Review Article

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A Comparison between Organ Donation laws in Spain and India

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Abstract

Organ Transplantation is one of our greatest scientific achievements, a miracle we have come to take for granted due to tremendous advances in medicine. However, the act of harvesting the organs of a deceased individual, though scientifically established, also involves a race against time to prevent ischemia and the ever present possibility of malpractice. Thus the social and legal aspects of organ donation seem to be as, if not more, complicated than the surgical and immunological aspects of transplantation itself. Indian law has various provisions to facilitate organ transplantation; however, rate of deceased donor organ transplantation is just 0.5 per million populations (PMP). In contrast, Spain is a leader in Organ Donation, with rate of 34.4 deceased donations PMP. In this article we aim to study the laws in both countries, and the possibility of adopting some of the policies implemented by Spain, so as to increase the number of donations in India.

Keywords: Organ Donation Law; Spain; India; Comparison.

Introduction

The history of transplantation stretches back many centuries, with many documents claiming organs, limbs or skin were transplanted from one to the other. However, other than that which has occurred in the last seventy years, most accounts of transplantation are more legend and less fact. Successful modern organ transplantation as we know it, with the transplantation of solid organs such as the liver, kidneys, heart etc has occurred more recently after decades of research in immunology and graft rejection.

The first successful kidney transplant was conducted in 1954 by Joseph Murray[1]. A kidney was transplanted from one twin to another, thus using the shared genetic traits to bypass the problems of graft rejection. Further research on immuno-suppression and the development of various new drugs like Cyclosporine and Tacrolimus greatly reduced mortality due to graft rejection. Thus, successful transplants of the kidney, liver, pancreas, heart and lungs became the norm.

Along with developments in the scientific arena, there was much debate in society to declare irreversible loss of brain function, or Brain-Stem death as a form of death. Organs could retrieved from brain dead individuals, as cardiac function and perfusion were unaffected, therefore protecting the organs from ischemic damage. In 1968, "A Definition of Irreversible Coma" was published by the Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death [1]. It conclusively established irreversible loss of brain function as a form of death, paving the way for organ harvesting and transplantation.

In India the Transplantation of Human Organs Act, established in 1994 also establishes Brain-Stem Death as a form of death, thus allowing the harvesting of organs.

It is estimated that the prevalence of end stage renal disease requiring a transplant in India is between 151–232 PMP. Taking these figures it can be estimated that more than 200,000 people require a kidney transplant in India. 1675 deceased donor kidney transplantations took place in 2015, according to reports released by the MOHAN

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foundation[2]. (It should be kept in mind that this data refers only to renal transplantation, and due to a lack of a national registry, data on other organs is lacking.)

As mentioned before, India has an abysmal rate of organ donation, at 0.5 per million population (PMP) [2], in contrast to Spain with a rate of 34.4 PMP in the year 2009 [3].

Thus it can be seen that number of organs needed far exceeds their supply, and India urgently needs to implement new policies and public awareness programmes to tackle the problem.

Spain : A leader in Organ Donation

Spain occupies a privileged position among large countries for having one of the highest rates of deceased organ donation. This is result of the implementation of a set of measures, mainly of an organizational and legislative nature, internationally known as the *Spanish Model of Organ Donation and Transplantation*.

The Spanish National Transplant Organization (ONT for *Organizacion Nacional de Transplantes*) is the technical agency of the ministry of health charged with overseeing donation and transplantation activities in the country. Donation activities are coordinated at National (ONT), Regional (17 regional networks) and Hospital (approximately 170 hospitals involved in 2009) levels. Each procurement hospital has a Transplant Coordinator (TC), with the responsibility of identifying donors, and converting potential into actual donors.

In addition to this, systematic early identification and referral of potential donors was a key component of increasing the number of donations. Potential donors include patients outside the Critical Care Unit (CCU), who are referred to critical care physicians and the TC staff. An important aspect of the Spanish system is the acceptance of organ donation as an essential aspect of End-of-life care and as another service to be offered by the CCU. The importance of communicating this principle to patients and their families has likely played a role in the appointment of TCs, the majority of whom are critical care physicians.

The use of Expanded Criteria Donors and promoting Donation after Circulatory Death are other measures implemented to increase the rate of donation in Spain [4].

