

# Comparative Analysis of Organ Transplantation

<sup>1</sup>solanki R.S,<sup>2</sup> Akshaya Desai

Address:

Author 1: Banasthali University, Banasthali, Rajasthan– 304022

\*Author 2: Amity University Mumbai, Mumbai - Pune Expressway, Bhatan Post - Somathne,  
Panvel, Mumbai, Maharashtra 410206

## Abstract:

Organ transplantation refers to a medical process whereby one person's organ is removed and transplanted to another person. This requires the consent of the donor in case he is alive and requires the assent of the next of kin in case the donor is dead. In most cases, the end state organ failure's only treatment is organ transplantation. Although its types include heart, lung, liver, pancreas, cornea, skin, and other transplants, the most carried out transplant is kidney transplantation globally.

## Research Methodology:

The research method adopted for this study is, Secondary Method, i.e., collecting data from existing resources. For comparative analysis of legislations, Government published data of various countries have been observed. Governments generally publishes a prodigious range of data online so that can be utilised for research purposes. This data is related to financial, social, and economic aspects. The Government websites are mostly free to access and contains most protuberant information of that country. Thus, this could be an effective method gathering the information.

## Objectives of the research:

1. Analyze the provisions of organ transplantation in various countries.
2. Identify if The Transplantation of Human Organ Act has been successful to achieve Right to Life across the globe?

This research compares legislations across 15 countries related to organ transplantation and compares it for finding the Right to Life component in it thereby.

## Introduction:

A human deceased-donor transplant was performed in the 1930s by the Ukrainian surgeon Yurii Voronoy and this was the first ever attempt of such-a-kind transplant.

Nowadays, due to the success in surgeries resulting from advances in medicine have made organ transplantations a frequent event. Yet, organ donations and transplantations adapt the particular experience of human beings related to the image they have of themselves, of body, life and death. If the apprehension of the superiority of life and the s endurance of the patients is a totally human phenomenon, the fact stays that the option of organ transplantation and its explanation rest on a great deal on the culture in which we live. The examination of the customs and tradition allows for a review of organ transplantation. All those philosophical

experiences strengthen questionings on the true sense of life with regards to self-fulfilment.

Following is the comparison of organ transplantation Laws across the countries.

## **Iran**

Organ transplantation in Iran began from a kidney transplant. At the first due to religious reasons, kidney transplant donors were limited only to living donor transplant. In the year, 1989, a fatwa (religious approval) was obtained from the Supreme Religious Leader which allowed the deceased donor organ transplant.<sup>i</sup>In the year 2000, the Brain Death and Organ Transplantation Act was passed. The act regulated that all the organ transplantation be performed only in University Hospitals approved by the Ministry of Health. A written consent from the first-degree relatives is required. Moreover, brain death is to be diagnosed and certified by 5 specialists appointed by the Ministry of Health and not members of the transplant team, including a neurologist, neurosurgeon, internal medicine specialist, anaesthesiologist, and forensic medicine specialist. By the end of 2018, there were 48,711 kidney transplants in Iran (which included 12,152 deceased donor organ transplants), 8,804 liver transplants (includes 5,918 deceased donor transplants). The deceased kidney donation transplant in Iran was 0.4 PMP (Per Million Population) stand at 15.18 at the end of year 2018. Same is the case with Liver transplantation which stood at 0.1 in the year 2000, now stands at 9.30. <sup>ii</sup>Since Iran uses opt-in system of organ donation wherein one has to actively sign up to donate the organs. And, if the donor has not obtained an organ donation card, the family with its consent can allow the organ to be removed from the brain-dead deceased.

