

## Literature Review

# Code of ethics and code of practice: Two relevant documents for an effective and secure operation of tissue establishments

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## Abstract

Tissue banking is an interdisciplinary medical practice more reliant than others in specialized fields and applying knowledge from other branches of science, particularly nuclear sciences. A further difference from other medical disciplines is the urgent necessity to include laws, norms, standards and statutory regulations, which differ in their juridical binding force. Adopting a code of ethics and a code of practice is one of the main tasks to be conducted by a tissue establishment after its founding. The aim is to include in these codes the main ethical principles associated with the different laws, norms, standards, and statutory regulations in force in each country in the field of tissue banking.

## Introduction

The use of human tissues in certain medical practices has proved that save lives and improve the quality of life of thousands of individuals in many countries worldwide [1]. For example, “doctors and dentists use human tissue for various medical purposes. Donated skin can meet critical needs in healing burns victims and reconstructive surgery. Donated bone can be implanted to replace cancerous bone; it can be used in knee and hip replacements and spinal surgery, and it can be processed into a powder for use in dental surgery. Donated heart valves can replace defective valves in young children, saving their lives” [2].

The success rates for transplantation of human tissues reported by several countries in the last years have ensured that processed human tissues can be used more frequently in specific medical treatments without increasing the recipient’s risk. Despite that, it is still necessary to adopt specific measures and procedures to avoid the possible improper uses by medical doctors in certain medical treatments of the human tissues procured by a tissue establishment [3], or its contamination during the processing of the tissue within the tissue establishment.

To ensure the safe use of human tissue in medical treatments, it is indispensable that the tissue establishment and medical staff observe a group of ethical principles adopted by the management of the tissue establishment

during the procurement, processing, sterilizing, storing, distributing, and using human tissues. There are three main characteristics associated with ethical principles to be followed by the tissue establishment and medical staff. These characteristics are the following:

- Be simple and clear;
- Indicate what is good for tissue donors, recipients, and society;
- Be a rational study of human actions and decisions in light of prevailing social values and other universal moral principles [4].

In many countries, tissue procurement and transplantation are no longer considered extraordinary or uncommon health care activities reserved for the most advanced countries in human health care. As the techniques become more refined with time, the possibility of a tissue transplant becomes a hope for more and more people suffering from different diseases, not only in advanced countries but also in several developing countries, particularly when no other medical treatments are available.

Tissue transplantation involves dead or living human donors. With living donors, two issues are important. One of them is to have the donor authorization for tissue donation.

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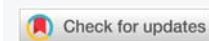
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The second is to procure the tissue free of contamination. In cases of dead donors, the authorized person should ask family members or legal representatives to consider the donation of tissues. In some countries, the tissue establishment staff are responsible for this sensible task. In others, nurses from the hospital or other trained hospital staff as hospital coordinators for tissue donations are required to conduct this sensitive task. In such situations, tissue establishment staff, nurses, or other trained hospital staff must be clear that there are going to deal with family members and legal representatives in an extremely sensitive moment. For this reason, these people must treat the donor's relatives or legal representatives with great sensitivity and respect for their opinions and criteria, offering them simple and clear answers to their concerns and questions.

It is important to note that current practices in tissue transplantation "raise several questions that need to be addressed jointly by clinicians, scientists, health regulators, and ethicists, as well as representatives of civil society" [5], including human tissue donors and recipients. Although several regulations on human tissue transplantation have been adopted in the past several years or are currently under consideration in several countries worldwide, national regulations and oversight of human tissue transplantation, as well as ethical guidance still non-existent or are ineffective in many countries around the world, particularly in the less advanced developing countries. For this reason, the lack of ethical guidelines and unmonitored or unregulated human tissue procurement and distribution represents a serious international risk to both donors and recipients of tissues [6]. That is particularly true when tissue is processed in one country and used in certain medical treatments in another. The international tissue banking community should adopt all necessary measures to reduce this risk to the minimum.

It is well known that tissue banking is an interdisciplinary medical practice more reliant than others in specialized fields and applying knowledge from other branches of science, particularly nuclear<sup>(1)</sup> sciences. A clear difference from other medical disciplines is the urgent necessity to adopt different laws, norms, standards, and statutory regulations, which could differ in their juridical binding force [6]<sup>(2)</sup>. For example,

<sup>1</sup>That is particularly true when the tissue establishment uses the ionizing radiation technique for tissue sterilization.

