

## Review Article

## Open Access

Paola Bin, Paola Delbon, Mauro Piras, Mariano Paternoster\*, Pierpaolo Di Lorenzo, Adelaide Conti

# Donation of the body for scientific purposes in Italy: ethical and medico-legal considerations

DOI 10.1515/med-2016-0060

received June 26, 2016; accepted June 7, 2016

**Abstract:** In recent years in Italy (and in the other European Countries) a new debated topic involves anatomists and the scientific world: donation of the body after death for scientific purposes. The aim of our analysis is to analyze the issue of voluntary body donation in Italy focusing first of all, on key principles of the disciplines of donation. Considering the rise of exhibitions and events in which death is spectacularized, the debate is focus on will, on respect and overall on the purpose for which the body is donated. Anatomical dissection is considered necessary in the direct learning of the human body, of surgical practices and new scientific techniques but the scarcity of programmes and regulations regarding the donation of bodies for study and research make it an uncommon practice. After discussing what are the constitutional principles underlying the issue we want to emphasize the need of a more effective and updated regulation to set limits and methods of a practice still essential for scientific progress.

**Keywords:** Body-donation; Unclaimed bodies; Informed consent; Anatomical dissection in research

## 1 Introduction

The donation and, more specifically, the possibility to leave the body after death to do research or educational activities in favour of medical-surgical education, has its roots in the principle of solidarity towards others. This purpose is pursued through the promotion of studies and research and, indirectly, based on the principle of global health protection.

Medical education and, especially, surgical training have always made use of corpses, and anatomical dissection was considered a necessary and indispensable method in the direct learning of the human body, surgical practices and new scientific techniques.

To date, the evolution of surgical techniques and of new technology has allowed for the development of multimedia tutorials. However, they cannot be applied to all cases and still cannot replace direct experience on corpses.

Today the most advanced countries, in terms of research, expect that anatomical dissection is considered to be as an important teaching asset in medical and surgical training. This also applies to Italy where such an educational necessity suffers an impact due to the lack of bodies available for practice. In turn, this arises from the scarcity of programmes and regulations regarding the donation of bodies for study and research.

The promotion of a more conducive culture to research in favour of donating the body to didactic-scientific purposes is indeed a common need which repeatedly emerges even in the pronouncements of various national and international scientific conferences and that also reflect the need for a clearer legislation. We analyzed Italian legislation on voluntary donation of the body and some of Italian and European bioethics opinions trying to outline general “guidelines”. Italian legislation on the subject is composed principally by “Mortuary Police Regulations” (Decree of the President of the Italian Republic no. 285 of 10 September 1990) and by Article 32 of the “*Regio Decreto*” no. 1592 dated 31 August 1933.

**\*Corresponding author: Mariano Paternoster**, Department of Advanced Biomedical Sciences, University of Naples „Federico II“, Naples, Italy, E-Mail: maupiras83@yahoo.it

**Paola Bin**, Department of Surgery, Radiology and Public Health, Public Health and Humanities Section, University of Brescia Italy – Forensic Medicine Institute, 25123 Brescia, Italy

**Paola Delbon, Adelaide Conti**, Department of Surgery, Radiology and Public Health, Public Health and Humanities Section, University of Brescia – Centre of Bioethics Research, Italy

**Mauro Piras**, Department of Surgery, Radiology and Public Health, Public Health and Humanities Section, University of Brescia Italy – Forensic Medicine Institute, Brescia, Italy

**Pierpaolo Di Lorenzo**, Department of Advanced Biomedical Sciences, University of Naples “Federico II”, Naples, Italy

Considering undeveloped legislation, it was necessary to analyze bioethical non-binding issues expressed in recent years. We searched literature on the medical literature database (PubMed) and Italian legal database using these terms: “body donation”, “cadaver donation”, “voluntary body donation” and “ethical aspects on body donation” in the period of time between 2000-2016.