While some similarities exist between the structure of the organizations overseeing donation and transplantation between two countries, the coordination and implementation at all levels is superior in the Spanish system as compared to India. Moreover, India's criteria for donors is rather limited, in contrast to the more flexible approach adopted by Spain.

Organizational Structure

India has a National Organ Transplant Programme (NOTP) under the Directorate General of Health Services. The National Organ and Tissue Transplant Organization (NOTTO) has been established as the apex body overseeing organ donation and transplantation in the country. Its functions include networking with regional and state organizations, as well as laying down guidelines and creating awareness. There are 5 Regional Organ and Tissue Transplant Organizations (ROTTO) located in Mumbai, Chennai, Kolkatta, Chandigarh and Guwahati. State networks (SOTTO) have yet to be put in place [5].

Thus it can be seen that the ONT and the NOTP are very similar. The 17 regional coordinating centres in Spain are more likely analogous to the state level SOTTOs soon to be set up. Due to the vast size and population of the country, India requires regional ROTTOs in the network, as intermediaries between the national and state bodies.

However the state bodies have not yet been set up, and are still in the planning phase. In addition to this some states have already set up coordination mechanisms of their own. An example of this is the Zonal Transplant Coordination Centres (ZTCC) that are present in Maharashtra. These are government organizations present in Mumbai, Pune, Aurangabad and Nagpur. Each monitors cadaver transplants and maintains a transplant registry in the city it's located in, while coordinating a network of hospitals. For example, the Mumbai ZTCC includes 3 municipal medical colleges, 1 government medical college, a central government hospital and 11 private hospitals [6].

Similarly, Tamil Nadu and Andhra Pradesh have an Indian Network for Organ Sharing (INOS) in each state. Unlike the ZTCC these are not government bodies, but networks that have been pioneered by the MOHAN foundation, a prominent Non-Governmental Organization in the field of organ donation[7].

Thus what India lacks is a system with a cohesive structure. Rather, there is a haphazard collection of individual organizations in different cities, with no established modes of communication between them.

The use of Expanded Criteria Donors

Expanded Criteria Cadaveric Donors are defined as donors above 60 years of age, or donors above 50 years of age with at least two comorbidities from among cerebrovascular cause of death, hypertension or renal insufficiency [8]. The survival of recipients of marginal kidney donors is inferior as compared to ideal cadaveric donor recipients, however it is significantly better than those transplant candidates who remained on maintenance dialysis treatment [9]. Expanded Criteria Donors can also play a role in liver transplantation [10].

Spain follows an 'old for old' strategy, where aged kidneys (organs harvested from aged donors) are preferentially allocated to old recipients, irrespective of HLA mismatch [6]. The efficacy of 'old for old' transplants has been shown, with recipients of this group showing an eight year actual graft survival comparable to old recipients receiving transplants from young donors; conversely young recipients of old donors showed a significantly worse actual graft survival [11]. Thus the use of Expanded Criteria Donors, and the adoption of an 'old for old' matching strategy is an effective way of expanding the donor pool while maximizing graft survival.

Donation after Circulatory Death

Donation after Circulatory Death (DCD) is used to define the harvesting of organs from individuals declared dead using circulatory criteria, not neurological criteria used in Donation after Brain Death (DBD). The modified Maastricht classification is most commonly used to classify circulatory death [12].

DCD is currently being practiced in various countries. A study conducted by the *European Committee on Organ Transplantation within the Council of Europe* documents 10 countries in Europe which have incorporated DCD in their organ donation and transplant protocols. Prominent among these were Belgium, the United Kingdom, the Netherlands (mainly controlled) and France and Spain (mainly uncontrolled) [13].

The United States of America, Australia and Japan also have established systems to facilitate DCD.

DCD is an accepted aspect of deceased donation, and has been described under the Critical Pathway for organ donation. The Critical Pathway was developed by a working group convened with the support of the *The Transplantation Society,* The Spanish *Organizacion Nacionale de Transplantes (ONT)* and the *WHO* [14].

It should be kept in mind that before the advent of donation after brain death, DCD was the only possible source for organs. Indeed, the first heart transplanted by Cristiaan Barnard was a retrieved from a DCD donor. In the wake of a profound lack of available organs, it is prudent to consider Donation after Circulatory Death to expand the donor pool.

