Essay

BIOETHICS IN ORGAN TRANSPLANTATION AND DONATION IN EL SALVADOR

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ABSTRACT

Throughout history, there have been codes to regulate human behavior. Currently, the field of medicine is one of the sciences that possesses and uses a greater number of codes of ethics. The beginning of the era of organ and tissue donation and transplantation has been no exception. This era began in the mid-20th century and has been advancing rapidly; however, it has not been exempted from being regulated by different legal and bioethical aspects. This essay addresses the fundamental bioethical principles, such as autonomy, beneficence, non-maleficence and justice in regards to organ and tissue donation and transplantation in the context of El Salvador. For the past 35 years, transplant procedures have been conducted in El Salvador. However, the current law only allows organ donation from living donors. With the new transplant law, it will be necessary to reassess the bioethical principles to ensure that the program is accepted by Salvadoran society. There are many challenges to be addressed from a bioethical perspective, so it is essential to learn from practices in other countries and adapt them to the current context of Salvadoran society.

Key words: bioethics, donation, transplantation, El Salvador.

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BIOÉTICA EN TRASPLANTE Y DONACIÓN DE ÓRGANOS EN EL SALVADOR

Abstract

A largo de la historia han existido códigos para normar la conducta humana. Actualmente, el área de la medicina es una de las ciencias que posee y emplea una mayor cantidad de códigos de ética. El inicio de la era de la donación y trasplante de órganos y tejidos no ha sido la excepción. Esta era inició a mediados del siglo pasado y ha ido avanzando de manera acelerada; sin embargo, no ha quedado exenta de verse normada por diferentes aspectos legales y bioéticos. En el presente ensayo se abarcan los principios bioéticos fundamentales, como la autonomía, beneficencia, no maleficencia y justicia, en torno a la donación y trasplante de órganos y tejidos en el contexto de El Salvador. Desde hace 35 años se realizan trasplantes en el país, no obstante, la actual ley solo permite la donación de órganos de donantes vivos. Con la nueva ley de trasplantes se tendrán que replantear los principios bioéticos, para que el programa sea aceptado por la sociedad salvadoreña. Existen muchos retos a cumplir desde el punto de vista bioético, por lo que es necesario tomar ejemplos de prácticas de otros países para adaptarlas al contexto actual de la sociedad salvadoreña.

Palabras clave: bioética, donación, trasplante, El Salvador..

INTRODUCTION

Since the beginning of history, there have been attempts to regulate human behavior; to define what is right and wrong. In all known cultures, there are codes or regulations on how society should behave in specific situations. It can be considered that the concept of "medical ethics" began during the Hellenistic period through the Hippocratic Oath. As knowledge has evolved and diversified in different sciences, it has become necessary to expand these codes, making it imperative to create codes of ethics for each emerging science or specialty.

Medicine is one of the classical examples of the impact of ethical codes, their application, and growth over time.The famous Hippocratic Oath has been modified and updated to meet current needs. Initially, scientific research on animals and humans was conducted without any regulations, and these activities allowed the dignity of people to be violated.

With the beginning of the new era in research, the era of human or animal organ and tissue transplantation also began, which is becoming increasingly common in humans and has led to the creation of new codes of ethics to govern this activity while safeguarding the fundamental principles of bioethics. This new medical specialty is a cause of ethical dilemmas that are still difficult to define and solve today. This essay will emphasize the relationship between bioethics and organ donation and transplantation in the context of El Salvador.

Development

Medicine is one of the sciences that has experienced significant growth in recent decades. The increase in knowledge through observation and direct experimentation on human beings has not been a smooth transition without drawbacks. Since the Hippocratic Oath, attempts to regulate the practice of medicine can be observed when facing situations where humans suffer from illness, marking the beginnings of professional ethics in the medical field. The Hippocratic Oath contains different statements that clearly emphasize what is now known as «principles of bioethics»; «not to administer deadly medicine» and «not to give abortive remedies» are clear examples of morality and ethics in the medical profession (1).

The development of bioethics principles has not been a simple process, various significant events have highlighted their importance. The clearest example of their significance was determined after World War II, during the Nuremberg trials. In these trials, it was possible to verify the experimentation in human beings that disregarded all their dignity. As a result, the Nuremberg Code was created, serving as a reminder of what considerations should be kept in mind during scientific research involving human beings (2). It is important to mention that during these trials, organ and tissue transplantation were performed between twins and humans. With the advent of donation and transplantation, these codes gain great relevance in the modern era of transplantation; however, it is important to remember the use of these documents in medicine is forbidden (3).