<sup>2</sup>Tissue banking is a specialized medical discipline, which, in accordance with generally recognized ethical principles and conscious that tissue donation from the population is carried out for unselfish or charitable reasons, is concerned with the organization and coordination of the tissue removal, processing, and preservation of tissues, their quality assurance, as well as the storage and distribution of these final products for therapeutic, diagnostic, teaching and research purposes and is controlled and licensed by official and competent national health care authorities or other competent authorities. In this regard, the term "tissue" includes all cells and tissues as well as the cell and tissue replacement materials of biological origin [6]. At the same time, it is important to highlight that the demand for human tissue for research purposes continues to increase, driven by the desire to: a) Increase understanding of disease processes; b) Improve diagnosis; c) Develop improved pharmaceuticals; d) Improve the quality of life of terminally ill patients; e) Meet the expectations of personalized treatments; f) Move away from animal models that are perceived to lack scientific relevance and carry their own ethical burden [12].

the adoption of a code of ethics and a code of practice is one of the main tasks to be conducted by a tissue establishment after its founding. The purpose is to include in these codes the main ethical principles associated with the different laws, norms, standards, and statutory regulations in force in each country in the field of tissue banking and medical practices.

Tissue banking activities are associated with various ethical concerns about such values as dignity, bodily integrity, autonomy, and privacy [7]. These ethical concerns have been included in a complex structure of private and public, national, and international standards and provisions. The main elements of this structure include, among others, the following:

- The International Declaration on Human Genetic Data (2003);
- The Recommendation of the Committee of Ministers of the Council of Europe (COE) to the Member States on research on biological materials of human origin [8];
- The FDA final rule on "Human Cells, Tissues, and Cellular and Tissue-Based Products;" Establishment Registration [9];
- The European Human Tissue Directive 2004/23/EC [10];
- The standards of the American Association of Tissue Banking (AATB); 2002 [11];
- The Swedish Act on Biobanks (2002) (Gassner, 2007).

### Method used

The method used for preparing this manuscript consisted of the outcome analysis of the implementation of the IAEA program on the ionizing radiation technique for tissue sterilization in more than 30 countries. The program supports implementing more than 36 national, regional, and interregional projects in Asia and the Pacific, Latin American, Africa, and Eastern European regions, involving more than 70 tissue banks.

### Results achieved

As a result of the program implementation mentioned above, more than 70 tissue banks were established or consolidated in more than 30 countries in four geographic regions. The implementation of these projects allowed the processing, sterilization, and use of thousands of tissues in several medical treatments, as detailed in Morales Pedraza [13].

### Discussion

#### Main ethical principles and issues

A decision or a problem involves ethical issues when:

- It deals with questions of human well-being;



- There is a necessity to balance the needs and interests of different people;
- Dealing with issues of significant importance on how we live if our lives are at stake;
- Someone wants to do what is right.

These are the reasons why living tissue donation is an ethical issue. It involves balancing the needs and interests of different people, primarily the potential tissue recipient and the potential tissue donor, and the well-being of those involved. However, it should be noted that while a person may support living tissue donation in principle, he or she may place certain limitations on their acceptance of the practice. Such limitations may include, among others, the following:

- It may be insisted that tissue donation is acceptable only on the understanding that the donor's life is not put at risk;
- That the donation is genuinely voluntary and not coerced or involves the request for payment;
- That tissue transplantation is the only medical treatment available to deal with the recipient's disease;
- That there are good prospects for tissue transplantation being a successful medical treatment (Ethical issues in donating organs or tissues by living donors. Ethical issues in organ donation, NHMRC, 1997) [14].

Why do some people decide to become living tissue donors? People choose to be living tissue donors or choose not to be for various reasons or a mixture of reasons. In many cases, the desire to donate tissues may be based "on the wish to save the life or improve the health of a relative with whom there are already bonds of affection and love. In other cases, a person may wish to do something to save the life or improve the health of an unknown person based on more impersonal ideas of helping others or giving to the community. Such donors may consider that the potential personal disadvantages or discomforts of donating are more than outweighed by the potential benefits to the person needing a transplant" [15].

