

AN EXAMINATION OF THE IMPACT OF THE ORGAN DONATION
BREAKTHROUGH COLLABORATIVE ON
KIDNEY TRANSPLANT ACTIVITY

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THESIS ABSTRACT

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Organ procurement policy has developed to combat the persistent shortages for kidneys, and some studies have detailed the results of one of the more recent initiatives, the Organ Donation Breakthrough Collaborative. This study examines the impact of the Collaborative with respect to kidney transplant activity. With the use of time series analysis, the study inspects the impact of the periods before and after the implementation of the Collaborative. With a time trend, the results show that the total kidney transplant activity has not significantly changed and lower quality kidneys are being promoted at a higher rate due to the policy.

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CHAPTER I

INTRODUCTION

The first successful human organ transplant in the United States was performed on December 24, 1954 between two living twins¹. The identical physiology of the persons allowed for the kidney transplant to be successful. The rejection of an organ causes the recipient's death, and the fact that the patients were twins increased the chances of survival. Since then, medical technology and, more specifically, immunosuppressive therapy have improved immensely. The immunosuppressive drug cyclosporine is usually mentioned as one of the most important discoveries in the realm of organ transplantation. With its approval for commercial use in 1983 and the introduction of similar drugs, transplants recipients no longer had to wait for the coincidence of medical compatibility between two persons whether it was with a family member or an acquaintance. As a result, the survival rates of organ recipients increased greatly. Furthermore, the use of organs from recently deceased individuals and the expansion of transplantation from kidneys to hearts, livers, lungs, pancreases, eyes, and other organs have led transplantation to be an important and viable method for the treatment of organ failure.

Despite the advancements in the U.S., there have been long-standing shortages of transplantable organs and other severe consequences. The waiting lists have grown

¹ The introductory chapter draws from David L. Kaserman and A.H. Barnett (2002).

yearly as these shortages have persisted. The alternatives to not receiving a kidney transplant include increased waiting times, dialysis, increased reliance on living donors, and, of course, death. In 1972, the U.S. Congress established the End Stage Renal Disease Program. The program provided funding for all dialysis (even today) and the initial waves of transplants. Beginning in the 1980s, private insurance companies started to cover transplants as transplantation became an acceptable form of successful treatment. These consequences occurred concurrently with, and perhaps were elongated by, the development of U.S. organ policy.

Kaserman and Barnett (2002) stated that “three major pieces of legislation have largely defined the legal and institutional landscape pertaining to organ procurement activities in the United States.” (p. 11) The 1968 Uniform Anatomical Gift Act was the first legislative attempt to increase the organ supply. One of its two main features was to recognize the premortem wishes of an individual to grant their organs for postmortem donation. Furthermore if expressed through a will or a donor card, hospitals did not necessarily have to obtain permission from surviving family members².

The National Organ Transplant Act (NOTA) was the second piece of legislation. Signed into law in 1984, NOTA had three aims: To increase the organ supply, examine the fairness of organ allocation process, and prevent the formation of organ markets. As a result of NOTA, four private and public institutions have been created. First, the Department of Health and Human Services (HHS) established the Division of Organ Transplant (DOT). A result of the establishment of DOT was the provision of funding

² Kaserman and Barnett (2002) “Only in situations where the decedent had neither executed such a directive nor explicitly objected to organ removal was the family to be allowed to make that decision. Thus, the 1968 Uniform Anatomical Gift Act attempted to assign primary property rights to cadaveric organs to the donor.” (p. 11)

for the Organ Procurement and Transplantation Network (OPTN) and the Scientific Registry of Transplant Recipients (SRTR). The OPTN now maintains a national listing of transplant candidates and is responsible for a computer matching system for the allocation of organs. The United Network for Organ Sharing (UNOS) is a private, non-profit organization that is now responsible for the OPTN's organ procurement and allocation activity. NOTA also authorized the DOT to create organ procurement organizations (OPOs). In the U.S., 58 OPOs exist with their own exclusive geographic region, and they face little competition³. The basic process of procurement and allocations is as follows: When an OPO acquires an organ, the organ is entered into the UNOS system to be matched with a patient on the waiting list. NOTA's largest impression on U.S. organ procurement was the prohibition of organ sales⁴.

The third piece of legislation was the 1987 Uniform Anatomical Gift Act. The update to the 1967 predecessor had three main aspects: Requiring hospitals to check the willingness of a patient to become an organ donor, instructing emergency personnel to reasonably check for a donor card of a victim, and proscribing organ purchases and sales⁵. States have also adopted laws corresponding to the above organ donation and procurement laws⁶.

³ In 2009.

⁴ Kaserman and Barnett (2002) adds that "(...) while organ donors and their families are proscribed from receiving payment for their consent to remove organs, all other parties involved in the production and supply of transplant services are exempted from the provision. They can all be paid." (p. 14)

⁵ *Ibid.* "Like its predecessor, the recent act continues to place legal priority on the donor's wishes regarding organ removal over the preferences of surviving family member." (p. 14)

⁶ *Ibid.* "Most notably, regulations issued by the Health Care Financing Administration in August 1998 require all hospitals receiving federal (...) funds to refer all in-hospital deaths to their regional organ procurement organization." This is known as 'required referral.' "Where organ donation appears feasible (...) the organization's representative will go to the hospital to approach the family." (p. 15)

By ostensibly trying to cure the shortage, these laws have further propagated it, which have required more regulation and other policy initiatives to mitigate the dire consequences while staying within the altruistic framework of the current organ procurement system. Such policy initiatives are the Organ Donation Breakthrough Collaborative and its successors.

This study is organized into five chapters as follows: Introduction, Literature Review, the Analytical Framework, Estimation and Results, and the Conclusion . The Literature Review provides an overview of the relevant theory and history of kidney transplant activity and policy. The third chapter builds the theoretical framework with discussions of the expected relationships among the variable choices. The fourth chapter estimates the theoretical models with an accompanying discussion of the empirics used. The results are examined with the lens of both statistical and economic significance and magnitude. The final chapter concludes the study with reflections of the results and suggestions for further research and policy changes.

CHAPTER II

THE LITERATURE REVIEW

The following chapter examines previous works relevant to the kidney transplant discussion. While there is discourse on the general subject of organ transplants, this study concentrates on the history, policies, and activity levels of kidney transplants. The following section looks upon the history of kidney transplants in the U.S., in particular, as well as the publicly initiated programs that resulted. Specifically, this study analyzes the impact of one of the more recent organ policies, the Organ Donation Breakthrough Collaborative (ODBC).

A handful of studies exist on the subject of the transplant policy. T. Randolph Beard, David L. Kaserman, and Rigmar Osterkamp (2010)⁷ examined organ procurement policy in the United States. Metzger et al. (2003), Sung et al. (2005), Saidi et al. (2007), Howard et al. (2007), and Leichtman et al. (2008) provide analyses of the impact of the ODBC and organ donor types. The most prominent recent treatment of transplant history and overall policy is Kaserman and Barnett (2002). Beard, Jackson, and Kaserman (2007; 2008) looked at kidney transplant activity between living and deceased donors as well as examining the current and alternative organ policies⁸.

Beard, Kaserman, and Osterkamp (2010) thoroughly and most recently examined the history of “a long series of reforms” to organ procurement policy that have an

⁷ Forthcoming, MIT Press.

