CHAPTER
14

BIOETHICAL AND LEGAL ISSUES IN TISSUE AND ORGAN DONATION OF HUMAN ORIGIN FOR TRANSPLANTATION

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1. Bioethics as a discipline

1.1. Introduction to Bioethics

Bioethics is the "systematic study of human behaviour in the field of life sciences and health care, to the extent that this behaviour is examined in the light of moral values and principles"[1].

"Bioethics deals with techniques and biomedical sciences applied to human beings, both at individual and social level. Its purpose is to define and clarify the ethical implications raised by techno-sciences and decision making. Its methods are necessarily multidisciplinary and interdisciplinary"[2].

The first definition serves to highlight the two components of the term bioethics as a discipline or field of study itself. On the one hand, Bio refers to life sciences and related technologies, which includes a variety of situations, from experimentation and clinical trials, health care, the study of the human genome and gene therapy to bionanotechnologies. However, these sciences and techniques have been studied not as scientific procedures, but as the impact that this procedures exert on people, and in some cases on components of the biosphere. This is precisely what the term Ethics accompanying Bio means, because ethics is the analysis of the human behaviour as it affects others and not just oneself. Therefore, it deals with public behaviour.

Ethics is presented as a binary system that differentiates between desirable or permissible behaviours to be adopted, and behaviours that should be prohibited or avoided. In more traditional terms, it distinguishes between "good / bad" behaviours, always referring to the realm of bio, as it has been mentioned. While knowledge itself may be considered ethically neutral, its applications and consequences may not, as they allow ethical judgments precisely because they affect human beings (as individuals, social groups and/or collectives) or the entire Biosphere.

As in the case of a large river, initially formed by numerous streams that converge, thanks to gravity and landscape, to be what we call river itself (and name it), in contemporary Bioethics numerous issues and aspects converge, shaping it as a discipline with its own characteristics.

After World War II, the discovery or at least the public disclosure of the experimental procedures performed during the Nazi period, in a context of absolute moral ruin, subjugation and humiliation, it is promulgated as what is probably the first text of contemporary bioethics: the Nuremberg Code, issued in 1946, which establishes the distinction between "permissible medical experiments" and those that should never be performed. The basic criterion used as prerequisite is the ethical one, namely that of "the voluntary consent of the human subject", apart from aspects related to experiment design.

The revelation, in the sixties and seventies, that also in countries with so-called democratic political systems, such as the U.S. and Sweden among others, experimental procedures using human subjects had been carried out without their knowledge and consent, and with negative consequences upon the subjects recruited, emphasized that the lack of ethics in this particular field was a serious issue. Thus, the first Declaration of Helsinki (World Medical Association) was adopted in 1964, and underwent subsequent revisions, establishing some "Ethical Principles for Medical Research Involving Human Beings", and referring to a term to be analyzed in more detail later on: the term or concept of "human dignity".

In the same line, the so called Belmont Report, published in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, in the U.S., provides some of the "basic ethical principles" in Biomedicine, understood as general criteria that serve as basis to justify the precepts and moral standards in Biomedicine, the most important of which is the "principle of respect for persons", the recognition of individuals' moral autonomy and their ability to make decisions that affect them.

Other imaginary torrents that contributed to the formation of this great river of contemporary bioethics were the numerous sentences given by judges and the Supreme Court in the U.S. over the seventies and eighties of the last century in favour of preserving individual freedom and the ability to decide including the healthcare environment. The peculiar features of the U.S. legal system allow judges to resolve claims based directly on the Constitution, without having to wait for legislative bodies to deliberate on the matter. Based on the jurisprudence generated, the U.S. Congress

passed in 1990 the Patient Self-Determination Act in which, for the first time, the right to grant advance directives (called living wills) and appoint a representative with full powers of decision when a patient had lost their personal autonomy acquired legal status. Hence, what in the Belmont report was called "Principle of respect for persons" acquired force of law.

In the European context, the "Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine" promulgated by the EU in 1997 and adopted by most member countries, has played an extremely important role. This agreement marks in the European context the transformation of criteria and ethical principles developed or proposed in the past in legal rules and apart from referring explicitly to the term "dignity", it makes a clear reference to human rights as basis for Bioethics.

Finally, in this quick run through the milestones of contemporary bioethics, we mention the "Universal Declaration on Bioethics and Human Rights" adopted by UNESCO in 2005, and that firmly merges Bioethics with Human Rights.

Let us now analyze in more detail the term or concept of "Dignity", which has been emerging as a key concept in contemporary bioethics. Dignity equals respect for everything worthy of being respected. It is like a label for "a dignified attitude or behaviour" that deserves (socially speaking) and is worthy of respect. Since the 2nd half of the last century, dignity of all human beings without distinction has been given ethics (and thus Bioethics) a base on which to establish its conceptual and procedural building. That is, humans consider themselves worth of dignity and therefore they demand respect without discrimination: respect for freedom (unique birthright, as Kant said in the early nineteenth century, implying that all the other rights are acquired), respect for personal decisions and choices, for moral autonomy as long as it is self-imposed. From here the ethical requirements of the current medical practice derive, as a general obligation to inform adequately and truthfully patients or agents appointed to take actions for their health, request and obtain their consent (permission or authorization) to take the most appropriate actions according to the case.

Thus, the respect for people, for their rights and choices, should be the

primary moral reference point. Any attempt to prevent, limit or interfere unreasonably with the exercise of personal moral autonomy is disrespectful and represents a type of damage or injury that nobody has the right to impose on others. It would be similar with imposing a certain conception of good and evil that needs not to be shared or accepted. The most obvious example in this regard is not requesting the consent of a person able to give it when actions need to be taken regarding their health, which contravenes the primordial moral duty of respect for peers. This lack of respect for one's dignity, freedom and rights may also cause unnecessary damage. This is precisely the ethical foundation of what in health is called informed consent.