There are two main reasons why decisions about living donation raise ethical considerations. These reasons are the following:

- First, these decisions are about using a donor in ways that may cause harm, risk of harm, pain, or loss. That harm or loss may be temporary or permanent;
- Second, they are decisions that are intended to benefit others. So, they are decisions that involve a balance between one person's interests and that of another (Ethical issues in the donation of organs or tissues by living donors. Ethical issues in organ donation, NHMRC, 1997) [14].

Various religious traditions may support living tissue donation, although different traditions may think about it in their way. For instance, a living tissue donation may be considered an opportunity to give oneself to another human being, even a stranger. In this view, tissue donation "can represent the highest capacity of human giving: The gift of life itself. Such giving benefits not only the receiver but also the giver and the society as a whole (Ethical issues in the donation of organs or tissues by living donors. Ethical issues in organ donation, NHMRC, 1997)" [14].

On the other hand, it is important to be aware of the following: One donor may yield several tissue transplant products, which could be used later in several medical treatments or research activities inside or outside the country, highlighting the need for safety measures in procuring, processing, sterilization, storage, distribution, and use of human tissues. The impact of any misconduct by the tissue establishment and medical staff during these processes may be significantly high and could seriously affect not only the recipient of the tissue but the donors as well. For this reason, each state should set itself the target to guarantee its citizens high and ethical standards in all health care activities, particularly in tissue banking, to avoid this. The protection must extend to all tissue donors and recipients, medical doctors, professionals, and technicians involved in procuring, processing, distributing, and using human tissues in certain medical treatments or research activities.

Concerning the removal of human tissues, the main ethical principles from the tissue donor's point of view are, among others, according to Quintana-Trias [16], the following:

- Respect for the human body, even after the person's death;
- Respect for the donor's autonomy and decisions;
- Protection of vulnerable people;
- Respect for private life and medical confidentiality of the tissue donors and tissue recipient.

The main principles affecting recipients of allografts are, among others, according to Quintana-Trias (1998), the following:

- The right to safe medical treatments;
- Using tissues for application in the human body can cause diseases and unwanted effects. Most of these can be prevented by careful tissue donor evaluation and the testing of each donation following strict rules established and updated according to the best available scientific advice (Directive 2004/23/EC of the European Parliament and the Council, 2004) [10];
- Patients' right to receive reasonable access to the therapeutic possibilities offered by the transplantation



of human tissues. This right's effectiveness depends partly on the greater or lesser availability of sterilized tissues and tissue donors prepared to donate tissues for medical treatment. It is important to stress that human tissue's clinical use may be constrained by limited tissue availability. Therefore, it would be desirable that the criteria for access to such tissues are defined transparently, based on an objective evaluation of medical needs (Directive 2004/23/EC of the European Parliament and the Council, 2004) [10].

Lastly, it is important to highlight that several countries accept that tissue transplantation programs be founded on the philosophy of voluntary and unpaid donation, the anonymity of both tissue donor and recipient, the altruism of the donor as a matter of principle, and solidarity between tissue donor and recipient. Several governments are taking steps to encourage a strong public and non-profit sector involvement in tissue transplantation services and the related research and development using human tissue to support this philosophy.

As there is a need to ensure human tissues' availability for medical treatments, governments should promote the donation of human tissues and support the supply of high-quality and sterilized tissues. It is necessary to promote information and awareness campaigns at the national level to donate tissues within the community to achieve that goal. These campaigns should help community members become tissue donors during their lifetime and let their families or legal representatives know their wishes following the procedure established for this purpose in each state (Directive 2004/23/EC of the European Parliament and the Council, 2004) [10].

### **The importance of a code of ethics for tissue establishments**

Why is a code of ethics necessary in a tissue establishment? Currently, the international community cannot be assured that human tissue quality and safety for transplants are properly guaranteed in all countries and regions. While certain acts of individual judgment engage in ethical decisions, conclusions should be reached in ways that result in as consistent practice as possible [17]. "A way of achieving this in a given area of activity is to formulate a code of ethics and a code of practice providing general guidelines within which individual decisions are be made" [3] by the tissue establishment staff.

