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The Italian law on body donation: position paper of the Italian College of Anatomists

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Abstract

In Italy, recent legislation (Law No. 10/2020) has tuned-up regulations concerning the disposition of one's post-mortem body and tissues, for study, training, and scientific research purposes. Several specific issues are discussed here, which may require addressing to optimize applicability and effectiveness of such an important, novel regulatory setting. Apparently unsolved issues may concern the grantees of teaching and training activities, the role of academic anatomical institutes, the role of family members into the donation process, the universal time limit indicated for any donation, the handling of corpses, the limited body donation, and its subordination to the donation of organs and tissues. Critical issues arise concerning the learners, the type of training and teaching activities which can be planned, the position of the academic anatomy institutes, the role of family members in the donation process, the duration of the donation, the eligibility of partial donation or the simultaneous donation of organs and tissues to patients awaiting transplantation. In particular, a universal time limit for donations (one year) makes it impossible to plan any long-term use of even specific body parts, which could be effectively preserved for advanced teaching and training of medical students, as well as specialized surgeons under training. The above-mentioned conditions produce a very limited use of corpses resulting in the inefficiency of the whole system of body donation.

Overall, the donors' scope for the donation of their body could indeed be best honored by a more flexible, tunable approach, to be handled on a case-by-case basis.

Furthermore, it is deemed necessary to closely monitor the events scheduled on corpses in public non-academic institutions or private enterprises. Useful insights are here proposed by the Italian Anatomists, hoping that they may be of inspiration in drafting the implementing regulation.

In conclusion, the present position paper brings into focus the critical issues deriving from the recently introduced Italian law regarding donation and use of the body after death, providing suggestions to lawmakers for future implementations.

Key words: Body donation program, law, regulation, cadaver lab, education.

1. Introduction

Practical anatomy teaching is still a fundamental part of healthcare education and research at all university levels and beyond, including specialist training, which has profoundly influenced medicine development as it is known in the modern days (Macchi et al., 2014).

Despite the thrilling improvement of information technology, the cadaver dissection cannot be replaced in current practice by any existing and emerging substitutes, such as dummies or virtual bodies (Chan et al., 2020; De Caro et al., 2009).

However, in recent decades, the progressive reduction of economic resources devoted to public universities jointly with the race to improve their bibliometric parameters, both in terms of Impact Factor and Hirsch Index, to pursue metrics aimed at evaluating research for career progression, has lead several academic anatomical institutes in Italy to reallocate funds intended for research and teaching activities, moving from cadaveric dissection on "table" to laboratory research on "bench." Furthermore, the number of young anatomical fellows spending part of their training to learn dissection techniques has remarkably decreased over time. To date, few public universities in Italy have a working dissecting room run by anatomists owning basic skills to carry out teaching and research on corpses. The rising trend in expanding university courses and their attendees, jointly to the spreading out of cadaver-labs, has caused the request of an increasing number of corpses, only in part replaceable by anatomical parts during ordinary surgical activity (Macchi et al., 2011).

Therefore, several body donation programs have been implemented mainly in Europe, the United States, and Asia over the last decades, representing a significant means of supply for anatomical corpses available for study, training, and scientific research purposes (Porzionato et al., 2012; Riederer, 2016).

The issue of body donation has profound ethical implications and calls for irreproachable and specific regulation to prevent hurting people's feelings and misleading conduct. In Italy, the legislative core reference goes back to the beginning of the last century, much later supplemented by edits (Italian Republic, 1990; Kingdom of Italy, 1933), notwithstanding the Italian National Bioethics Committee harshly criticized the original document in its content (Italian National Bioethics Committee, 2013).

Consequently, the lack of policies devoted to making easier this liberal gesture of high moral value hindered the full maturation of donation programs, with the resultant restraint in the number of donations. In June 2019, a hearing on the issue was held in Rome by the politicians promoting the bill. The consultation allowed the Italian College of Anatomy to expose the critical points of a system that did not favor nor encourage body donation. A new law has

recently been introduced after the matter had been addressed several times over more than a decade (Italian Republic, 2020). Nevertheless, some critical points remain, both on the medicolegal and the anatomical side, and theoretically, at least in part, could be amendable through the implementing regulation being drafted (Bolcato et al., 2020; Boscolo-Berto et al., 2020).

Therefore, following a scientific initiative by the President of the Italian College of Anatomists and despite the restrictions imposed by the pandemic CoViD-19, a working group formed by Italian academics of anatomy was set remotely to analyze the regulations and procedures currently used in Italy to manage the body donation. This effort is part of a more extensive project focused on body donation regulation, carried out by the authors and by other academicians of anatomy. The comparative, critical, and scientific study gave rise to the present position paper, which aims at drawing the international whole anatomic community's attention to the Italian updated regulatory framework's lights and shadows, to share the principles and controversies underlying the legislation on the matter of body donation, as well as to draw the attention to critical issues if other countries should undertake the same legislative remodeling in the future.

