

Body donation for research and teaching purposes: operational criteria and ethical aspects

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Abstract. Italy continues to legislate on the donation of one's body and post-mortem tissues for the purposes of study, education, and scientific research. With the new Regulation n. 47 dated February 10, 2023, specific rules have been established regarding the activities of research centers, the procedures for receiving bodies, and the criteria for exclusion. Additionally, the regulation outlines initiatives that regions and local health authorities must adopt to promote donation policies among healthcare professionals and citizens. This new regulation represents a significant advancement for the anatomical community, providing practical guidelines for body donation programs. In these educational initiatives, universities and reference centers also play a central role as they can engage in informative and ongoing dialogue with the community. This dialogue aims to help dispel psychological barriers, irrational fears, and concerns surrounding body donation. This article briefly presents the new Italian regulatory framework, highlighting the main critical issues and ethical dilemmas. Furthermore, it discusses some ethical and deontological concerns of the new rules that require improvement, and provides recommendations for good practices.

Key words: Body donation, research and education, dissection, organ donation, Italian Law no. 10/2020, ethics

Introduction

Three years after the approval of the law on post-mortem body donation (Law n. 10/2020 entitled "Rules on the disposal of one's body and post-mortem tissues for the purposes of study, training, and scientific research"), Italy has adopted Decree n. 47 dated February 10, 2023 ("Regulation containing rules on the disposition of one's body and post-mortem tissues for the purposes of study, training, and scientific research"). This implementing discipline aims to effectively implement the aforementioned legislation, which is now grounded in ethical principles such as self-determination, awareness, responsibility, and solidarity (1, 2).

In particular, this regulation provides detailed information on the activities of research centers. It outlines the specific reasons why certain body donations cannot be accepted, as well as the methods and duration of body preservation. The regulation also sets criteria for requesting, transporting, using, and returning the bodies.

Additionally, the regulation establishes guidelines for initiatives that regions and local health authorities must undertake. These initiatives aim to promote awareness of the provisions outlined in the law and encourage donation policies among healthcare professionals and citizens.

This is a long-awaited regulation by scientific and academic institutions aimed at promoting the

field of research and education on cadavers in Italy (3). The country has a unique and pioneering history of anatomical dissections dating back to the 1500s. However, this practice has been lacking in Italian universities and research centers for a considerable time due to a shortage of cadavers, which has led to their importation from abroad (4, 5).

The new regulation addresses this issue and provides a framework that allows for the proper availability and utilization of cadavers for educational and research purposes. This practice is considered of utmost importance in the training of students and specialists, as well as in the continuous professional development of experts in the field. It marks a significant step forward in revitalizing and supporting the study of anatomy in Italy.

The previous Italian regulation raised many ethical concerns, as it only allowed the use of cadavers that met two criteria: 1. they were not covered by the transportation expenses of the deceased's relatives or fraternities and organizations, and 2. they were not requested by relatives within the same family group, except in cases of suicide.

The approval of the law enabled Italy to align itself with ethical principles aimed at promoting solidarity, including towards non-human animals (6, 7), while respecting personal autonomy and self-determination (8, 9).

The Italian decree of August 23, 2021, had already identified the reference centers for the preservation and use of deceased bodies. However, the detailed regulation of the matter required the definition of implementing rules, which was entrusted to a specific government regulation.

In this article, considering the international context, we briefly present the new Italian regulation framework, highlighting the main critical issues and ethical dilemmas. We also discuss some aspects of the new rules that need improvement and suggest recommendations for good practices.

The regulation framework point by point

This regulation establishes several key aspects related to body donation:

1. It specifies the methods and timelines for the management of deceased bodies, including their burial when restitution is not requested.
2. It defines the communication procedures between reference centers and the civil registry office.
3. It establishes the grounds for the exclusion of body use.
4. It provides coordination provisions with the civil registry system.
5. It defines guidelines for information initiatives aimed at promoting the dissemination of body donation practices.

