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Policy Analysis on Cadaveric Kidney Donation and Transplantation

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The increase of successful rate of kidney transplantation has made this treatment as a major preference for patient with end-stage renal disease. As a result, the waiting list for kidney transplantation has been progressively increasing every year. This condition has forced many countries to make policies to increase the supply of kidney. This article discussed three major policies on cadaveric kidney donation. The first policy is opt-in system which requires people to register as a donor before their death (informed consent). The second policy is opt-out system in which every individual is automatically treated as a donor (presumed consent) unless otherwise requested. The third policy is regulated-paid donation in which the donors receive financial incentives for their kidney donation. The purpose of this study is to review these three main strategies including whether or not the policies have an impact to increase kidney donation. It was found that the reviewed policies have less effect on increasing the number of kidney sources. It seems that these policies were not effective without public willingness for renal donation. Furthermore, the transplantation facilities and procedures such as, transplant center hospitals, skilled medical personnel and transplant network also played important roles to increase kidney donation. As conclusion, to increase the supply of kidney, the implemented policy should be supported by good public attitudes and effective transplantation system.

Keywords: policy analysis, presumed consent, informed consent, financial incentive, kidney donation.

1. Introduction

Since the discovery of immunosuppressant* in 1960, organ transplantation has been widely performed and seems to be the gold treatment for an end-stage of organ failure patient. As of 2015, around 84,347 of kidney transplants had been carried out in 89 countries¹⁾. Also, advances in organ transplant technology that increased the graft's and the patient's survival rate have made kidney transplantation becomes a preference over dialysis[†] treatment. Renal patients who received a kidney transplant live longer than those stayed on dialysis. Patients with a kidney transplant at the age of 55 have 10 years longer live expectancy than dialysis patient^{2,3)}. Kidney transplantation is also more cost effective than dialysis^{4,5)}. In the United States, hemodialysis treatment costs approximately \$87,000 annually⁶⁾, while the average cost for post-operative care for kidney transplant

is only around \$29,000 per year⁷⁾.

Because of those wider benefits of kidney transplant over dialysis, the number of patients who register for kidney transplant increases sharply every year. Meanwhile, the supply of transplantable kidneys is much less than the demand. Based on the US Organ Procurement and Transplantation Network (OPTN) as of January 2018, around 95,354 patients were waiting for kidney transplant. With the shortage of kidney sources, the renal patient could wait 5-10 years to get kidney transplant. This condition has forced many countries to seek new strategies in order to expand kidney donor pool. Advances in biomedical technology offer an attractive strategy to create bio-artificial kidney by combining human cells and compatible materials⁸⁻¹⁰⁾. Unfortunately, this technology is not expected to be available in the upcoming decade¹¹⁾. A policy based-strategy is therefore the most possible approach to increase the rate of kidney donation.

In many countries, such as Japan, U.S and U.K the kidney donation and transplant from deceased (cadaver) donor is carried out under an informed consent law

* a drug that prevents the body from rejecting foreign materials

† a therapy for patient whose kidney unable to filter blood adequately

which provides an explicit consent for organ removal before death. In contrast, most of the European countries practice presumed consent principle which treat all the deceased as potential kidney donors unless the objection “not to donate” is mandated prior death. Currently, although it is not permitted in most countries, financial incentive for cadaver donor has also been either examined or implemented in some countries¹²⁾.

Transition of organ donation law into presumed consent is often associated as a solution to boost kidney donation rate¹³⁻¹⁵⁾. The debate in defense of financial compensation for organ donor has also been developing in some countries such as Canada¹²⁾ and Singapore¹⁶⁾. Although many interesting views, challenges, and solutions were discussed, the studies were mainly focused only to individual policy and a comparison study among multiple policies was limited. Therefore, it is necessary to review these three policies in more major situation, not limited to the individual country. This study was aimed to 1) evaluate whether or not that these three mentioned policies have an impact to increase kidney donation, and 2) identify and clarify the actual key factors that increase the kidney donation number from cadaveric donor.

2. Limitation

This study was limited to the discussion of kidney transplant and donation from deceased (cadaver) donor.