Just as medicine has advanced in its different areas, the application of bioethics codes in the profession has also been necessary, especially when it comes to organ donation and transplantation in humans. The basic principles of bioethics, proposed by Potter—justice, beneficence, non-maleficence, and autonomy—continue to be the pillars on which current medicine is based to conduct any type of medical trial (4).

The first human-to-human transplant was performed by the Ukrainian surgeon Voronoy in 1933, and it involved a kidney transplant that resulted in failure 48 hours later due to graft rejection (5). This milestone in the era of surgery and the beginning of heterologous transplants brought more advances and bioethical issues that have been gradually defined over time. In 1955, Murray performed the first successful homotransplantation in identical twins, recei-

ving the Nobel Prize in 1990 (6). An important breakthrough that made transplants possible between different blood groups was the introduction and discovery of immunosuppressants. In the era of immunosuppression and improvements in surgical techniques, transplants advanced further, including more complex and life-critical organs. In 1963, Starzl performed the first successful liver transplant, becoming the father of liver transplants (7).

There is no doubt that organ donation and transplantation have saved many lives throughout the history of modern medicine. However, like any advancement, they have not been free of controversy. Once the era of organ and tissue transplantation began, a number of ethical dilemmas arose.

Organ and tissue transplantation began before the introduction of the principles of bioethics proposed by Potter. However, the Nuremberg and Helsinki Codes already existed at that time.

Over time, the possibility of transplants has been pushed to its limits, including the use of embryos for the purpose of organ or tissue transplantation, which would otherwise be impossible to obtain once the product is fully developed. This raises new dilemmas, such as when life begins and how far genetic manipulation can be pursued for benefits and at what cost (8).

On a global scale, it is estimated that 120,000 transplants were performed in 2018, which only meets 10% of the worldwide demand for organs and tissues (9). In the European Community, 34,285 solid organ transplants were performed, with 85% of them involving kidney and liver transplants and Spain being the world leader in this field (10). According to the Spanish National Transplant Organization (ONT), the donor rate in Spain is 40.2 donors per million inhabitants, while for the rest of the European Community, it is 18.4 donors per million inhabitants. Between 2010 and 2017, the number of donations and transplants in Spain increased by 4,540; however, in 2019, the increase was only 161, mainly due to the COVID-19 pandemic (10). Currently, the waiting list is estimated at 58,000 people and continues to increase each year, which means that the demand always exceeds the supply. Of these patients on the waiting list, 3-4% pass away while waiting for a transplant (10).

It's unfortunate that the current data on the number of donors and transplants in El Salvador, as well as a waiting list, couldn't be found through a search in MeSH, PUBMED, and Scielo. However, it is important to note that in the country, chronic kidney disease is the predominant condition that causes the most demand for organ transplantation. The Salvadoran Institute of Social Security (ISSS) began its live donor transplant program in 1985, and by 2022, more than 800 kidney transplants from live donors had been performed. Currently, there is no national database available that provides information on the overall situation regarding the need for organs or tissues and the number of transplants being performed in the different healthcare systems in the country.

The success of developed countries, such as the members of the European Union, lies in the fact that they have laws that promote organ donation and transplantation. In El Salvador, there is currently only one living donor law, which limits the availability of organs.

In 2022, the Legislative Assembly of El Salvador approved the new Law of Organ and Tissue Transplants, which includes the deceased donation process and the creation of the National Transplant Center. This new law will allow for an expansion in the number of available organs and tissues; however, the cultural beliefs and perspectives of the Salvadoran population on this matter should be taken into account. In addition to technical and legal aspects, it is important to consider an analysis of the basic principles of bioethics.

Autonomy

It is defined as a person's ability to make their own decisions without being forced to make one against their will. In the context of donation, this principle is crucial; it is essential to start from the premise that donation is a voluntary, altruistic act, and an individual decision. In order to donate, a person must physically document their willingness to donate their organs in the event of brain death, as deceased donor, or to participate as a living donor.

No one can coerce a potential donor or their family to donate. Current programs for organ allocation or distribution ensure that the donor and recipients remain anonymous, according to a list managed by individuals unrelated to the technical aspects of transplantation. If the patient is unable to state their willingness to be a donor, the family is responsible for making that decision unless the patient has explicitly stated their refusal to be a donor.

All organ donations must be free of charge. In the event that the donor has not stated their intention, the autonomy of the body is assumed by the family; this is a complex issue, because when a person is legally declared brain dead or deceased, the person would lose all their rights since they would cease to exist as an individual.

