



# The balancing of organ donation and organ shortage is a mass mess

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## Abstract

The Earth is a gift for living beings in the universe. The systematic study of science and technology has led to several discoveries and innovations that helped to fulfil the desires of human life. The modern scientific development had celebrated the success of transplantation of human organs to the tune of imagination that only evolved in fictional stories. The study and contributions of human anatomy and techniques of surgery by the medical professionals has led to the concept of transplantation has a therapeutic measure and later biotechnological concept of immunology has drastically changed organ transplantation to a new level of success in tackling organ rejection. The concept of organ donation is a service to help the diseased that will allow the recipient to strengthen his life span with the support of donated organ and it's the first step of organ transplantation. The modern world had achieved all kinds of success to live up to the expectations in all the fields, but the organ shortage is an example of failure to understand the priorities of a welfare society. The collective efforts of organisations in regional and international law are lagging to tackle the illegal mass operators of organs that has created a mess around the world.

The study is focused on the legal challenges to cope with socio structural issues in organ donation and lacunas in procedural methods of organ transplantation that created a way for organ trafficking and the balancing business of foundations to address the shortage to fulfil the desired social cause to achieve public health and safety in the society.

## Introduction

A concept of surgical treatment to replace defective human tissue have invaded in the 6<sup>th</sup> century BC, which described carefully conducted plastic surgery. The surgical records from 600 BC contain accounts of plastic surgery, and the question of the use of tissue from the donors appear in surgical works of medical times. The advance of medicine revealed that disease might result from problems within a specific organ, rather than from a diffuse imbalance in body, physicians began to harbour wider ambitions for grafting damaged organs. The availability of anaesthesia and measures to combat infection in the 18<sup>th</sup> century made surgery even more promising. The surgeons realised in the mid-19<sup>th</sup> century that the body's rejection of grafted tissue was a form of immunity, they turned to bio medical scientists for help in understanding and dealing with this obstacle to transplantation. The combined efforts of surgeons and biologists in attempting to understand the bodies most complex and mysterious mechanism, to detect the tiniest deviation from its own structure.

The legal considerations played a major role about the concept of who owned the body of a deceased person. The grave robbing scandals of the early 18<sup>th</sup> century necessitated, and the corneal grafting became more widespread in 1950's. However, the law makers implemented changes to allow quicker acquisition of donated

tissues. In 1960's the kidney organ donation became possible which led legal changes and controversy in organ donation with rapid medical advances in the modern world. The transplantation issues were among the first group of ethical concerns that gained prominence in medicine. The religious beliefs had adverse influence on clinical practise, but a new cadre of bio chemist emerged, and increasingly the public became involved in medical decision making. The bio chemist soon began to debate such as equity and utility in the distribution of scarce donor organs, xeno grafts and stem cell use. The government and insurance providers had to acknowledge the realities of organ transplantation. The famous reported case "Bonner vs Moran" in 1940's a Washington surgeon R.E Moran, attempted the slave donor procedure attributed to Tegliacozzi in the 16<sup>th</sup> century. Moran joined a young boy to his badly burned but blood type compatible cousin using a pedicle skin flap. The graft failed, and serious complications and litigation followed. He case became celebrated in the Medico-Legal world but not because of deplorable surgery but for not obtaining proper permission from the young donor's family and this case established the necessity for informed consent for surgery particularly children.

A formal program for the donation of corneas after death was covered in old British Law the Anatomy Act of 1832. The laws regulating the organ transplantation are of having major task in balancing the organ shortage with protecting rights of the donors as such the developed countries have come up with liberal concepts to promote organ donation among the living donors to mobilize the recipients in harmonizing the situation with such public policy and awareness program that had lesson the burden of law making agency in understanding the need of living beings as such the people's approach towards donation is not a subject of conflict of interest between the donor and the recipient, it is an admiration of sacrifice in the human society.