One very different and unique practise which is only followed in Iran is that of legalizing the sale and purchase of kidney for renal transplant. Iran is the only country in the world where it is legal to buy kidney. Before 1988, a lot of people from Iran used to travel to India to get a renal transplant. In 1988, Iran legalized living non-related donation (LNRD) of kidneys and established an associated transplantation system. This government-organized system regulated and funded the transplantation process and compensated the donors for their organ. A third-party independent association was set up to arrange contact between donors and recipients. This agency, the Dialysis and Transplant Patients Association (DTPA), still carries out this function to this day and is staffed on a voluntary basis by end-stage renal failure patients.<sup>iii</sup>A person in need of kidney is referred to the DTPA. If someone is unable to afford and pay for the renal transplantation, the charitable organization play an active role and help these poor people. The government also pays the donor an amount. In addition to payment from the government, donors also receive free health insurance and often payment from the recipient or a charity. The receiver of the 'new' kidney is provided with highly subsidized immunosuppression and charitable organizations allow those unable to pay for the transplant themselves to receive a new organ. Importantly, it is illegal for the medical and surgical teams involved or any 'middleman' to receive payment.<sup>iv</sup>This has in turn resulted into people not travelling abroad for transplant tourism and elimination of illegal and commercial transplants. Following this a lot of people visited Iran for transplant tourism. Later a regulation was passed which restricted foreigners to transplant kidneys in Iran.

## **The USA**

The primary law which governs organ transplantation in USA is Uniform Anatomical Gift Act (UAGA). The UAGA is a model legislation drafted by the Uniform Commissioners that is then passed into law state by state. The Uniform Commissioners are a body of law and policy experts appointed by the governors of each state to identify areas that would benefit from uniformity nationwide but which cannot be federally regulated because they fall under the reserved powers of the state.<sup>v</sup>The core principle of UAGA is the Gift law principle. The system of donation is opt-in system. The UAGA relies on gift law principle over the informed consent as it is ill suited for the organ donation regulation. The principle of informed consent relies on understanding risks and benefits and available alternatives. Since there is not risk to the donor after donation as donation occurs after death, the principle of gift law seems more suitable and hence is used. Moreover, the gift principle ensures that the organ transplantation is voluntary and not done in exchange for any monetary consideration. Contract law requires a mandatory consideration which in this case would not fulfil the purpose, while the gift law would. This complies with the federal law (National Organ Transplant Act (NOTA)) which prohibits the sale of organs.

The UAGA permits an adult of sound mind to donate any specific body part or all of them upon his death. To do so, he has to express in writing his consent on a declaration with his signature.<sup>vi</sup>If there is no declaration as to donation prior to death, the next of kin can decide to donate the organs of the deceased.

The (National Organ Transplant Act 1984, regulated the recovery and allocation of organs in the USA. The NOTA being a federal law, is applicable to all the states. The aim of the NOTA is to facilitate the organ donation and ensure the equitable allocation of donor organs. NOTA bans the sale of organs and punishes the same with a 5-year jail and \$50,000 fine. NOTA authorised the Depart of Health and Human Sciences to establish a nationwide Organ Procurement and Transplantation Network (OPTN) to coordinate the donation and transplantation system and process. The function of the OPTN is to maintain the nationwide register of organs transplants, the waitlisted organ transplant candidates, allocation of donor organs to the waitlisted candidates, sets policy for organ allocation and quality standard for organ extraction.<sup>vii</sup> The organ allocation has to be done on the basis of urgency of the organ. The OPTN is run by a non-profit private organisation, The United Network for Organ Sharing (UNOS)

Organ Procurement Organisations have been setup by NOTA. The function of the OPOs is to increase the number of registered deceased organ donors and, when those donors become available, to coordinate the donation process from donor to patient. The potential organ donors are to be reported by the hospital to the OPOs

## **U.K.**

The current organ transplantation laws in UK have originated from the Human Tissue Act 1961 and the Corneal Grafting Act 1952. These statues governed the removal of organs and

tissues and their use. The Human Tissue Act 2004 applicable to England, Wales, and Northern Ireland and the Human Tissue (Scotland) 2006 applicable to Scotland. These laws cover the aspects of removal, storage and transplantation of organs and the use of corpses. While the Human Tissue Act of 2004 allows organ transplantation from live and deceased donor, the Scotland Human Tissue Act of 2006 does not allow donations from a living donor and constitutes such act of transplantation as a punishable offence.<sup>viii</sup>

The consent for organ donation in UK can be written as well as oral. The consent has to be given by the deceased before his or her death. A third party, who can be from his family relative or friend can also give a consent. The UK law does not require for appropriate consent if the in some way or the other the consent in writing mention about the organs to be used for transplantation. The Scotland law also accepts written and oral consent to organ donation. The Scotland law further goes on to say that when a person has consented a donation, no one is legally empowered to override and if one has not consented, it is the duty of the clinicians to ensure that the organ donation does not take place. This thereby tells us that the UK uses the Opt-in system of organ donation.