3. Policy Descriptions

3.1 Informed Consent

In informed consent countries, organ transplant should be performed based on the altruistic principle, thus organ donation is treated as an act of gift and that any compensation due the action is not allowed. By law, the informed consent is an advance approval from individual to donate organ after death. It usually provides consent to medical authority of which organs that can be taken according to the deceased’s will. Majority of countries follow this informed consent regulation which

include USA, Australia, Japan, Denmark, England, Germany, The Netherlands, Canada, and Switzerland¹⁷⁾.

The individual registers as an organ donor through a designated body as simple as registering either by mail, email, or phone call. In some states of USA, the registration can be signed up online and they will send the donor card once the registration finished. Most states let the registrant to choose what organs and tissues they want to donate and any revisions or even withdrawal can be updated at any time¹⁸⁾.

In informed consent, the individual is regarded as a non-donor by defaults. They need to take action if they want to be a donor. Unfortunately, the individual who wanted to be a donor often fails to have informed consent before death. Thus, without a real action of the individual to get a donor card or to join the organ donor registry, the donation rate in the informed consent countries is hard to increase.

By law, when the deceased carrying a donor card or registration on the organ procurement center, the surgeon has appropriate consent for a removal of the organ. However, in real practice, before the organ removal is performed, the medical authority is likely to ask for family’s consent though the donor carries a donor card or has made a registration for organ donation. Therefore, the family’s decision renders a de facto authority of the transplant surgeon¹⁹⁾. The surgeon is unlikely to recover the organ without a consent from the family.

3.2 Presumed Consent

In informed consent countries, the system is an “opt-in” system, where individual voluntarily becomes organ donor. In contrast, in presumed consent countries, the system is known as an “opt-out” system which assumes that every deceased is willing to become organ donor. This means that the medical staff has an authority to remove organs for donation unless the patient declares the objection clearly prior death.

Presumed consent system has been adopted in majority of European countries including Spain, Norway, Austria, Belgium, France, Italy, Poland and Portugal²⁰⁾.

Table 1. Comparative Evaluation of Organ Donation and Transplantation System.

System	Advantages	Drawbacks
Informed consent	<ul style="list-style-type: none"> • No moral and ethical problems 	<ul style="list-style-type: none"> • Slow increase of donation rate • False negative (the kidney donation cannot be proceed if no informed consent made though the individual want to donate)
Presumed consent	<ul style="list-style-type: none"> • Significant increase of kidney donation 	<ul style="list-style-type: none"> • Moral and ethical questions • False positive (the transplant authority may take organ against donor’s will)
Financial incentives	<ul style="list-style-type: none"> • Reduce financial burden of the donor and the family • A potential to increase kidney donation 	<ul style="list-style-type: none"> • Moral and ethical questions • Against some religious views

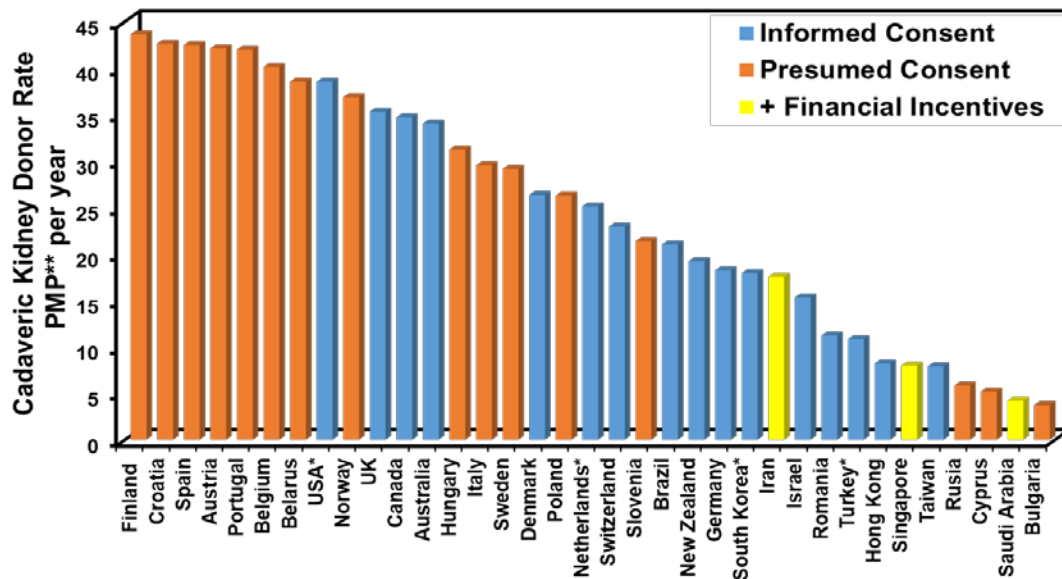


Fig 1. Kidney Donation Rate from Deceased Donor in 2016. Source: The International Registry of Organ Donation and Transplantation²⁸. *2015, ** per million population.