### **Organ Donation**

The organ transplantation is acknowledged as ethical medicine and an enough supply of organs for transplant is a good to be fought for.

In UK the legal provision governing the medical and scientific uses of the dead human body have largely emanated from statue law in UK that is the human tissue act of 1961 for organ transplantation and the corneal grafting act 1952 for corneal transplantation. These statutes governed the removal and use of tissue and organs taken from deceased bodies. The changes in the law as regards presumed consent have been abandoned for the present in the UK, since the organ donation task force recommended that there be no change to the current opt in regime because among other things passing such legislation could back fire and produce an increase in the already higher rate of family refusals to donate the organs of their deceased relatives as such should focus on organisational arrangements with regard to organs procurement to increase organ donation the four principle developments summarised are:

1. Transplant coordinators
2. The Central office for support
3. Reimbursement
4. Closed attention paid to the media

In the United States culture is deeply steeped in individual rights, starting with the constitution and mirrored through the many laws, regulations and cultural norms that prioritise individual autonomy. A right based culture is well matched with the, UAGA legal framework requiring an affirmative, warranty decisions to make a gift under this opt-in policy, the nation experienced over 27% growth in deceased organ donors and transplants in the past 10 years and the measures favourably worldwide. Some areas of united states significantly exceed donation rate in Spain, which is widely regarded as the world leader.

The organ donation principle uniquely designed to support the system of transplantation in USA. Understanding how the laws are designed and operate in practise provides insight into organ donation practises and performances and illuminates how the law is utilised to drive the change in the field. The Uniform Anatomical Gift Act is a model legislation drafted by the Uniform Commissioners then passed into law state by state, the uniform commissioners are the body of law and policy experts appointed by the governors of each state to identify areas that would benefit from uniformity in nationwide but which cannot be federally regulated because they fall under the reserved powers of the state. The organ donation is one of those areas the experience and policy of the deceased organ donation should be consistent through the country regardless of what state you live or die. Because the matters of public health, contracts/gifting and a state or reserved power of the state to

regulate so too is organ donation, which involves components of each of those areas. Recognising the need for a single approach to organ donation policy the UAGA has been enacted in every state providing national consistency through state law. The UAGA establishes gift law as a central legal principle in the USA opt-in system of organ donation. Because the medical providers are trained in the central health law doctrine of informed consent, they are often surprised to learn that organ donation laws do not follow the same legal principle. Informed consent is the concept of permission granted by a patient for a particular treatment after a facilitated understanding of risks and benefits including available alternatives. The deceased donation however presents neither risks nor benefits to the donor because the donation occurs after death, moreover individuals provide permission for donation in advance of death making it unknowable what organs or tissue will be suitable to actually donate at the time of death for these reasons, informed consent has a legal structure is ill-suited for the regulation of organ donation. The Gift law requires three basic elements which are Donative Intent, transfer and acceptance. The fulfil of these elements results in a legally binding transfer of a gift from the donor to recipient. The donative intent under the UAGA can be fulfilled either by an adult before death or a surrogate (next of kin) at the time of donor's death. The UAGA does not incorporate an informed consent standard, donation professionals utilise the term "authorisation" vs "consent". Although both terms mean legal permission this distinction aligns the terminology with the underlying legal principle and individual authorises an autonomic gift whereas a patient provides informed consent for a medical treatment. Current legislation governs the removal, storage and use of corpses and parts of corpses for transplantation. In USA the donor registries have been successful with the annual growth for the past ten years and over 142 million registered donors as of January 2018, representing over 54% of the adult population. If an individual is registered there is a legally binding permission for donation at the time of donor's death and the family members do not have right to over right this decision.