⁸ Beard, Jackson, Kaserman (2008) “A thorough and objective evaluation of the [ODBC] has not, to our knowledge, been conducted.”

“overall track record [that] is mixed at best.” Beard, Kaserman and Osterkamp (2010) explains how “[t]he plain evidence of rising waiting lists, lengthening time until transplant, and patient desperation” have introduced these reform suggestions of which only some “have produced measurable results.” (p. 1) These reactions to the shortage are intertwined with their own successes. Untangling these responses is a significant undertaking and requires historical context.

Beard, Kaserman, and Osterkamp (2010) started their historical analysis by looking at three categories of policies. The first category deals with the behavior of both potential and actual donors. Some examples in the category, that exhibit this donor behavioral influence, are advertising and changes in donor consent laws. The purpose of advertising is to educate people to make an informed decision regarding donor consent. The laws that regulate the items in this category are, among state laws, the ones mentioned in the first chapter. Among public programs, there are private ones as well. Beard, Kaserman and Osterkamp made note that “physicians almost always ask permission of surviving family members before removing organs” no matter the wish of the donor. This observation seems to contradict the wish of the law which puts premortem consent at the behest of the deceased.

Beard, Kaserman and Osterkamp (2010) continued, “A second type of program aims to increase the extent to which the existing pool of potential organ donors is realized.” The category includes paired exchange programs which “are under intense study in the U.S.” These programs are, basically, transplant scenarios between two patients in which an original donor gives a kidney to someone who is worse off. In the extreme case, that person then gives his or her poorer kidney to another, and so on until

the last organ is useless⁹. Utilization of sub-par organs such as those from non-heart beating and marginal sources falls into this category. Beard, Kaserman and Osterkamp explained that these “donors exist in relative abundance already whereas standard criteria comprise perhaps only 1% of all hospital deaths,” and programs such as the ODBC “provide hospitals with both incentives to aggressively pursue donations, and additional resources to support such efforts, also seek to make efficient use of potentials that already exist in the system.” With the dissemination of these best practices, the promise is that the performance of all the hospitals will increase¹⁰. Beard, Kaserman and Osterkamp offered a caveat that “[s]uch approaches, of course, are limited by the potential supply of donors.” The supraconstraint makes itself apparent in the supply-side of the shortage at the legal zero-price of eliciting transplants¹¹. The demand for kidneys is the direct cause for the waiting lists.

The third category represents the programs that reduce the demand for transplants. Beard, Kaserman and Osterkamp (2010) illuminated the fact that “[m]any individuals needing kidney transplants, for example, suffer from poorly-managed diabetes, or they have untreated hypertension that results in organ damage.” The situation seems that a lot of the demand for kidneys derives itself from preventable problems. Renal problems and failures manifest themselves in the demand for transplantable kidneys. By minimizing

⁹ Kaserman and Barnett (2002) “Medically feasible to receive more than one renal transplant over patient’s lifetime. (...) Success rates, however, tend to decline with the number of kidney transplants a patient has received.” (p. 161)

¹⁰ Beard, Kaserman, and Saba (2006) “Noting the wide variation in relative performance across existing OPOs, these parties allege that the organ shortage can be eliminated by bringing the performance of all OPOs up to the observed level of those with the highest collection rates. Such a proposal, however, rings hollow in the absence of a practical and effective method to bring about the necessary increase in performance.” (p. 15)

¹¹ At the legal price of zero, the quantity demanded of kidneys for transplantation exceeds the quantity supplied. This inequality is the shortage for a specific period of time. Waiting lists are summations of multiple periods of shortages.

some of the known causes for renal failures, demand could theoretically be decreased, at least up to some level. Beard, Kaserman and Osterkamp duly noted the “[p]rograms that seek to increase donation rates are (...) limited by the absolute numbers of patients who die under circumstances consistent with donation.” As stated before, the ODBC is an example of the second sort of program, a supply-side and procurement program, and its goals are consistent with wanting to induce behavior in hospitals and potential donors.

The official report of the ODBC stated that, “[t]o raise awareness about organ and tissue donation as national public health issue and increase donation rates, U.S. Secretary of Health and Human Services (HHS) Tommy G. Thompson initiated the *Gift of Life Donation Initiative* in April 2001.” (p. 1) There were six components of the initiative. Among them were the following five: corporate workplace education, model donor card, forum on donor registries, consideration for a national medal, and integration into driver education classes. Thompson announced the sixth component on April 25, 2003: The Organ Donation Breakthrough Collaborative. The purpose of the initiative was “to generate significant, measurable increases in organ donation by helping the national community of organ procurement organizations (OPOs) and hospitals to quickly identify, learn, adapt, replicate, and celebrate ‘breakthrough’ practices of their colleagues that are associated with higher donation rates”. (p. 2) Among their goals were to increase average conversion rates, increase donations, increase transplantation by 6,000 per year, help save lives of thousands of people, and prevent up to 17 deaths per day¹².

¹² The final report included the following: “On September 9th and 10th, 2003, HRSA will launch Phase 2 of this effort by conducting the first in a series of three workshops designed to support rapid replication of breakthrough practices.” (p.2) The report continued, “[a]s part of phases three and four, OPOs and hospitals will apply practices in their own organizations and monitor and celebrate anticipated successes.” (p.2)

Sung et al. (2008) stated that “[t]he aim of this initiative is to increase the number of organs transplanted at each program by giving centers the tools to examine their own practices.” (p. 924) Sung et al. (2008) mentioned further that the goal of the first collaborative, the ODBC, as well as its successors, the Organ Transplantation Breakthrough Collaborative (OTBC) and the Organ Donation and Transplantation Breakthrough Collaborative (ODTBC), with the latter two being initiated in 2005 and 2006 respectively, “[was] to increase the number of organs available for transplantation and the number of organs available for transplantation and the number of organ transplants in the U.S.” (p 925) Leichtman et al. (2008) added, “[r]ecognizing the opportunities to increase the pool of available organs extend beyond increasing conversion rates a second round of collaborative, the National Organ Transplantation Breakthrough Collaborative, was convened in October 2005 with the objective of increasing the average number of organs transplanted per donor to 3.75.” (p. 952)

The discussion of donation rates and absolute numbers of patients is relevant to the analysis of the ODBC. One of the goals of the policy was to increase the conversion rates among all hospitals¹³. Beard, Kaserman and Osterkamp (2010) stated that the approach is plausible in that “the very large observed differences in the donor yields across hospitals.” Beard, Kaserman and Osterkamp gave the definition of conversation rates as follows: “[T]he rates at which potential brain dead donors within target age groups are recruited as actual organ donors.” Beard and Kaserman cites that “reforms

¹³ Beard, Kaserman, and Osterkamp (2010) “As a result, ‘required referral’ was introduced, which sought to make hospital refer potential donation opportunities to appropriate regional authorities, such as the OPOs in the U.S., (...). Further reforms, such as the Spanish model and the OBC in the U.S., replace regular hospital personnel with specifically-trained expert teams who make requests of family members, relieving hospital workers of this difficult and unwelcome task.”

such as the [ODBC] can almost certainly increase conversion rates and save lives by expanding transplantation” but “unlikely to provide enough additional organs to stabilize waiting lists.” This caveat is relevant to any discussion of success attributed to the ODBC.