In Asia, presumed consent was first introduced in Singapore in 1987²¹). In practice, there are 2 types of presumed consent: hard or soft, which relates to how far the family's consideration is placed¹⁵). Transplant team in countries with hard presumed consent, such as Austria and Singapore, is likely to remove organs from a deceased donor without asking the family's view. Spain has been practicing a soft presumed consent in which the medical staff is urged to consult with the donor's family prior the organ removal²²).

Many transplant professionals suggested that presumed consent system is the best to increase donations rate because by default every individual (including of those who have no preference) is treated as a potential donor. In fact, an individual who does not request for "not donating" does not mean he/she agrees to be a donor. Thus a false positive where the transplant authority takes organ against donor's will is likely occurred¹⁷. In this case, due to those moral and ethical problems, the informed consent is seen as a better system than presumed consent.

3.3 Financial Incentives

Most countries practice the altruistic system for organ transplantation because this policy is recommended by the World Health Organization (WHO). However, some countries are trying to seek an alternate attempt which may seem controversial. The most controversial regulation is paid organ donation which allows to give financial incentives to the donor. This concept believes that the gratefulness over the altruistic act alone is not enough to endure the harm and loss because of organ donation. Financial disadvantage, such as uncovered medical expense and lost wages during donation process, tends to discourage people for being a donor. Therefore,

financial incentives offer a protection for donor and the family's and help to reduce short- or long-term financial burden as a consequence of organ donation. Some transplant experts also believed that a regulated financial incentives has a potential to increase organ donation while eliminating illegal practice of organ markets¹²). Despite many potentials of regulated system of incentives, the protests against it remains continue.

The opponents claimed that financial compensation for donor is wrong in principle and unethical. Yet, numerous transplant scholars have concluded financial incentives should not be considered against ethical issues^{16,23}).

The form and the amount of financial incentives are regulated by the policy authority. Such incentives can be in the form of direct payments (cash) or indirect such as health insurance, funeral cost, reimbursement of wage loss, or travel cost for the family to the medical center to give consent. In Saudi Arabia, the government will reward 50,000 riyals to the deceased's family and 50% discount of Saudi Airlines²⁴). In Qatar, travel and counseling support is provided for the deceased's family at the time of donation²⁵). While in Singapore, the government provides 50% subsidy of the medical expense for the deceased's immediate family for 5 years following donation²⁶). Table 1 summarizes the advantages and drawbacks of each regulations.

4. The impact of the implemented policy on cadaveric kidney donation

It is quite difficult to withdraw which the best system to increase kidney donation rate since each regulation has its own benefits and drawbacks. To see the actual condition of the current kidney donation, Figure 1 shows cadaveric kidney donation rate in presumed consent

Table 2. Statistical data of organ donation rate and public attitudes.

Country	Legal System	Organ Donation Number* per year (PMP) ³⁷⁾	Willingness to donor (%) ³⁸⁾	Family's willingness to consent organ donation ³⁸⁾
Netherlands	Informed Consent	56.1	64	62
Romania		13.3	31	34
Spain	Presumed Consent	49.74	61	59
Bulgaria		5.31	42	44

countries, informed consent countries and countries having financial compensation. Although the 7 highest donation rate are occupied by presumed consent countries, some countries with relatively high donation rate also practice informed consent system (Figure 1). The donation rate in the U.S, for example, is comparable with that in Belarus, though these countries practice different systems. Yet, it is also surprising to see that the lowest donation rate is occupied by Bulgaria which is a presumed consent country. Saudi Arabia is also suffering from low donation rate though having financial compensation scheme. These suggests that the implemented policy may have less effect on the number of kidney cadaveric donation and that other factors may take into account.