2. The regulatory framework and its contradictions in Italy

2.1. The past

The scientific community has long established that practice on corpses cannot easily find alternatives by means of virtual devices or experimental animal models. Accordingly, the anatomical dissection of a human body still maintains a paramount value in teaching and training (De Caro et al., 2009; Pan et al., 2020). The donation of one's body after death to science allows activities of study, training, and scientific research to enhance the teaching of anatomy, to bolster surgical learning, to set up surgical techniques, to test new devices, or to deepen medical knowledge on degenerative diseases (Larner et al., 2015). However, the limited number of body donations resulting from disinformation on the subject and the outdated regulatory framework, along with the rising number of training courses and research activities, has led to the shortage of corpses, as noted worldwide (De Gama et al., 2020; Riederer et al., 2015).

In Italy, the founding principles on which the regulatory sources overlapped over time initially referred to the constitutional principles stated in article 9 and 32, which recall the promotion of the development of culture, scientific and technical research, with the protection of health as a fundamental individual right and a collective interest (Constituent Assembly of

the Italian Republic, 1948). However, the Consolidated Law of which at the Royal decree No. 1592/1933 has long regulated the matter, with a twofold implication inconsistent with the above-mentioned constitutional principles, at least in their practical application.

Firstly, in an omissive perspective, it legitimated, in the sole interest of the community, the exploitation of the corpse of unknown people or of people for whom the relatives or associations they belong did not propose to organize the funeral or take charge of the transport (Kingdom of Italy, 1933).

Secondly, in a commissive perspective, it indirectly admitted the chance of a binding denial by relatives at the time of body delivery for scientific purposes, as later reaffirmed by the provisions of the Mortuary Police Regulations (Italian Republic, 1990).

These regulations were criticized by the Italian National Bioethics Committee, as they were both reputed defective. The Committee invokes the principle of altruism and solidarity inspired by the donation of the body to the community for study, training, and scientific research purposes, which embody the meaning of continuity of life after death and indirectly contributes to health protection. In this perspective, the donation, with all its load of ethical and moral implications, can only be the expression of a liberal and conscious decision demonstrated through the donor's informed consent (Italian National Bioethics Committee, 2013). A simple mechanism of silence-assent cannot automatically apply, forcing unexpressed solidarity. On the opposite, in case of having a donor's informed consent to the body donation, its annulment by any family member with a different convincement must not be allowed (Italian National Bioethics Committee, 2013). The restrictions thus provided posed an obstacle to the implementation and functioning of the body donation programs.

2.2. The future

Recently, law No. 10 of February 10th, 2020, entitled 'Rules regarding the disposition of one's body and post-mortem tissues for study, training, and scientific research purposes' was introduced in Italy (Italian Republic, 2020), after the matter had been debated for over a decade (Supplementary file). The law contains several normative references (Table 1) and consists of ten articles.

2.3.1. Article 1 - Matter of law

1. This law lays down rules on the disposition of one's own corpse and post-mortem tissues for study, training, and scientific research purposes by subjects who have expressed their consent in life according to the formality established by article 3.

2. *The use of the human corpse or post-mortem tissues is inspired by the principles of solidarity and proportionality and is regulated in such a way as to ensure respect for the corpse.*
3. *The corpse and tissues of subjects whose death has been ascertained with a certificate issued by the bodies in charge... can be used for study, training, and scientific research.*
4. *After demise and death declaration, the corpse of the deceased must remain in the morgue for at least twenty-four hours before being destined for study, training, and scientific research.*

Although the law aims to make study, training, and scientific research on cadaver possible, it is noticeable that it pays indirectly particular attention to a small group of end-users such as surgeons, who need to simulate surgical procedures on the cadaver, the so-called cadaver-labs. Indeed, the proposal to keep a donated body available for a single year prevents the use of conservative body treatments that allow extensive use in benefit of a more significant number of learners and for longer times, as typically required in an academic setting in favor of first- and second-cycle studies or single-cycle master's degree in medicine and surgery. Therefore, it is encouraged to use donated bodies in short timing, as requested by surgeons and actually carried out in the cadaver labs organized for their training. Consequently, the body thus handled will hardly be suitable in further and different teaching and training activities. This lead to the limited use of corpses resulting in the inefficiency of the whole system of body donation. Consequently, the donor's memory cannot be best honored, since the chance of implementing teaching and training programs in favor of the highest possible number of learners is lacking.

