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ABSTRACT

In recent decades, developed nations, such as the United States, have seen the gap between the demand and the supply of transplantable organs widen, despite national campaigns intended to promote donor registration. This organ shortage crisis has deprived thousands of a basic quality of life and has caused a substantial increase in the cost of alternative medical care such as dialysis. In an attempt to address the shortage, some countries have instituted explicit “opt-out” and “priority allocation” policies that operate under the principle of presumed consent and offer higher priority on transplantation lists to registered donors. This paper seeks to justify such legislation, exploring the ethical implications and highlighting the potential benefits of an opt-out and priority allocation organ donation system. It argues that such policies should be made a legislative priority in order to strengthen the national organ donation system of the United States.

Introduction

Overview

Over the course of the last century, the advancement of transplantation techniques combined with factors including increased incidence of metabolic disease and population aging have caused an increased demand for viable organs and tissues (Wynn, 2011). Unfortunately, the demand for such biological materials significantly surpasses the number available for donation. In January 2019, the U.S. Department of Health and Human Services reported that over 113,000 Americans were registered on the national transplant waiting list and roughly 20 registered patients die each day waiting for a donation (U.S. Department of Health and Human Services, 2019). Despite increased public awareness campaigns and other attempts to promote donor registration, the gap between supply and demand continues to widen as the number of patients on waiting lists has continued to climb over last decade (Abadie & Gay, 2006). The pressing shortage has created a forum for debate amongst U.S. legislators on the policies of two diametrically opposed systems: the opt-in (explicit consent) and the opt-out (presumed consent) systems of organ donation registration. The current protocol for organ procurement and allocation in the U.S. operates under the guidelines set out by an opt-in system. The inability of the current system to effectively address this ongoing organ deficiency underscores the need for change at the state and federal level.

In response, this paper argues for a departure from the current opt-in system and the theoretical, subsequent adoption of opt-out and priority allocation system.

Organ Shortage as a Public Health Issue

Transplantation as a Solution to Organ Failure

While the need for transplantable organs can be traced back to antiquity, it was not until the twentieth century that advancements in modern medicine have been able overcome the technical limitations that previously prevented it from becoming the routine practice it is today (Starzl, 1994). Early twenty century attempts at renal xenotransplantation between human recipients and mammalian donors (i.e., sheep, pigs, goats, and of transplanted organs. It was not until 1944 when Peter Medawar demonstrated that rejection of transplanted organs is an immunologic process in itself.
Medawar’s work focused on the rejection of skin grafts, using rabbits and cattle to investigate the process. His research identified immune responses via lymphocyte infiltration of genetically different grafts as being responsible for organ rejection and found that an exchange of skin grafts between monozygotic, as well as dizygotic, pairs retained their test twin grafts with little to no indications of rejection, while still demonstrating rejection of grafts from unrelated third party donors (Anderson et. al, 1951). In a bold application of Medawar’s work, a team led by physicians Joseph Murray, John Harrison, and John Merrill performed the first long-term successful kidney transplant between identical twins in 1954 (Merril et. al, 1956). Their landmark success paved the way for the development of increasingly better methods of histocompatibility matching, organ procurement and preservation, and numerous innovations in surgical techniques. Such efforts ultimately made it possible to successfully engraft all of the major organs and bone marrow cells in humans.

Organ Shortage as a Public Health Issue

Since 1995, over 161,000 patients registered on waiting list have died before an organ became available in the U.S. (OPTN, 2019). More recent statistics from the U.S. Department of Health and Human Services reported that as of January 2019, over 113,000 Americans were registered on the national transplant waiting list and roughly 20 of those patients die each day waiting for a donation (U.S. Department of Health and Human Services, 2019). The increasing demand for transplantable organs compounded with the nationwide deficit of registered donor has deprived thousands of American patients of a new and better quality of life. Despite campaign efforts and other attempts to promote donor registration, the gap between supply and demand continues to widen.