If during the lifetime of the deceased person had not stated his intent to donate organs, a nominated representative can be allowed to take decisions in the regard appointed.<sup>ix</sup> While in Scotland, the decision is to be made by the qualifying relative (nearest relative). Highest class of listed relative available is to take the decision. Only the consent of one person in such a class is required by law.<sup>x</sup>

Minors who possess decision making capacity are allowed to take decisions for themselves. In case of death of the minor the decision is to be made by the person who has the parental responsibility at the time of death.<sup>xi</sup> A child above the age of 12 can donate his organ in Scotland, if the same is authorized and certified in writing. In case of death of the child, the person with parental rights can take the decisions and also take decision if the age of the child is less 12.<sup>xii</sup>

Licence is required to perform an organ transplant as per the section 16 of the HTA 2004. Section 32 provides for prohibition on buying and selling of organs. Advertising for suppliers of material for reward is also prohibited under this section.

Section 33 of the HTA 2004 makes it an offence to remove and transplant an organ from the living person unless it satisfies the circumstances mentioned. The circumstances include where the HTA is satisfied that no reward has been given in relation to the transplant.

While applying for a driving licence in UK, a question is asked in regard to organ donation. If one does not answer the question or ignores it, the application remains incomplete and they are not able to continue with the application. There are three options provided on the organ donation, the options are as follows:

- i) Yes, I would like to register;
- ii) I do not wish to answer this question now;
- iii) I am already registered on the NHS Organ Donor Register. In short, if the

question is not answered, the person applying for licence does not get the licence unless the question has been answered.<sup>xiii</sup>

The Organ donation law in UK is soon to change from opt-in system to the opt-out system. The law is being changed to save and improve lives as someone or the other dies every day in the UK. The new law will be coming into effect from the 20<sup>th</sup> of May 2020.<sup>xiv</sup>

## **Australia**

In Australia organ and tissue donation is governed by the ‘Human Tissue Act 1982’ in each Australian State and Territory. These Acts are very similar in each jurisdiction, and create different legal frameworks for living and deceased tissue donation.

Organ and tissue donation is also governed by guidelines issued by the National Health and Medical Research Council (NHMRC) which outline ethical standards for donation, and their implications for clinical practice.

Brain death is accepted form of death in the Australian law.

The Ethical Practice Guidelines outline principles for organ donation and transplantation. The principles emphasise:

- that donation of organs and tissues is an act of altruism and human solidarity;
- organs and tissues for transplantation should be obtained in ways that respect human dignity, respect the wishes of the deceased, and give precedence to the potential donors and family’s needs over the interest of organ procurement; and
- that the choice not to donate should be respected and the family shown understanding for their decision.<sup>xv</sup>

The Human Tissue Acts provide a priority list of family members who may be the senior available next of kin consulted about tissue removal. If the first person is not available, then the next person on the list must be approached.

Where the deceased donor is an adult (i.e., a person aged over 18 years), the priority order is the same in each State and Territory:

- Spouse or de facto, domestic or same sex partner
- Adult son or daughter
- Parent
- Brother or sister.

Where a **deceased donor is a child**, the priority order (in all States except Western Australia and Queensland) is:

- Parent

- Adult brother or sister
- The child's guardian.

In Queensland and Western Australia a child's domestic partner or spouse will be given priority over a parent, sibling or guardian (however, in Western Australia the spouse or de facto partner must have attained the age of 18).

'Parent' is defined differently in some States. For example, the New South Wales definition includes biological parent, step-parent or adoptive parent. In South Australia parent includes 'the guardian of the child'. The Australian Capital Territory, Tasmania, Victoria and Western Australia Acts specifically exclude from the definition of parent a guardian or anyone else in loco parentis. In Queensland a parent includes a person who under Aboriginal tradition or Island custom, or other cultural traditions, is considered a parent of the child.

