laws or guidelines that prohibit trade in it. As a result, sales of human biological material stored in hospital biobanks are legally held, even without the consent of the persons from whom the material was taken [9].

Although Spanish law bans trade in the human body or its parts, the "commercial donation" of gametes for purposes of medically assisted procreation or for research is allowed in Spain, and precise rates are specified [11].

In an international context, the case of umbilical cord blood donated at birth for philanthropic purposes and stored in public biobanks that are part of international networks is of interest. Cord blood "is a high value commodity frequently trading at £15,000 to £20,000 per unit. In a growing number of cases patients receive costly multiple transplants to increase the likelihood of therapeutic success (…). This represents a substantial income for those banks selling CB given that the cost of storage is, on average, considerably lower (usually less than 10% of the export price). Based on units traded through the World Marrow Donor Association (WMDA), the international CB market was worth in excess of £20 m during 2008 and is rising sharply" [12].

It is thus evident that human biological material is treated in many countries as property and that property rights may be granted.

This raises questions on, among other things, the "ownership" of the human body and its parts, an issue that is not generally addressed explicitly in national legislation. Without entering into the merits of this problem, which is not germane to the present article, it is worth recalling that: "This leads to the possibility of exploitation by others, which in turn remains unsanctioned because the initial refusal to grant property rights to the source means that no civil remedies are available and no criminal sanctions in relation to the dishonest appropriation are possible" [13]. Hoppe suggests "a third way in terms of property classes. That of *bioequity* or *property in biomaterial*" [13]. The omission of any notion of "ownership" of the human body or its parts from legislative frameworks is prompted by the laudable desire to avoid forms of commercialisation. Paradoxically, this failure to provide a legal definition of ownership could encourage rather than contain ethically unacceptable forms of trade.

ON COMPENSATION FOR THE DONATION OF HUMAN BIOLOGICAL MATERIAL

In common with other institutions, the WHO recommends that: "National law should ensure that any gifts or rewards are not, in fact, disguised forms of payment for donated cells, tissues or organs. Incentives in the form of "rewards" with monetary value that can be transferred to third parties are not different from monetary payments" [1].

According to Directive 2002/98/EC "Modern blood-transfusion practice has been founded on the principles of voluntary donor services, anonymity of both donor and recipient, benevolence of the donor, and absence of profit on the part of the establishments involved in blood transfusion services" ("Whereas" n. 20); "Member States shall take the necessary measures to encourage voluntary and unpaid blood donations with a view to ensuring that blood and blood components are in so far as possible provided from such donations" (Article 20) [14].

Article 18 of the Directive 2004/23/EC [4] reads as follows: "As a matter of principle, tissue and cell application programmes should be founded on the philosophy of voluntary and unpaid donation, anonymity of both donor and recipient, altruism of the donor, and solidarity between donor and recipient. Member States are urged to take steps to encourage a strong public and non-profit sector involvement in the provision of tissue and cell application services and the related research and development".

Article 12 of the same Directive requires that the Member States "shall endeavour to ensure voluntary and unpaid donations of tissues and cells" [4]. However, it provides for "compensation which is strictly limited to making good the expenses and inconveniences related to the donation" [4]. The inclusion of "inconveniences related to the donation" could give rise to problems, as it could be interpreted as aimed at recruiting volunteers whenever these are judged to be in short supply. This practice could thus be construed as a financial stimulus of a kind that constitutes a disguised form of payment.

The notion of "unpaid donation" does not, however, rule out the possibility of "reimbursements" to cover expenses and missed earnings associated with donations (travel expenses, absence from work, etc.). Such procedures, which may verge on actual payments, are effectively envisaged in several countries.

The debate concerning these issues is a lively one: in the UK, for instance, where trade in human biological material is prohibited [15], the Nuffield Council on Bioethics published a report on *Human bodies: donation for medicine and research* [16] that proposed a "ladder" of procedures to facilitate donation. The first four rungs of this ladder are ethically uncontroversial and easily permissible, while the last two are ethically more complex and should be considered only when existing levels of altruism are not sufficient to cover a public health need; even then, they should not cause harm to donors or impinge on other important interests.

Table 1
List of documents regarding the principle of non-commercialisation of the human body or its parts

World Health Organization

World Health Organization. Resolution WHA28.72. *Utilization and supply of human blood and blood products.* Twenty-eighth World Health Assembly, Geneva, 13-30 May 1975. www.who.int/entity/bloodsafety/en/WHA28.72.pdf.

World Health Organization. *Availability, safety and quality of blood products.* Report by the Secretariat. Sixty-third World Health Assembly, Geneva, 17-21 May 2010. WHA63/20. Agenda item 11.17. http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_20-en.pdf

World Health Organization. *Availability, safety and quality of blood products.* Sixty-third World Health Assembly. Geneva, 17-21 May 2010. WHA63.12. Agenda item 11.17. http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_20-en.pdf.