Three institutions play a significant role in post-mortem body donation:

1. Reference centers: These institutions are designated for the preservation and utilization of donated bodies.
2. Donor: This refers to the individual who decides to donate their body for scientific purposes after death.
3. Fiduciary: The fiduciary is a person designated by the donor to ensure that their wishes regarding body donation are respected and implemented.

According to Article 2 of the new Regulation, the reference centers include university facilities, high-specialization hospital companies, and scientific research and care institutes (IRCCS). These centers are identified for the preservation and use of deceased bodies for study, education, and research purposes. They must meet the requirements established by the Ministry of Health decree and be registered in the national list.

The role of the "donor" (in Italian "disponente") is defined by the voluntary nature of the donation, as explicitly indicated in the current legislation. The principle of informed consent and advance directives (L. 219/2017 "Provisions for informed consent and advance directives") is emphasized, stating that the free and explicit will to donate must be expressed in the forms established by law (authenticated private writing, testament drawn up by a notary, personal delivery of the declaration of intent to the registry office at the municipality of residence) by an adult individual. Minors cannot be donors (10).

The fiduciary (in Italian "fiduciario"), introduced in the aforementioned Italian Law no. 219/2017, is responsible for interpreting and ensuring that the donor's wishes are respected (11, 12).

The legislation specifies the criteria for excluding deceased bodies from donation. These include bodies related to violent deaths or suspected criminal activity (requiring forensic autopsies), cases where diagnostic confirmation is requested, infectious diseases, recent diagnostic or therapeutic treatments involving radioactivity, severe mutilation, suicides, or deaths occurred abroad.

The regulation also allows the discretion of the center to refuse a body in cases where there is a lack or incompleteness of documentation attesting to the absence of infectious or communicable diseases, or a delay in transporting the body to the center exceeding 7 days. Additionally, the certifying physician who confirms the death may identify another reference center based on proximity if the initially designated center is unable to accept the body due to contingent reasons related to the organization of their activities.

The regulations stipulate that activities of study and education on the body should not take place immediately. The body must remain in the mortuary for at least twenty-four hours before being allocated for such activities.

Special attention is given to the responsibilities of the reference centers concerning a respectful reception of cadavers, the identification, assessment of the body's condition, registration of relevant documentation, and implementation of measures to ensure traceability throughout all stages of use, including for the purpose of subsequent return, ensuring the donor's privacy and

the health of the personnel involved also by periodical vaccination (Table 1).

These provisions aim to ensure proper handling, documentation, and accountability throughout the process of utilizing donated bodies for study, training, and research purposes.

The regulation confirms that the activities of the reference centers must align with scientific research projects that have received favorable opinions from the ethics committee, which is subject to a profound revision.

Surgical training activities do not require an opinion from the ethics committee but only require authorization from the healthcare management of the respective institution.

The regulation stipulates that, once the body has been used, it should be returned to the family in a dignified condition within twelve months from the date of delivery. If the family does not request the return of the body, it should be appropriately buried or cremated, taking into account the deceased's known wishes.

Furthermore, the regions and local health authorities, in collaboration with the reference centers, are required to implement information and communication initiatives regarding the possibility of body donation. These initiatives should target medical and healthcare personnel, as well as citizens, and may involve municipal administrations and voluntary associations.

Table 1. Good practice recommendations proposal to improve the management of cadavers after the approval of the Italian law
Facilities must be appropriate for the proper and respectful reception of cadavers and protected from unauthorised personnel
Personnel engaged in study and research activities on cadavers should be vaccinated periodically
The absence of parental or friendly relations between the donor subject and the operators, including students, should be verified before any activity
Donor medical records should be carefully evaluated to highlight any possible diseases of the donor.
Copies of the donation declaration should be kept by both the donor's relatives and the institution.
Records should be kept for at least twenty years from the date of disposal of the human remains.
Any disclosure of images of the body and its parts should strictly be subject to prior authorisation by the donor.
Strict limits for displaying the cadavers, especially on social media, should be set up to respect the privacy of the donor (and surviving relatives).
No individual should be identifiable from any images.
A reception protocol and procedure for reporting arrival (who to inform, phone number, etc.) should be introduced
A supervisory committee to define the use of bodies and planning according to teaching, special courses and research, should be established

These provisions aim to ensure the respectful treatment of bodies used for study, training, and research purposes, while also promoting awareness and understanding of the option to donate one's body after death among healthcare professionals and the general public.