What are a code of ethics and a code of practice? "A code of ethics is a basic presentation of principles and ideals and has a regulatory, educational, and cultural integration function. A code of practice is a detailed description of the actions to be performed and not performed and of the sanctions that attach to non-performance" [3]. For all the reasons mentioned above, the adoption of a code of ethics and a code of practice, and the harmonization of existing regulations and

standards at international and regional levels in the field of tissue banking, should be one of the highest priorities for the tissue banking community and competent national health care authorities in interested countries during the coming years [3].

The use of a code of ethics has been universally recognized as an important document for tissue establishment's effective and safe operation. As foundational documents, a code of ethics can provide the framework that tissue establishment staff must use to fulfill their activities and public responsibilities during the procurement, processing, sterilization, storage, and distribution of tissues.

A code of ethics provides detailed, specific prohibitions and a broader set of principles designed for government actions in specific areas, in this case, tissue banking. The value of a code of ethics comes from both reasoning demands in understanding such codes and their ability to appeal to emotions [18].

A code of ethics should establish what the Director of the tissue establishment expects from the staff and what they can expect from the Director. It should describe values and principles that all tissue establishment staff should follow and the procedures to help them make ethical decisions and report and to deal with violations of the values, principles, rules, and policies established by the Director of the tissue establishment <sup>(3)</sup>.

A code of ethics has two parts: These parts are the following:

- The requirements, regulations, principles, and ideals of the tissue establishment;
- The commitment of the tissue establishment staff to conform to and uphold those regulations and ideals in force.

The commitment to such principles could require tissue establishment staff to undertake an oath, promise, or another undertaking to adhere to the Code of Ethics in force. It is a good place for tissue establishment staff to show their commitment to their community's basic laws and moral standards in the field of tissue banking, including the principle of individual autonomy [19].

Each state should have in force and promote an ethical policy, a code of ethics, and a code of practice to be applied to all tissue banking activities in the country to ensure respect for the human being and the deserved dignity and autonomy. This ethical policy and related codes should be prepared based not only on ethical principles already adopted at the national level but bearing in mind ethical principles in force at international and regional levels and in specific countries with a broad experience on this subject.

<sup>3</sup>For additional information on this subject see Morales Pedraza (2011).





## Objectives and functions of the code of ethics

According to Lozano Aguilar [20] the objectives and functions that codes of ethics fulfill are, among others, the following:

- Influencing tissue establishment staff's conduct with the added notion that this change stems from standards and moral rules [20,21];
- Reflexively formulating shared responsibilities within the tissue establishment and publicly expressing criteria, values, and ends that identify it, with an emphasis on reflection, shared responsibilities, and legitimacy [20];
- Institutionally self-adopting a commitment with fundamental ethical pretensions in decision-making within the tissue establishment, to be expounded both internally and externally of the tissue establishment staff [20,22];
- Stipulating what the profession demands from tissue establishment operators and medical doctors associated with the tissue establishment activities, what others may expect from the practice, and what the profession offers to tissue establishment staff and medical doctors associated with the tissue establishment activities (such as identity, cohesion, corporative support, rights, and economic resources) [20];
- Serving the purpose of communication among tissue establishment staff and medical doctors associated with the tissue establishment activities (what the profession is, what a skilled professional is) and with society [20].

It is indispensable that tissue establishment staff should not tolerate any wrongdoings or improper ethical conduct at any time and by anyone. They should take appropriate measures to act quickly to correct any deviation from the ethical policy, the Code of Ethics, the Code of Practice, and the set of ethical principles in force by the health care competent authorities and the tissue establishment management in the field of tissue banking. Any violations of the codes mentioned above by any tissue establishment staff should be subject to disciplinary actions. The level of disciplinary action against a tissue establishment staff will depend on the seriousness of the indiscipline detected.

An ethical policy should ensure that a tissue establishment's activities are conducted by all its staff and the medical staff associated with these activities with professionalism, integrity, and respect of the potential tissue donor, tissue recipient, family members, and legal representatives. During tissue procurement, tissue establishment staff should treat the tissue donor, the donor family, the legal representative, and hospital staff fairly and respectfully.