World Health Organization. *Guiding Principles on human cell, tissue and organ transplantation.* Sixty-third World Health Assembly. Geneva, 17-21 May 2010. WHA63.22. www.who.int/entity/transplantation/Guiding_PrinciplesTransplantation_WHA63.22en.pdf.

World Health Organization (WHO Expert Group). Expert Consensus statement on achieving self-sufficiency in safe blood and blood products based on voluntary non-remunerated blood donations (VNRBD). *Vox Sang* 2012;103(4):337-342.

World Health Organization. *Global consultation on universal access to safe blood transfusion*. Ottawa, 9-11 June 2007. www.who.int/entity/bloodsafety/ReportOttawaConsultation2007.pdf. (Chapter 10: Recommendations).

World Health Organization. *The Melbourne Declaration on 100% voluntary non-remunerated donation of blood and blood components.* 11 June 2009. www.who.int/worldblooddonorday/MelbourneDeclarationWBDD09.pdf.

International Declarations

Dublin Consensus Statements
O'Mahony B. The Dublin Consensus Statement 2012 on optimised supply of plasma-derived medicinal products. *Blood Transfus* 2013; DOI 10.2450/2013.0044-13.

O'Mahony B, Turner A. The Dublin Consensus Statement on vital issues relating to the collection of blood and plasma and the manufacture of plasma products. *Vox Sang* 2010;98(3p2):447-50.

O'Mahony B, Turner A. The Dublin Consensus Statement 2011 on vital issues relating to the collection and provision of blood components and plasma-derived medicinal products. *Vox Sang* 2012;102(2):140-3.

European Union and Council of Europe

European Union
Council of the European Communities. Council Directive 89/381/EEC of 14 June 1989 extending the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products and laying down special provisions for medicinal products derived from human blood or human plasma. *Official Journal of the European Communities* L188, 28 June 1989.

European Group on Ethics in Science and New Technologies [Group of Advisers on the Ethical Implications of Biotechnology to the European Commission]. *Opinion n. 2 - Products derived from human blood or human plasma.* 12 March 1993. http://ec.europa.eu/bepa/european-group-ethics/docs/opinion2_en.pdf.

Council of the European Union. Council Recommendation of 29 June 1998 on the suitability of blood and plasma donors and the screening of donated blood in the European Community. *Official Journal of the European Communities* L203, 21 July 1998.

European Union. Charter of Fundamental Rights of the European Union. *Official Journal of the European Communities* 2000;C364:1-22. (Art. 3).

European Parliament, Council of the European Union. Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC. *Official Journal of the European Union* L33 8 February 2003.

Commission of the European Communities. *Report to the Commission to the Council and the European Parliament. Report on the promotion by Member States of voluntary unpaid blood donations.* Communication COM(2006) 217 final. 17 May 2006. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2006:0217:FIN:EN:PDF.

European Parliament (Yannakoudakis M, ed.). *Motion for a European Parliament Resolution on voluntary and unpaid donation of tissues and cells.* 29 June 2012. www.europarl.europa.eu/sides/getDoc.do?type=REPORT&reference=A7-2012-0223&language=EN#title1.

Council of Europe
Council of Europe. *Recommendation R(95)14 on the protection of the health of donors and recipients in the area of blood transfusion.* 10 October 1995. http://wcd.coe.int/com.instranet.InstraServlet?Command=com.instranet.CmdBlobGet&DocId=528618&SecMode=1&Admin=0&Usage=4&InstranetImage=43143.

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. http://conventions.coe.int/treaty/en/treaties/html/164.htm. (Art. 21).

Council of Europe. *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.* Explanatory report. 1996. http://conventions.coe.int/Treaty/EN/Reports/Html/164.htm.

(continues)

Table 1 (continued)

Council of Europe, European Directorate for the Quality of Medicines & HealthCare - EDQM. *Blood and Blood Components. Safety, Quality, Training and Ethical Matters Concerning Preparation, Use and Quality Assurance. Council of Europe Resolutions, Recommendations and Convention.* 1st edition. 2012. www.edqm.eu/site/blood_and_blood_componentspdf-en-31120-2.html.

National Bioethics Committees

France
Comité Consultatif National d'Éthique pour les Sciences de la Vie et de la Santé (CCNE). *Avis 28. Avis sur la transfusion sanguine au regard de la non-commercialisation du corps humain. Rapport* (Opinion 28. Opinion on blood transfusion with reference to not making commercial use of the human body. Report). 2 Décembre 1991. www.ccne-ethique.fr/docs/fr/avis028.pdf.

United Kingdom
Nuffield Council on Bioethics. *Human bodies: donation for medicine and research*. 2011. www.nuffieldbioethics.org/sites/default/files/Donation_full_report.pdf.