Presumed Consent

The system of Presumed Consent is also known as the opt-out system, where unless the deceased has specified that he does not want to donate organs in life, consent for donation will be assumed.

This system of Presumed Consent is not strictly implemented, and the wishes of the family of the deceased are always respected [6]. In fact, the statute for presumed consent was present in Spain ten years prior to the organizational changes, with no change

Table 1: Main elements of the Indian and Spanish models of transplantation

Country	INDIA	SPAIN
Organization	National Organ and Tissue Transplant Organization (NOTTO) Regional Organ Tissue and Transplant Organization (ROTTO) (5 regional centres) State Organ Tissue and Transplant Organization (SOTTO) yet to be established	ONT (*Organizacion Nacional de Transplantes*) National Level Regional level (17 regional coordinators) Hospital level
Transplant Coordinator	Present in registered hospitals, may be:- Doctors, Nurses, Non-Medical professionals such as social workers, Counsellors etc.	Present in the registered hospitals – Almost always doctors (Mostly Critical Care Physicians or Nephrologists) assisted by nurses in large centres
Expanded Criteria Donor	Accepted occasionally, No provision for an old-for-old system	Routinely utilized, old-for-old model followed
Donation after Circulatory Death	Not permissible under THOA	Permissible under law and carried out mainly in three cities with large populations
System of Presumed Consent	Absent	Present, but not implemented strictly

Table 2: Expanded Criteria Donors

Expanded Criteria Donors
All donors aged 60 years or older
Donors aged 50 – 59 years with at least two of the following comorbidities
Cerebrovascular cause of death
Hypertension
Renal Insufficiency (Serum Creatinine above 1.5 mg/dL)

Table 3: Modified Maastricht classification of DCD

Category	Description	Type
I	Dead on arrival	Uncontrolled
II	Unsuccessful resuscitation	Uncontrolled
III	Anticipated cardiac arrest	Controlled
IV	Cardiac arrest in a brain-dead donor	Controlled
V	Unexpected arrest in an Intensive Care Unit (ICU) patient	Uncontrolled

Table 4: Possible measures to increase organ donation in India

Elements that can be implemented in the Indian set-up
*Implementation of a **systematic organizational approach** with coordination at various levels ranging from National, Regional, State and Hospital levels*
*To establish a **single multi-party system** incorporated at the various levels of coordination mentioned above, and prevent the proliferation of individual organizations in different states and cities*
*Establishing mechanisms to facilitate **Donation after Circulatory Death***
*Establishing mechanisms to retrieve organs from **Expanded Criteria Donors** and implementing an 'old for old' system*

in Organ donation rates [15].

It should also be kept in mind that most Indians have yet to come to terms with the moral issues associated with organ donation, and many are distrustful of the procedure. The implementation of measures like presumed consent, where 'presumed' can be misinterpreted as 'forced', might alienate society further.

Conclusion

Although India has laws and various systems in place to facilitate organ donation, they seem to be falling short, as the low rate of deceased organ donation shows. After a study of the policies present in Spain, there is a possibility that their implementation can lead to an increase in the number of organs retrieved for transplantation, and make the mechanism for retrieval of organs more efficient.

A single multi-party system of coordination at all levels is the key to ensuring greater retrieval of organs and their efficient distribution. The current scenario is quite disorganized, with various individual organizations working independently in different regions. It is possible that with so many different entities, chances to harvest and allot organs may have slipped through the gaps in communication.

In addition to this, a change in donor criteria should be considered in response to the ever increasing need for more organs. This includes Expanded Criteria Donors and Donation after Circulatory Death. Amendments to the law, along with the formation of new guidelines and protocols can accomplish this.

As mentioned before, the system of Presumed Consent is not very effective, and not suited to the needs of the Indian system. Our current opt-in system should remain, and the focus should be on strengthening it.

Currently, Indian hospitals and medical teams are very capable of conducting transplants. There is no doubt that scientifically and surgically, we have the knowledge and skills for these procedures. However it is the organizational and legal aspects that require fine-tuning. Improvement in these spheres will benefit patients on the waiting list, and save many lives.

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