We can also characterize the current Bioethics from another point of view, according to which the main task of bioethics is to help culture clarify its views of reality and values. In other words, bioethics plays a major role in the process of understanding culture and the healthcare system establishes, by means of bioethics, its proper place within a culture. For example, deciding when human life ends makes the difference between describing the removal of a human heart as murder or as organ recovery for transplantation, leading to the need to establish the difference between human biological life and human personal life, a rather banal issue.

Asking an ethical question means searching for a basis other than force to resolve a moral discrepancy. This should be the minimum required. Therefore, the only source of moral authority will be the consensus, the consent authority, the authority of those who decide to work together to reach agreements. For this reason, the basic bioethical principle is the consent or permission derived from the essential respect for the human being.

It is another crucial aspect for Bioethics in the context of societies with democratic will, the so called open societies. Actually, a central aspect of Bioethics is to acknowledge the plurality of moral choices that characterize the current societies and to promote the need of a minimum framework of agreement according to which individual belonging to diverse "moral communities" may feel related through a common structure that allows the resolution of conflicts with a certain degree of agreement.

The elaboration of decision making procedures to which all those who are involved can participate is a step of fundamental importance. In case of disagreement, the law establishes the limits of what is allowed; the close relationship between Bioethics and Law derives from here, understood as a norm of behaviour that illustrates the general will and as a method to resolve moral conflicts within a society.

The law and the democratic political choice intervene here, when the respect of Human Rights is concerned, rights accepted worldwide and promoted as a model of life and society to be reached.

Therefore, a moral framework is provided within which the individual belonging to different moral communities may feel connected through a common moral structure which may lead to a common Bioethics, a kind of moral lingua franca for the contemporaneous society in order to avoid the absolute moral relativism.

The second definition highlights another key aspect of current bioethics: the necessary and indispensable multidisciplinarity and interdisciplinarity of its analysis and approaches. One of the main contributions of bioethics is its ability to unite people and approaches from different disciplines and practices with a common goal: to promote and defend in the field of bio the utmost respect, the greatest dignity of all human beings.

To conclude, the mission of bioethics is not to establish some immovable principles that connect on the basis of the new biological natural right, the society and the democratic legislator. On the contrary, the mission of bioethics is rather to provide information, conceptual clarification and analysis of the progress in biomedicine with ethical dimension. Bioethics in general, and the part of it that we call bioethics and law in particular, can be described, in very general terms, as a philosophy committed to the problems of the current times.

1.2. Bioethics and Law

Bioethics addresses above all the analysis of the ethical, but also the legal and social implications of the scientific discoveries and biotechnology applications to propose fair guidelines of conduct. When applying and implementing its proposals, law is involved as since the birth of this new

discipline, Bioethics and Law walk together when crucial issues are raised such as informed consent, patients' rights, conflicts about the origin and the end of life or seeking agreement in plural contexts. The relationship between Law and Bioethics is intrinsic. As law's contribution is critical to bioethics, the contributions of bioethical analysis should be considered extremely useful to Law when clarifying the issues raised by biotechnology, since both disciplines share a common goal: the respect and the promotion of the human rights recognized.

Bioethics and Law have implications that subscribe to the general environment of relationships between ethics and law, and which enable to determine the interactions between the so-called bioethical principles and constitutional values, considered as basic guidelines for legislation and social life. This is possible due to the framework provided by human rights, which are the basis established for coexistence and proposed as suitable to support decision-making when bioethical dilemmas or problems require it due to its double moral and legal imperative. Thus, the reference to human rights, whatever the merits of those who make them is a starting point and an unavoidable limit, particularly when considering that pluralism is a value and a fact in our society. Consequently, it seems appropriate to admit that the basic principles that underpin Bioethics and BioLaw are not other than those included in the Universal Declaration on Human Rights, United Nations (1948).

The defence of the fundamental rights appears today, in addition to the need to ensure an effective compliance with the established rights and to extend them to everyone, as the major challenges derived from the important transformations that the world is experiencing in the field of biotechnologies on which bioethics reflects. Human rights are called to be the regulating criterion of the new forms of control and emerging possibilities, advocating and promoting respect for freedom, equality and dignity of every human being.

The classic principles of bioethics such as autonomy, beneficence and non-maleficence, and justice are paralleled in the legal system with the respect for human rights. In the bioethical reflection the principle of autonomy and justice refer to freedom and equality, values and rights that constitute the core of human rights and the so called dignity. Freedom, individual autonomy, is a fundamental legal principle based on the respect

for the will of individuals, within the general legislative framework. As it happens when referring to the ability of each individual, the acceptance of the individual autonomy is a general rule, and its limitation is an exception that must be justified in each case.

Many examples can be given to support the idea that the principles of Bioethics and BioLaw are not only common but are the core of the new generation of human rights. Therefore, they face identical challenges: failure to identify issues, serious shortcomings in the protection system not yet sufficiently consolidated, low social definition of problems and lack of consensus concerning the preferred options. Law is facing the challenge of creating agreement frameworks regarding the use of biotechnology and biomedicine.

1.3. Principles of Bioethics

In the area of scientific knowledge the word "principle" usually indicates one or more universal statements that represent in our supposition the way nature functions and from which we can understand and predict the behaviour of bodies. In the field of ethics, by extension, principles should serve to guide decision-making in current or complex situations. However, this analogy should not be carried too far, as the obvious differences between object and method is, of course, crucial. In the specific field of contemporary ethics called Bioethics, the "principalist"(3) method counts with four basic principles (also sometimes called ethical duties) to be considered when judgments and consistency are looked for. They are considered normative generalizations, as they must serve to guide the conduct to follow and differs from "rules" as they are more limited in scope (less universal) than "principles". Anyway, these principles should be understood as general guides whose concrete application to particular cases must address the circumstances (not to be confused with consequences) of each case. We refer, of course, to the so-called four "basic principles" (autonomy, beneficence, non-maleficence and justice) converted from the eighties in the canon of Bioethics and will be further developed in another section.