Several elements should be considered during the discussions of any ethical policy, code of ethics, and code of practice associated with the procurement, processing, sterilization, storage, distribution, and use of human tissues in certain medical treatments. Among these elements are, according to Morales Pedraza [3], the following:

- All tissue establishment staff should expect and have an obligation to always conduct themselves within high ethical standards and legal principles, according to an ethical policy and the Code of Ethics and the Code of Practices adopted by the tissue establishment management;
- Tissue establishment should operate respecting all laws and regulations adopted by the national competent health care authorities in the field of tissue banking;
- No payment should be given or received regarding tissue donations and other activities conducted by the tissue establishment staff outside of those specifically authorized by the national competent health care authorities and the tissue establishment management;
- Conflicts of interest must be avoided between the tissue establishment staff and tissue donors or family members, or legal representatives;
- Tissue establishment management should facilitate and support valuable research activities using human tissues for the welfare of the community, but within the legal and ethical framework established by the competent national health care authorities in this field;
- Tissue establishment staff should provide the best possible services to tissue donors and recipients. They should place the highest priority on quality, timeliness, and competitiveness in providing these services.

It is important to highlight that a code of ethics typically proscribes actions. Indeed, codes of ethics are largely about actions. Nevertheless, the view that codes of ethics are simply rules that dictate what actions are to be performed and what actions are not to be performed is too narrow. For one thing, a code of ethics typically mentions virtues, vices, and actions. Virtues and vices are habits or dispositions to act. They are not simply actions but elements of a person's character. For another thing, a code of ethics is, or ought to be, concerned with affective attitudes as well as actions. Attitudes are important because they motivate actions [19].

A code of ethics can also be used to reinforce desirable behavior and undesirable change behavior by the tissue establishment staff. For this reason, it must be used in conjunction with complaints and discipline systems, appropriate reward structures, effective conflict resolution



processes, and ethics education programs. The purpose is to attend not simply to the behavior (action) itself but also to the character (habits) and affective attitudes that motivate that behavior of the tissue establishment staff [19].

Based on what has been said above, at least two questions arise. The first question concerns the reason or reasons for prescribing some actions. Sometimes codes do provide reasons for their prescriptions. But generally, a code of ethics is too brief to elaborate on all issues. For this reason, a code of ethics should not attempt to detail specific skills or knowledge necessary to successfully undertake the activities within a tissue establishment. The second question concerns the education program. A code of ethics and associated ethical education should be an essential element in the initial formal and informal education programs and continuing education programs adopted by the competent national health care authorities in the field of tissue banking.

It is important to note that practical knowledge of ethical principles and ideals and their application is not a static issue. Ethical problems and their solutions change periodically. For this reason, there is a need for ongoing revision of the Code of Ethics, ongoing education concerning changes to this Code, and especially ongoing education in applying the principles and ideals expressed in the Code.

Finally, it is important to highlight that an effective code of ethics is not merely a text. Rather, it exemplifies the fundamental principles and values of a tissue establishment. A code of ethics can also contain values. Nevertheless, the critical elements in a code of ethics are the clear articulation of ethical principles derived from such values. In other words, values are general moral obligations, while principles are the ethical conditions or behaviors to be expected [18].

### **The importance of a code of practice for tissue establishments**

A code of practice is an important document that complements a code of ethics. While the latter addresses the ethical behavior that directs the donation, procurement, processing, and distribution of human tissues for transplantation, a code of practice ensures its implementation. It contains a general description of the actions a tissue establishment staff should or should not perform to safeguard the safety and rights of tissue donors, recipients, and tissue establishment staff and their obligations. "It covers effective ways to provide safe human tissues of reliable quality for transplantation, identify and manage risks to all stakeholders and products, review current practices and take corrective action, when necessary, thereby guaranteeing compliance with the Code of Ethics [24]."

For this reason, a code of practice can be defined as a set of written guidelines issued by an official body or a professional association to its members in the field of tissue

banking to help them comply with its ethical standards. A code of practice should specify the requirements for the activities of tissue establishments staff for procuring and processing human tissues for therapeutic use and research activities [24].

A code of practice sets out all the requirements for good management practice that collectively ensures that processed human tissues within the tissue establishment consistently meet the specifications established. It sets the benchmark for practices that the tissue establishment staff should follow. Alternative approaches may be permitted, provided it can be demonstrated that the Code's intent is met promptly and effectively and meets quality objectives.