Concerning the ethical commitment, the use of the corpse in the anatomical room by learners and trainees for study, training, and scientific research is an opportunity to deepen the ethical aspects of body donation (Ghosh, 2015). Regrettably, the learners are not explicitly trained in Italy regarding the meaning of body donation as an altruistic choice with a high moral value and social impact. These notions are currently offered based on the autonomous initiative of single academic anatomical institutes, representing one more commitment and use of resources, which are a further challenge in times of tight economic circumstances. Therefore, it would be appropriate to introduce lectures on specific ethical topics of interest for the body donation as a broader interpretation of the obligation to provide the information required by law (McHanwell et al., 2008).

On the other hand, the law provides that after the declaration of death, at least twenty-four hours must elapse before the corpse can be used for scientific and training activities,

accordingly to other countries (Italian Republic, 2020; University of Antwerp, 2020). However, death is ascertained by the irreversible termination of all brain functions, e.g., following a prolonged cardiac arrest verified by a flat electrocardiogram lasting at a minimum of 20 minutes, or following a devastating and definitive lesion to the whole brain documented by clinical and instrumental evaluations aimed at defining the cause of the injury, the unconsciousness state, the absence of all the reflexes of the brain stem and spontaneous breathing after apnea tests, jointly with the lacking of electrical brain activity detectable by electroencephalogram. In the latter case, the observation could not last less than six hours for adults (Italian Republic, 2008, 1994, 1993). A shortened observation would allow for the better preservation of the anatomical parts to be used in neuroanatomical and neuropathological research.

2.3.2. Article 2 - Promotion of information

1. *The Minister of health promotes, in respect of a free and conscious choice, information initiatives aimed at spreading the knowledge of the provisions of this law among citizens, using the resources available under current legislation for the implementation of institutional communication projects.*
2. *The regions and Local Health Units adopt, in accordance with the discipline laid down by the regulation referred to in article 8, initiatives aimed at:*
 - a) *to spread the knowledge of the provisions of this law among general practitioners, family pediatricians, physicians of public or private healthcare facilities, and health care professionals;*
 - b) *disseminate correct information on the use of the human corpse and post-mortem tissues for study, medical training, and scientific research purposes among citizens, by appropriate actions promoted by municipal administrations and voluntary organizations.*

The new law extends to several public institutions the role of promoting initiatives to inform the public by fostering the body donation culture in respect of a liberal and mindful choice. The awareness campaign will also use general practitioners, family pediatricians, physicians of public or private healthcare facilities. It will have the practical purpose of making people aware of the beneficial implications of body donation for study, training, and scientific research purposes. It will be necessary to find the most suitable approach and content to transmit this information without hurting social or religious feelings.

Furthermore, it should also be emphasized that body donation for scientific and training

purposes is entirely consistent with organ and tissue donation. This is a further gesture in the spirit of giving towards living people in a condition of severe illness, for whom transplantation represents the last way forward to restore health or even preserve life (Italian National Bioethics Committee, 2013). Certainly, the donated body and thus conferred would probably have a different and lesser didactic and formative value but is coherent to the ethical conception of its priority use already recognized and fully accepted.

2.3.3. Article 3 - Expression of consent

- 1. The act of disposing of one's corpse or post-mortem tissues takes place by means of a declaration of consent to the use of the same ... The declaration is delivered to the settlor's Local Health Unit, which has the obligation to keep it and to transmit its information contents electronically to the database ...*
- 2. The settlor, in the declaration referred to in paragraph 1, also indicates a person of his trust, hereinafter referred to as 'trustee', who is responsible for communicating the existence of specific consent to the physician who ascertains the death ... In the same declaration, the settlor can indicate a substitute of the trustee who plays the role in the event of his death or supervening incapacity, where they occurred before the settlor's death, as well as in the case of objective impossibility for the trustee to perform the tasks provided for in this law promptly.*
- 3. The trustee and his possible substitute must be people of age and capable of understanding and wanting. The acceptance of the appointment by the trustee and the substitute takes place through the signing of the declaration of consent. A copy of the declaration of consent is issued to the trustee and substitute. The trustee and the substitute can withdraw their acceptance at any time by written deed, which is communicated to the settlor.*
- 4. The assignment of the trustee, as well as his substitute, can be revoked by the settlor at any time in the same way as for the appointment and without obligation to state reasons.*
- 5. The settlor can revoke the consent at any time in the manner prescribed by paragraph 1. The revocation must be communicated to the Local Health Unit that transmits it to the database referred to in paragraph 1. In cases where reasons of emergency and urgency prevent the withdrawal of the consent already expressed with the forms referred to in paragraph 1, it can be expressed with a verbal declaration collected or videotaped by a physician, with the assistance of two witnesses.*
- 6. For underage, consent to the use of the corpse or post-mortem tissues must be expressed in the forms referred to in paragraph 1 by both parents exercising parental responsibility or*

by legal guardians or foster caregivers ... The revocation referred to in paragraph 5 is also expressed by one of the subjects of which in the first sentence of this paragraph.