The proponents of the "principalist" method tend to characterize these "principles" as prima facie, when approaching those who try to distance themselves from a deductivist ethical theory (as the Kantian one) taken as case based ethics.

Indeed, to say that these principles require prima facie means that there is no omnipresent hierarchical order and its flexible application to specific cases allows compromise, negotiation, search for original and concrete decisions, without resorting to the mechanical application of a hierarchical order. They are, therefore, the good reasons provided to each case as guidelines in making the best decision, which avoid words like always or never and leave instead room for choosing according to the circumstances of each case, the proper weight of the ethical demands that each of these principles entails. However, the following question arises: is it possible to sustain this pattern of ethical reasoning when it comes to what is to make concrete decisions in specific situations? Is it possible to avoid any kind of hierarchy between the so-called "ethical principles", in this case in Bioethics, without falling into pure relativism or without yielding to the weight of the "circumstances" or "consequences" that may derive from our decisions?

1.4. Basic Ethical Principles in Bioethics

1.4.1. Autonomy (respect for persons)

Since 1978, when the so called Belmont Report was developed as the final result of the work of the U.S. National Commission, the principle of respect for persons, later amended as the principle of individual autonomy, has become a fundamental pillar in current bioethics and should be considered one of its fundamental principles. Generally speaking, the conditions for the use of personal autonomy are as following: a) autonomous decisions are intentional, b) made being aware of the actions proposed, of their meaning and the consequences that may arise c) taken in the absence of external constraints to the person. Moreover, a) it should be seen as an absolute condition but b) and c) can occur in varying degrees. In this regard, self-regulation is essential to personal autonomy, without external interference that pretend to control, and without personal limitations that prevent making a choice. If these conditions are sufficient for a particular person, it must be regarded as a moral agent, and therefore the right to have opinions, to choose and take action based on their values and personal beliefs must be recognized.

1.4.2. Non maleficence

This ethical principle requires not doing harm purposefully and is widely accepted by the most diverse ethical theories, but it is also unanimously understood that it distinguishes from any possible obligation to do good to others (providing benefits, promoting their welfare, etc.). The obligations imposed by the principle of non-maleficence are often more stringent than required by the principle of beneficence, although in some cases the best result-understood from a utilitarian point of view- would be acquired by acting beneficently. That is, in other words, the ethical conflict called paternalism.

Therefore, generally speaking non-maleficence simply requires intentionally refraining from actions that may cause harm. The term "harm" is understood extensively, and includes deception as well, knowing that deception does not consist in any "action" directly observable. Non-maleficence also includes the obligation to prevent and avoid errors (malpractice or others) and medical negligence.

1.4.3. Beneficence

Most ethical theories not only require refraining from doing harm, according to what is understood by “harm", but also contributing to a better welfare. That is the core of “beneficence”: to take positive steps to help others and not just refrain from harmful acts. However, in certain circumstances, benefits and disadvantages must be put in balance, as it is the case in surgery.

Moreover, the principle of beneficence imposes a duty to help others to promote their legitimate interests, particularly helping them to exercise their rights properly and respecting their autonomous decisions without imposing the views and values of the "beneficent" that, with the best of intentions, would run the risk of causing more harm than good. In other words, one can hardly hide behind the obligation of beneficence to violate the principle of non-maleficence if there is conflict between the two ethical requirements. Hence, the so-called "coercive paternalism" (compelling others by any means to act or decide according to what we judge as good) should not come under the concept and obligations of beneficence.

1.4.4. Justice or equity

To provide equitable (or fair) treatment to others is undoubtedly an ethical requirement of great importance. If we think of societies with a public health system, this principle requires that each person be treated according to their needs (health or health care, in this case) without suffering from any negative discrimination for any reason. To continue our example, there is neither better nor worse patients, only patients who need to be cared for in the best way possible. The limit can only be set by the medical (or socio-medical) resources that a company or an institution disposes of. These resources (whose actual allocation is usually decided by politics or, at least, health policy) are to be distributed equally between those who are in need. The opposite is to cause maleficence, in this case by negative discrimination. That is what is usually meant by distributive justice, a term already proposed by Aristotle, which refers to "equal, equitable and appropriate distribution in the society, determined by justified norms that structure the terms of social cooperation"[(4)]. Aristotle also showed that equals should be treated equally, and unequal must be treated unequally, that is, that no matter the relevant field considered (patients in need of an organ for transplant, for example), the individuals equal in this environment (in our example, patients on the waiting list) should be treated equally (establishing criteria as objective as possible when developing this list).

But the respect for people's rights and, especially, the respect for their autonomous decision is also a matter of justice, provided that they do not cause damage or harm to other people or generate great injustice. The latter is particularly important in cases such as the buying and selling of organs for transplant among living beings. Should this practice be socially and legally allowed for the sake of personal autonomy when someone accepts to "donate" an organ in exchange for financial compensation? Or to put it another way, is there enough ground to put in force the prohibition, at least in theory, for buying and selling organs on a "free" market? This is a paradigmatic case of how personal autonomy is diminished or even nullified by the "donor" need, for which the sale of a non-vital organ becomes an atypical source of income, and which therefore, can be hardly understood as a free and autonomous decision. The general ban on such "donations" is the only way to protect vulnerable people, precisely due to their need to increase their financial resources,

from the injustice of considering the human body a good like any other, similar to a new form of slavery.

