

## Ethical Principles in the Field of Tissue Banking

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### Letter to Editor

Within the medical profession a group of ethical principles was developed with the purpose of protecting the dignity of all patients subject to certain medical treatment, independently of their social and economic position within the society, particularly poor patients who cannot afford the processing fee and respecting their religious belief, colour of the skin, political thinking, and gender, among others. The use of sterilized tissues, such as bone and skin just to mention only two examples, in specific medical treatment cannot only save lives, but can improve significantly the quality of life of patients suffering from cancer, burns, car accidents, and other diseases.

Taking into account the specific characteristics of tissue banking, a group of ethical principles that are applied in the medical field, should be applied also in the field of tissue banking, with the purpose of safeguarding the integrity of the tissue recipient. The following are a group of ethical principles adopted by the American Medical Associations that could be also applied in the field of tissue banking:

Provide competent medical health care services, with high quality, compassion and respect for human dignity and rights, during the procurement and transplantation of tissues;

Be honest in all professional interactions with tissue donors and recipients, and should report physicians deficient in character or competence, or are engaging in fraud or deception to appropriate health care authorities, including the maximum authorities of the tissue banks during the procurement of the tissues and of the hospital where the tissue is procured or transplanted;

Respect the law and regulations in force in the field of tissue banking and also recognise a responsibility to seek changes in those requirements, which are contrary to the best interests of the patient, including the procurement protocol that should be applied by the tissue bank operators and the medical team in charge of the tissue procurement;

Respect the rights of patients, colleagues, and other health care professionals involved in the procurement or transplantation of tissues, and shall safeguard patient confidences, medical history and privacy within the constraints of the law and regulations in force, unless legal actions require the access to all patient medical data;

Continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health care professionals during the procurement or transplantation of tissues;

Active participation in activities contributing to the improvement of the health care of all members of the community, supporting the implementation of public awareness strategies for the increase of tissue donation;

Assume the highest responsibility during the medical treatment of a patient, independently of their social and economic position within the society, particularly poor patients who cannot afford the processing fee, and respecting their religious belief, colour of the skin, political thinking, and gender, among others;

Support access to medical care for all people, without any type of discrimination, based on the social and economic position of the patients within the society, including poor patients who cannot afford the processing fee, and respecting their religious belief, colour of the skin, political thinking, and gender, among others.

At the beginning of the use of tissues for transplantation purpose, different types of infections affecting the recipients receiving these tissues were reported. The main cause of these infections was the use of tissues not adequately sterilized. For this reason, tissues transplanted were rejected by the recipient. Due to these negative results, medical doctors were sceptic in the use of tissues for certain medical treatment. At the same time, there were no sufficient knowledge of the benefits of tissue transplantation within the medical community in several countries, and there were not enough trust in the use of sterilized tissue in certain medical treatment, particularly by orthopedics.

The use of different tissue sterilization techniques, particularly the ionization radiation technique, reduced significantly the number of patients suffering infections after tissue transplantation and enhanced public trust and confidence in the use of sterilized tissue for transplantation purposes. Increase confident and trust in the use of sterilized tissues was the only manner that competent national health care authorities of several countries have in their hands to increase tissue donation. However, this public trust and confidence should be based, according to the Australian government and other health care authorities, on the following ethical principles:

- The donation should be altruistic and for the benefit of others and for this reason, should not involve any kind of payment to tissue donors, with the exception of specific payment associated with certain activities that must be carried out by them, such as travel, accommodation fee, among others;
- The choice to donate should be adopted on the basis of informed consent and should be voluntary. For this reason, donors of tissues should not be subject to any kind of pressure from the medical team, the tissue bank representatives, transplant coordinators, donor families or by any other competent authority;
- The choice to donate (or not) should be respected and should include the right to change a donation choice or to cancel it anytime;
- The family's consent to donate (or not) their relative's tissues should be respected, unless a clear commitment to donate (or not) were made by the deceased person following clear regulations in force in the country on the subject;