## Israel

Israel is the only Jewish majority and explicitly Jewish state. This is mentioned because of the fact that people practising this religion were sceptical to the idea of organ donation and transplant. Israel's organ transplant and brain death law, the Israel Transplant Law: Organ Transplant Act, 2008 and Cerebral-Respiratory Death Act, 2008, was passed and came into force in the year 2010. The Organ Transplant and Brain-Respiratory Death Law responded to three major challenges to organ procurement in Israel:

- Confusion regarding determination of death,
- Organ trafficking and unethical transplant tourism, and
- The critical dearth of transplantable organs both live and cadaveric.<sup>xvi</sup>

The 2008 act defined brain death, with its intention to strengthen brain death determination to satisfy both medical and religious needs. There is an autonomy provided to the family members on testing of brain death. Many of the families refuse the brain death test and hence only a few brain deaths detected and therefore lower organ availability and transplantation. Three degrees of priorities are mentioned in the act, as follows,

- 1) Maximum priority is extended to patients who have a first-degree family member who was a cadaveric donor, or have themselves previously been live donors. Maximum priority takes immediate effect with no waiting period.
- 2) Regular priority rewards registered donors of at least 3 years, although this waiting period was initially waived to encourage greater public participation when it was first introduced in 2011. Priority points act as a tie breaker by giving an advantage to consented donors over non-donors in cases of similar medical need.
- 3) Second priority awards a small number of points to individuals with first-degree relatives who are registered as an organ donor.<sup>xvii</sup>

For every organ, i.e., heart, lung, liver and kidney there is a specific criteria defined for the priority allocation of organs. The first one being common in all is the 'Medical Emergency'.

While the other criteria differ from organ to organ.<sup>xviii</sup>

Israel maintains one single national waiting list containing the data of patients awaiting the transplants.

### **South Africa**

The National Health Act of 2003 regulates the organ donation and transplantations in South Africa. Chapter 8 of this act specifically deals with the organ donation and transplantation. A person above the age of 18 years can donate organs if he has provided in writing. If the person is below the age of 18 years, then the parents or the guardians must provide the same. The act does not speak about consent in regard to living donors.<sup>xix</sup> Persons younger than 18 years may not donate tissue that is not replaceable by natural processes, nor may they donate gametes. No part can be removed or donated by a mentally ill person.<sup>xx</sup> Though the act does not mention anything about the donation of organs and tissues from a living person, these regulations cover up the ambiguity. Moreover, it is also an offence to receive any financial consideration in exchange of donation of blood, organs tissues or gametes.<sup>xxi</sup> A person convicted of either of these offences may be fined or imprisoned for up to 5 years or both.<sup>xxii</sup>

However, the Act allows a health care provider registered with a statutory health professional council to receive remuneration for any professional service rendered.<sup>xxiii</sup> For transplantation of an organ into a person who is not a South African citizen or a permanent resident, a permission from the Cabinet Minister responsible for health.<sup>xxiv</sup> If any person does the transplant without the permission, then there is a punishment of fine or 5-year jail or both<sup>xxv</sup>.

Section 62 (1) of the National Health Act 2003 provides persons who are competent to donate organs. It says that any person who is capable of making a will can donate his or her organs through, will, a document signed by him with at least two competent witnesses, or an oral statement made in presence of two competent witnesses.<sup>xxvi</sup> As per the Section 1 of the Wills act of South Africa, any person above the age of 16 is competent to make a will. Moreover, if a person does not nominate any person or institution to receive the organs, the donations stand null and void.<sup>xxvii</sup> If the legally empowered person who can take a decision on the behalf of the deceased, is nowhere to be found then the Director-General of Health may donate any specific tissue of that person to an institution or a person, provided all the 'prescribed steps' have been taken to locate the person authorised to give consent.<sup>xxviii</sup>

Section 65 provides for the revocation of the donation. The section goes as, 'A donor may, prior transplantation of the relevant organ into the donee, revoke the donation in the same way in which it was made. In the case of donation by a will or other document, revocation may be by the intentional destruction of such will or document by the person making it.' Any sort of publication about removal and donation of organs from living and deceased donors without prior permission of the donors, is strictly prohibited.