Fortunately, in the past decades, the logic of exploitation legitimated by the previously existing regulation has never effectively been put into practice in Italy. The Italian National Bioethics Committee criticized the alleged consent obtained according to the principle of silence-assent, as it is not resulting from the awareness of the shared ethical values underlying the body donation. Likewise, the International Federation of Associations of Anatomists (IFAA) and the European Federation for Experimental Morphology (EFEM) have also blamed this practice, which is still running in some countries (Ghosh, 2015; International Federation of Associations of Anatomists (IFAA), 2012; Italian National Bioethics Committee, 2013). Recently, some regions in Italy have attempted to introduce regulations allowing for body donation, despite the limits of previous legislation. However, this attempt was unsuccessful due to opposition of the State Attorney's Office (State Attorney's Office of the Italian Republic, 2019).

The new law is undoubtedly a step forward in the regulation of a long-neglected area of interest, into which the value of personal choices was not taken into account, especially concerning the "after death". The corpse cannot be considered a mere object, but certainly, one is not dealing with the person who was in life (Italian National Bioethics Committee, 2013). This is a matter of respect for personal willingness and also for personal dignity. The donation appeals to an altruistic and solidaristic principle, evinced through the individual self-determination in favor of the community.

Moreover, the law provision implies a further significant ethical, albeit indirect, implication. It makes surgical experimentation on animal species less attractive; animals are often used alive in procedures having limited and questionable educational value due to anatomical differences between humans and animals, just think of intestinal surgery in pigs (Martini et al., 2015).

The involvement of family members in the body donation process should be encouraged. This is mainly due to the psychological meanings of such a symbolic choice and its impact on bereaved family members, who may suffer from the 'endless' feelings perceived when the corpse of their familiar is not buried but donated for an unlimited time (Italian National Bioethics Committee, 2013; Stroebe and Schut, 2010).

A further issue that is not considered by the recently introduced law is that some donors may be interested in restricting the donation only to some anatomical parts (e.g., brain, heart), or in excluding some anatomical districts from use and dissection (e.g., face, genitals). This

propensity, and the belief that it is not possible to comply with such a request, could limit the number of donors. Guaranteeing this binding possibility by law and respecting it would undoubtedly be an incentive for those who feel the need for it (Italian National Bioethics Committee, 2013).

2.3.4. Article 4 - Reference centers

1. *The Minister of health, in agreement with the Minister of education, university, and research, after an agreement within the permanent Conference for relations between the State, the regions and the autonomous provinces of Trento and Bolzano, identifies Universities, High Specialty Hospitals and Scientific Institute for Research, Hospitalization, and Healthcare (IRCCS) to be used as reference centers for the conservation and use of the corpses for the purposes referred to in this law.*
2. *The activities of the reference centers of which in paragraph 1 which require the use of the corpses or its organs or tissues must comply with the scientific research projects for which the territorially competent independent ethical committee ... has issued a favorable opinion. The surgical training activity, where in line with the educational plan of the authorized reference centers, does not require the opinion of the ethics committee but only the authorization by the health management of the belonging structure.*

The introduction of reference centers for the conservation and use of corpses for study, training, and scientific research purposes allows the concentration of activities on institutions that can live up to the task without wasting resources and skills or, even worse, tolerating a jungle of do-it-yourself services. In Italy, few centers have implemented body donation programs (Padova, Bologna, Torino, Milano, Palermo, Roma-Sapienza, Firenze), and only in an academic setting. Among these, the Institute of Human Anatomy of the University of Padua has long since activated a body donation program with quality certification and has been recently was appointed as a reference center in the Veneto region (Orsini et al., 2021; Porzionato et al., 2012; Regional Council of Veneto - Italian Republic, 2019). This national management system guarantees the acknowledgment of a public authority competent in handling cadavers and anatomical parts, conservation and custody, their use for scientific and training purposes, and finally, their return in dignified conditions to family members. The independent ethics committee territorially competent must issue a favorable opinion for using the corpse, consistent with the scientific research projects or the surgical training activities developed and proposed. To not weigh down the system, if they are in line with the educational plan of the reference center, the permission granted by the health management of

the belonging Local Health Unit will suffice. However, it should be noted that the human anatomy institutes are not in established agreements with the national or regional health service of which Local Health Units are part, in which case the equivalent permission by the referent university director should be accepted, as an alternative to what is inconsistent by law.