2. International legal framework on human organ donation and transplantation

This section analyses the international legal framework for donation and transplantation of organs and tissues of human origin from a bioethical perspective, systematizing international legal instruments issued by two international organizations with a leadership position in encouraging bioethical debate internationally such as: the Council of Europe and UNESCO, along with the regulations issued by the European Union.

Firstly, the concept of bioethics should be clarified as following: an interdisciplinary reflection on the ethical, legal and social implications of new technologies and biomedical problems, taking as reference and limit the internationally recognized human rights.

The possibility to consider organ and tissue donation in brain dead patients according to the criteria accepted by the scientific community, and then to legally proceed, as it is the Spanish case, is one of the first bioethical questions raised since the second half of the 20th century, at a time of technical progress in medical care that allows absolutely novel situations and the dilemma of who should make decisions regarding organ donation in persons who cannot express their will by themselves[5].

The donation and transplantation of organs and tissues of human origin has been the subject of international regulation in the light of scientific and technical advances with the intention of protecting the rights of those involved, both donor and recipient and distinguishing between living and deceased donor. Currently, the international community focuses on the fight against the so called "transplant tourism", on avoiding the buying and selling of organs and thereby exploiting vulnerable people due to the economic and social context in which they live. Due to shortage of organs for transplants, new possibilities are contemplated as crossover and chain donations including the figure of the Good Samaritan, with its advantages

and reservations especially from the perspective of person protection[6]. For those interested in exploring the organ and tissue donation and transplantation issue, either from medical, legal or any other point of view, it is essential to learn about the international regulations and national legislation, according to where the professional activity is undertaken. It is also necessary to add a bioethical perspective and address the social and political context, but also the underlying ethical issues, as well as the ethical or bioethical principles that imbue the legal response regarding the respect for personal autonomy when making healthcare and research decisions, and the principle of justice. The first relates to enhancing decision-making as the right to freedom is a fundamental right. The principle of justice appeals not only to solidarity but also to equitable distribution of resources and disagrees that the vulnerable ones get exploited. An overview of international regulations is further on provided on organ donation and transplantation, including the provisions of the European Union as well as the Spanish organization and transplant model, which inspired the Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 207, 6.8.2010).

2.1. WHO guiding principles on human cell, tissue and organ transplantation

The Fortieth World Health Assembly, recognizing the scientific progress achieved in human organ transplants in many Member States; concerned at the trade for profit in human organs among living human beings; affirming that such trade is inconsistent with the most basic human values and contravenes the Universal Declaration of Human Rights and the spirit of the WHO Constitution; commending the measures taken by some Member States to regulate human organ transplants and their decision to develop a unified legal instrument to regulate these operations develop the Guiding Principles for Human Organ Transplants, endorsed by the 63rd World Health Assembly in May 2010, in Resolution WHA63.22

1. Consent for deceased donor's donation
2. No conflict for the definition of death determination
3. Deceased but also consenting live donors
4. Protection of minors and incompetent persons
5. No sale or purchase

6. Promotion of donation no advertising nor brokering
7. Responsibility on origin of transplant
8. Justifiable professional fees
9. Allocation rules
10. Quality safety efficacy of procedures and transplants
11. Transparency and confidentiality

Among others,, WHO urges Member States: to implement effective national oversight of procurement, processing and transplantation of human cells, tissues and organs, including ensuring accountability for human material for transplantation and its traceability (Governments are responsible).

To take measures to protect the poorest and most vulnerable groups from "transplant tourism" and the sale of tissues and organs, including attention to the wider problem of international trafficking in human tissues and organs[7].

2.2. The Convention on Human Rights and Biomedicine of the Council of Europe, 1997

The Convention on Human Rights and Biomedicine of the Council of Europe[8], an international legal instrument applicable to all countries that consent to it, discusses the application of biology and medicine focusing on protecting the rights of individuals and their dignity, which may be affected by such interventions. Put into force in Spain in 2000, the Convention is also known as the Oviedo Convention, according to the city where it was signed in 1997. The Council of Europe is an international organization of regional government for the protection and promotion of human rights and fundamental freedom, pluralistic democracies and the rule of law, created in 1947 and which includes all EU member States.

The donation and transplantation of human organs is referred to in a specific chapter (Chapter VI) which states that the recovery of organs and tissues from living donors is allowed only for the therapeutic benefit of the recipient, when there is no alternative therapy of comparable effectiveness and when the organs cannot be recovered from a deceased donor (Article 19). Any profit with respect to the human body and its parts is absolutely prohibited by the Convention, which specifies that the use

of any part of the human body recovered within a procedure may only be used for the purpose for which it was stipulated when information provided and consent given. (Chapter VII).

As a starting point, the Convention states that any intervention, whether for medical or research purpose, requires the consent of the person concerned, according to the information previously provided. Their consent may be revoked at any time. This is to respect the autonomy of the individual, their rights and freedom, especially when decisions need to be made concerning medical or biological interventions, as well as their privacy and confidentiality of health data. In the case of organ transplantation, the Convention states that the consent must be explicitly stated, and must be given in writing or before a competent authority. No tacit consent can be considered due to the nature of the intervention and its consequences.

The Convention sets out a number of details in order to protect people who cannot give consent themselves to the recovery of organs for transplantation (Article 20). Along with the general rule on consent, organ recovery in persons who lack the capacity to give their consent for this purpose is exceptionally added. The recovery may be approved when there is no compatible donor able to give consent, when the recipient is a brother or a sister of the donor, when donation is performed to preserve the life of the recipient, and when there has been specifically and written authorization from the child's legal representative according to the legislation in force and the competent authority (the older and more mature the child, the more decisive their opinion will be). Finally, one can proceed with organ recovery if the potential donor did not object to it. Similarly, in elder people who do not have the capacity to consent to recovery due to a mental disability, a disease or a similar reason, recovery cannot be proceeded without the permission of their legal representative, authority, person or institution designated by law (paragraphs 2 and 3 of Article 6).