Allocation of organs is done on a points awards basis. Patients are allocated points according to the following criteria:

- Time on the waiting list
- Age
- Previous transplants
- Sensitization
- Other medical issues, e.g. A lack of vascular access on dialysis.<sup>xxix</sup>

## **Spain**

Spain is regarded as the world leader in organ donation and transplantation. They have developed their own model which have then been adopted and incorporated by many countries as per their demographics. The Spanish law 30/1979 about “Organ Procurement and Transplantation” is a law of presumed consent, where it is explicitly indicated that “organ procurement from deceased donors with therapeutic or scientific purposes could be performed if the patient did not express refusal previously”.<sup>xxx</sup> Spain was the first country to implement the opt-out system of organ donation.

The Spanish National Transplant Organization, Organización Nacional de Trasplantes (ONT) established in 1989, is the technical coordinating institution that belongs to the Spanish Ministry of Health, Social Services and Equity. The ONT coordinates donations and transplantations performed on a national scale, assuring the best use of cells, tissues and organs in accordance to the principles of cooperation, efficacy and solidarity. Its main objective is to promote altruistic donations with the sole goal that each Spanish citizen who needs a transplant will have the best chance to obtain it.

Donation activities in Spain are coordinated at three different levels; at a national level (ONT), 17 autonomous regional coordinators and at the hospital level. The ONT and regional coordinators provide the link between policy and technical processes and all national policy initiatives require inter-regional consensus. At the hospital level, each procurement hospital is directly in charge of developing an effective donation process.<sup>xxxi</sup>

Since 1992, Spain has maintained the world record for PMP organ donors. In 2019, the rate was 48.90 PMP, totalling 2,301 donations and 5,801 transplanted organs, an average of 6.3 donations and 15 daily transplants.

Among the factors that contributed to the success of the Spanish model were the central role attributed to the transplant coordinator and the concern with training to communicate “bad news” and to convince the family of the importance of authorizing the donation. Since its inception, ONT has trained more than 18,000 coordinators.<sup>xxxii</sup>

## **Brazil**

Brazil had passed Presumed Organ Donation Law which made every citizen an organ donor after death, unless there was a personal documented against donation. In October next year, the law was abolished. The new provides that authorisation by the person, or his first or second degree relative should be provided or else organ donation is not possible.<sup>xxxiii</sup>



The Brazilian Association of Organ Transplantation, regulates the organ transplant law in the country. As per the Article 4 of the ABTO, the aim of the organisations are as follows,

- Promote and stimulate the development of every activity related to the organ and tissue transplantation;
- Congregate professionals and entities involved or interested in organ and tissue transplantations;
- Contribute to establish the rules and create and improve the due legislation for organ and tissue transplantation
- Stimulate organ and tissue donation, offer technical and logistic support for the organization and functioning of centres where notification, harvesting and distribution of organs and tissues are performed;
- Stimulate the research and collaborate to spread knowledge on organ and tissue transplantation;
- Promote the accomplishment of congresses, symposiums, lectures and other activities related to organ and tissue transplantation;
- Spread to the general public the available knowledge resources, always respecting the professional ethics and the humanitarian, scientific, and moral meaning of the organ and tissue donation for transplantation;
- Stimulate the exchange between similar entities.
- Promote the accomplishment of educational, sportive and cultural events related to transplanted patients, donors and their relatives.<sup>xxxiv</sup>

Procurement, donation, and transplantation is coordinated, supervised, and stimulated by the National Transplantation System. The centres are not geographically distributed according to a strict planning framework. Organ procurement, retrieval of organs, and 95% of all LTs are financed by the Brazilian Public Unified Health System. Free and open access is granted to Brazilian nationals and foreign citizens with a permanent residency visa. As per the data provided by the ABTO, Brazil stands second among all the countries with regard to the number of transplants performed.<sup>xxxv</sup>

In Brazil, more than 90% of transplants are funded by the Sistema Único de Saúde – Unified Health System (SUS)<sup>xxxvi</sup>. In 2017, this rate was 98% for kidney and pancreas transplants, 96% for heart and kidney, 95% for liver, 93% for lung and 90% for pancreas transplants. Since 2008, the budget for this type of surgery has more than doubled, from R\$ 453.3 million to R\$ 942.2 million in 2016.