5. Key factors to increase cadaveric kidney donation

The implementation of organ donation policy should not be based upon success story on other countries. Every society differs from one another which is defined by culture, religious view, and life values. It is therefore important to examine the public attitudes toward organ donation. This includes the willingness to donate organ and willingness to give consent for family member to donate.

Table 2 shows statistical data of organ donation rate and public attitudes in some European countries. It obviously showed that countries with high level of donation rate (such as Netherlands and Spain) tend to have higher level of willingness to donor and willingness to give consent to other family member to donate (>50%), regardless the system practiced in those countries. On the contrary, countries with low level of such public attitudes toward organ donation (such as Romania and Bulgaria) have low donation rates. Those suggest that there is a linear relation between public attitudes and organ donation rate.

According to the Eurobarometer survey in 2010, the low level of public attitudes is influenced by several reasons which are dominated by the lack of public trust in the organ donor and transplant system and the fear of manipulation of human body. Public distrust of the system leads to an increase number of the unwilling organ donor and a protest against presumed consent

system in Russia^{27,28)}. To promote and improve the public awareness on organ donation and transplantation, educational campaign is a vital approach. Studies showed that the more the public is informed about the various aspect of organ donation and transplant, the higher the public awareness^{29,30)}.

Other important factors are the transplantation system and infrastructure. It is reported that a sharp increase in waiting-patient numbers for transplant is not caused by the fact that there is lack of voluntary donor, rather caused by procedural matters such as no immediate follow up from a medical professional to recover vital organ from a deceased donor³¹⁾. In other words, medical authority failed to identify every potential donor in their hospital. Lack of transplant coordinator was considered to be the main reason behind kidney shortage^{32,33)}.

The kidney donation process, from the detection of potential donor until the kidney is successfully transplanted into recipient's body, should be performed effectively in relatively short time, less than 30 hours³⁴⁾, otherwise the kidney will lose its viability. Therefore, these complex and multiple-steps procedures require good communication and coordination between the donor hospital, family (for giving consent immediately), and transplant center. It is observed that countries with relatively high donation rate have mostly a well-established management system that supports the process, such as the US, Netherlands, Spain and Iran, as summarized in Table 3. The system in those countries consists of at least: Transplant center, Donor Hospital and National Transplant Network.

Transplant center is a hospital that has transplant facility and trained transplant team to perform organ transplantation. Transplant network is a competent authority to procure and allocate organs in a regional or national level. The transplant network can be a private or public organization under a license of the government like in the US, Spain and Netherlands or an association of organ transplant that is run voluntary like in Iran. The function of these bodies is mainly to link all professionals involved in organ donation and transplantation. Also in most of established system, there is a very clear and effective procedure on who and how to approach a family consent when a deceased donor is available. In Spain, a transplant coordinator (usually a

Table 3. Components of Organ Donation Systems in High Kidney Donation Rate Countries. *kidney transplant center, **dialysis units.

Countries	Number of Transplant Center	Number of Donor Hospitals	Transplant Network/Number
Netherlands ^{39,40}	8	100	The Organ Center of the Dutch Transplant Foundation (NTS)/ 60 units
Iran ⁴¹	25	302**	Dialysis and Transplant Patients Association (DATPA)/ 79 regionals units
US ⁴²	244*	6-78/ OPO	Organ Procurement Organization (OPO) / 58 regional units
Spain ⁴³	29	170	The National Transplant Organization (NTS)/ 17 regional units

physician) is in charge to identify every deceased potential donor and approaching their family to get consent³⁵. In Netherlands, a special trained-donation practitioner is recruited to assist every transplantation process such as approaching the deceased's family to get a consent³⁶.

To establish such an integrated system, a high investment as well as government's commitment are needed. These costs include building the transplant facility and training the transplant personnel. Finally, the combination between good public attitudes and effective transplantation system may result a positive effect in the increasing number of kidney donation rate.

6. Conclusion

The effectiveness of kidney donation and transplantation policies have been discussed through a comparative study. It was found that the reviewed policies have a little correlation on the level of kidney donation rate. It seems that these policies were not effective without good public attitudes including willingness to donate their own organ or those of deceased family member. Furthermore, the transplantation system and facilities such as, transplant center hospitals, skilled medical personnel and transplant network also played important role to increase kidney donation. In conclusion, to increase the supply of kidney, the implemented policy should be supported by a good public attitude and an effective transplantation system.

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