In order to properly analyze any temporal effects on transplants, the sources of transplants must be established. While discussing kidney transplants, there are two broad categories of donors: Deceased and living. With regards to deceased donors, there have been three types established by the transplant community¹⁴. While the criteria have changed over the relative short period of time that the data has been kept, the current titles are as follows: Standard criteria donors (SCD), extended criteria donors (ECD), and donors after cardiac death (DCD). Standard criteria donors cover the deceased donors that have died under hospital care. An extended criteria donor categorizes a more marginal usefulness for kidneys. Donors after cardiac death, once known as non-heart beating donors, are donors from whom kidneys are transplanted despite the fact that the flow of blood has stopped for a period of time. The criteria for ECD transplants have changed over the last decade¹⁵. In fact, the incidence of change occurred during the year before the ODBC implementation. The problem brought upon by this coincidence complicates the analysis.

¹⁴ Among the entities that define donor types are the OPTN/UNOS Organ Availability and Kidney/Pancreas Committees.

¹⁵ Saidi et al. (2007) “Before the organ donation collaborative, the term ECD was used to classify subsets of DD that are aged 60 years or older and those aged 50-59 years with at least two of the following characteristics: history of hypertension, SCr level greater than 1.5 mg/dL (132.6umol/L) and cerebrovascular cause of death.” (p. 2772)

When facing a transplant situation, a living donor (LD) is the most medically preferred¹⁶. The time of the operation is easily scheduled and a proper match can be made. A costlier alternative to a deceased donor is a kidney from an LD. Traditionally, a patient brings a volunteer for donation¹⁷. The insurance companies bear the financial costs for the recipient while the living donor bears the implicit costs. Some of these costs include loss of income and increased chance of future health problems associated the lack of a second kidney. There is also considerable stress for both parties, and there is the creation of tension amongst family members.

Beard, Kaserman and Osterkamp (2010) highlighted a probably common problem in the donation game. Since there needs to be a “donor-recipient genetic match,” Beard, Kaserman and Osterkamp wrote that “many individuals who need transplants are only able to recruit a donor who is unable to provide them with a compatible organ” and, therefore, show that although a living donor is willing he or she is not necessarily able, and vice versa.

Metzger et al. (2003) offered an ideal deceased kidney donor: “The ideal deceased organ donor is a younger person who dies from traumatic head injury that is isolated to the brain and leaves the thoracic and abdominal organ function intact.” (p. 114) An interesting comment that Metzger et al. revealed was that “the term ‘expanded’ be used to refer to the donor whose organs may be associated with poorer outcome because the term

¹⁶ Kaserman and Barnett (2002) “Specifically, while short-term success (one-year graft survival) rates are approximately equal for living and cadaveric donor kidney transplants the long term success rates diverge significantly.” (p. 127)

¹⁷ Beard, Jackson, and Kaserman (2007) “The welfare calculus is muddled, of course, by the facts that (1) living donor kidney transplants typically have better patient outcomes, and are medically superior, and (2) donating a kidney while alive, although quite safe, is not completely without risk, and does impose higher removal costs, medical care expenditures, and so on.” (p. 11)

‘marginal’ may be considered pejorative by the patients who receive them, as well as by the programs that transplant them.” (p. 114)

Beard, Kaserman and Osterkamp (2010) noted that “utilization of these substandard sources is actually greater (...) because on average fewer kidneys are obtained from such marginal donors. For example, the average SCD provided 1.68 kidneys for transplantation in the U.S. in 2005 (...), while the typical ECD provided only 0.90 grafts in the same year.” There are advantages and disadvantages to using nonstandard organs. Beard, Kaserman and Osterkamp stated that nonstandard organs are “in relatively abundant supply.” The most vital criterion between standard and nonstandard is a functioning heart. With the lack of a functioning heart, “potential donors (...) often die under conditions that present enormous challenges to transplantation, and an expensive effort would be required to create and maintain a system for harvesting such organs in a timely manner.” Beard, Kaserman and Osterkamp realized that “patients selected for ECD grafts are not identical to those selected” for SCD ones, and it is almost “certain that, taking the likely characteristics of ECD and DCD organs into account, one expects grafts performed using such organs to be less medically satisfactory in most cases.” (p. 27) Kaserman and Barnett (2002) stated that the situation is not “that such operations should not be performed” but that “the relevant comparison may be between accepting a substandard graft and receiving no graft.” Saidi et al. (2007) contemplated the comparison with respect to one of the alternative treatments, dialysis: “If we consider an increased an increased risk of complications and death for those who

have to wait, kidney transplants clearly save more lives and cost less as a treatment than does dialysis.” (p. 2772)¹⁸

The inherent problem of donor classification and the criteria by which hospitals classify kidneys haunt any inter-temporal evaluation of the ODBC. In light of that, Beard, Kaserman and Osterkamp (2010) examined the underlying current of difficulties that complicates evaluating the “success” of the ODBC. These difficulties include the “modified criteria applied to donors under the program.” Beard, Kaserman and Osterkamp gave the example that the ODBC accepted donors up to 70 years old as SCD while until 2006 the policy classified donors over the age of 60 as ECD. Beard, Kaserman and Osterkamp called for a “further examination of the mix of donors” in order to evaluate the effects over time.

Beard, Kaserman and Osterkamp (2010) stated that “[e]vidence suggests that OBC has produced increases in measures donations among participating hospitals.” (p. 10) Beard, Kaserman and Osterkamp added that “the ability of participating hospitals to sustain observed donor gains is unclear”; since the SCD criteria was changed to include older donors, “one can increase donor rates with no real improvement.” The undercurrent of these changes, “inevitable in a system characterized by shortages,” is the partial endogeneity of donor classifications and waiting lists is that they “evolve on their own in response to shortage conditions.” Beard, Kaserman and Osterkamp warned that “caution must be attached to any conclusions” of any ODBC success, because “the issue of sustaining gains must be considered.” Beard, Kaserman and Osterkamp added that

¹⁸ Saidi et al. (2007) “(...) on average, recipients of ECD kidney transplants lived 5 years longer than transplant candidates who remained on dialysis, whereas SCD transplant recipients had a 13-year survival benefit.” (p. 2772-2773)

“[i]n the case of the [ODBC], the focus of donor population remains brain dead hospital patients who are free of numerous diseases (e.g. hepatitis, HIV, tuberculosis, and cancer), less than 70 years old, and so on.” An examination of the donor mix may reveal an increase in only deceased donors like SPD, however.

Sung et al. (2008) recognized that “[m]uch of the growth in organ donation has coincided with the establishment of the National Organ Donation Breakthrough Collaborative.” Sung et al. mentioned that “the expansion of the donor pool by increasing use of expanded criteria donors (ECD), donors after cardiac death (DCD) and those standard criteria donors (SCD) not previously considered for organ donation” as well as increases in the size of donor registries and the “recognition of the primacy of first person consent documentation” have been key influences in the high numbers of consents and recoveries. (p. 922)

Sung et al. (2008) noticed an increase of the number of kidney transplants. Sung et al. (2008) states that the “trends coincide with the implementation of the Organ Donation Breakthrough Collaborative and trends in donation and utilization of individual organs tend to follow these overall patterns.” (p. 924)

Sung et al. (2008) noted that “... the disparity between the increase in consented organ donors and the more modest increase in transplants can be at least partially attributed to an overall decrease in organ quality based on chronic disease and increasing numbers and types of organ donors being considered.” (p. 926) These attributions to the disparity are due to the relaxations to SCD and ECD criteria.