Furthermore, it is important to highlight that a code of practice requirements adopted by the government are minimum requirements, and the tissue establishment management is free to adopt a stricter code if considered necessary and convenient. Many tissue establishments in several countries have already implemented comprehensive, modern quality systems and risk management approaches that may exceed the government's minimum standards.

The Code of Practice should provide systems consistent with the monitoring and controlling of human tissues and facilities' processing. The procurement and processing of human tissues are risky activities. The main risks are, among others, the following:

- The human tissue (donated or laboratory-cultured tissues) may contain harmful viruses, bacteria, or prions;
- The intended use of the human tissue may not be supported by clinical evidence;
- If appropriate processes are not adhered to, the way the human tissue is processed can mean that the tissue could be contaminated or altered, converting the product into non-efficacious or non-viable for its foreseeable use in medical treatments or research activities.

A code of practice should not limit the development of new concepts or technologies that improve tissue establishment activities. However, these new concepts and technologies should be validated and must provide a level of quality assurance equivalent to those set out in the Code of Practice in force [25].

Finally, it is important to note that a code of practice needs to be based on scientific principles and objectives that could be applied without restrictions to emerging tissue technologies. It also needs to provide tissue establishment management with the flexibility to apply tailored approaches to manufacturing controls suitable to their product.



## Objectives and functions of the code of practice

A code of practice's objective is to provide a set of principles and procedures that, when followed by tissue establishment staff, help ensure that the tissue processed will have the required quality. "The purpose of a code of practice is to set down the responsibilities of tissue establishment staff in regulating their work. A code of practice is intended to complement rather than replace or duplicate existing tissue establishment staff's policies, and it forms part of the wider package of legislation, requirements, and guidance related to staff employment. Tissue establishment staff are responsible for ensuring they meet the standards set out in the code, provide high-quality services, and promote public trust and confidence in tissue bank activities [3]".

Therapeutic Goods (Manufacturing Principles) Determination No. 1 of 2013 from Australia shows several ways to achieve the objective of a code of practice [25].

## The quality system in the code of practice

The Code of Practice should be based on a quality system<sup>(4)</sup> approach. It forms the basis of good practice in all tissue establishments. It will be used as a reference when competent national health care authorities inspect the tissue establishment.

A quality system defines and documents a series of systematic processes to be followed by all those working within the tissue establishment. These processes aim to avoid any kind of mistake by the tissue establishment staff during the procurement and processing of the tissues. However, if a mistake does happen, then the Code of Practice should be used to identify the cause or causes of the mistake. Then, the Code of Practices should be amended so that particular mistakes will not occur again [26].

Based on what has been said above, the Code of Practice should set out specific procedures and safety requirements concerning the following:

- Processing, which includes donor screening, donor testing, tissue collection/retrieval, tissue preservation, tissue packaging, tissue labeling, and tissue quarantine;
- Sterilization of the procured tissues;
- Storage of the sterilized tissues;

- Record keeping of the tissue procured, processed, sterilized, storage, and used in medical treatments;
- Distribution of the sterilized tissues;
- Importation of sterilized tissues;
- Error detected;
- Accident occurred;
- Violations detected or reported;
- Adverse reaction, investigation, and reporting.

The Code of Practice aims to maximize human tissue safety by clearly stipulating the protection requirements adopted by the national competent health care authorities, thus making them mandatory (Guidance Document for Cell, Tissue and Organ Establishments: Safety of Human Cells, Tissues, and Organs for Transplantation, Canada Minister of Health, 2009) [27].

## Role of the code of ethics and code of practice

The main role of an ethical policy, a code of ethics, and a code of practice is to promote a culture of frankness, responsibility, and truthfulness in all tissue banking activities conducted in the country. It should allow the use of tissues processed in one country for medical treatment in another, with a minimum contamination risk for the patient [3]. A code of ethics is written to guide the behavior of tissue establishment staff. Any final analysis of the impact of the Code of Ethics must include how well it affects behavior in all tissue establishment staff and people working or associated with the tissue establishment [18].

Effective ethical conduct is a team effort in which each team member should be familiar with the ethical policy, the Code of Ethics, the Code of Practice, and the set of ethical principles adopted by the national competent health care authorities. These ethical principles are described in Morales Pedraza [13].

