

## Body donation in Italy: the need to guarantee the best quality

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Italy has promulgated law no. 10/2020 'Rules relating to the directives of one's body and tissues *post-mortem* for study, training, and scientific research purposes' that uniformly regulates the donation of corpses for scientific research, generating along Italy a prolific and renewed scientific debate on the centrality of the study on corpses, mainly from the point of view of teaching anatomy [1-4].

Thus, is of particular value and importance the position paper of the Italian College of Anatomists which takes advantage of the request by the Italian Ministry of Health for interested centers, to expose some critical issues, necessary to guarantee the quality of the overall body donation program [5].

The law in fact indicated in a generic way in Article 4 the characteristics that the Reference centers had to possess:

*'Article 4 - Reference Centers*

*1. In agreement with the Ministry of Education, University, and Research and after coming to an agreement within the permanent conference for relations between the State, regions, and autonomous provinces of Trento and Bolzano, the Ministry of Health identifies universities; high-specialty hospitals; and the Scientific Institute for*

*Research, Hospitalisation, and Healthcare (IRCCS) reference centers for the conservation and use of corpses for the purposes referred to in this law. [...]*

In this way, the task of selecting the candidate centers was leaved to the Ministry of Health, which in fact has recently issued an implementing decree with the indication of fourteen (from 'a' to 'n') necessary requirements [6], to be evaluated by an inter-ministerial working group, even if any limitation on the number of competent centers for each region is clearly stated.

- The center must be an autonomous structure, with personnel exclusively dedicated to the body donation program (requirement a); with restricted access to authorized personnel (j); it must fulfill the hygienic requirements to contain chemical, biological, and carcinogenic risks (b); with adequate ventilation, temperature, humidity (h).
- The specific health surveillance of the workers must be guaranteed in case of exposure/handling of carcinogenic substances (i.e., formaldehyde) (b and k) and at least semi-automation of corpses handling is needed to reduce the manual handling of loads (f).
- The structure must have a body reception room, for an initial external examination (c); a material

deposit and a body deposit (d); refrigerated cells (at +4°C/39.2°F and -20°C/-4°F) (e), without specifying the number; tables with adequate hygienic requirements (i), without specifying the number; the possibility to attend dissection for students and the availability of classrooms for teaching (l); must have an administrative office dedicated to the entire management of corpses (m).

- The definition of a standardized management procedure, in the form of an operative protocol (n).

However, has to be acknowledged that very few and incomplete data are currently available on the practice of body donation, for example on the average number of corpses donated throughout the national territory, on the number of corpses donated and handled by regions or single centers, on the activity actually carried out by single centers. To date, the certification of quality, the recognition as a regional reference center and a tradition of research and training only for the University of Padua has emerged [7]. The position paper lists other centers with growing experience in the field of body donation [5], but without providing data. Not knowing the data means be unaware of the extent of the phenomenon, therefore not even the minimum requirements for a structure to accommodate the corpses (e.g., requirement 'e' about refrigerated cells) and to use them for research and training in a university and clinical setting.

Recent interventions by the Italian Group of Forensic Pathologists (GIPF) and the Italian Society of Legal Medicine and Insurances (SIMLA) [8] have further illustrated, during CoVID-19 pandemic, how the Ministry of Health lacks knowledge of the requirements of the anatomical and dissecting rooms, and that there is no census on the number of dissections carried out in Italy for judicial, clinical and training purpose, to have a wide perspective on the overall corpses' management. There is therefore a widespread lack of an estimate that at least illustrates the dimensions of the phenomenon.

The criticism launched by the Italian College of Anatomists also, and obviously, concerns the financial investments in anatomical training towards computerization and simulation at the expense of the real practice on corpse [5, 9-11]; thus hoping for a correct allocation of the financial resources envisaged by the new law, always according to the principles of effectiveness, efficiency, economy and transparency, and definitively calling for an update, like the wise survey carried on in China [12].

Part of the issue undoubtedly hinges on information campaigns aimed at citizens, about this

practice and its possibilities: without the training of citizens, the body donation for research will remain a circumscribed and limited practice.

For what has been discussed, looking at the implementing decree, we therefore briefly propose some consideration, that in our opinion appear essential in the selection of those centers, that will subsequently receive the corpses, preserve them and above all organize both scientific research - biological and medical - and training courses for students, doctors, and surgeons.

1. First, a census by the Ministry of the number on corpses handled by the various centers concerned - by anatomist, clinical and forensic pathologists-, and the related activities, is needed. The practice on the corpse in fact concerns more originally anatomical study and the teaching of systematic anatomy, but also deals with forensic studies, and, no less, on experimental and purely clinical anatomical-pathological research. Not involving these scientific areas could limit the potential of the body donation program, restricting it into mono-disciplinary research.

2. About the assessment of the structural, personnel and instrumental requirements of these centers, some doubts remain. The capacity of corpses' storage for this specific purpose (e) is not mentioned but is fundamental. The law provides that, in the absence of specific provisions from the donor, the donation of the body lasts one year, after which the corpse is returned to the family. Therefore, both a temporary storage of corpses (annual) and a longer term one, for those corpses embalmed or undergone to other conservation procedures, must be envisaged. But without a previous census, and without the definition of the number of centers along Italian territory, is difficult to set a number. At least a storage availability of ten corpses per year dedicated to body donation program.

Also about requirement relating dissecting tables (l), the number of tables specifically dedicated to forensic, clinical and anatomical dissection must be disclosed, to allow also multiple trainees dissecting courses [12]. At least two table, with one dedicated to body donation program.

3. In consideration of the activity of experimental research, university training, surgical practice, etc., the fundamental qualification of the reference center must be that of a university, in which are 'universally' joined sciences, also with the paramount role of humanities (bioethics, arts, and law) [13, 14]. These institutions must be authorized by the local health authority because rise public hygiene issues since many centers (Institutes of

Anatomy and/or of Forensic Medicine) are often not related to public health system and otherwise could not deal with corpses. In our opinion, reference centers must be identified in the I.R.C.C.S. (Istituto di Ricerca e Cura a Carattere Scientifico, meaning *Scientific Institute for Research, Hospitalisation, and Healthcare*) structures: high level health structures constitutively joined with university, dedicated to research in all biological fields. However, in Italy, there are 51 I.R.C.C.S., of which only 21 are public, and with an unequal distribution over the territory, and taking into account that also the inhabitants are differently distributed over the 20 Regions, a further selection must be made.

4. Specifications for the selection of reference centers were also expected regarding the scientific and training activities, but the decree completely and incredibly lacks details. A clear specification of the lines of experimental research on corpses on the one hand, with the central role of the competent Ethical Committee; and of didactic activities on the other, with anatomical dissection and surgical training practices, will be warmly envisaged. It is important to choose centers that had a tradition or an experience on the management of corpses and on the consequent study, with high quality standard. Further requirements are needed, for instance the number of scientific projects, in a design or final phase; the number and quality of the scientific publication; the number and types of scientific and humanistic disciplines involved; the number of corpses handled per year by the center, with specification on the portion dedicated to research and training; the number of overall students and attendees involved.

We conclude with the awareness that only with the participation of all those involved in the donation of the body, which obviously includes adequate information to citizens, it is possible to properly select reference centers for the body donation program, to guarantee the quality of anatomical training and the quality of scientific research. A dignified body donation program for a new Humanism.

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