Brain death is an accepted criterion in Brazil for organ donation. But the lack of knowledge among the masses about the concept of brain death and the fact that it is irreversible prevents a lot of potential organs from donation.

## **Singapore**

Singapore is the first commonwealth country to enact a presumed consent (opt-in system) of organ donation. If one read the act related to organ transplant and donation, it is a very

noticeable feature that the acts are very short but extremely well defined. The inclusion of legislative history at the end of the act makes it easier to understand how the act has evolved through the years.

Singapore enacted the Medical (Therapy, Education and Research) Act (MTERA) In 1972. This was the first legislation in the country which dealt with the use of the bodies of deceased persons or parts thereof for purposes of medical or dental education, research, advancement of medical or dental science, therapy and transplantation, and for other purposes connected therewith. It did not enact the principle of presumed consent. Human Organ Transplant Act in the year 1987, was enacted to removal of organs for transplantation, for the prohibition of trading in organs and blood, and for purposes connected therewith. The HOTA's core principle is that of the presumed consent i.e., the opt –out system of organ donation. HOTA deals with recovery and removal of specific organs like, the kidney, liver, heart and cornea.<sup>xxxvii</sup> HOTA covers all Singapore Citizens and Permanent Residents 21 years old and above, who are not mentally disordered, unless they have opted out.<sup>xxxviii</sup> MTERA relies on the concept of out-in system where one can donate his organs or tissues to be used for transplant, education or research purposes after his death. MTERA legislation uses the word gift, which also signifies that there is no presumed consent in regard to the organs covered by the MTERA. Under MTERA, a gift of all or any part of a body under section 3 may be made by the donor either in writing at any time or orally in the presence of 2 or more witnesses during a last illness.<sup>xxxix</sup>

Moreover, under section 12 of the HOTA, which is about the proposed recipient of the organ. The section mentions that if a person has opted out from the organ donation, then he will receive a less priority when he requires an organ transplant.<sup>xl</sup> The objection to removal of organs can be registered under the section 9 to the Director of Medical Services.

Organ donation and transplant for monetary consideration is a punishable offence under this law with a maximum fine of \$10,000 or maximum imprisonment of 12 months or both.<sup>xli</sup> The degree of punishment is more when such valuable consideration is provided for removal of organs from the body of another person. In case of removal of organs from the body of another person, the person who offers, the person who receives the consideration and the middleman or any other party involved can be punished with a maximum fine of \$100,000 or maximum imprisonment of 10 years or both.<sup>xlii</sup>

A few highlights with some differences between HOTA and MTERA are as follows,

|                     | HOTA  | MTERA  |
|---------------------|---|--|
| Inclusion           | All Singapore Citizens & Permanent Residents (excludes mentally challenged) | No nationality requirement, anyone can donate. <sup>xliii</sup> (excludes mentally challenged) |
| Age limit (minimum) | 21 years  | 18 years <sup>xliv</sup>   |

|         |  |   |
|---------|--|---|
| Purpose | Provide patients with organ failure with a suitable donor organ, for the purpose of transplantation only | Transplantation, medical education, medical research <sup>xlv</sup> |
| Consent | Presumed (opt-out)   | Opt-in (pledge organs)  |

The HTOA was amended to include the removal of organs from non-accidental deaths i.e. in other way the brain death. Brain death definition is similar to those used in countries such as Australia, Canada, Denmark, the United Kingdom and the United States of America.

A living donation can occur when the donor has provided his consent to do so, and the same is approved by transplant ethic committee. Transplant ethics committee ensure that the consent has been obtained, the person is not mentally challenged and there is no organ commerce involved or the consent has not been obtained by fraud or undue influence. Violation of these rules attracts a punishment of maximum fine of \$10,000 or maximum imprisonment of 12 months or both.<sup>xlvi</sup>

### China

China was widely known for the practise of removal of organs from the executed prisoners for the purpose of organ transplantation. But still the organ donation system lagged way behind the world system. The organs were removed from the executed prisoners without the consent of their family. This practise was followed till 2014. From January 1, 2015 this practise has been stopped. Hangzhou Resolution was signed by the hospitals to stop the use of organs of executed prisoners.