Sung et al. (2008) provided a detailed rate analysis of kidney donations and transplants. Sung et al. concluded that the “trends indicate that the continued expansion of the DCD

kidney donor pool includes a greater percentage of kidneys likely to be transplanted than for SCD and ECD, where increases in recoveries have outpaced increases in transplants.” (p. 929) One of the main goals of the ODBC was to increase conversion rates amongst all Donor Service Areas (DSAs). Leichtman et al. (2008) noted that “the average conversion rate grew from 48% in 2002 to 65% in 2006” while “the counterbalancing average discard rate was 13% in 2002 and 16% in 2006.” (p. 949) This outpacing of recovery rates to transplant rates implies an increase of wasteful actions.

Sung et al. (2008) examined the trends in living donation. There was a decrease in the number of living donors. Sung et al. notices that the “trend, combined with the recent increase in deceased donors, has resulted in the number of deceased donors exceeding the number of living donors for the third straight year.” (p. 931)¹⁹ Sung et al. predicted that “small decrease in living donors in the past 2 years may represent a saturation point in the supply of living donors, or it may be related to the increase in transplants from deceased donors.” (p. 931)

Sung et al. (2008) concluded that “[r]apid increase in deceased organ donation have been achieved since the implementation of the [ODBC] in 2003, and have largely been attributed to this effort.” (p933)

Beard, Jackson, and Kaserman (2007) found evidence of a substitution effect between deceased and living donors. They added that if there is an “increase the supply

¹⁹Leichtman et al. (2008) stated that, “[t]he number of living-related kidney donors grew from 3224 in 1997 to a peak of 4349 in 2001. Since then, the number of living related donors decreased to 3952 in 2006.” Leichtman et al. added that from the same time period “the number of living unrelated kidney donors grew steadily from 655 to 2312.” (p. 943) Also, Leichtman et al. stated that “[t]he donation of pre-transplant dialysis exposure is recognized as having a significant adverse affection post-transplant kidney allograft and patient survival.” (p. 955)

of deceased donors, it seems reasonable to anticipate a reduction in the supply of living donors as waiting lists and expected waiting times begin to decline.”

Beard, Jackson, and Kaserman (2007) stated that “[a]s the waiting lists grow and the death toll mounts, it seems likely that sheer desperation is playing an increasingly important role, and that a greater portion of living donations are being motivated by direct payments and/or intrafamily emotional coercion.”

With regards to the decisions made amongst different donor types, Beard, Jackson, and Kaserman (2007) claimed “an important change in cadaveric donor practice in recent years is the use of both non-heart beating donor organs, and so-called expanded criteria donors,” and that “[i]n both cases, the urgency imposed by the shortages has induced surgeons to turn to organs of lesser quality, forcing patients to accept worse outcomes than those offered by regular criteria donation.”

There are two general interpretations of the results of the ODBC. Howard et al. (2007) wrote that “[t]he experience to date is encouraging” but that the situation “is also unclear whether quality improvement can yield additional gains in the conversion rate.” (p. 2169) Beard, Jackson, and Kaserman (2008) stated that “the initiative is not going to resolve shortage” and “[e]ven if, contrary to reasonable expectations, all OPO relative inefficiencies were miraculously eliminated (...), the increase in donor collection rates would still be insufficient to eliminate the shortage.” (p. 26)

With these general theoretical findings, the next chapter will focus on an analytical structure of the question of performance of the ODBC and its effects.

CHAPTER III

THE ANALYTICAL FRAMEWORK

The following chapter builds a theoretical framework with which to properly analyze the effects on transplant activity. The purpose of the study is to examine whether the ODBC has improved the current situation caused by over 30 years of lasting kidney shortages. An increase in donation and, more importantly, transplantation activity signifies an improvement. While donation is obviously important in the process, transplantation is the direct cause of saving lives. For example, a donated kidney may simply not be transplanted due to medical mismatch or other errors.

The overarching conceptual model must be designed to inspect whether there has been change in transplant activity since the implementation of the ODBC. The study is going to use time series estimations since the transplant activity of a previous period affects the activity of the current period.

In the simple representation of the model, the total transplant activity ($TRANSPLANT_t$) is a function of the lagged values of the total transplant activity ($TRANSPLANT_{t-1}$) and a dummy variable for the periods before and after the ODBC ($POLICY$). The general model is represented as follows:

$$(1) \quad TRANSPLANT_t = f(TRANSPLANT_{t-1}, POLICY)$$

The conceptual model is relatively simple. However, a more specific model is to be utilized if the study is to inspect the transplant activity for kidneys.

The clear choice for the dependent variable of the model is total kidney transplant activity (TOT_t). The level variable is the number of nationwide kidney transplants. Since previous studies have used the logarithmic transformation of similar organ transplant data, this study employs a transformed variable for all of the relevant organ data (Beard, Jackson, and Kaserman 2007).

$$(2) \quad TOT_t = f(TOT_{t-1}, POLICY)$$

A more specific conceptual model (2) treats the total transplant activity of the current period (TOT_t) as a function of the total kidney transplant activity of the previous period (TOT_{t-1}) and the OBCD. One of the stated goals of the initiative is to increase the number of donations as well as transplants. If the ODBC is indeed effective, the overall number of transplants should increase. There should be a markedly different level of activity from the periods before and after the start of the initiative. If not, the results will either show that the initiative introduced no significant change or a decrease in activity. The latter result would mean, perhaps, that inefficiencies are now present, or the policy has exacerbated previous inefficiencies²⁰.

In order to thoroughly inspect the situation, this study examines the effects seen in the not only the total activity level of kidney transplants but also the levels of different donor types on one another. More specifically, if the ODBC has affected transplant activity of one donor type, this change may have caused a change the activity of another donor type. Perhaps, a substitution effect is present that will effectively offset any improvements introduced by the program.

²⁰ T. Randolph Beard, David L. Kaserman, and Richard P. Saba (2006)

The model of equation (2) purports that the log-transformation of transplant activity is a function of previous transplant activity (TOT_{t-1}) and whether or not the current period occurs before or after the ODBC commenced ($POLICY$). All of the models in this study will follow this structure in order to inspect these relationships. By merely changing the category of donor types, the study examines the effects of the ODBC. While investigating the effect on the total transplant activity is generally important, the effects on living donor transplant should be analyzed separately.

The next model dissects the effects on the transplant activity from living donors. Since transplants from living donors are, at least, partial substitutes for transplants from deceased donors, the question is important. The question to answer with this model is whether the ODBC has affected living donor transplant activity (LD) since the policy focused on increasing deceased donor transplants. Of course, the analysis of the deceased donor transplant activity is critically more important than donation activity. Theory suggests that living donor transplant activity has a negative relationship with cadaveric donor transplant activity. This suggestion is logical; as opportunities for a cadaveric donation appear less and less likely (what happens often for people on waiting lists), patients become more desperate and look increasingly at family members for organs²¹.