### **Spanish Model**

Since the Spain has the highest rate of deceased organ donation in the world, it may be easy to assume that it is a direct consequence of presumed consent legislation. If the above legislation held the key to organ procurement success, then all the countries with similar legislation would be among the countries with the highest rate of organ donation and this is clearly not the case. This assumption fails to take into account any of the factors that makes this Spanish system so successful. The Spanish legislation which introduced the presumed consent for deceased organ donation way back in 1979 however the rate of deceased organ donation only started to raise after the Spanish National Transplant organisation was created in 1989. The key features of ONT which contributed to success include a national network of specifically trained, part time, dedicated and strongly motivated hospital physicians in direct charge of the whole process of donation. This impressive evolution in the result of set of measures of a organisational nature, which taken as Spanish model of organ donation they are the only set of initiatives that have proven effective in increasing deceased donor rates in a sustained way.

### **Law and Organ**

There are two pieces of legislation of organ transplantation, the law 30/1979 which deals with organ extraction and transplant and royal decree 2070/1999 which regulates the activities of procurement and clinical use of human organs and territorial coordination in matters of organ and tissue donation and transplantation. The decree is more specific focusing on organisational aspects and dealing with particular problems not addressed by the law, including diagnosis of death.

### **The basic principles of law 30/1979**

Article-1, the therapeutic purpose of transplantation. The purpose of substantially improving their life span or quality of life. The law states that the organs may be used for therapeutic or other scientific purposes on relation to deceased organ donation and such donation must be gratuitous, based on solidarity and altruism.

Article-2, States no compensation will be made for organ donation, anonymity shall be assured for both the donor and the recipient, the doctor in charge of the transplantation team must ensure that the recipient is fully aware of the nature of the intervention and of what a transplant involves, that they know about the possible risks and forcible advantages, both physical and physiological that may result from the transplant. The patient must also be informed that the necessary histocompatibility immunological test has been performed as between the donor

and the recipient in an authorised laboratory and if the recipient is minor or lacks mental capacity then consent must be signed by their parents or legal representatives. The organ retrieval must be only be carried out in authorised health care institutions. Finally, the law refers to the most important feature of its organisational model, facilities should be provided to create organisations at national and regional level and cooperation will be faster at an international level to ensure timely circulation of deceased organs for transplantation in order to find the most suitable recipient.

The royal decree flushes out the principles contained in law, as well as introducing to other important aspects of transplantation, namely education and promotion. It states that the health care authorities must provide information to general public about organ transplantation and the expected benefits for the patients. As regards promotion and publicity, the awareness campaigns must be general, and must highlight the voluntary, altruistic and disinterested nature of organ donation and transplantation. The publicity focusing on the need for any specific person to receive an organ is forbidden. In Spain only 7% of all renal transplant are from living donor. The ONT recently issued a statement that it aims to increase the level of living organ donation to at least 15% of all Kidney transplant in the next few years. One way to do this is through paired donations and the first paired donation was performed in June 2009 however living organ donors still face a number of socio economic difficulties in relation to organ donation, one of the concerns employment legislations, the risk of having difficulties at work and eligibility for insurance requires reformation or necessary changes in the policy to facilitate the organ donor. The article 4 of law and article 9 of royal decree states legal requirements for living organ donation, it is necessary for donor to consent otherwise the organ extraction would constitute a criminal act a punishable injury for which the health care professionals involved would also be disqualified from professional practise.

The valid consent organ donation requirements

1. The potential donors must be of legal age and have full mental capacity, the minor consent will not be valid, and parents are legal guardians may not consent to the removal of their children's organs and there should be no expectations.
2. Consent must be informed and in writing, the donors must be made aware of material risks of the intervention, as well as forcible consequence of the decision, both somatic and psychological, and possible repercussions on their personal, family and professional life as well as expected benefits for the recipients.
3. A medical evaluation is required to determine the donors or healthy persons and their health will not be endangered by organ donation. The organ shall be compatible with the donor's life and its functional capacity must not be substantially diminished. The examination will be made by a physician who is not involved in transplantation process. The regulation does not require a genetic link between donor and recipient.
4. 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. Before it considers a case, the committee will need to have access to medical reports on both donor and recipients, their consent and the transplant coordinator report. The ethics committee report ensures the process will be done with due respect to legal and ethical principles.
5. Certain legal formalities need to be complied that the potential living organ donor must give their consent anew before the judge in charge of the civil registry. The donor needs to be accompanied by three people who will also need to sign the organ donation consent document, the doctor who will carry the organ extraction, the doctor who explained the potential donor and issued medical report and the person who authorises the operation. Before the judge doctors will once again provide the relevant information and the document will be signed by all and the judge will authorise it. Once the consent given before the judge, operation to extract the organ may take place after 24hrs have lapsed in order to give final chance to revoke donors consent.