The Regulations on Human Organ Transplantation was issued in 2007, Amendment (VIII) to the Criminal Law of the People’s Republic of China was issued by the Supreme People’s Court in 2011 criminalizing trafficking of human organs, and Interim Provisions on Human Organ Procurement and Allocation was issued by National Health and Family Planning Commission in 2013.<sup>xlvi</sup>

The new system is transparent, impartial and fair in nature. The system is administered by the National Health and Family Planning Commission of the PRC with the help of Red Cross Society of China. They established National Organ Donation and Transplantation Committee which consists of five administration branches: organ donation, organ procurement and distribution, the medical system for organ transplantation, organ registration after transplantation and organ transplantation supervision.<sup>xlvi</sup> In the new system, the organs from the prisoners can be taken, but now without their consent. In 2010, a pilot organ donation program was introduced in China which evolved into a national program and distribution system - the China Organ Transplant Response System (COTRS) in 2013.<sup>xlvi</sup>

Organ trade of valuable consideration is an offence in the PRC.<sup>1</sup>As per the Regulations on

Human Organ Transplantation 2007, China follows opt-in system wherein the person who intending to donate has to provide in writing his consent to donate his organs.<sup>li</sup>The minimum age for living organ donation is 18 years.<sup>lii</sup>A living donor can donate organs only to the donor's spouse, lineal relatives, collateral relatives by blood up to the third degree of kinship, and a person for whom there is evidence to prove that he has developed a kinship with the donor due to his supporting or other reasons.<sup>liii</sup>In case of living organ donation to other person who is not in relation, a clinical committee is set up which checks about the consent and if there is any organ trade involved.<sup>liv</sup>Majority countries across the world include transplantation of organs as well as tissue, but China on the other hand is an exception to this. Regulations on Human Organ Transplantation 2007, allows only organs to be donated, the tissues like cornea, bone marrow or human cells cannot be donated.

Generally, the countries across the world follow two definitions of death, the brain death and the cardiac death. China has classified deaths into three categories. The first one being the global accepted definition of brain death. The second category being the cardiac death. The third category which is china exclusive is brain death awaiting cardiac death. Since the brain death law has not yet been established, and family members cannot accept donations of organs under cardiac beating, donations should be made according to the DCD procedure, that is, life support should be removed, and donations should be made after cardiac arrest. The C-III is in line with China National conditions.<sup>lvivi</sup>

### COMPARISON CHART OF COUNTRIES

| Country   | Legislation                                     | Consent system  | Determination of death of donor    | Type of Donor  | Other Special features   | Sale of Organs               |
|-----------|---|---|------------------------------------|--|--|------------------------------|
| Australia | Human Tissue Act 1982                           | Opt-in / Consent of Family  | Brain Death & Cardiac Death        | Live donations from and to related and non-related         | Organ Allocation System  | Illegal & punishable offence |
| Brazil    |   | Opt-in / Consent of Family (1 <sup>st</sup> & 2 <sup>nd</sup> degree) | Brain Death & Cardiac Death        | Live donations from and to related and non-related         | Organ transplants funded by the Unified Health System (SUS)    | Illegal & punishable offence |
| China     | Regulations on Human Organ Transplantation 2007 | Opt-in / Consent of Family  | Brain death awaiting cardiac death | Live donation from relatives or emotionally related donors | Only transplantation of organs is allowed, no tissues or cells | Illegal & punishable offence |
| India     | Transplantation of Human Organs Act, 1994       | Opt-in / Consent of Family  | Brain Death & Cardiac death        | Live donation from “near relatives” and un-related donors  |  | Illegal & punishable offence |