## 2 Results

In Italy, the regulations regarding the possibility of making entire body and/or organs available after death are relatively undeveloped. With the exception of the legislation on the removal of organs and tissues for transplantation, the donation of the body is not subject to specific laws. Information regarding this field are currently provided by the Mortuary Police Regulations which, after an adequate period of observation, and according to Article 40, establishes that an unclaimed body can be intended for teaching and for scientific studies (in accordance with Article 32 of the “*Testo Unico delle Leggi sull’Istruzione Superiore*” that regulated in the past Italian education) after consignment to the University’s anatomical theatre. The same Regulations also provide for the possibility of removing the skeleton, parts or organs of these bodies, in order to preserve them for demonstration, study and research purposes in duly authorised anatomical institutes and museums. However, removal and conservation must be authorised from time to time by the local health authority [1]. The collection and preservation of corpses and their anatomical parts is also allowed when a technical consultant/expert, appointed for a judicial autopsy, can take samples of biological tissues and/or fluids if deemed essential for a comprehensive execution of his/her assignment. In this case, the consultants have no legal obligation to provide information to the relatives of the person subject to the autopsy. However, this should not represent a derogation allowing the use of the material taken for scientific research or for purposes other than those of the autopsy, which must remain confined to judicial investigation needs.

Article 32 of the “*Regio Decreto*” no. 1592 dated 31 August 1933, (Approval of the Act on Higher Education), still in force today, stipulates: “*the corpses [...] whose carriage is not done at the expense of relatives within the sixth degree of the family group or confraternities or associations that have assumed the commitment of the hearses of their member and those from forensic-medicine laboratory (except suicides), and that are not required by the relatives*

*included in the aforesaid family group, are reserved for education and scientific surveys*” [2].

This legislation is definitely obsolete as well as ethically questionable, however, proving the fundamental lack of an adequate legislation in this matter.

Moreover, in an opinion expressed in 2013, the CNB (Italian National Bioethics Committee), albeit stressing the importance of donating, pointed out the ethical unacceptability of what provided in Article 32 of the “*Regio Decreto*”. The intended use of these corpses for scientific purposes indeed involves exploitation by the collectivity of the bodies of the deceased persons found to be unknown or not having relatives providing for the burial [3].

Moreover, the release of corpses for educational purposes does not consider the possibility of the deceased having voluntarily offered their bodies for such purpose. In fact, the regulatory approach was concerned about the “unclaimed” corpses and did not provide any rules on possible “voluntary” donation. The lack of legislation on this matter raises the question of how corpses can be intended for scientific use. Theoretically, there is no law that prohibits donating one’s body for scientific research purposes and under the circumstances described by Article 32 of the Royal Decree, this type of donation is allowed regardless of any previous consent of the deceased. Therefore, reaching the conclusion that such a donation is admitted as legitimate, with regard to form it has become necessary to resort to the instrument of the last will and testament as an expression of the deceased’s will (although not strictly having a financial nature), at least until an adequate change in legislation comes about. In that regard, it should be noted the presence of regional laws (e.g., Article 70 paragraph 2 of Lombardy’s Regional Law dated 30 December 2009) that have addressed this issue by providing that, in case the deceased had expressed the will of his/her own body to be intended for research and education, the parties entitled must notify the Authority. Apart from the legality aspect, what emerges from legislation is a substantial implicit consent to the donation of the body [1].

When not within the framework of the previously described meagre legislation, in Italy use of corpses is unlawful (Article 413 of the Italian Penal Code).

Similarly in Europe, the situation is not entirely clarified. The Trans-European Pedagogic Research Group for Anatomical Sciences highlighted the fact that there exist considerable variations in the legal and ethical frameworks throughout Europe concerning body bequests for anatomical examination. Such differences seem to reflect cultural (and religious) variations as well as different legal and constitutional frameworks. There are different views

concerning the “ownership” of cadavers and concerning the need (perceived by different societies and national politicians) for legislation specifically related to anatomical dissection. Furthermore, there are different views concerning the acceptability of using unclaimed bodies that have not given informed consent [4].

In a USA multivariable analysis, assessing the independent relation of sociodemographics and attitudinal factors to willingness to consider donation, it was determined the amount of variation in willingness to consider donation among the study population in which 49% reported they would consider whole body donation. That survey concluded that demographic and attitudinal factors are strongly related to willingness to consider whole body donation [4].

At the light of the growing interest and willingness of the population, national and international, in donation of the body is necessary to clarify what are the main issues related to this practice and that pass necessarily, first of all, in an appropriate informed consent [5].