The intention of the Council of Europe to adopt this legal measure has been to meet the challenges posed by the advancement of scientific knowledge and technology and the applications that may derive from them, since they can interfere with the rights of the individuals and their dignity. That is why the Convention is accompanied by a series of Protocols to adapt the legal response to a rapidly and constantly changing

reality such as that of medicine and biology today. According to the issue concerned, the Additional Protocol on transplantation of organs and tissues of human origin, adopted in Strasbourg on 24 January 2004, and put in force in May 1, 2006 (CETS no. 186), will be further highlighted.

The Convention on Human Rights and Biomedicine sets forth other issues as well, which are not the object of the analysis of the current chapter, such as nondiscrimination for genetic causes.

2.3. The Universal Declaration on Bioethics and Human Rights, UNESCO, 2005

UNESCO, specialized agency of the United Nations for the promotion of peace through education, science, culture and communication, holds a leading position in bioethics at international scale, primarily to promote bioethical debate and awareness on its themes, such as in organ transplantation. It also has enacted a number of key legal instruments in bioethics as the Universal Declaration on Bioethics and Human Rights, adopted by acclamation on 19 October 2005[9].

The Declaration "addresses ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions" (Article 1). Similar to the Convention on Human Rights and Biomedicine, this international legal instrument linking bioethics to international law of human rights, recognizes the autonomy of individuals responsible for decision making and consent as prerequisite to proceed with a preventive, diagnostic and therapeutic intervention. The consent must be free and informed. It applies similarly to the field of scientific research.

Along with the principle of autonomy and informed consent, establishing specific provisions for people who cannot give consent themselves, the Declaration upholds the following principles: human dignity and human rights, benefits and harms, respect for human vulnerability and personal integrity, privacy and confidentiality, equality, justice and equity, non-discrimination and non-stigmatization, respect for cultural diversity and pluralism, solidarity and cooperation, social responsibility and health, sharing of benefits, protection of future generations, protection of the environment, the biosphere and biodiversity. When implementing the Declaration and

deciding on transnational practices, it is the States as authors and addressee of the Declaration that need to take adequate actions to fight against illicit trafficking of organs, tissues and biological samples, genetic resources and genetic-related materials (Article 21). The above mentioned principles should apply to transnational practices, meaning that all transnational biomedical activity either for welfare or research should be conducted in accordance with the principles established.

2.4. Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation.

This Directive[10] sets out a common framework on quality and safety standards for organs of human origin intended for transplantation into the human body. It also aims to protect donors and optimize exchanges between Member States and third countries.

This Directive covers only those organs to be transplanted into the human body, and not the use of organs for the purposes of research. It applies to donation, procurement, testing, characterization, transplantation of organs.

It does not apply to blood, blood components, human tissues and cells, organs, tissues and cells of animal origin.

Member States shall implement a quality and safety framework which defines the parameters of all stages of the chain from donation to transplantation.

The Action plan on Organ Donation and Transplantation (2009-2015) sets forth ten priority actions in the field.

2.4.1. Charter of Fundamental Rights of the European Union Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation

In December 2009, with the entry into force of the Lisbon Treaty, the Charter became legally binding just as the Treaties did. Our focus is one

of the first articles of this text which now is part of the primary law of the European Union, which recognizes the right of integrity - everyone is entitled to their physical and mental integrity - as it refers to interventions on humans in medicine and biology. The article establishes the free and informed consent of the person concerned as a fundamental premise. It also prohibits eugenic practices, in particular those aiming at the selection of persons, and that the human body and its parts to be treated as a source of financial gain. Finally prohibits Reproductive cloning of human beings is also prohibited (Article 3)[11]

3. The regulation in Spain

The regulation of organ transplantation in Spain is set out in Law 30/1979, 27 October which deals with organ extraction and transplant, and Royal Decree 1723/2012, 28 December, which regulates the activities of procurement, clinical use and territorial coordination of human organs for transplantation, as well as quality and safety requirements.

The Spanish National Transplant Organisation (Organización Nacional de Trasplantes) (ONT) was created in 1989. This legislation does not apply to blood and other blood derivatives[12], human cells and tissues, or reproductive cells and tissues[13].

Organ donation for therapeutic purposes must be gratuitous, based on solidarity and altruism. No payment will be made to the organ donor. Article 2 of the Law states that “no compensation will be made for organ donation under no circumstances can the donor receive economic compensation, and the recipient will not be made to pay for the transplanted organ”. Reimbursement of certain expenses is, however possible.

Donation is anonymous[14]. The donor’s family may not have access to the identity of the recipient, nor may the recipient or their family have access to the identity of the donor. This requirement does not apply when the recipient is a relative or close friend of the donor. As any other medical intervention, transplantation requires the patient’s informed consent[15]. The doctor in charge of the transplantation team must ensure that the recipient is fully aware of the nature of the intervention, what a transplant involves, that they know about the possible risks and foreseeable

advantages, both physical and psychological, that may result from the transplant. The patient must also be informed that the necessary histocompatibility immunological tests have been performed as between the donor and recipient in an authorised laboratory. Informed consent must be provided in writing by the patient, and if the recipient is a minor or lacks full mental capacity, then the consent must be signed by the parents or legal representatives. Organ extractions must be carried out in authorised health care centres[16].

Finally, Law 30/1979 refers to what has become the most important feature of the Spanish system, namely its organisational model: 'facilities should be provided to create organizations at national and regional level [note that it is not an obligation], and cooperation will be made at an international level to ensure timely circulation of deceased organs for transplantation in order to find the most suitable recipient[17].

The law makes a distinction between living and deceased organ donors[18]. Since requirements for consent differ (informed consent for the former, presumed consent for the latter) and specific formalities exist for each, they are to be examined separately.