On this facet, it is necessary to make an explicit reference to the Institutes of Human Anatomy, which are only present at the academic level. They are naturally qualified for available logistics and skills to better cope with the commitment requested to the reference centers, and have always been recognized as the only recipients in the management of the body for scientific purposes (Italian Republic, 1990). The expertise required to implement an efficient system aimed at using the corpse for study, medical training, and scientific research purposes is manifold and complex. They range from the reception of the body and its predisposition to storage, the assignment of the bodies for suitable activities, the conservative treatment necessary for the preparation of long-lasting prosections, to the preparation of museum educational samples. Moreover, the control of safety standards, the registry updating, the traceability of the anatomical material and its use, or the quality certification of the whole process, requires resources, training, and devoted personnel.

An answer could be ensured by the anatomical scientific societies hypothetically, which through an ad-hoc expert committee, would provide on the one hand the certification of suitability for all centers with an active body donation program, on the other the accreditation of the institutions that are candidates to manage training events on the corpse, even if not donated in Italy. This would guarantee at the same time the minimum professional standards, the respect of ethical principles underlying the body donation, and the safety requirements for scheduled activities to comply with. Overall, this is in the shared interest of the institutions, the donor, and the community as a whole (Champney, 2019, 2016; Champney et al., 2019). Furthermore, it is deemed necessary to closely monitor the events scheduled on bodies in public non-academic institutions or private enterprises. To this purpose, independent institutional review committees housed in the academic reference centers could be established, with territorial competence by proximity. This would ensure both the scientific value of the event and the correct attitude towards the use of corpses. These elements are necessary to endorse the quality of content on a case-by-case basis. In this way, the whole process could be better coordinated in response to both teaching needs (without covering expenses) and training demand (often supported by sponsors) in a shared and public interest that is nonaligned to a mere profit logic (Champney, 2019, 2016).

Finally, as in other countries, the donor's right to independently choose the reference center to which to donate his/her corpse should also be protected, in compliance with the principle of self-determination and the fiduciary relationship that is established during information meetings and joining the program (University of Antwerp, 2020).

2.3.5. Article 5 - Establishment of the National List of reference centers for the conservation and use of the corpses

- 1. The National List of reference centers identified pursuant to article 4 for the conservation and use of the corpses is established at the Ministry of health.*
- 2. The List, which can be consulted on the website of the Ministry of health, is updated promptly in order to allow the physician who ascertains the death to identify the reference center responsible for the area, to which he reports the death of the settlor.*
- 3. The reference center, acquired the proof of the express consent by means of the database referred to in article 3, takes the corpse informing the settlor's Local Health Unit.*
- 4. The implementation of the provisions set out in this article is carried out within the human, instrumental and financial resources provided for by current legislation and, in any case, without new or greater burdens on public finance.*

The activation and constant updating of a single list of reference centers for body donation will allow rapid feedback in favor of physicians involved in the certification process of death. The center thus identified and informed, will be able to retrieve the proof of the donor's consent expressed in life through the national database. This virtuous automation will reduce the margin of error and waste of time of the whole process.

2.3.6. Article 6 - Restitution of the corpse

- 1. The reference centers identified pursuant to article 4, which have received the corpse of a person referred to in article 1 for study, training, and scientific research purposes, are required to return the corpse to the family in dignified conditions within twelve months from the date of delivery.*
- 2. The charges for the transport of the corpse from the moment of death until its return, the costs relating to the burial, as well as the costs for any cremation are borne by the reference centers identified pursuant to article 4, within the resources allocated for research projects.*

The recent law states that the donated body can be retained for a maximum of one year and subsequently returned to family members in dignified conditions. This is a terminological

issue: what does “dignified condition” mean? Sometimes, the return of a body in dignified conditions such as to allow relatives to view the body is not possible, as a consequence of the activities carried out according to the will of the donor. In this case, exposure to relatives should be prevented, eventually by proposing cremation as a possible alternative, and in any case by recommending a farewell before the delivery of the corpse to the body donation center.