Global Strategies to Address Transplantable Organ Shortages

Global Strategies

Organ scarcity is not unique to the United States; it is a pervasive challenge that all medically advanced countries face. In recent decades, global political strategies have taken steps to address the shortage by changing two components of transplantation legislation: presumed consent and allocation priority. The implementation of these two systems operate effectively by changing the status quo of organ donation and giving registered donors priority among the pool of individuals in need of organ transplantation. The joint implementation of these two systems has yielded beneficial effects in countries such as Israel and Singapore. Proving national and international efforts are effective in facilitating change when they are supported by regional and global action within agreed policy frames.

Explicit opt-out laws have long been among the major interventions used to increase the pool of potential donors in countries such as Austria, Belgium, the Czech Republic, Finland, France, Greece, Hungary, Israel, Italy, Luxembourg, Norway, Poland, Slovenia, Spain, Sweden and Turkey. There is evidence that supports the association between presumed consent and increased donation rates and that countries with opt-out laws have rates 25 to 50% higher than those in countries requiring explicit consent (Abadie & Gay, 2006). One study found that the rates of deceased donor rates (per-million population) were 42.7% higher in opt-out countries. However, the study revealed a paradox in which the opt-in countries reported 70.5% higher rates of living donors compared to opt-out countries (Abadie & Gay, 2006). Hence, presumed consent appears to be only one of several influential factors. Other factors include potential donor availability, transplantation infrastructure, health care spending and public attitude towards donation (Rithalia et. al, 2009), as well as an agreement of the next-of-kin and donor registry infrastructure (Bilgel, 2012).

In 1987, Singapore introduced the Human Organ Transplant Act, which instituted an opt-out system that presumed consent to removal of organs for transplantation upon death and apply priority allocation. Under priority allocation systems, those who object and withdraw their consent to donate upon their death also forfeit a priority stop on the national transplantation waiting list, should they require a transplantation in future. The combined system not only changed the status quo of donation but provided an incentive for donation: receiving priority on the waiting list (Breyer & Kliemt, 2007). A concern with combining the opt-out and priority allocation system is that the priority rule cannot prevent the free-rider problem if the introduction of an opt-out system has already generated a sufficient organ supply. Overall, Singapore’s combination of presumed consent and priority status has been successful in increasing organ donations.

Following suit, the Organ Transplant Act came into effect in Israel in 2010. The new law introduced a priority point system to motivate individuals to donate their organs by granting prioritization in organ allocation to candidates who have either been registered as organ donors for at least three years prior to transplantation request, or have given explicit consent for organ donation of their deceased next-of-kin (Lavee et. al, 2010). Israel’s system also rewards those who are willing to act as living donors for kidney or liver donation with a preferential status as a recipient. A person can also gain priority points by signing a donor card, making a non-directed/non-specified organ donation during their lifetime, or being a first-degree relative signing a donor card or consenting to procurement of organs after death. The resulting tiered system includes maximum priority, regular priority and second priority. Maximum priority is granted to candidates if: (i) consent has been given for organ donation from a deceased first-degree relative or (ii) they donated a kidney, a lobe of their liver or a lobe of their lungs in the course of their life to a non-specified recipient. Regular priority is given to candidates who hold a donor card, that is, those who have consented to donate their organs after their death. Second priority is granted to candidates with a first-degree relative who holds a donor card, even if they do not hold a donor card themselves. As a result, the act has led to a record number of signed donor cards.
and, ultimately, a significant increase in the numbers of transplants (Cronin, 2014)

The Spanish Model

In 2016, Spain boasted an impressive number of deceased donors at 43.4 per million population (pmp), an increase from 39.7 pmp in 2015 and 36 pmp in 2014. The 2016 Spanish rates are much higher than the EU average (19.6 pmp) and the U.S. average (26.6 pmp). Having the world’s highest rates of donation per capita, Spain has become the world leader in organ transplants. In 1979, Spain instituted its opt-out system through the implementation of presumed-consent legislation and since then, has required all prospective donors to be declared dead on neurological criteria by a minimum of three physicians (Gundle, 2005). Once death has been declared, any individual who has not formally registered an opposition is considered a potential donor and the process of organ procurement begins. This system, combined with an ingrained societal respect for organ donors, has contributed to Spain’s successful organ procurement program.