3.1. Living organ donors

Legal requirements for living organ donation are in Article 4 of Law 30/1979 and Article 8 of Royal Decree 1732/2012. It is necessary for the donor to consent; otherwise organ extraction would constitute a criminal act, punishable as injuries (article 156 Spanish Criminal Code), for which the health care professionals involved would also be disqualified for professional practice. Consent must be given by a person of legal age, with full mental capacity. Organs may not be procured from persons who, due to mental deficiency or illness, or any other reason, lack capacity and therefore are not able to express their consent in an express, free and conscious manner. Minors' consent will not be valid, and parents or legal guardians may not consent to the removal of their children's organs.

The law does not include any exception. Mention must be made to the case of a minor who sought judicial authorisation in order to enable her to donate part of her kidney to her baby girl. In this case, both the organ donor and the intended recipient were minors. The case involved a 17

year old mother who wanted to be an organ donor for her baby daughter who was suffering from a disease which could lead to her death if it reached its acute state and no compatible donor was found. At the time the under-age mother was unable to give legal consent to organ extraction, although she would be able to do so in a few months' time when she reached full legal age. By this time, it may have been too late for her baby and this made it a very dramatic case. The grandmother of the sick baby applied to the courts to try and obtain judicial authorisation for organ donation in the case of her daughter. The Court of First Instance in Sevilla authorised the organ donation in a ruling given on 18 October 2007. This solution received a great deal of media coverage. Although the ruling was perceived to be just and fair, it was nevertheless illegal in technical terms as it was contrary to the law(19).

Consent must be informed, and in writing. Potential donors must be informed about the material risks of the intervention(20), as well as the 'foreseeable consequences of the decision, both somatic and psychological, and the possible repercussions donation may have on their personal, family and professional life, as well as the expected benefits for the recipient'(21).

In practice, this is usually undertaken by the transplant coordinator, who will also inquire about the 'potential donors' decision to donate, their personal and professional situation and any other relevant data in order to determine whether the decision is made freely(22).

Potential living organ donors may face socioeconomic difficulties, such as the effects this will have on their employment and also on their insurance policies. These problems do not necessarily ensue in all cases, but in order to ensure that they do not, the law should be amended(6).

A medical evaluation is required to determine that donors are generally healthy persons and that their health will not be endangered by organ donation. The examination will be made by a physician who is not involved in the transplantation process(23). The donor and recipient need not be genetically linked. The ethics committee of the hospital where the transplantation is to take place must issue a report approving organ retrieval in relation to the living donor(23).

Finally, the potential living organ donor must give his consent anew before the judge. The donor will be accompanied by three persons who will also sign the organ donation consent document: the doctor who will carry out the organ extraction, the doctor who examined the potential donor and issued the medical report, and the person who authorises the operation (usually, a representative from the authorised healthcare centre, or the transplant coordinator). Before the judge, doctors will, once again, provide the relevant information, and the document will be signed by all. If at any time, any of the aforementioned persons has any doubts about the manner in which consent is given (ignorance, coercion, non altruistic) they may oppose the organ donation. Otherwise the Judge will authorise it.

Once consent is given before the judge, the organ extraction will not take place before 24 hours (cooling- off period) which gives the donor a final chance to change his/her mind. Consent may be revoked up to the moment of organ retrieval[24], with no formalities needed and no adverse pecuniary consequences (there is no need to pay compensation or expenses to the health care centre and/or to the recipient).

3.2. Deceased organ donors

The vast majority of organs in Spain are provided by deceased donors. The first Spanish transplant law was developed in 1979 based on Royal Decree 426/1980, that regulates the removal of organs from deceased donors after brain death. In 1996 the "Spanish Consensus Document on extraction of organs from donors after cardiac death" was published but specifically excluded Maastricht type III donors. Royal Decree 2070/1999, defined the legal framework for the removal of organs from dead donors after brain death and cardiac death type I-II. The last amendment to the law, the Royal Decree 1723/2012, of 28 December which is the transposition of Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010, includes and defines the three above conditions (brain death, uncontrolled asystole (type I-II of Maastricht) and also regulates the donation of controlled asystole or Maastricht type III.

Diagnosis of death must be made before any organ retrieval takes place. Diagnosis can be done either by irreversible cease of cardio- respiratory function or by irreversible cessation of brain function. Death after cardiac arrest must be certified by one physician, but a declaration, of brain death

must be signed by three physicians, one of which must be a neurologist or a neurosurgeon and the other, the head of the unit where the patient is hospitalised. The physicians who are involved in the diagnosis of death cannot be involved in the organ retrieval or the transplantation team[25].

For donation in death after uncontrolled cardiac arrest, once a person is certified as dead, the deceased's body is turned over to the team in charge of transplantation who may apply preservation techniques with judicial authorisation[26]. Because time is so relevant here, the law states that if a judge does not refuse authorisation within fifteen minutes of the request, then consent may be presumed[27]. When the physician receives express judicial authorisation, or when there is a fifteen minute lapse without a reply, they may then proceed to apply preservation techniques (and extract samples for the court in the case of accidental death)[27]. If the cause of death seems unclear and organ retrieval could interfere with the autopsy and the criminal investigation, authorisation will be denied[28].

Different scenario is set for donation in patients who die after cardiac arrest secondary to the application of Life Support Treatment Limitation by their treating doctor who deemed treatment to be futile (Controlled cardiac arrest). Once death has been certified, the deceased body is turned over to the team in charge of transplantation, who may apply preservation techniques without the requirement of judicial authorisation for that matter.