Discussion

In recent decades, the Italian legislator has been actively involved in shaping laws regarding the human body, with the aim of emphasizing the principle of self-determination. The advancement of biomedicine and interventions has brought the body into focus, blurring its boundaries and altering the relationship humans have with it.

The use of the human body has been a long-standing issue, and throughout history, concerns have been raised due to its perceived sacredness. The evolution of medical and scientific thought has been strongly influenced by specific cultural contexts in different historical periods.

Traditionally, the body was seen as an inseparable union of body and soul, representing the entirety of the human being. In various cultures and traditions, the human body is not considered merely as an object composed of tissues, organs, and functions, but as an integral part of the individual. Each person expresses and manifests themselves through their body. Even in ancient Greek mythology, stories highlight the sanctity of the body, as desecration of a human corpse was seen as an unjust act that could provoke the wrath of the gods (13).

However, in our contemporary society, the concept of the body's uniqueness and its equivalence to the person is no longer taken for granted. Advances in science and technology, including transplantation techniques and the ability to dissect and store body parts in research centers, have challenged traditional notions. The boundaries between what is considered natural and artificial have become blurred.

The ability to separate and manipulate different parts of the body, as well as the potential to replace organs with artificial alternatives, raises complex ethical, legal, and philosophical questions. These include considerations about personhood, the

autonomy of the body, the ownership of the deceased's body, confidentiality and disclosure, privacy, and the boundaries between human and non-human entities (14-17).

As society continues to grapple with these advancements, it becomes increasingly important to engage in thoughtful discussions and establish appropriate frameworks that balance scientific progress with respect for human dignity and individual autonomy. Finding the right balance is crucial to navigating the ethical, legal, and philosophical challenges presented by these developments.

The new regulation strengthens the idea of overcoming the traditional perception of the body as a limitation to individual freedom, highlighting the value placed on individuality and personal autonomy. This aligns with the international trend and is reflected in various laws at the local level, such as advance directives, pain therapy and palliative care, and assisted suicide (18). The Italian code of medical ethics also embraces this new conception (19).

Unlike the provisions for advance directives, where appointing a fiduciary is optional, in the case of consent for post-mortem donation, appointing a fiduciary is mandatory. The fiduciary is responsible for communicating the existence of consent to donation to the physician certifying the death.

Special attention should be given to the commitment of regions and healthcare institutions to raise awareness among physicians and healthcare professionals about the provisions of the law. Informative and educational actions are necessary to increase understanding of the importance of post-mortem donation, its practical potential, and its social implications. These actions aim to overcome prejudices and cultural barriers surrounding embodiment and death, which carry strong symbolic aspects (20).

Efforts to promote donation may include the use of informative materials such as brochures and websites to disseminate information (Table 2) (21, 22). It is worth noting that body donation, unlike organ donation, may face more resistance due to a lack of understanding of its benefits to scientific knowledge development and advancement for the entire community.

Studies have shown a lack of knowledge about the law among university students, particularly in

Table 2. Informed Consent Checklist for Ethical Body Donation

- Purpose and ethical values of body donation
- Practical utility of donation
- Criteria for Exclusion and Inclusion
 - Information on the professional and ethical training of the subjects involved in the donation
 - Warranties concerning compliance with the deceased's wishes at every stage of study and research
 - Warranties concerning respect for the donor's dignity at every stage of study and research
 - Informed consent form
 - Procedures for the return of the body to the family
 - Information on ceremonies of appreciation or gratitude
 - Link and reference to which information can be obtained

the health field. Better information, especially among health students, is needed to foster critical discussions on the topic (23).