Nuffield Council on Bioethics. *Solidarity. Reflections on an emerging concept in bioethics*. 2011. www.nuffieldbioethics.org/sites/default/files/ncob_solidarity_report_final.pdf.

Associations and Scientific Societies

European Blood Alliance. Folléa G, De Wit J (Eds.). Blood*, tissues and cells from human origin.* 2013. http://ebaweb.files.wordpress.com/2013/01/eba_online.pdf.

International Society of Blood transfusion (ISBT). *A code of ethics for blood donation and transfusion* (Adopted by General Assembly of ISBT, July 12, 2000. Amended by the General Assembly of ISBT, September 5, 2006). 2006. www.isbtweb.org/about-isbt/code-of-ethics/.

Professional Associations

American Medical Association. *Code of Medical Ethics. Opinion 2.08. Commercial use of human tissue.* 2007. www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion208.shtml.

American Medical Association (Council on Ethical and Judicial Affairs). *Who should profit from the economic value of human tissue? An ethical analysis.* CEJA report E - A90. June 1990. www.ama-assn.org/resources/doc/code-medical-ethics/208a.pdf.

International Organizations

OECD
Organisation for Economic Co-operation and Development (OECD). *Guidelines for the licensing of genetic inventions*. 2006. www.oecd.org/dataoecd/39/38/36198812.pdf.

UNESCO
United Nations Educational, Scientific and Cultural Organization (UNESCO). *Report of the International Bioethics Committee (IBC) on consent.* Paris: UNESCO; 2008.

United Nations Educational, Scientific and Cultural Organization (UNESCO). *International Declaration on Human Genetic Data.* 16 October 2003. www.unesco.orgnew/en/social-and-human-sciences/themes/bioethics/human-genetic-data/.

United Nations Educational, Scientific and Cultural Organization (UNESCO). *Universal Declaration on Bioethics and Human Rights.* 19 October 2005. www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights/.

The six rungs proposed by the Nuffield Council are [16]:
- Rung 1: The dissemination of information concerning the need for donations of bodily material for the treatment of other people or for medical research;
- Rung 2: Measures to recognise the value of and gratitude for altruistic donations; these could vary according to both the form of each donation and the circumstances of the donor;
- Rung 3: Measures to remove possible barriers and disincentives to donation encountered by those disposed to donate;
- Rung 4: Additional measures to prompt or encourage persons already disposed in principle to donate for altruistic reasons;
- Rung 5: Interventions that offer benefits in kind to encourage persons not ordinarily disposed to donate to contemplate doing so;
- Rung 6: Financial incentives that improve the financial position of the donor as a direct result of donating.

CONCLUSIONS

The report by the Nuffield Council [16] sparked a lively debate [17].

In discussing these issues it is useful to note that the documents listed in *Table 1* concur in recommending that the donation of blood, cells and tissues should be voluntary and unremunerated. Vigilance is thus necessary to ensure that legitimate and proper reimbursements to donors (for travel, genuinely incurred expenses, loss of earnings) should not effectively conceal more or less explicit forms of payment. This is not an easy task because the boundary between reimbursements and payments is frequently blurred. The relevant regulations need therefore to be as explicit as possible: "National law should ensure that any gifts or rewards are not, in fact, disguised forms of payment for donated cells, tissues or organs. Incentives in the form of 'rewards' with monetary value that can be transferred to third parties are not different from monetary payments" [1].

It should also not be forgotten that donations necessarily involve third parties (mainly healthcare professionals) as well as appropriate and frequently costly procedures and equipment, for all of which a fair price should be paid. It has to be acknowledged that there is a "need to cover legitimate costs of procurement and of ensuring the safety, quality and efficacy of human cell and tissue products and organs for transplantation…." [1]. The storage and processing stages are not cost-free and the relevant expenses are borne by the facilities that use the donated (and variously modified) blood, cells and tissues.

In some cases the processing of voluntarily donated cells, tissues and blood renders the end-products very different from the original biological material, and various of these products may be marketed [18]. This is ethically acceptable only in so far as the donor was fully informed and freely gave consent. It is usual in these cases for at least part of the end-product to be assigned to a public health scheme in recognition of the altruistic gesture of donation. At all events care must always be taken to ensure that donations are totally voluntary and that the entire procedure is carried out in compliance with current legislation.

It is the task of legislators and national authorities not only to define the most appropriate regulations to ensure that any reward offered to donors cannot be construed as some kind of economic incentive, but also to spread the culture of donation so that the public can fully appreciate how a life may depend on a simple gesture of altruism.

Conflict of interest statement

There are no potential conflicts of interest or any financial or personal relationships with other people or organizations that could inappropriately bias conduct and findings of this study.

Received on 16 August 2012.
Accepted on 23 October 2013.

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