Moreover, the one-year period is insufficient to match and carry out most of the scientific and training activities. In fact, on the one hand, the scheduling and arrangement times of congress events and training courses that frequently involve international learners and teachers are not taken into account, on the other, the need to harmonize the teaching programs on corpses in favor of students based on needs that become evident during the academic year, and in response to requests raised during the course are ignored. For example, the conservative treatments of corpses require a substantial investment of time, money, and trained personnel. These efforts can be compensated by keeping the anatomical material available over several years in favor of many users. In this way, the memory and the will of the donor would be best honored. The Italian experience achieved directly in the field indicates that almost all donors, in the full freedom of choice granted to them, currently decide for an indefinite body donation term. The few who decide for a time limit, indicate a term of 3-5 years. It is noteworthy that, unless in particular circumstances where social, ethnic, or religious beliefs limit the availability of the body to one year, in Western countries granted time frame varies on average from three years in the United Kingdom and Belgium to four years in Spain, in line with the literature (De Gama et al., 2020; Park et al., 2011; United Kingdom, 2004; University of Antwerp, 2020). In Turkey, it is possible to retain prosecutions for 20 years and skeletal collections for up to 50 years, while in France there is no time limit for the return of the corpse (French Republic, 2000; Gurses et al., 2019). Overall, while the one-year time limit is inadequate, a period of at least 3-5 years could stand for a sound compromise.

2.3.7. Article 7 - The discipline of donations of money for study, training, and research purposes

- 1. The use of the corpse, parts of it, or post-mortem tissues cannot be for profit.*
- 2. Any donations of money made by private individuals for study, training, and scientific research purposes through the use of the corpses or deriving from the finalization of research projects are intended for the management of the reference centers identified pursuant to article 4.*

To date, there are no private companies in Italy that have running body donation programs for direct profit, through the sale of corpses or anatomic parts, or indirect through the disproportionate reimbursement of expenses incurred for the activity carried out. Furthermore, the law has recently introduced the possibility to prevent their possible onset into the future, since only the Universities, High Specialty Hospitals and Scientific Institute for Research, Hospitalization, and Healthcare (IRCCS) can be recognized as reference centers for the conservation and use of the donated corpses for study, training and scientific research purposes. However, nothing can prevent Italian private companies from purchasing donated corpses or their anatomical parts abroad (Champney, 2016; Champney et al., 2019; Nie and Jones, 2019). Over time, several international anatomical scientific societies harshly criticized those mentioned foreign companies. This is not because they recruit donors by ensuring coverage of transportation costs and possible cremation of the corpse, but due to the large profit margins derived by the disproportionate reimbursement of expenses paid by the institutions that use that material worldwide for teaching and training (American Association of Anatomists (AAA), 2018; American Association of Clinical Anatomists (AACA), 2017; International Federation of Associations of Anatomists (IFAA), 2012). Likewise, private entities that organize and manage training courses for healthcare professionals in Italy can obtain substantial profits from their activity. That is to say, outside the body donation process, the conservation and use of corpses regulated by the recently introduced law, there is a grey area in which private companies can independently conduct their parallel business on the corpse based on abroad donated – and purchased – bodies. Rules do not regulate this activity at all, and one wonders how to oversee their practices, the quality of events, the respect for ethical principles and the dignity of the corpses, as well as the adequacy of the educational program for learners so that the anatomical material is not wasted and training efficiency is maximized. In this regard, it would be appropriate to introduce a supervisory authority, to guarantee the principle of transparency and fairness, also because in the eyes of the community everything occurs within the broader project of the use of the corpse for science, whatever its origin. In line with this expected rigour, the chance of direct or indirect profit through the disproportionate reimbursement of the expenses incurred by the organizers of these events should be prevented, at the same time avoiding the possibility for teachers and sponsors to profit from their role. This would originally prevent the training courses on the corpse from becoming an opportunity for economic speculation. Rather, the possible establishment of foundations and non-profit organizations with the participation or under the university patronage could be useful and functional to support study, training, and scientific

research activities without profit-aims.

2.3.8. Article 9 - Financial provisions

1. The implementation of this law must not result in new or higher burdens on public finance.

The public administrations interested in the relative implementation provide it with only the human, financial and instrumental resources available under current legislation.

This article raises two questionings. The first concerns the provision that several new centers will be set up, which implies significant at least initial costs for starting the activity, with regards to personnel, training, logistics of support, cold rooms, etc. It is unthinkable that everything can be set up with a “zero economic balance”, that is, without precise financial allocations aimed at establishing a dedicated center where before there was nothing: it would be a mere utopia. Furthermore, the coverage of costs for the transport, the burial or cremation of the corpses is provided by the resources allocated for research projects managed by the reference centers. This leads to the transfer of resources from the field of research to logistics, with an economic loss for the centers that have an active role in body donation. The second questioning concerns the practical effects of the recently introduced law, which could theoretically result in a significant increase in body donations, as observed in other European countries. In the Netherlands, e.g., requests for body donation over time have increased to the point of having to pause the recruitment of donors not to overload the morgues of anatomy institutes. In this desirable and fearful perspective, it will be necessary to foresee how to manage a possible surplus of corpses, defining if it is possible to refuse a donation or if the network of reference centers will have to face together the absorption of the offer, and consequently, who will cover the additional costs due to the transport to distant reference centers (Bolt et al., 2012).