Currently, medical student curricula do not include training programs on the approach to cadavers. Such training is essential not only from a technical perspective but also for the pedagogical aspects it provides, introducing students to a realistic approach to death and a solidarity-oriented view of life. It helps develop qualities like respect, compassion, and empathy for patients.

The current regulation could have established more definitive rules to ensure training for all healthcare professionals on topics related to death, respect for cadavers, and the importance of donation. Unlike other regulations that require mandatory training in areas such as patient communication, pain therapy, and palliative care, the current legislation does not mandate a similar course on the approach to cadavers and the anthropological aspects related to the deceased body and their families.

The idea that the approach to cadavers should be limited to forensic experts overlooks important pedagogical aspects. The encounter with a cadaver can contribute to educating individuals about vulnerability awareness, respect, solidarity, and the ethics of gift.

Adequate training equips healthcare professionals to participate in donation programs consciously and effectively communicate and explain the purposes and critical issues involved in such an altruistic gesture (24).

Universities and reference centers play a central role in these training initiatives. In addition to managing bodies, they can engage in ongoing informational and educational dialogue with the community to reduce

emotional barriers associated with body donation (25).

Expressing gratitude for the gift received can also contribute to increasing awareness and a sense of responsibility towards this morally significant act (20).

Promoting centers that receive donated bodies, supporting educational initiatives for healthcare professionals and the community, and ensuring assurance of respectful treatment for donors are crucial (26, 27). The recognition of the gift can also be acknowledged in scientific publications.

The dissemination of these initiatives to the community can help foster a relationship of trust and collaboration. Several studies have shown that a combination of the anatomical component in the physician's curriculum, gratitude ceremonies, and promotion policies for body donation programs could contribute to the training of future high-quality medical students and professionals (27).

Encouraging the publicity of centers that receive donated bodies is important, including support for educational initiatives aimed not only at healthcare professionals but also at the community. This will provide potential donors with the necessary assurance that their bodies will be treated with respect and dignity. The recognition of this gift could also be expressed in scientific publications.

Another important aspect relates to cases of individuals suffering from irreversible chronic conditions who died in accordance with advance directives. According to the new law, this situation is clearly distinguished from previous cases of suicide and homicide and, for this reason, it is considered permissible. However, from an ethical perspective, the uniqueness of this case should raise further concerns, even with regard to the effects resulting from the

interaction between the law on advance directives and body donation.

Sacrificing oneself for the community is a unique characteristic of human beings and one of the highest expressions of human dignity. It is possible that many vulnerable individuals or those belonging to marginalized populations refuse specific treatments through advance directives to participate in post-mortem research as a means to overcome their sense of frustration. Historically, research using the bodies of marginalized individuals without their consent has been widely employed in medicine and anthropology, including the formation of documented skeletal collections. Emotionally, some questions arise: Should marginalized and weak people be allowed to donate their bodies to overcome their feeling of frustration? What ethical, legal, and medical rules can define in advance which reasons are worthy of protection to donate one's body?

In this vein, restricting their freedom, only in specific cases and based on objective and well-founded reasons, may be necessary. After all, if individuals are recognized the right to refuse life-saving treatments through advance directives, there is even more reason for advance directives to be used to consent to participation in post-mortem research.

Conclusion

The new implementing regulation of the law on body donation represents a further step towards patient autonomy and centrality. Body donation allows patients to continue to have control over their own bodies even after death. This law undoubtedly represents a step forward towards the centrality and supremacy of the person, but its impact in daily practice should be tested and supported by specific healthcare policies (28).

The promotion of a policy of gifting and the effectiveness of donation programs are closely related to the existence of a rigorous and clear discipline, as well as the safety and adequacy of facilities and procedures that centers must adopt for the storage, preservation, care, and management of human bodies within departments. This includes considerations for the return of human remains in terms of methods,

timing, and costs, as well as the steps to be taken to support and encourage a research-oriented donation policy.

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