The Spanish model for opt-out donor registration offers simple and practical principles to guide the development and implementation of policies at both the national and state levels. Taken together, these principles reflect the multifaceted determinants of organ transplantation and the coordinated multi-sectoral action required to implement effective legislation.

The Case Against Opt-Out Organ Donation Legislation

Libertarianism and Organ Donation: Loss of Autonomy

The primary points of contention within the default debate are between opt-in and opt-out statutes, founded in the interpretation and adherence to the autonomy of the donor under the assertions of the Libertarian model. Those in objection to the presumed consent model assert that such systems place limitations on and unjustly reduce patient autonomy. According to this view, it is wrong to invade and assume possession of someone’s body without that person’s consent (Gill, 2004), and that the government is already too involved in the lives of its citizens. Such claims are founded upon the principles set out under libertarianism, a political ideology that places emphasis on safeguarding individual liberties and minimizing government involvement in the affairs of its citizens. One of the fundamental assumptions of libertarianism is the right to self-ownership; libertarianism asserts the full right to control the use of one’s own person and the need for explicit consent without external influence or coercion (Vallentyne, 2008). Proponents of this ideology would argue that presumed consent laws further invade the affairs of the governed by assuming possession over their body, and thus violating their right to self-ownership.

An Imperfect Solution

While it is evident that opt-out systems are successful in increasing rates of registered organ donors, it is important to note that it is not a failsafe solution. Even in opt-out countries such as Spain and France, a near 100% registration rate does not translate into surplus of organs, a fact often overlooked when advocating for opt-out systems. Even in countries with presumed consent, there is still a waiting list for organs. This can be attributed to the fact that majority of registered donors do not die in ways or conditions suitable for organ donation. In fact, only approximately 3 out of every 1000 deaths occur in a way that allows for organ donation (U.S. Department of Health and Human Services, 2019). While the institution of opt-out systems increases the rates of registered donors, the death of an organ donor does not guarantee an organ donation.

The Case in Favor of Opt-Out Organ Donation Legislation

Utilitarianism and Organ Donation: Increase Autonomy

On the other side of the argument are those who believe the United States should adopt a system of presumed consent for organ procurement. They respond to the argument over a loss of autonomy by countering that a presumed consent model actually provides more autonomy than expressed consent because it allows the donor, not his or her family members, to make the final decision. They maintain that asking a family for a loved one’s organs at a time of intense grief is cruel and unnecessary and that, by presuming consent, the family’s conflict over this decision is avoided. Furthermore, there are those who argue that the burden of communicating and registering preference should fall on those who object to donating, not those who support it, because the goal of transplantation is one that must be widely accepted by the public. Communicating objection rather than acceptance would also increase accuracy, asserting that objectors are more likely to register their opposition than supporters are to sign up as donors. Anecdotally speaking, people are more inclined to write bad reviews than they are good ones; more inclined to express opposition than approval. Following this argument, there would be fewer mistakes in interpreting a potential donor’s wishes. To conclude this line of reasoning, Gill (2004) suggests that all mistakes in interpreting a donor’s preferences have the same moral worth; it is no worse, Gill says, to assume that someone wants to donate, take his or her organs, and then find out that he or she objected than to wrongly assume that someone did not wish to donate and therefore forgo potential organs.

Moreover, survey data indicates a significant disagreement between preferences for donation and donor card registrations. In particular, results from a well-known survey (Gallup, 1993) indicate that while most Americans favor organ donation (89%) and would like to donate their organs after death (69%), only a few grant permissions for postmortem organ procurement on their driver’s license or organ donor card (28%).