The Article 5 of law and Article 10 of royal decree deal with specific requirements necessary for deceased organ donation. The death clarification and the management of the potential organ donor has well as presumed consent requirement is focused in the above provisions. Diagnosis of death must be made before any organ extraction takes place and can be based on their irreversible cessation of cardiorespiratory function or 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 them must be neurologist or neurosurgeon and other is the head of the unit, where the patient is hospitalized. The physicians who involved in diagnosis of death cannot be involved in organ inspection or organ transplantation.

**Organisational Network:**

The transplantation procurement has been organised in three strong coordinated levels national, regional and local (In Hospital). The ONT is an autonomous health authority attached to Spanish ministry of health and social policy. It is responsible for organ promotion in charge of coordination and support covering the whole process of organ procurement allocation and transplantation. It manages waiting list and transplant registries, organises transportation, compiles statistics, ensures public awareness and provides information to general public and gives ongoing training and education for health professionals and manages media relations.

**Steps of process:**

1. Donor detection
2. Legal aspects
3. Family approach
4. Organisational aspects
5. Management of resource
6. Communication

At regional level *Co ordinador Autonomico De Trasplants* (CAT) works as a links between the in-hospital transplant coordinators at local level and the ONT, as well as with the other autonomous committees.

A third level of transplantation network in house transplant coordinators who play key role in identifying potential donors, approaching the families and managing the whole process of transplantation. The council of Europe issued a recommendation in 2005 which required that transplant coordinators be appointed in every hospital with an intensive care unit. The transplant coordinators are mainly physicians and receive support from nurses in hospitals and they are accountable to medical director of the hospital and not to the transplant team. The number of small hospitals involved in procurement of organs with such part time transplant coordinators has increased in Spain. The contribution these small hospitals make to an organ donation and transplantation activity is considerable. 40% of the diseased organs donors and detected and referred by these small hospitals. Several countries including Italy, Australia, Argentina and Uruguay have implemented the keyway of Spanish model.

A prerequisite of Spanish model is a national publicly funded health care system, which provides full coverage to the population, financial resources must be dedicated to transplantation, particularly in relation to hospital reimbursement for organ procurement and transplantation.

**Organ Shortage:**

The ethical and legal issues concerning organ donation and transplantation have been the subject of debate in many countries. Technological developments in the field have opened the possibility of transplanting an increasing number of human organs to those in need. The number of organs available for transplantation, however, has not kept pace with such developments. In UK the gap is widening between number of persons on the national waiting list for organs. In the end of financial year 2009-10 the persons national waiting list was 7,980 and approximately 1000 people are dying each year for want of a solid organ transplant. Not only transplant waiting times are increasing but rates of development of end stage organ failure and disease are continuing to increase among black and ethnic minority populations. Generally, decline in heart beating donation represents a major problem with regard to addressing the problem of organ shortage. The government in UK established an organ donation task force to maximise a range of options to address the problem, the report published in 2008 recommendations are:

1. Donor identification and referral.
2. Donor coordination
3. Organ retrieval arrangements.

The most important need to be clear political leadership and commitment to address the issue in order to achieve desired result. A clinical director for transplantation has been appointed to implement the task force, 14 recommendations relating to resourcing systems and infrastructural factors that the health care professionals involved gave failed sufficiently proactive in approaching the potential donors and their families and appropriate infrastructure and training in the field have been lacking in the terms of promoting organ donation. The

commission action plan is ambitious in its scope, there is a need to prioritise the implementation of efficient and effective organisational structures for achieving the objective of increased organ availability at national level, particularly through deceased organ donation.