Due to the lack of sufficient organs to meet the need to save lives, several countries like Spain and Argentina have considered that every patient who arrives at the emergency unit is a potential donor, unless they have stated otherwise. The Spanish law states: «presumed consent» in which all Spanish citizens are potential donors as long as the deceased's family opinion is taken into account (11).

This law has generated an ethical dilemma regarding the autonomy of individuals; however, it prioritizes the well-being of the majority over that of the minority. The fundamental principle of this law is to increase the availability of organs, considering that a deceased donor can save up to seven lives through the donation of vital organs. Many transplant experts argue that this law undermines the right to autonomy and may be counterproductive in terms of decreasing voluntary donor offers. Moreover, they believe that this law entails a form of coercion (12). A syste-

matic analysis by Rithalia et al. determines that in countries with this type of «presumed consent» law, the donation rate was higher compared to those without it (13).

Another highly debated issue from an ethical standpoint, concerning autonomy, is the practice that China carried out until 2014, in which the principle of autonomy was virtually disregarded in death row prisoners, as their organs were procured for transplantation regardless of their willingness, clearly violating the principle of autonomy; however, due to international pressure, as of 2015, only inmates who express their willingness to be donors will be considered candidates for organ donation (14).

Beneficence

Beneficence is considered as those acts or decisions that are for the benefit of the individual. Again, part of what is dictated by the Hippocratic Oath can be observed in this principle when it mentions: «I will give no deadly medicine to anyone if asked, nor suggest any such counsel...» (1). This principle, before being proposed by Potter in the mid-70s of the last century, had already been considered in other codes of scientific research, such as the Declaration of Helsinki and the Belmont Report, which place the individual at the center of all research and where the priority is the well-being of the person as a research subject (15,16).

The main benefit of organ and tissue donation is to prolong or save the lives of those individuals who are facing terminal illness of a particular organ or system, such as liver failure or end-stage renal disease. It is quite challenging to define the principle of beneficence in the case of living donors since it is the only surgery in which an injury is caused to a healthy patient (organ extraction; for example, a kidney) who may suffer surgical complications and even death.

As a result, donation is considered an altruistic act. The principle of beneficence is clear for the recipient, as it will extend their life expectancy and improve their quality of life. On the other hand, this principle is non-existent for the deceased donor since they must be declared brain dead and have little, if not null, chance of recovery before being considered a deceased donor. The benefit that the living donor or the family of the deceased donor may perceive is psychological, that is, they feel that they did the right thing according to their beliefs. Similarly, for families who decide to give consent for their loved ones to be deceased donors, a potential benefit could be that they will not incur in medical expenses, and they may receive assistance with funeral arrangements and costs (13). Regarding the consideration of any type of financial benefit for any of the parties involved—living donors, families of deceased donors, or transplant teams—there is already an ethical code addressing this, the Declaration of Istanbul of 2018 (17).

The Istanbul Declaration was created in 2008 due to the imprudent practices that were being carried out in relation to organ donation and transplantation; it is estimated that up to 10% of transplants worldwide were unethical practices. Currently, this declaration is endorsed by more than 135 medical societies in the field of organ transplantation (17).

This declaration establishes that the benefits of transplantation should be maximized and shared equally among those who need them, without resorting to unethical practices. Therefore, it was proposed to provide an ethical guide for professionals and policymakers. In 2018, the Declaration was updated in response to new clinical, legal, and social developments (17).

Non-maleficence

This principle refers to not inflicting harm intentionally. Many apply the premise coined by Hippocrates «primum non nocere» in this principle (18). This ethical principle emphasizes that no study or activity involving a human being should cause more harm than benefit. When applied to organ and tissue transplantation, a reflection must be made on which patient will be benefited and who may be harmed. It is the origin of a great moral dilemma, as in the case of a living donor, it is difficult to justify putting the health and life of a healthy person at risk for the sake of someone who is ill. To mitigate this moral dilemma, institutions provide psychological support to reduce any sense of obligation or pressure that the donor may feel coming from the recipient's family.

In certain countries like Spain, advertising or solicitation of organ donations is prohibited to reduce potential harm, especially by avoiding incentives for public or economic recognition (19).

This principle is one of the most debated when it comes to donation: how can it be justified to harm a healthy person? One of the premises to consider the validity of transplants is that the survival rate after organ donation should be greater than 50% at 5 years.

Another sensitive point in organ and tissue donation and transplantation from a deceased donor is the diagnosis of brain death. The diagnosis of brain death should never be made solely to justify the use of organs for transplantation. In cases of individuals with severe and irreversible brain injuries, who do not meet brain death criteria, it is ethically questionable whether it is appropriate to place them on mechanical ventilation and circulatory support or consider them as potential donors.