2.3.9. Article 8 - Implementing regulation

1. Within three months from the date of entry into force of this law, with regulation to be adopted ... we:

a) establish the methods and times, in any case not exceeding twelve months, for the conservation, for the request, for transport, for the use and for the return of the corpse in dignified conditions to the family by the reference centers of which in article 4, providing that the corpses for which the family they belong to does not request restitution can be buried, as well as the procedures for communications between the civil registrar and the reference centers;

b) indicate the reasons to exclude the use of the corpses for the purposes referred to in this law;

c) provide for connections with the civil status system ...;

d) lay down the discipline of the initiatives provided for in article 2, paragraph 2.

The implementing regulation to which the law refers has not yet been issued. This is an opportunity to (at least partially) rectify and better define the controversial aspects exposed in the present paper. However, one wonders how much the implementing regulations can intervene to correct a law that has already expressed itself in a sometimes peremptory way on some problems, without leaving room for a declination that allows their correction.

Technically, the implementing regulation is a provision subsequent to the promulgation of the law calling for it. It finalizes its provisions and perfects its regulatory significance. It is adopted by the Presidency of the Council of Ministers within three months since the promulgation of the law. However, it is not a binding term, and there are known cases of laws for which the implementing regulations have never been adopted. This circumstance renders the original law-making useless, which cannot be applied in practice.

2.3.10. Article 10 - Repeal

1. Article 32 of the consolidated text of the higher education laws, referred to in the royal decree No. 1592 of August 31st, 1933, is repealed.

The Royal decree No. 1592/1933, stated that '*All corpses from hospitals are subjected to clinical autopsy. The corpses [omissis] whose transport is not done at the expense of the relatives included in the family group up to the sixth degree or by confraternities or associations that may have undertaken commitments for funeral transport of the associates and those coming from the medico-legal investigations (excluding suicides) that are not requested by relatives included in the said family group, are reserved for teaching and scientific investigations*' (Kingdom of Italy, 1933).

Consistent with the criticisms of the Italian National Bioethics Committee, the logic of exploitation of the corpse of unknown or of people whose family relationships and friendships vanished as enshrined in this article, was finally suppressed. Therefore, it prevails the principle of self-determination of the individual through the liberal expression of a conscious will inspired by values of solidarity and altruism, addressed to the community to which the donor belonged in life (Italian National Bioethics Committee, 2013).

3. Conclusion and future perspectives

At the end of a debate that lasted over a decade, the law no. 10 of 10 February 2020, entitled 'Rules regarding the disposition of one's body and post-mortem tissues for study, training, and scientific research purposes' was introduced in Italy. It represents the effort to regulate a sensitive and manifold issue in order to allow the body donation and its use for study, training, and scientific research purposes, steadily based on respect for the corpse. However, the provisions only partially clarify the principles of fulfillment, limits, and control envisaged for these activities. Critical issues arise, concerning the learners, the type of training and teaching activities which can be planned, the position of the academic anatomy institutes, the role of family members in the donation process, the duration of the donation, the eligibility of partial donation or the simultaneous donation of organs and tissues to patients awaiting transplantation.

These uncertainties and interpretative weaknesses can still be addressed, as the implementing regulation required by law has not yet been approved. The present paper is intended to continue the constructive discussion on the topic, so that the promulgated law could be improved to meet the needs of the reality best it intends to regulate.

Simultaneously, the Italian community of anatomists must make self-criticism to address all the issues that have led to a decrease in the number of centers performing anatomical dissections for the benefit of medical students and residents. Is it possible to reverse this ongoing trend? In addition to the changes called upon for this law and the increase of public funds reserved for anatomical training, what is needed? What can Italian anatomists do in the meantime? Could it be useful to create networks on a geographical basis, to bring people and resources together with the aim of creating synergies between centers in sharing what still few universities can afford but which is essential for anatomical training? Our community must make all possible efforts on several fronts to not neglect an aspect of medical education that represents - for known historical reasons - a point of pride and merit of Italian medical culture.