Even though the law establishes a presumed consent system (opt-out)[29], in practice, Spain works as an informed consent system (opt-in). Consent is always obtained, and families' wishes are always respected, even when the deceased relative had a donor card authorising organ donation. One of the main reasons for applying an opt-in system is the need to build trust. If, regardless of what the law says, physicians will not override the family's wishes, it sends a strong message of respect which, in turn, generates trust. It also avoids conflict and bad publicity, which could also undermine trust in the organ procurement system.

4. Organ trafficking and commercialism

Organ transplantation, one of the medical miracles of the twentieth century, has prolonged and improved the lives of hundreds of thousands

of patients worldwide. The many great scientific and clinical advances of dedicated health professionals, as well as countless acts of generosity by organ donors and their families, have made transplantation not only a life-saving therapy but a shining symbol of human solidarity. Yet these accomplishments have been tarnished by numerous reports of trafficking in human beings who are used as sources of organs and of patient-tourists from rich countries who travel abroad to purchase organs from poor people. In 2004, the World Health Organization, called on member states "to take measures to protect the poorest and vulnerable groups from transplant tourism and the sale of tissues and organs, including attention to the wider problem of international trafficking in human tissues and organs"[1].

4.1. The Declaration of Istanbul on Organ Trafficking and Transplant Tourism

To address the urgent and growing problems of organ sales, transplant tourism and trafficking in organ donors in the context of the global shortage of organs, a Summit Meeting of more than 150 representatives of scientific and medical bodies from around the world, government officials, social scientists, and ethicists, was held in Istanbul from April 30 to May 2, 2008. Preparatory work for the meeting was undertaken by a Steering Committee convened by The Transplantation Society (TTS) and the International Society of Nephrology (ISN) in Dubai in December 2007. That committee's draft declaration was widely circulated and then revised in light of the comments received. At the Summit, the revised draft was reviewed by working groups and finalized in plenary deliberations.

This Declaration represents the consensus of the Summit participants. All countries need a legal and professional framework to govern organ donation and transplantation activities, as well as a transparent regulatory oversight system that ensures donor and recipient safety and the enforcement of standards and prohibitions on unethical practices.

Unethical practices are, in part, an undesirable consequence of the global shortage of organs for transplantation. Thus, each country should strive both to ensure that programs to prevent organ failure are implemented and to provide organs to meet the transplant needs of its residents from donors within its own population or through regional cooperation. The

therapeutic potential of deceased organ donation should be maximized not only for kidneys but also for other organs, appropriate to the transplantation needs of each country.

Efforts to initiate or enhance deceased donor transplantation are essential to minimize the burden on living donors. Educational programs are useful in addressing the barriers, misconceptions and mistrust that currently impede the development of sufficient deceased donor transplantation; successful transplant programs also depend on the existence of the relevant health system infrastructure.

Access to healthcare is a human right but often not a reality. The provision of care for living donors before, during and after surgery– as described in the reports of the international forums organized by TTS in Amsterdam and Vancouver[2-4]–is no less essential than taking care of the transplant recipient. A positive outcome for a recipient can never justify harm to a living donor; on the contrary, for a transplant with a living donor to be regarded as a success means that both the recipient and the donor have done well.

This Declaration builds on the principles of the Universal Declaration of Human Rights[9]. The broad representation at the Istanbul Summit reflects the importance of international collaboration and global consensus to improve donation and transplantation practices. The Declaration will be submitted to relevant professional organizations and to the health authorities of all countries for consideration. The legacy of transplantation must not be the impoverished victims of organ trafficking and transplant tourism but rather a celebration of the gift of health by one individual to another.

Of approximately 170 persons invited, 160 agreed to participate and 152 were able to attend the Summit in Istanbul on April 30-May 2, 2008. The draft Declaration prepared by the Steering Committee was furnished to all participants with ample time for appraisal and response prior to the Summit. The comments and suggestions received in advance were reviewed by the Steering Committee and given to leaders of the appropriate work group at the Summit. (Work group leaders were selected and assigned from the Steering Committee.)

The Summit meeting was formatted so that breakout sessions of the work groups could consider the written responses received from participants prior to the Summit as well as comments from each of the work group participants. The work groups elaborated these ideas as proposed additions to and revisions of the draft. When the Summit reconvened in plenary session, the Chairs of each work group presented the outcome of their breakout session to all Summit participants for discussion. During this process of review, the wording of each section of the Declaration was displayed on a screen before the plenary participants and was modified in light of their comments until consensus was reached on each point.

The content of the Declaration[30] is derived from the consensus that was reached by the participants at the Summit in the plenary sessions which took place on May 1 and 2, 2008. A formatting group was assembled immediately after the Summit to address punctuation, grammatical and related concerns and to record the Declaration in its finished form.

4.2. The Madrid resolution

The Third Global Consultation on Organ Donation and Transplantation was organized by the World Health Organization in collaboration with the Spanish National Transplant Organization (ONT) and The Transplantation Society (TTS), and supported by the European Commission.

The consultation, held in Madrid from 23rd to 25th March 2010, brought together 140 government officials, representatives of international scientific and medical bodies, and ethicists from 68 countries.

Participants in the Madrid Consultation urged WHO, its Member States and professionals in the field, to regard organ donation and transplantation as part of each nation's responsibility for meeting the health needs of patients in a comprehensive manner, addressing conditions leading to transplantation from prevention to treatment.

Every country, in light of its level of economic and health system development, should progress towards the global goal of meeting patients' needs on the basis of resources obtained within the country for that country's population and through regulated and ethical regional or international cooperation when needed. The strategy of striving for self-

sufficiency encompasses the following features: actions should (i) begin locally, (ii) include broad public health measures both to decrease the disease burden in a population and to increase the availability of organ transplantation, (iii) enhance cooperation among the stakeholders involved, and (iv) be carried out on the basis of the WHO Guiding Principles and the Declaration of Istanbul, emphasizing particularly voluntary donation, non-commercialization, maximization of donation from the deceased, and meeting the needs of the local population in preference to "transplant tourists."