Equation (3) follows the same structure of the general conceptual model by looking at the transplant activity of the current period against previous transplant activity and using presence of the ODBC as an instrument of bisection. In this case, the previous

²¹ Beard, Jackson, and Kaserman (2007) “(...) donations from living donors are assumed to represent acts of some desperation, since the medical advantages of live donor transplant would seem to be insufficient to motivate such an act when an appropriate deceased donor organ is available.”

periods of both living donor transplant activity (LD_{t-1}) and total deceased donor transplant activity ($SPSCD_{t-1}$). The SPSCD can be further divided to be the sum of both sub-par donor transplants (SPD) and standard criteria donor transplants (SCD). The next model is as follows:

$$(3) \quad LD_t = f(LD_{t-1}, SPSC_{t-1}, POLICY)$$

Equation (3) is similar to Equation (1) in that it will look at transplant activity against a previous period while considering the installation of the ODBC. The model will investigate the SCD transplants (SCD_t) by looking at a lagged SCD transplant variable (SCD_{t-1}) and a binary variable for the ODBC ($POLICY$). The general model is as follows:

$$(4) \quad SCD_t = f(SCD_{t-1}, POLICY)$$

The final model investigates the effect of the ODBC on the so-called sub-par donor transplants (SPD). As stated before, the DCD and ECD compose the sub-par category. If SCD is an ideal origin for transplants from a deceased source, both DCD and ECD are not. The general model is as follows:

$$(5) \quad SPD_t = f(SPD_{t-1}, POLICY)$$

To represent what equations will be estimated, the explicit versions of equations (2), (3), (4), and (5) are as follows:

$$(6) \quad TOT_t = \alpha_0 + \alpha_1 TOT_{t-1} + \theta POLICY + \varepsilon_t$$

$$(7) \quad LD_t = \beta_0 + \beta_1 LD_{t-1} + \beta_2 SCSP_{t-1} + \pi POLICY + \omega_t$$

$$(8) \quad SCD_t = \gamma_0 + \gamma_1 SCD_{t-1} + \kappa POLICY + \mu_t$$

$$(9) \quad SPD_t = \lambda_0 + \lambda_1 SPD_{t-1} + \psi POLICY + \xi_t$$

Table 1 lists all of the variables and other descriptive content of the equations. ε , ω , μ , and ζ are normally distributed spherical errors which may be autocorrelated. This study seeks consistent estimates of the parameters α_0 , α_1 , θ , β_0 , β_1 , β_2 , π , γ_0 , γ_1 , κ , λ_0 , λ_1 and ψ .

The data is the number of renal transplants performed with an observation length from the second quarter of 1994 to the fourth quarter of 2007. The data used in the study was based upon OPTN data through UNOS sources. Data is available starting from the first quarter in 1988, but since ECD was not collected until the second quarter of 1994, the data truncation exists²².

The number of transplants performed is a more meaningful choice for unit of observation rather than the number of donations. Kaserman and Barnett (2002) provide situation in which donations do not necessarily mean transplantation: “For various reasons, a number of organs are collected but do not get transplanted. The organs may exhibit physical flaws that are discovered when they are removed from the cadaver, they may be damaged during removal or transplant, and so on.” (p. 140) So, transplantation is an important action for patient survival.

From the previous background history of kidney transplants, this study has the following hypotheses. The total kidney transplant activity is expected to positively affected by the ODBC and the previous period's activity. Living donor-transplant activity should exhibit a substitution effect with the number of deceased donor-transplants. The

²² There was ambiguity about which periods to choose to be after the initiation of the ODBC. There were two phases. During the initial phase, the ‘best practices’ from the transplant hospitals and donation centers were observed and collected; the next phase was for the learning and application of the practices. The choice of the beginning date for the *POLICY* variable was therefore chosen to be the third quarter in 2003 since the first phase began in that period.

policy is expected to not have a significant effect on LD transplants since the policy aimed to increase deceased donations and not living donations²³. As for the two models for the deceased donor-transplants, the policy effect is expected to be both positive and large, since there is room for expansion into deceased donation. The same expectation hold for the lagged counterpart of each donor type.

In the next chapter, the results of the estimations for the explicit models are presented as well as a new complementary group of equations. The economic interpretation of each of the coefficient estimates follow the results.

²³ Also, it would be an anomaly for the ODBC to increase living transplants as people, plainly speaking, do not want to be cut open

Table 1:
Definitions and Descriptive Statistics

Variable	Definition	Mean	Std. Dev.	Min.	Max.
TOT_t	Total number of kidney transplants from all donor types in a given quarter	3483.200	543.672	2607	4552
LD_t	Transplants from living donors in a given quarter	1315.291	318.360	725	1774
SCD_t	Transplants from standard criteria donors in a given quarter	1755.345	145.539	1526	2221
ECD_t	Transplants from extended criteria donors in a given quarter	319.273	62.757	189	445
DCD_t	Transplants from donors who suffered cardiac death in a given quarter	93.291	86.347	14	311
SPD_t	Transplants from sub-par sources (DCD and ECD)	412.564	143.457	222	737
$SPSCD_t$	Transplants from deceased sources (SPD and SCD)	2167.909	268.410	1821	2911
$\alpha_0, \beta_0, \gamma_0, \lambda_0$	Constant terms				
$LOGTOT_t$	Logarithmic transformation of TOT	8.144	0.158	7.866	8.423
$LOGLD_t$	Logarithmic transformation of LD	7.149	0.265	6.586	7.481
$LSPSCD_t$	Logarithmic transformation of $SPSCD$	7.674	0.118	7.507	7.976
$LOGSCD_t$	Logarithmic transformation of SCD	7.467	0.081	7.330	7.706
$LOGSPD_t$	Logarithmic transformation of SPD	5.969	0.324	5.403	6.603
$POLICY$	Dummy variable with '0' for periods before the initiation of the Organ Donation Breakthrough Collaborative (2003 QIII) and '1' otherwise	0.309	0.466	0	1
$TIME$	Linear time trend			1	55
$\varepsilon_t, \omega_t, \mu_t, \zeta_t$	Error terms				
t	Time period (quarter of one year)				

CHAPTER IV

ESTIMATIONS AND RESULTS

The following chapter estimates the specified models from the preceding chapter. Before attaching any conclusions to the Ordinary Least Squares (OLS) results, a few tests need to be conducted in order to confirm the use of an econometric method. There is risk that the time series estimations exhibit unit root processes in which a correlation exists among the error terms. The tests used were Augmented Dickey-Fuller, Dickey-Fuller General Least Squares, and the Phillips-Perron. All tests had a least one case in which a unit root process is present for the variables. In order to continue to use OLS in the estimations, a test for cointegration is necessary.

Using Engle-Granger methodology, the residuals of the relationships in the estimations in questions are tested for stationarity. The result of the finding is that the OLS results are stationary. The stationarity implies that the results are super-consistent, and OLS estimation is correct to use for the time-series evaluation.

Before estimation, there is a very high chance of autocorrelation. Since we do not know P or ρ for that matter (like σ in OLS), we cannot obtain BLUE estimates and lose nice finite sample properties. As previous practice for similar data dictated, the run of estimations use Newey-West standard errors with three periods of lag (Beard, Jackson, & Kaserman 2007). By using this variance estimator in the presence of autocorrelated

disturbances, the estimation will yield the appropriate t-statistics²⁴, especially since the sample size is relatively small. As previously stated, OLS is the method of time-series estimation for all the following estimations.