The problem of supply shortage in transplantation medicine, which is usually referred as an organ shortage. A lot of money is being spent on advertising to encourage people sign a donor card a measure which is considered as helpful in increasing the number donor organs available for transplant. However, what both political as well as public do not realise is that not every donor card holder will become an actual donor. There is only a small group of patients who can donate vital organs, who die after a complete brain failure. According to a German foundation for organ transplantation there are approximately 2000 brain dead people in Germany per year, other study speaks up to 3000 to 4000 brain dead patients, yet measured against the number of patients who are waiting for organ (11,000 in Germany) and due to the fact that normally not every organ is transplantable. Most people believe that they could donate organs even after lying in the morgue for 1 or 2 days, off course this is not possible organs of a corpse are not transplantable as they would poison the recipient. The reason for false assumption is not only lack of information or ignorance. A rapidly growing demand for organs caused by the fact for an increasing number of diseases, organ transplantation is seen as the one best way of therapy. The lack of organs brought about by intrinsic problem of the transplantation system and not because of the lack of willingness to donate the organs. as such the raise in demand for organs results in morally questionable practise to obtain organs. Even though an unsolvable structural problem of transplantation medicine in its current shape exists, there is an enormous willingness for donation that outrages the inequalities to balance human life. The moral pressure on living and dying human beings to serve as an organ and tissue reserve will increase the negative consequences of organ shortage as well, we have sadly become familiar with organ trafficking.

#### **Drawing conclusions out of Dichotomies:**

1. In Spanish model the regulations are very imprecise about the exact nature of ethics committee report, weather it is binding or not and what exactly ethics committee is required to do as such it should analyse medical aspects of the transplantation (To see good chances of success) or whether it should instead or in addition consider the legal and ethical aspects. Since ethics committee does not generally issue binding reports but rather operate in a consulting capacity such report would generally not be binding.
2. The difficulties to improve donation and transplantation activity encountered in Latin America, such as lack of public health financial coverage for the entire population in many countries.
3. The conflicting provisions of law and practise in deciding brain stem death and the concept of consent deciding factor had posed hurdles to organ donation and the transparency in the system is a serious concern in implementing the transplantation surgery.
4. The accountability of hospitals getting license for organ donation and transplantation and the hospitals have to share their data about the short and long term outcomes of transplantations and the facilities provided for such transplantation has to be monitored and an awareness programs have to be conducted to motivate the health workers to serve the cause with at most dedication.
5. There is a need for change in regulatory policy of insurance coverage and reimbursement to recipients to bear the pre and post-operative expenses and or such other tax relaxations to uplift them and to promote the cause within the society to create community awareness.
6. There is need for advanced scientific tests that reduces the burden of waiting list of recipients to get threptic treatments that can avoid and look for alternative options for healing the disease of the recipient.
7. There is a need that the international organisations or foundations should work to build a platform to establish cooperation among the nations to serve the cause for saving life of an individual by providing financial assistance and a systematic organisation to achieve the goals of saving human life in competing world environment.
8. The United Nations Organisation (UN) should take a lead to collaborate with the countries in neutralising commercialisation of life saving medicine and biotechnology to cultivate the unity by formulating new guidelines for organ transplantation and to establish a unilateral body of experts committee in therapeutic practise and they have to cooperate with other bodies or boards created by regional or national functionalities to serve the purpose of organ donation in mobilizing all available resources to upliftment of human being.
9. There is a need that a globally connected web networking platform to be created with updated information and current statistics for the world organ donors and recipients directory or data are made available for information

and awareness that also communicates between the functionalities who are between the donor and recipients and such other donation related information's available for research and education purpose.

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