There is a new concept that will be used in El Salvador and that is already used in countries that perform deceased donor transplantation: «brain death». The concept of cardiac or circulatory death is typically used when there is an absence of heartbeats; however, the concept of brain death is defined as «the irreversible cessation of all functions of the intracranial neurological structures» (23). This diagnosis must be made based on scientific data and by qualified individuals. Receiving a relative's diagnosis of brain death is a traumatic situation for a family, and the support of social workers and psychologists is required for the family to make the appropriate decision without compromising the previously established ethical principles.

Due to the recent approval of the law for deceased donors in El Salvador, it will be essential to assess how the population reacts to this diagnosis and the possibility of organ donation. It will be

necessary to create campaigns to raise awareness of the importance of donation and the concept of deceased donors and brain death, since there is a need to eliminate any possible notion from the country's culture that the diagnosis is made for the purpose of obtaining benefits from the organs.

Justice

Justice refers to the idea that all human beings have an innate dignity and should have equal opportunities. In medicine, the principle of justice is probably one of the most challenging to fulfill, as it often depends on the financial capacity of individuals and the country to ensure access to healthcare services. An individual who seeks care at a private institution receives a more personalized service and has access to more advanced technology than at a public institution. The failure to achieve justice is generally beyond the competence of healthcare personnel and is more related to the aforementioned economic limitations.

The demand for organs exceeds the available supply in every country worldwide. One of the most significant ethical dilemmas is how to distribute these organs; in other words, who has priority to receive an organ in order to survive. To facilitate this decision, a national organ system has been established to maintain an orderly list of transplant needs, especially when it comes to a deceased donor. This list aims to uphold the principle of justice by relying on scientific evidence and is based on classifications according to the degree of insufficiency of each organ. For instance, to allocate a liver to a patient with liver failure, the MELD (Model for End-Stage Liver Disease) classification is used, which implies that higher scores indicate a greater risk of death from liver failure within the next three to six months. Therefore, organs are allocated based on disease severity rather than the time a patient spends on the waiting list (24).

Similarly, different classifications and staging systems are used for various organs. In addition to these classifications to prioritize patients on waiting lists, the most advanced countries in the field of transplants have a system similar to the United Network of Organ Sharing (UNOS) in the United States of America, which was established in 1984 and oversees all transplant-related activities nationwide, including the coordination of the waiting lists and organ allocation (25).

To reduce potential injustice in organ and tissue donation and transplantation, the Declaration of Istanbul (2008) was created to prevent organ trafficking and injustice in organ allocation (16).

In El Salvador, there is only access to transplantation and donation from living donors, with kidney transplantation being the most frequently performed procedure in the country. The only institution with a solid and continuous transplant program in the country is the Salvadoran Institute of Social Security, primarily conducting kidney transplants. As of 2016, there was a waiting list of 52 people under evaluation to receive a donor kidney. However, there is no waiting list in the country for other diseases, so the establishment of these local committees and a national transplant system will face a challenging

task when initiating the process of deceased donors, not only due to technical aspects but also due to the need to educate the population about the importance of donation.

The Benjamín Bloom National Children's Hospital and the Rosales National Hospital occasionally perform kidney transplants, as immunosuppression is very costly and prioritization is necessary based on need and resources availability. With the new Organ Donation and Transplantation Law in El Salvador, it is expected that the number of transplants will increase in the country.

Various strategies have been devised to meet the demand for organs and tissues, address the ethical dilemma of justice, and increase organ availability. The "presumed consent" law promoted by countries like Spain has increased the availability of organs. Additionally, measures such as educating the population and healthcare workers, expanding donor criteria, providing benefits to the families of donors, and encouraging living donors are aimed at increasing the supply of organs, thereby enhancing the principle of justice (26).

As described earlier, the entire process of organ donation and transplantation involves multiple steps, including the introduction of the National Transplant Law, the National Transplant Council, local ethics committees, the creation of waiting lists, and the allocation of organs; it is undoubtedly a colossal endeavor, but not an impossible one. In addition to what was mentioned before, there is a campaign to raise awareness among the general population and healthcare workers about what the entire management entails. The main and probably the most difficult thing is not to break the principles of bioethics throughout the entire process.

A very important aspect in the country, apart from the ethical one, is the religious perspective regarding organ donation and transplantation, especially from deceased donors. Kobus et al. conducted a study evaluating the population's views on organ donation based on their religion and age; the study concluded that younger individuals were more in favor of deceased organ donation compared to those over 60 years old, furthermore, 96% of the participants agreed with organ donation, regardless of their religious beliefs (27).