It is important to note that successfully implementing an ethical policy and related codes requires the active participation and support of all tissue establishment and medical staff associated with the tissue establishment activities. However, it is also important to know that a code of ethics cannot by itself guarantee ethical behavior for the tissue establishment staff. "Moreover, a code of ethics cannot resolve all ethical issues or disputes or capture the richness and complexity involved in striving to make responsible choices within the tissue banking community [28]."

## The need to update the code of practice

A code of practice must be regularly updated to ensure that regulation remains updated, relevant, and credible. Most countries revise their Code of Practice in force every five years to keep up with industry changes and manufacturing and testing technology modifications.

<sup>4</sup>The quality systems described in a code of practice should cover the tissue establishment buildings and premises, environmental controls, managerial responsibilities, donor selection and testing, written agreements or contracts with third parties, testing of tissues to specifications, standards for the processing and storage of tissue, documentation and record-keeping and transport of tissues. The Director of the tissue establishment has overall responsibility for the quality system's policy, implementation, and operation. Such a system must be relevant to the tissue establishment's goals and the needs of the organizations it supplies. All staff members must be familiar with the quality system and responsible for the quality of their work. For more information about the quality system in a tissue establishment, see Morales Pedraza (2015) and Morales Pedraza and Lobo Gajiwala (2012).



## Good management practices associated with a tissue establishment

Human tissues are increasingly popular in several countries, with widespread use among orthopedic surgeons, particularly in knee surgery. According to Vangsnes and others [29], in 2005 in the USA, more than 60,000 allografts were used in knee surgeries by the American Orthopedic Society for Sports Medicine members. Many other human tissues are also used for other medical treatments.

As the use of allograft tissue increases, the safety of allografts remains an issue of paramount importance.

To avoid the use of contaminated human tissues in medical treatment, the tissue establishment should have, according to Therapeutic Goods (Manufacturing Principles) Determination No. 1 of 2013 from Australia:

- A quality system in place;
- Control manufacturing processes and a mechanism to evaluate any changes to the process that are necessary to introduce. They should validate any changes that affect the quality of the tissue to ensure compliance with tissue specifications;
- Train personnel in all aspects of processing the human tissue procured by the tissue establishment staff and associated activities conducted by them and medical doctors that affect the quality of the processed human tissues;
- Adequate premises and equipment to undertake ancillary procedures, storage, and production, including quality control and dispatch areas, as well as the appropriate equipment for qualification, calibration, performance verification, maintenance, and the monitoring of use;
- Documentation setting out tissue establishment policies, manufacturing procedures, quality control procedures, ancillary procedures, and records of outcomes in all areas of the tissue establishment;
- Establish a complaint and recalls system for recalling processed human tissues before transplantation or implantation in a recipient;
- A system for managing critical material to review, rejecting, recovering, reprocessing, and reworking materials that do not fulfill the tissue establishment requirements;
- A system to ensure that the collection and processing of human tissues are undertaken in such a way to prevent cross-contamination, mix-ups, and bacterial contamination during procurement, processing operations, packaging, and release of the sterilized

tissue for medical treatment or research. All critical processes should be either verified or validated;

- Quality control practices adopted;
- Computer systems connect with all steps in the processing of human tissue. This computer system's objective is to ensure that the system meets the same quality system requirements for those manual functions that it replaces. There should be a written protocol to verify and validate the computer system, including confirming the accuracy and reliability of the data collected directly from the equipment, backup of the system, and contingency plans if the system fails.

## Harmonization practices promoted by the code of practice

A code of practice should also promote harmonizing regulatory practice within the country and at regional and international levels. Why is harmonization so important for the tissue banking community? According to Indech [30], today's marketplace globalization impacts every business sector, including the health care sector. Regulatory authorities and industry have long acknowledged that national boundaries are crossed regularly for harmonizing health care legislation due to international consensus on safety, efficacy, and quality principles, offering [31,32].

## Conclusion

A code of ethics and a code of practice are important documents to be adopted by all tissue establishments, independently of whether the tissue establishment operates in a developed or a developing country. Both codes establish the values, principles, standards, and ethics that tissue establishment staff should observe during their duties. Both codes are intended to guide and support the tissue establishment staff and management in their conduct, decisions, and activities. Together, these two documents will also enhance public confidence in the tissue establishment's integrity and strengthen respect for and appreciation of the community's tissue establishment's role.

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