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Table and legend to table

Table 1. Normative references of law No. 10 of February 10th, 2020

Legal entity	Regulation	Reference	Normative matter	Permanent hyperlink
Italian Republic	Decree of the President of the Republic	No. 285 September 10th, 1990	Approval of the Mortuary Police Regulations.	https://www.gazzettaufficiale.it/eli/id/1990/10/12/090G0312/sg
Italian Republic	Decree-law	No. 158 September 13th, 2012, converted with modifications by the law No. 189 of November 8th, 2012	Conversion into law, with amendments, of the decree-law No. 158 of September 13th, 2012, containing urgent provisions to promote the development of the country through a higher level of health protection.	https://www.gazzettaufficiale.it/eli/id/2012/11/10/012G0212/sg
Italian Republic	Law	No. 3 January 11th, 2018	Delegation to the Government on clinical trials of drugs as well as provisions for the reorganization of the health professions and for the health management of the Ministry of Health.	https://www.gazzettaufficiale.it/eli/id/2018/1/31/18G00019/sg
Italian Republic	Law	No. 400 August 23rd, 1988	Discipline of Government activity and regulation of the Presidency of the Council of Ministers.	https://www.gazzettaufficiale.it/eli/id/1988/09/12/088G0458/sg
Italian Republic	Law	No. 184 May 4th, 1983	Discipline of the adoption and custody of minors.	https://www.gazzettaufficiale.it/eli/id/1983/05/17/083U0184/sg
Italian Republic	Legislative decree	No. 211 June 24th, 2003	Implementation of Directive 2001/20/EC relating to the application of good clinical practice in the conduct of clinical trials of drugs for clinical use.	https://www.gazzettaufficiale.it/eli/id/2003/08/09/003G0229/sg
Italian Republic	Decree of the President of the Republic	No. 396 November 3rd, 2000	Regulation for the revision and simplification of the civil status order.	https://www.gazzettaufficiale.it/eli/id/2000/12/30/000G0442/sg
Italian Republic	Law	No. 578 December 29th, 1993	Rules for ascertaining and certifying death.	https://www.gazzettaufficiale.it/eli/id/1994/01/08/094G0004/sg
Italian Republic	Law	No. 219 December 22nd, 2017	Rules regarding informed consent and advance treatment provisions.	https://www.gazzettaufficiale.it/eli/id/2018/1/16/18G00006/sg
Italian Republic	Law	No. 205 December 27th, 2017	State budget for the financial year 2018 and multiannual budget for the three-year period 2018-2020.	https://www.gazzettaufficiale.it/eli/id/2017/12/29/17G00222/sg
Kingdom of Italy	Royal decree	No. 1592 August 31st, 1933	Approval of the Consolidated Law on Higher Education Laws.	https://www.gazzettaufficiale.it/eli/id/1933/12/07/033U1592/sg

Supplementary material

Supplementary file. Previous bills presented over the years

Bills presented to the Chamber of Deputies of the Italian Republic				
Year	Number of bill	Parliamentary term	Proposer(s)	Title
2004	5083	XIV	Battaglia A. et al.	Post-mortem body donation for study and scientific research purposes
2006	1020	XV	Zanotti K. et al.	Provisions on post mortem body donation for study and scientific research purposes
2008	746	XVI	Grassi G et al.	Provisions regarding post mortem body donation for study and scientific research purposes
2009	2690	XVI	Brigandi M. et al.	Provisions regarding the use of the corpse for study, research and training purposes
2010	3491	XVI	Miglioli I.	Provisions regarding post mortem body donation for study and scientific research purposes
2011	4251	XVI	Testa N.F. et al.	Provisions regarding post mortem body donation and the use of corpses for study, scientific research and training purposes
2011	4273	XVI	Di Virgilio D. et al.	Provisions regarding the donation and post mortem use of the human body for study and scientific research purposes
2013	1250	XVII	Bianchi D.	Provisions regarding the use of the corpse for study, research and training purposes
2013	702	XVII	Grassi G. et al.	Provisions regarding post mortem body donation for study and scientific research purposes
2013	100	XVII	Binetti P.	Provisions regarding post mortem body donation and the use of corpses for study, scientific research and training purposes
2018	600	XVIII	Mandelli A.	Provisions regarding the donation and post mortem use of the human body for study and scientific research purposes
Bills presented to the Senate of the Italian Republic				
Year	Number of bill	Parliamentary term	Proposer(s)	Title
2018	122	XVIII	De Poli A. et al.	Provisions regarding post mortem body donation and the use of corpses for study, scientific research and training purposes
2018	176	XVIII	Rizzotti M. et al.	Provisions regarding post mortem body donation and use for study, scientific research and training purposes
2018	697	XVIII	Binetti P.	Provisions regarding post mortem body donation and the use of corpses for study, scientific research and training purposes
2018	733	XVIII	Sileri P. et al.	Rules on the disposition of one's own body and post-mortem tissues for study,

training and scientific research purposes