This new paradigm develops a comprehensive strategic framework for policy and practice directed at the global challenge of the increasing incidence of chronic non-communicable diseases, a shortage of organs for transplantation, and unmet patient needs from a practical perspective. Therefore the Madrid Resolution comprehends both a pledge to progress in increasing organ donation and satisfying transplantation needs and a roadmap showing how these goals may be achieved.

The national responsibility of meeting patients' needs should be met primarily through each country's own resources, with specific regulated and ethical regional or international cooperation when appropriate. National accountabilities can be broadly defined as the creation of a national planning context for chronic diseases treatable through organ transplantation that encompasses capacity control, regulatory control and determination of the appropriate ethical environment[31].

4.3. Strategic planning for the 4Ds program (Developing Donation from Deceased Donors)

The meeting organized in Geneva in July 2010 at the request of The Transplantation Society by the World Health Organization in collaboration with the Spanish National Transplant Organization, focused on how deceased donation can be developed and consolidated in countries throughout the world and, in particular, in those with local difficulties.
The updated plan of WHO in the field includes three elements:

- **Self-sufficiency**: WHO intends to offer guidance for suitable donation and transplantation to countries. The paradigm of self-sufficiency was in-depth explored during the *Third Global*

Consultation on Organ Donation and Transplantation held in Madrid in March 2010. Maximization of deceased donation is the aim of the 4Ds program[32], first started in Kuwait in 2008.

- **Legal and Organizational Framework**: WHO will assist countries in the development of a legal and organizational framework for organ donation and transplantation, through the WHO GPs and the Istanbul Declaration on organ trafficking and transplant tourism. In parallel, WHO intends to guide countries for setting up an organizational and legal framework on death determination. The WHO standards in this regard have to be positioned within the global health care competencies of the WHO, and not particularly linked to organ donation and transplantation.

- **Regulatory oversight**: Guidance on safety and quality aspects is to be provided by the WHO, with regards to issues and inspection, vigilance and surveillance.

4.4. The Doha communique of the Declaration of Istanbul Custodian Group, April 14, 2013

To mark the Fifth Anniversary of the Declaration of Istanbul and to evaluate progress in implementing its principles and recommended proposals, seventy members of the Declaration of Istanbul Custodian Group (DICG) met in Doha, Qatar from April 12-14, 2013. The participants were heartened by the steps taken by health authorities in many countries that have prohibited transplant commercialism and have greatly reduced the flow of transplant tourists to sites where organ trafficking, including from executed prisoners, occurs. The Doha participants also commended the adoption of safe, effective, and accountable practices that meet the needs of transplant recipients while protecting the rights of donors, such as the creation of systems of follow-up care for donors and the development of successful deceased donor programs in a number of countries. It was recognized, however, that many challenges still remain, and the participants therefore endorsed the adoption of means of reporting organ trafficking, the development of more complete registries of transplants of all organs from deceased and living donors, increased cooperation with law enforcement authorities combating human trafficking, and the use of international conventions to ensure that organs are obtained and used in an ethical, safe and transparent fashion.

4.5. Other initiatives

As it is one of the topics of recent debate, we recommend reading the joint study published by the Council of Europe and United Nations on trafficking in organs, tissues and cells as well as trafficking in human beings for the purpose of organs recovery.

In 2008, the Council of Europe and the United Nations agreed to prepare a Joint Study on trafficking in organs, tissues and cells and trafficking in human beings for the purpose of the removal of organs. This Joint Study was prepared in the framework of the co-operation between the two international intergovernmental organisations, in particular in keeping with the United Nations General Assembly Resolution on Co-operation between the United Nations and the Council of Europe (A/RES/63/14), which specifically states: "The General Assembly[,] [T]akes note with appreciation of the entry into force on 1 February 2008 of the Council of Europe Convention on Action against Trafficking in Human Beings, to which any non-member State of the Council of Europe may accede after having obtained unanimous consent of the parties to the Convention, commends the enhanced co-operation between the United Nations and the Council of Europe in this regard, and expresses its appreciation for the preparation of a joint study on trafficking in organs, tissues and cells and trafficking in persons for the purpose of the removal of organs".

The Study notes, first of all, that trafficking in human beings for the purpose of organ removal is a small part of the bigger problem of trafficking in organs, tissues and cells ("OTC"). Secondly, it highlights the existence of widespread confusion in the legal and scientific community between "trafficking in OTC" and "trafficking in human beings for the purpose of the removal of organs".

Thirdly, the Joint Study underlines that solutions for preventing the two types of trafficking had to be different because the "trafficked objects" are different: in one case the "organs, tissues and cells" and in the other case the "person him/herself" who is trafficked for the specific purpose of removing his/her organs. One of the major aims of the Joint Study is therefore to distinguish between trafficking in OTC and trafficking in human beings for the purpose of organ removal.

The Joint Study only covers trafficking in OTC for the purpose of transplantation. Other purposes of trafficking in OTC are outside the scope of the Joint Study. The starting point of the Joint Study is the prohibition of making financial gains with the human body or its parts. This principle was established for the first time in a legally binding instrument in Article 21 of the 1997 Council of Europe Convention on Human Rights and Biomedicine [CETS No. 164]: “The human body and its parts shall not, as such, give rise to financial gain”. The principle was then reaffirmed in the 2002.

Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin [CETS No. 186]. Article 22 of the Protocol states: “Organ and tissue trafficking shall be prohibited”. The principle of the prohibition of making financial gains with the human body is also very important in order not to jeopardise the donation system based on altruism, both from living and from deceased donors, which must be the basis of the organ transplantation system. Given that trafficking in organs mainly exists because of the lack of available organs, it is also essential to take the organisational measures needed to increase the availability of organs for transplantation.

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