Based on the results of the previous study, introducing and promoting a culture of donation in El Salvador should not be a problem, regardless of age and religion. It would be very useful to perform a survey and study in our country about the perception of organ donation and transplantation, evaluating the perspective of Salvadoran culture and society.

Conclusions

Organ and tissue donation, whether from living or deceased donors, has given rise to many bioethical dilemmas since the beginning of the transplant era. Throughout this medical era, efforts have been made to establish codes to uphold the principles of bioethics. From an ethical standpoint, there is not always complete agreement with the entire process of organ and tissue donation and transplantation. The shortage of organs to meet the demand has led to expanding donation criteria and seeking alternatives to increase donations worldwide.

The country lacks statistical data and centers that can perform the entire donation and transplantation process. With the newly approved law, it is expected that donations and transplants will increase. Various international studies have shown that by carrying out an adequate and supervised process, bioethical principles are not violated. In El Salvador, a careful selection must be made, according to the established norms and guidelines, to comply with all principles. Upon concluding that organ and tissue donation and transplantation are ethically accepted worldwide, all orientation and awareness protocols and activities must be implemented in order to educate the entire population and promote the acceptance of this practice, thus demonstrating that no ethical standards are violated. Models from more developed countries should be adopted to develop strategies that promote a culture of donation among the population, healthcare workers, and anyone who can influence the different communities in El Salvador.

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PROMOTING INTELLECTUAL PROPERTY AT THE EVANGELICAL UNIVERSITY OF EL SALVADOR

CATI-UEES
Centro de Apoyo a la Tecnología e Innovación
Universidad Evangélica de El Salvador

Introduction

Intellectual property has become an asset of great importance to foster innovation and protect intellectual creations. According to the Legislative Assembly of El Salvador in the «Law of Intellectual Property», Article 1 states that the provisions contained in this Law aim to ensure sufficient and effective protection of Intellectual Property, establishing the foundations that promote, foster, and protect it.

Intellectual Property encompasses literary, artistic, scientific, and industrial property (1). In this context, the Evangelical University of El Salvador relies on the Centro de Apoyo a la Tecnología e Innovación (Technology and Innovation Support Center) since 2022, which plays a fundamental role in the promotion and management of intellectual property.

What is the Technology and Innovation Support Center CATI-UEES

The Technology and Innovation Support Center CATI-UEES aims to provide advice to students, researchers and professors of the Evangelical University of El Salvador in identifying and protecting their innovations using the various figures of intellectual property..

What is Intellectual Property

Intellectual property (IP) refers to creations of the mind, such as inventions, literary and artistic works, symbols, names, and images used in commerce.

How IP is Classified

Intellectual property (IP) is classified into two categories: 1) Copyright and related rights, 2) Industrial property.

Copyright and Related Rights

What can be registered as copyright. Books, pamphlets, novels, short stories, writings, speeches, lectures, forensic reports, professorial explanations, and any other similar works. Musical compositions, with or without lyrics, as well as dramatic and dramatic-musical works. Projects, plans, models, and designs of architectural and engineering works. Computer programs. Sculptures and works of painting, drawing, engraving, lithography, and graphic comic strips, comics, as well as their drafts or sketches and other plastic works, whether applied or not. Graphics, maps, and designs related to topography, geography, and science in general. Photographic works and works expressed by a process analogous to photography.

1 Law of Fostering and Protection of Intellectual Property. (n.d.). WIPO Legislative Texts database of El Salvador's intellectual property legislation. https://wipolex-res.wipo.int/edocs/lexdocs/laws/es/sv/sv001es.pdff

Industrial Property

Industrial property is classified into:

1. Utility Models and Industrial Designs
2. Patents for Inventions
3. Trademarks
4. Trade Names
5. Commercial Advertising
6. Emblems

Why you should register your IP

1. To use it exclusively.
2. To commercialize goods and/or services.
3. To transfer it to others.
4. To protect it in a foreign country.
5. To have evidence to prove ownership to third parties.

Services offered by the CATI-UEES

The Evangelical University of El Salvador, through the Technology and Innovation Support Center, provides the following services:

1. Technical advice to students, researchers, faculty, staff, and the general public.
2. Assistance in Copyright Registration.
3. Assistance in Trademark Registration.
4. Assistance in registering Utility Models and Industrial Designs.
5. Assistance in registering Invention Patents.
6. Assistance in registering Trade Names.
7. Assistance in registering Commercial Advertising.
8. Assistance in registering Emblems.

Contact

For more information and to request services, please contact:

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