### 3 Discussion

What emerges from the current national and international situation is therefore the difficulty of debate on an ethical level and, even more, on the legislative one given the many issues involved in donation of the body.

First of all, there is a need to regulate the key principles of the discipline of donation: the importance of increasing the opportunities of research and medical training, which stand at the basis of a more effective protection of public health (a constitutionally recognised value under Articles 9 and 32 of the Italian Constitution), and the respect for the body of the deceased, which is essential for the bond with the person and its sentimental value [6].

Once these fundamental principles are firmly anchored, the value and modes of the consent expressed by the donor should be established both for biosamples (residual tissues or biofluids surplus to diagnostic requirements) and post-mortem.

It is widely accepted that donor consent should be sought and obtained before biosamples or total body can be used in research [7].

In this regard, the focal point of the opinion expressed in 2013 by the Italian National Bioethics Committee is exactly the need for accurate information and a valid consent, which cannot obviously be reduced to collective and generalised information usually considered the basis of tacit consent. The living person who expresses

his consent must be aware and informed and be given the possibility of choosing the allocation of his corpse for research or educational purposes as well as to limiting research and dissection to certain parts of body [8,9].

In other countries (England, Wales and Northern Ireland) the Human Tissue Act establish donor consent as the baseline principle for the retention and use of organs and tissue to for purposes beyond diagnosis and treatment, although further statutory consent exemptions do exist in certain circumstances, notably use of anonymised tissue from the living for research committee approved research projects. Generally it is recommended a generic consent but one common criticism is that this kind of consent form is not sufficiently “informed” as future research uses are not known at the time of donation. Empirical research examining public and patient preferences has highlighted that there is no clear consensus on the issue [10].

In addition to focusing on the individual and on precise pre-mortem provisions, necessary for promoting decision-making autonomy as well as for the respect of the corpse, integration with a more collective discipline would be appropriate. The controls, abuse prevention and limitations to research should indeed be strictly regulated, especially in those situations involving the body of a person not bound with the persons that are entitled to act for the protection of his/her body. To date, these are the only situations provided for by legislation.

There is a need to increase the culture of body donation through awareness-raising campaigns. In fact, it should be taken into account that, in terms strictly related to education and medicine, any corpse may be intended for education and research regardless of age and health state. Even the bodies of elder people can contribute to the study of elder age pathologies [11].

Some Countries conducted projects aimed at obtaining informed donors’ bodies for the purpose of teaching anatomy with the aim to determine the declared donors’ characteristics and to establish the possible motivation for body donation [12, 13].

Individuals who donate their bodies to medical science have most often a giving nature consistent with their prime motivation to donate their body so that it may be useful to medical science. This kind of information could be important for assisting the identification of potential body donors in new and established bequest programs. The analysis of the profile of donors may be useful to understand better for which groups of people death is not to be perceived as the end, and may become a value, which can be beneficial to living people.

In August 2014 the International Federation of Associations of Anatomists produced a “Recommendations

of good practice for the donation and study of human bodies and tissues for anatomical examination". They focused the attention overall on ethical standards and on the importance of informed consent from donors [13].

The IFAA recommendations should be seen as the gold standard for these matters and should be adopted by national associations of anatomists. The first and central claim of the recommendations is to require a formalized informed consent from donors who are entirely free in their decision. This respects the personal autonomy of the deceased and the dignity of his/her mortal remains and acknowledges a continuity between the living person and the dead body. The requirement of an entirely free decision excludes minors and other "incompetent" individuals, and also explicitly prisoners on death row. This is in line with the general approach that a consensus that must be free of coercion [6].

A study exploring the UK general public's view towards consent for the use of biosamples for biomedical research highlighted that survey participants exhibited a desire to retain active choice and control when donating and over the uses to which their biosamples might be put preferring an opt-in system and specific consent. However these results differ from those reported during focus group discussion where preference was for less restrictive consent models (that are likely to increase availability of biosamples). These differences might be accounted for by the fact that focus group participants were given more background information about the use of residual biosamples in research and had time to consider the benefits disadvantages of the different approaches undeligh the importance of "information" on "type" of consent models [14,15].

## 4 Conclusions

Having acknowledged the importance of promoting the donation of the body for scientific purposes, which is based on the broader concept of health protection, today the need for a better legislation on the matter becomes rather evident.