- Donor families should be treated with respect, compassion, and dignity by the medical team and by the tissue bank team in charge of tissue procurement. The donor families should have the right to be informed of all details related to the procurement of the tissues and on its future use;
- The needs of the donor and their family should take precedence over tissue procurement;
- The recipient should give its written consents to tissue transplantation;
- The privacy and confidentiality of donors and recipients should be respected by the medical team involved in the procurement or transplantation of tissues, except in cases involving legal proceedings;
- The primary obligation of doctors is with their patients. It can be seen as a conflict of interest for the same medical team to look after both the donor and the recipient. There should be a separation of roles between the medical team involved in caring for the donor and their family, the medical team involved in retrieving the human tissues, and the medical team involved in caring for the recipient;
- The system for undertaking human tissue donation and transplantation should be safe, accountable, transparent, and has the capacity to meet the current and future demands for, and availability of human tissues.

There are two groups of ethical principles that tissue banks should promote. One group of principles is associated to the donors of the tissues and the other group of principles with the recipient of the tissues. In the case of donors, there are two categories that need to be considered: Living donors and deceased donors.

It is important to highlight, according to the American Medical Association, that living donation from an individual who lacks decision-making capacity should only be considered in exceptional circumstances and observing the following ethical principles:

- The risk to the donor is clinically acceptable and the tissue to be procured is regenerative;
- There should be an expected benefit to the recipient as a result of the transplantation of the tissue and there is no other equivalent alternative;
- Donation of tissues should be a last resort and should be carried out when the medical doctors confirm that there is no other alternative that can be used in the medical treatment;
- All efforts should be made to ensure that the potential donor understands and appreciates the significance of the tissue donation;
- An independent judgment considers the donation is not contrary to the donor's overall best interests (e.g., where a child's donor may save the life of their parent or sibling); any additional required legal authorization should be obtained, where relevant (e.g., court or tribunal), following the legal procedures established in these cases;

- Reimbursement for expenses associated with living donation such as medical care, travel, accommodation, meals, and lost wages should be a common practice.

One important element that needs to be considered, in the case of living donors, if this person is competent to take the decision on whether a tissue donation will be good for him/her, on the basis of the information that should be provided by its medical doctors and if this person can understand the possibly benefit from receiving a tissue transplant.

With regard to the removal of human tissues, the main ethical principles from the donor's point of view are, according to Paul Flaman and Garrett and others, the following:

- Respect for the human body, even after the person's death;
- Respect for the autonomy of the donor; thus, tissue may not be removed whenever the person refuses. For deceased persons, this implies that tissues may not be removed if the person refused consent or do not give authorization for the removal of tissues during her/his lifetime or change its previous decision to donate before death informing of this change to its families or legal representatives;
- Protection of vulnerable people, namely people unable to give consent or authorization or have a difficult economic situation;
- Respect for private life and medical confidentiality;
- The right to prior information on the conditions of the tissue removal and the expected use of the human tissues procured;
- The right not to be subjected to unjust discrimination, which could result from the revelation of data collected from the donor or the family to third parties (e.g., employers and insurance companies);
- Living donation should take place only where there are clinically acceptable risks of short and long-term harm to the donor and a high likelihood of success for the recipient;
- Living donors should consent to donation. The decision to donate must be free and informed;
- The living donor has the right to change their mind to donate at any time;
- The autonomy and welfare of the living donor should take precedence over the needs of the recipient to receive a human tissue;
- There should be independent and separate assessment, advice, and advocacy for the living donor.

Lastly, it is important to highlight that most countries accept, as a matter of principle, that tissue transplantation programmes be founded on the philosophy of voluntary and unpaid donation, with some exception, anonymity of both donor and recipient, the altruism of the donor and solidarity between donor and recipient, and in the use of a group of well-known ethical principles already applied in all medical fields.