|          |   |                            |                             |   |  |                              |
|----------|---|----------------------------|-----------------------------|---|--|------------------------------|
| Iran     | Organ Transplantation and Brain Death Act, 2000   | Opt-in / Consent of Family | Brain Death & Cardiac Death | Live donation is a regulated paid donor system or a monetary gift as a “token of appreciation” by central govt. | Organ trade is legal   | Legal                        |
| Israel   | The Israel Transplant Law - Organ Transplant Act, 2008 and cerebral-Respiratory Death Act, 2008 | Opt-in / Consent of Family | Brain Death & Cardiac Death | Live donations from and to related and non-related  | Autonomy of brain death test in hand of family<br><br>First priority to one who has pledged to donate organs | Illegal & punishable offence |
| Japan    | Organ Transplant Act 2010   | Opt-in / Consent of Family | Brain Death & Cardiac Death | Live donations from and to related and non-related  | Donor can choose his definition of death   | Illegal & punishable offence |
| Pakistan | The Transplantation of Human Organs and Tissues Act, 2009                                       | Opt-in / Consent of Family | Brain Death & Cardiac Death | Live donations from close blood relative and non-close blood relative   |  | Illegal & punishable offence |

|              |   |  |                             |  |   |                              |
|--------------|---|--|-----------------------------|--|---|------------------------------|
| Singapore    | Human Organ Transplant Act, 2009 (HOTA) and Medical (Therapy, Education and Research) Act | Opt out for 4 organs (kidney, liver, heart and cornea); Opt in for any organ or tissue not covered by HOTA | Brain Death & Cardiac Death | Live donations from and to related and non-related                                 | Organ Allocation System<br><br>Low priority to opted out citizen                                      | Illegal & punishable offence |
| South Africa | National Health Act 2003  | Opt-in / Consent of Family   | Brain Death & Cardiac Death | Live donation to related; unclear on non-related.                                  | Point system allocation of organs.  | Illegal & punishable offence |
| South Korea  | The Organ Transplantation Act 2000  | Opt-in / Consent of Family   | Brain Death & Cardiac Death | Live donations from and to related and non-related                                 | Priority system   | Illegal & punishable offence |
| Spain        | Transplantation Law 1979  | Opt-out/ presumed consent  | Brain Death & Cardiac Death | Live donation with voluntary consent from relatives or emotionally related donors. | First Country to have opt-out system<br>Highest deceased donor per million population since 25 years. | Illegal & punishable offence |

|     |  |  |                             |   |                                     |                              |
|-----|--|--|-----------------------------|---|-------------------------------------|------------------------------|
| UK  | The Human Tissues Act, 2004  | Opt-in / Consent of Family<br><br>Opt-out from 20 <sup>th</sup> May 2020 | Brain Death & Cardiac Death | Live donation from genetically or emotionally related donors. | Soon to change into opt-out system. | Illegal & punishable offence |
| USA | National Organ Transplantation Act, 1984<br><br>Uniform Anatomical Gift Act, 196 | Opt-in / Consent of Family   | Brain Death & Cardiac Death | Live donation through organ swapping                          |                                     | Illegal & punishable offence |

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4. <sup>iv</sup> *ibid*
5. <sup>v</sup> Glazier, A.K., 2018. Organ donation and the principles of gift law. *Clinical Journal of the American Society of Nephrology*, 13(8), pp.1283-1284.
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7. <sup>vii</sup> Purpose of OPTN, [https://optn.transplant.hrsa.gov/media/1506/optn\\_charter\\_ii\\_-\\_nov\\_04.pdf](https://optn.transplant.hrsa.gov/media/1506/optn_charter_ii_-_nov_04.pdf)
8. <sup>viii</sup> Section 17 of the Human Tissue (Scotland) 2006.
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11. <sup>xi</sup> Section 2(7), Human Tissue Act 2004, <http://www.legislation.gov.uk/ukpga/2004/30/contents>
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14. <sup>xiv</sup> Organ Donation Laws in England, <https://www.organdonation.nhs.uk/uk-laws/organ-donation-law-in-england/>
15. <sup>xv</sup> Ethical guidelines for organ transplantation from deceased donors 2016, <https://www.nhmrc.gov.au/sites/default/files/images/nhmrc-ethical-guidelines-organ-transplant.pdf>
16. <sup>xvi</sup> Lavee, J., Ashkenazi, T., Gurman, G. and Steinberg, D., 2010. A new law for allocation of donor organs in Israel. *The Lancet*, 375(9720), pp.1131-1133.
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20. <sup>xx</sup> Section 56(2) of the National Health Act No. 61 of 2003 (South Africa).



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22. <sup>xxii</sup> Section 60(2) of the National Health Act 61 of 2003 (South Africa).
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