Table 2 illustrates the results for the main hypothesis regarding the total activity in the number of kidney transplants, TOT_t . Recall that the important point for investigation is to determine if the ODBC matters. First and most strikingly, all of the coefficient estimates for the explanatory variables are statistically significant. The total number of kidney transplants from the previous period ($t-1$) has a positive effect upon the current period (t). Since the organ variables are in logarithmic form, a ten percent increase in the total number of all types of kidney transplants from the previous period, TOT_{t-1} , will increase the current period's living donors by 8.6 percent. Using the mean of the total levels of kidney transplants for 2006 (about 4273 grafts per quarter)²⁵, an increase of about 427 grafts in the previous quarter increases the next quarter total by about 367²⁶.

Table 2:
OLS Results for TOT_t

	Coefficient	Standard Error	T-ratio
Constant	1.138	0.342	3.33***
TOT_{t-1}	0.860	0.042	20.25***
<i>POLICY</i>	0.028	0.014	1.93*
N	55		
F-value	903.33***		

*Note: The model is estimated using STATA. *** and ** denotes statistical significance at the one and ten percent level, respectively. Standard errors are the Newey-West variant. T-ratios are absolute values. Organ variables are measured in logarithms.*

²⁴ Despite contradictory direction by theory and practice, L was chosen to be 3. Greene (2003) states that “[c]urrent practice specifies $L \approx T^{1/4}$.”

²⁵ See appendix.

²⁶ This study uses 2006 as the typical year with regards to kidney transplants levels. The means from that year are used as a reference to analyze the relationships amongst time periods and donor types.

The variable of investigation, *POLICY*, is positive and statistically significant. Using the mean of *TOT* to convert the logs into levels, tangible results can be examined (rather than percentages). The coefficient of *POLICY* is small and, indeed, so is the effect of the ODBC. There seems to be an increase of about 99 renal grafts per quarter. The increase seems to be consistent with the aims of the initiative. As will be examined later, exogenous temporal effects may be present. To further investigate the question of the effects of the ODBC, the living and deceased donor types must be analyzed separately.

Any analysis of renal transplants and performance of the policy in question must control for the mix of donor types. To refresh estimations completed by Beard, Jackson and Kaserman (2007), the second model inspects the relationship between living and deceased donors in the periods before and after the initiation of the ODBC. Table 3 reveals the results of the estimated model. The F-statistic is significant at the one percent level. The coefficient estimates of the variables LD_{t-1} and $SPSC_{t-1}$ show the expected signs. LD_{t-1} appears to mostly explain LD_t .

Table 3:
OLS Results for LD_t

	Coefficient	Standard Error	T-ratio
Constant	2.908	0.914	3.18***
LD_{t-1}	0.998	0.028	35.62***
$SPSC_{t-1}$	-0.378	0.140	2.69**
<i>POLICY</i>	0.052	0.027	1.92*
N	55		
F-value	1746.22***		

*Note: The model is estimated using STATA. ***, ** and * denote statistical significance at the one, five and ten percent level, respectively. Standard errors are the Newey-West variant. T-ratios are absolute values. Organ variables are measured in logarithms.*

The deceased transplants from the last period ($t-1$) is likewise significant and negatively affects living donor transplants. By using transplant totals from 2006, around 38 percent of all transplants originated from living donors. A ten percent increase in deceased donor transplants (about 260) reduces living donor transplants by 3.8 percent (about 61). The result echoes Beard, Jackson, and Kaserman (2008) with respect to a substitution effect being present. Their analysis included a caution that “the implication of this finding for resolving the shortage through increases in deceased sourced grafts is not encouraging.” They continue by providing an explanation for this result: “[T]he extent to which theoretically available organs are actually harvested and transplanted into patients is a matter of effort and choice by hospital authorities, so it is not inconceivable that deceased donor transplants might respond to wait list counts and living donor activities.”

To expand previous work, the dummy variable for the policy is installed in order to pin down any effect. As it appears, *POLICY* has positively increased the number of living donor transplants, *LD_t*. By performing a percentage analysis and converting the logarithmic effects against the means for the relevant period, the ODBC has increased the level of *LD* by about 70 transplants per typical quarter. The result seems counterintuitive since the ODBC aimed to increase deceased donor transplants but not necessarily living donor transplants. This may be mitigated once we add another specification for time.

Having dealt with living donors in the policy context, this paper turns to the inspection of the different types of deceased donor transplants. Table 4 discloses the estimated results for *SCD*.

Table 4:
OLS Results for SCD_t

	Coefficient	Standard Error	T-ratio
Constant	6.078	0.622	9.77**
SCD_{t-1}	0.182	0.084	2.17***
$POLICY$	0.101	0.023	4.38***
N	55		
F-value	46.11***		

*Note: The model is estimated using STATA. *** and ** denote statistical significance at the one and five percent level, respectively. Standard errors are the Newey-West variant. T-ratios are absolute values. Organ variables are measured in logarithms.*

Once again, the model is simple with a lagged variable and a dummy for eliciting the policy effect. The coefficient estimates are significant, at least at the five percent level, and have positive relationships with the dependent variable. A ten percent increase in SCD count of the previous period ($t-1$) increases the transplants of the same type by 1.8 percent. As for the policy variable, there is a significant and positive impact on SCD_t . Using the previously used mean-conversion method, the presence of the policy accounts for roughly 187 additional transplants from standard criteria donors per quarter.

To continue with the analysis, Table 5 illustrates the results for the innovated term, SPD_t , which consists of the sum of DCD_t and ECD_t . When compared to SCD and LD , these sub-par organs are simply not preferred. However, they are preferred to no kidney transplant at all. The coefficients are significant and positive. A ten percent increase in SPD from the previous period ($t-1$) will only increase the current period t by 1.1 percent. The relatively large policy coefficient is of particular interest. Putting levels to the percentages, ECD and DCD composed approximately 15.4 percent of transplants performed in 2006. The situation seems to be that the ODBC has had a large relative effect on SPD_t by increasing its transplant count by 170 per quarter.

Table 5:
OLS Results for SPD_t

	Coefficient	Standard Error	T-ratio
Constant	5.150	0.318	16.21***
SPD_{t-1}	0.111	0.058	1.93*
$POLICY$	0.533	0.088	6.09***
N	55		
F-value	45.80***		

*Note: The model is estimated using STATA. *** and * denote statistical significance at the one and ten percent level, respectively. Standard errors are the Newey-West variant. T-ratios are absolute values. Organ variables are measured in logarithms.*

When comparing the effects of the ODBC on SCD_t and SPD_t , sub-par sourced transplants increase almost as much as standard criteria sourced transplants. As mentioned in a previous chapter, there is available capacity for hospitals to expand in relation to SPD and ECD in particular. This finding seems to be related to the increase in the aforementioned discard rates.

Previous work by Beard, Jackson, and Kaserman (2007) has dictated that consideration be made with regards to an exogenous temporal effect. With regards to the central question of whether the OBC matters, a time trend should be added to existing specification. The models will be re-estimated with the addition of a time trend variable.

The results for the above models are sensible and seemingly appropriate via the hypotheses. However as mentioned by Beard, Jackson, and Kaserman (2008), linear temporal progression needs to be considered. As previously practiced, an alternate specification will be made to the models. The Newey-West correction will be retained for each of the re-estimated equations.

To mirror previous analyses, Table 6 illustrates the results for the time trend specification of the total number of kidney transplants per quarter. As before, the

previous period ($t-1$) has a significant (albeit at a ten percent level) and positive effect on the current period (t). However, the effect is smaller in magnitude when taking time into account. A ten percent increase in the last period-totals explains an increase by 1.6 percent. Using the mean of the quarterly totals from 2006, an increase of about 68 transplants would be expected from a ten percent increase of the previous quarter.