Ultimately, supporters of presumed consent law also employ a utilitarian argument as support for
implementing such a policy that claims that presumed consent provides the greatest good for the greatest number of people by harming no one and benefiting many. This paper argues that there is a proportionate moral case in favor for the implementation of presumed consent legislation within the United States. From a utilitarian perspective, it represents the routine disposal of a highly valuable commodity, one which has the potential to save lives.

**Potential Economic Impact of Organ Donation**

The economic toll of organ impairment and dysfunction place an immense strain on healthcare infrastructures. In 2014, more was spent by Medicare on chronic renal disease treatment, such as dialysis, than all cancer treatments combined, despite cancer claiming nearly 12 times as many lives as chronic renal disease. (Liyanage et al, 2015). On a national level, the United States Ultimately, the burden of cost of end-stage organ disease is a global economic crisis, with over $1 trillion spent over a decade on chronic renal disease alone (Liyanage et al, 2015).

In recent years, the question of how many defaults influence economic choice has become an issue of great interest amongst legislators, in part because it is believed that organic default systems can reduce the burden placed by chronic disease on both the individual and healthcare infrastructures. As a model, the presumed-consent policy in Spain is cost-effective, saving the National Health Service more than 200,000 Euros in medical costs for each kidney transplant preformed on a patient on dialysis (Lopez-Nava, 2001).

**Corrective Vision: A Model for Legislation Consideration**

This section briefly sketches a plausible model for organ donation in the U.S. Although simple, the model takes into consideration three components of transplantation legislation implemented globally and their effect in addressing the organ shortage crisis: (1) the implementation of presumed consent policies; (2) the implementation of allocation priority systems for registered organ donors (3) educational programs for hospitals, ICU staff, coordinators, and the general public.

**Implementing Presumed Consent Policies**

According to the concept of presumed consent, anyone can be an organ donor after his or her death unless the individual had documented objection during his or her lifetime and permission of family members is not required. In countries that have accepted the concept of presumed consent, such as Spain, there is the highest number of organs from deceased donors.

**Reciprocal Allocation of Organs**

Universal donor systems place no special conditions on the relationship between donor status and transplant allocation, whereas contingent entitlement systems mandate reciprocity by giving consenting potential donors’ priority on transplantation waiting lists.

**Educational Programs**

One of the greatest barriers to increasing the rates of organ donation is the lack of education and misconceptions of organ donation by the public. Within the past decade, Donor Action Programs have been carried out across Europe in the form of public education programs via broadcast and print media, schools, universities, and public awareness campaigns. This, in conjunction with training programs for hospitals and ICU staff, have resulted in a 53% increase in organ donation (Tuppin & Savoye, 2006).

In the U.S., with support from the Department of Health and Human Services and the Health Resources and Services Administration, the Program of Organ Donation Break-Through involving collaboration between the transplant community and the general public was established in 2003 (Abouna, 2008) As a result, the number of organs from deceased donors increased by 8% per year (Punch et. al, 2007). It has also been recommended by the United Network for Organ Sharing that general physicians should educate their patients about organ donation (United Network for Organ Sharing, 2007). Raising awareness has shown to increase the rates of organ donor registration by creating a better public understanding of the process and generating better public attitudes towards donation.

**Conclusion**

The current protocol for organ procurement and allocation in the U.S. operates under the guidelines set out by an opt-in system. The inability of the current system to effectively address this ongoing organ deficiency underscores the moral need for change at the state and federal level. In response, this paper has argued for a departure from the current opt-in system and the ethical justification of a theoretical, subsequent adoption of opt-out and priority allocation system.

While it seems unlikely that the United States will make the transition to a system of presumed consent for organ procurement in the near future, the ethical impetus of transitioning to an opt-out system remains a priority in American medicine today, along with the autonomous right of the competent patient to make all of his or her own medical decisions. Based on the proportion of people who report being willing to donate their organs and those who actually register to do so, the organ shortage problem stems in large part from a moral failure to obtain permission to recover organs. This critical problem requires education, action, and a national conversation about human agency versus human life.

**References**


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