Moreover, the new forms of entertainment (exhibitions, TV programmes, etc.), together with the indiscriminate spread of information that has not much to do with science and research, need a redefinition of the ethical boundaries of overexposing death and corpses.

The need for a legislation that is clearer and more precise, in addition to its deriving from an ethical necessity, also arises from scientific progress, which allows

the constant and continuous expansion of the fields of research.

In Italy, legislation is clear on the importance of scientific research in health protection (principle constitutionally expressed), however it is not possible to say the same about possibilities, on methods and on practical principles. Currently, the rules are too sparse and obsolete, dating back to the mid- 900 and the directives can only be derived and then easily circumvented.

The aim of a clearer and updated legislation, currently fragmented and obsolete is inextricably linked to the expression by the ethical authority of a clear and binding opinion that has as its central point the correct information for the expression of a valid informed consent. Such an opinion in Italy up to now has been exclusively expressed in 2013 by Italian National Bioethics Committee. However, it has not followed a normative construction process desirable in the coming years.

It is also recommended that all countries in Europe should adopt clear legal frameworks to regulate the acceptance of donations for medical education and research. In European countries there is the need for unified informed consent, with donors being given clear information upon which to base their decision, intentions to bequest being made by the donor before death and for encouraging donors to discuss their wishes to bequeath with relatives prior to death. Finally, countries should clarify legislation to regulate transport of bodies or body parts across national borders and must discourage of any moves towards commercialization in relation to bequests.

**Conflict of interest statement:** Authors state no conflict of interest

## References

- [1] Scolaro S., *Manuale di Polizia Mortuaria – la disciplina nazionale e regionale*, Maggioli Editore, Santarcangelo di Romagna, 2013
- [2] Article 32 of the "Regio Decreto", *Testo Unico delle Leggi sull'Istruzione Superiore*, Edizione 1592, Ist.poligrafico dello Stato, 1933
- [3] <http://presidenza.governo.it/bioetica/pareri.html> - Post-mortem donation of the body for study and research purposes, Italian National Bioethics Committee, approved on 20.05.2013
- [4] McHanwell S., Brenner E., et al., *The legal and ethical framework governing Body Donation in Europe - A review of current practice and recommendations for good practice*, *Eur. J. Anat.*, 2008, 12 (1), 1-24
- [5] Winkelmann A. *Consent and consensus-ethical perspectives on obtaining bodies for anatomical dissection*. *Clin Anat.*, 2016 Jan;29(1), 70-77

- [6] Cornwall J., Perry G.F., et al., Who donates their body to science? An international, multicenter, prospective study, *Anat. Sc.i Educ.*, 2012,5(4), 208-216
- [7] Wilkinson T.M., Respect for Dead and the Ethics of Anatomy, *Clinical Anatomy*, 2014, 27, 286-290
- [8] Wendler D., One time general consent for research on biological samples, *BMJ*, 2006, 332, 544-547
- [9] Jones D.G., Whitaker M.I., Anatomy's Use of Unclaimed Bodies: Reasons against Continued Dependence on an Ethically Dubious Practice, *Clinical Anatomy*, 2012, 25, 246- 254
- [10] Jones D.G., Searching for Good Practice Recommendations on Body Donation Across Diverse Cultures, *Clinical Anatomy*, 2016, 29, 55-59
- [11] Lewis C., Clotworthy M., et al., Consent for the use of human biological samples for biomedical research: a mixed methods study exploring the UK public's preferences, *BMJ Open* 2013, 3, 1-12
- [12] Cornwall J., Perry GF., et al, Who donates their body to science? An international multicenter, prospective study, *Anat Sci Educ*, 2012, 5, 208-216
- [13] Rieder B.M., Body Donations Today and Tomorrow: What is Best Practice and Why?, *Clinical Anatomy*, 2016, 29,11-18
- [14] Bajor G., Likus W., et al., "Mortui vivos docent" or who gives his body to science? The analysis of the personal questionnaires of Polish donors in the Conscious Body Donation Program, 2015, 19, 1-10
- [15] Boulware L.E., Ratner L.E., et al., Whole body donation for medical science: a population-based study, *Clin Anat.* 2004, 17(7), 570-577