Table 6:
OLS Results for TOT_t with a Time Trend

	Coefficient	Standard Error	t-ratio
Constant	6.573	0.758	8.67***
TOT_{t-1}	0.165	0.097	1.71*
<i>POLICY</i>	-0.008	0.014	0.62
<i>TIME</i>	0.008	0.001	6.92***
N	55		
F-value	354.55***		

*Note: The model is estimated using STATA. *** and * denote statistical significance at the one and ten percent level, respectively. Standard errors are the Newey-West variant. T-ratios are absolute values. Organ variables are measured in logarithms.*

With the inclusion of the time trend, the policy effect disappears. The result suggests that the ODBC does not increase or decrease the total transplant activity, and if the estimation was significant, the effect would be a decrease of about 30 kidneys. *TIME* has a significant effect on transplant activity, but the effect is small in magnitude.

The next model re-estimates the number of living donor-transplants. Table 7 provides the results. The living donor-transplants from the previous period still appear to have a significant effect on the subsequent period. A ten percent increase of transplants would result in a 6.9 percent increase in the following quarter. Using the average activity levels in 2006, an increase of 160 living donor-transplants boosts the activity of the next quarter by about 111 living donor-transplants.

Table 7:

OLS Results for LD_t with a Time Trend			
	Coefficient	Standard Error	T-ratio
Constant	7.255	1.586	4.57***
LD_{t-1}	0.698	0.077	9.10***
$SPSC_{t-1}$	-0.694	0.169	4.10***
$POLICY$	-0.007	0.019	0.34
$TIME$	0.008	0.002	3.97***
N	55		
F-value	1699.81***		

*Note: The model is estimated using STATA. *** denotes statistical significance at the one percent level. Standard errors are the Newey-West variant. T-ratios are absolute values. Organ variables are measured in logarithms.*

The time trend itself is small in magnitude and large in significance suggesting a gradual increase over time. The interpretation of the nature of a linear time trend is merely a simple account for population growth. The presence of the time trend eliminates any significant effect attributed to the $POLICY$ dummy variable. The result seems to compensate for the counterintuitiveness of the policy coefficient from the original LD_t model in Table 3. If any effect at all, the presence of the dummy would be small in magnitude and negative (about 9 kidneys less).

The new specification appears to increase the magnitude of the deceased donor-transplants of the previous period. Ironically, the estimated coefficient is similar to the one for LD_{t-1} . A ten percent increase in deceased donor-renal grafts means a 6.9 percent decrease in the number of living donor-grafts of the current quarter. The two coefficient estimates suggest a similar percentage change, but to distinguish the level changes, conversion to level numbers is appropriate. In terms of actual transplants, 266 more deceased donor-transplants from the previous quarter reduce the transplants from living donors by about 111 in the current one.

The result provides strong evidence for a substitution effect between the deceased donor-transplants of last period and the current number of LD transplants. The interpretation is that patients do not continue to seek medically suitable and willing living donors if they get kidneys from deceased donors. However, the substitution is not one for one. For completion, the time effect is significant yet small.

The new estimates of the third model reveal results consistent from before with the exception of the lagged variable. Table 8 illustrates the results.

Table 8:
OLS Results for SCD_t with a Time Trend

	Coefficient	Standard Error	t-ratio
Constant	6.720	0.629	10.68***
SCD_{t-1}	0.090	0.086	1.06
<i>POLICY</i>	0.059	0.024	2.45**
<i>TIME</i>	0.002	0.001	3.02***
N	55		
F-value	41.80***		

*Note: The model is estimated using STATA. *** and ** denotes statistical significance at the one and five percent level, respectively. Standard errors are the Newey-West variant. T-ratios are absolute values. Organ variables are measured in logarithms.*

The SCD transplants from the previous period is no longer significant at explaining the current period. Even if SCD_{t-1} had an effect, it would be small. A ten percent increase in SCD_{t-1} would result in a 0.9 percent increase in the next period. An increase of 201 standard criteria-transplants in 2006 raises the transplants by only 18 grafts in the next quarter.

The addition of a time trend keeps the effects of the Collaborative present at the five percent level of significance. With the mean of SCD in a typical quarter from the relevant period being 1755 transplants, the policy effect is an increase of about 107 SCD

transplants per quarter. The estimate of the policy effect is consistent with that one found earlier. Yet, the increase is roughly half of what was found in the first specification. To be complete, time is significant but small.

The final regression estimates SPD_t while factoring in an exogenous time trend. As was the case with the previous (SCD_t) time trend-model, the coefficient of the lagged dependent variable does not significantly affect the current period of sub-par kidney transplants. If it were significant, the effect would be negative.

Table 9:

OLS Results for SPD_t with a Time Trend			
	Coefficient	Standard Error	T-ratio
Constant	5.585	0.071	78.33***
SPD_{t-1}	-0.013	0.016	0.79
<i>POLICY</i>	0.239	0.055	4.32***
<i>TIME</i>	0.014	0.001	10.14***
N	55		
F-value	176.38***		

*Note: The model is estimated using STATA. *** denotes statistical significance at the one percent level. Standard errors are the Newey-West variant. T-ratios are absolute values. Organ variables are measured in logarithms.*

Along with the alternate specification of the third model, the policy variable does not disappear in this specification of the fourth model. In fact, the effect has decreased by more than half. The policy effect is approximately 112 additional transplants per quarter. The interpretation of the relatively large increase, with 413 average SPD-transplants per quarter is that the ODBC has had a larger effect on lesser-quality organs. As discussed before, these kidneys have generally poorer outcomes. The finding is consistent with earlier empirical evidence. To be complete, time is significant but small.

Using the time trend specification, the ODBC means nothing in the first two estimations while its effect is both positive and significant in the two deceased donor equations. The overall effect is uneven for different donor types. The policy appears to help SCD transplants while it seems to have a much larger relative effect for both ECD and DCD grafts. LD transplants have no significant or direct effect originating from the policy. The results as presented do not provide compelling evidence that the OBC is particularly effective.

The linear time trend variable for all of the above relevant models captures the effects of the population growth and other growth effects. The trend removes any secular effect that was previously attributed to the policy in the first two models estimated. The economic interpretation that since population grows at a constant rate, *POLICY*, in the first specifications of TOT_t and LD_t , was incorrectly attributed with increasing transplant activity. As the situation appears to be, *POLICY* was significant because it incorrectly picked up exogenous growth effects since the ODBC was initiated in the last several periods of analysis. With the time trend, the policy effects disappeared in the TOT_t and LD_t regressions. The policy effect did stay with the two deceased donor types of SCD_t and SPD_t .

Once one controls for the growth rate from the population over time, *TIME*, the situation becomes muddled with regards to confirming any substantially positive total effect coming from the ODBC. The policy had an effect for cadavers, but the effect on living donors, if any, is negative.

CHAPTER V

CONCLUSION

The previous empirical analysis provides evidence that the impact of the ODBC is not that impressive. While increasing donations, it has done so by increasing the number of lower-quality organs. The policy initiative has had little, if any effect on total kidney transplant activity. The deceased donor-transplant activity did increase but with a relatively large increase in sub-par transplants. The ODBC promoted relatively more lower-quality organs than regular criteria organs.

The conventional wisdom in policymaking seems to be that even a relatively small increase in cadaveric kidneys represents some call for continued action as opposed to alternative policies. This claim is supported by the two successor-programs that followed (the OTBC & ODTBC). Their logic seems to be a small increase merits more attempts at more small increases which will not solve any waiting list problems. Policymakers see an increase in donation trends and believe that this means a total increase in transplants. However, there is discrepancy that appears when one accounts for discard rates. Beard, Kaserman, and Osterkamp (2010) added that “[c]ertainly, deaths on the waiting lists, and removals for deterioration in condition, which are counted as reductions in the list, are wholly unlike reductions arising from successful transplants. One should arguably include a large fraction of deaths and illness removals in any accounting of the costs of the current policy.” Also, once one accounts for population

growth and other secular effects that increase exogenously with time, the policy effect used as evidence for success disappears. Since the time trend captures all the outside effects, the plain fact is that the policy is left analytically alone.

As for living donation-transplants, the effect from the ODBC is not present. If there is any, it is negative. Transplants from living sources represent desperation for patients and their families. The above results show that if a kidney from a deceased donor surfaces, even from a marginal source, the patients choose to accept the kidney rather than stay on the waiting list and dialysis treatment which would further decrease their chances of a better organ. Beard, Jackson, and Kaserman (2007) stated that “[s]ince there is no evidence that living donation of kidneys reduces cadaveric donation, and cadavers typically give all transplantable organs, we need not fear that increases in living kidney donation will somehow trigger reduced availability of the other organs utilized in transplantation.”

There are future opportunities for research involving the same or similar data used in this study. Studies could examine the effect of the ODBC on both related and unrelated living transplants as the number of unrelated donors have increase in the past decade while related donors have stayed approximately constant. Studies can use more recent data to more clearly dissect the effects of public policy. Also, a separate study could be conducted with regards to the timing of the relaxation of ECD criteria.

With regard to policy changes stemming from kidney procurement policy, Beard, Kaserman, and Osterkamp (2007) offered, “(...) kidneys represent the most severe case of organ shortages, and most proposals that would successfully address the problem of kidneys would solve the problem for other organs using cadaveric donors. Each deceased

donor provides an average of 1.5 kidneys for transplant, but at most one heart and liver.”
However, the presence of the substitution effect between living and deceased transplants warrant some attention to the possibility of policy changes as conventional ones may have a detrimental effect.

REFERENCES

- Beard, T. Randolph, John D. Jackson, and David L. Kaserman. 2007. "Deceased-Living Donor Substitution and Transplant Waiting List Changes." Auburn University.
- Beard, T. Randolph, John D. Jackson, and David L. Kaserman. 2008. "The Failure of U.S. Organ Procurement Policy." *Regulation*, 30(4): 22-31.
- Beard, T. Randolph, David L. Kaserman, and Rigmar Osterkamp. 2010. "The Shortages of Organs for Transplant: Economic Causes, Human Consequences, Policy Responses." Cambridge, MA. MIT Press.
- Beard, T. Randolph, David L. Kaserman, and Richard P. Saba. 2006. "Inefficiency in Cadaveric Organ Procurement," *Southern Economic Journal*, 73: 13-26.
- Howard, David H., Laura A. Siminoff, Virginia McBride, and Monica Lin. 2007. "Does Quality Improvement Work? Evaluation of the Organ Donation Breakthrough Collaborative." *HSR: Health Services Research*, 42(6, Part 1): 2160-2173.
- Kaserman, David L., and A.H. Barnett. 2002. *The U.S. Organ Procurement System: A Prescription for Reform*. Washington, DC: The AEI Press.
- Leichtman, A.B., D. Cohen, D. Keith, K. O'Connor, M. Goldstein, V. McBride, C.J. Gould, L.L. Christensen, and V.B. Ashby. 2008. "Kidney and Pancreas Transplantation in the United States, 1997-2006: The HRSA Breakthrough Collaboratives and the 58 DSA Challenge." *American Journal of Transplantation*, 8(Part 2): 946-957.
- Saidi, R.F., N. Elias, T. Kawai, M. Hertl, M.-L Farrell, N. Goes, W. Wong, C. Hartono, J. A. Fishman, C.N. Kotton, N. Tolkoff-Rubin, F.L. Delmonico, A.B. Cosimi, and D.S.C. Ko. 2007. "Outcome of Kidney Transplantation Using Expanded Criteria Donor and Donation After Cardiac Death Kidneys: Realities and Costs." *American Journal of Transplantation*, 7: 2769-2774.
- Sung, R.S., J. Galloway, J.E. Tuttle-Newhall, T. Mone, R. Laeng, C.E. Freise and P.S. Rao. 2008. "Organ Donation and Utilization in the United States." *American Journal of Transplantation*, 8(Part 2): 922-934.

APPENDIX

Data					
Quarter	DCD	ECD	LD	SCD	Total
1988 QI	0	0	438	1582	2020
1988 QII	0	0	486	1849	2335
1988 QIII	0	0	457	1884	2341
1988 QIV	0	0	436	1746	2182
1989 QI	0	0	460	1614	2074
1989 QII	0	0	477	1697	2174
1989 QIII	0	0	512	1681	2193
1989 QIV	0	0	454	1761	2215
1990 QI	0	0	503	1561	2064
1990 QII	0	0	533	1913	2446
1990 QIII	0	0	551	2037	2588
1990 QIV	0	0	507	1812	2319
1991 QI	0	0	578	1722	2300
1991 QII	0	0	618	1732	2350
1991 QIII	0	0	631	1971	2602
1991 QIV	0	0	569	1857	2426
1992 QI	0	0	647	1659	2306
1992 QII	0	0	645	1907	2552
1992 QIII	0	0	647	1895	2542
1992 QIV	0	0	595	1743	2338
1993 QI	8	0	648	1666	2322
1993 QII	8	0	740	1978	2726
1993 QIII	22	0	769	1973	2764
1993 QIV	23	0	694	1830	2547
1994 QI	8	0	711	1748	2467
1994 QII	19	253	795	1716	2783
1994 QIII	33	189	776	1734	2732
1994 QIV	20	219	725	1701	2665
1995 QI	29	248	786	1544	2607
1995 QII	25	262	910	1671	2868
1995 QIII	21	263	893	1736	2913

1995 QIV	28	224	800	1643	2695
1996 QI	14	280	864	1581	2739
1996 QII	32	281	978	1687	2978
1996 QIII	32	237	956	1684	2909
1996 QIV	17	278	874	1608	2777
1997 QI	42	283	900	1548	2773
1997 QII	24	299	1040	1688	3051
1997 QIII	28	256	1046	1620	2950
1997 QIV	24	293	943	1669	2929
1998 QI	23	342	967	1561	2893
1998 QII	25	303	1146	1720	3194
1998 QIII	30	306	1169	1710	3215
1998 QIV	28	264	1138	1720	3150
1999 QI	35	310	1088	1582	3015
1999 QII	31	311	1171	1654	3167
1999 QIII	39	241	1237	1791	3308
1999 QIV	39	354	1221	1656	3270
2000 QI	40	318	1256	1615	3229
2000 QII	39	255	1419	1746	3459
2000 QIII	41	297	1415	1866	3619
2000 QIV	42	304	1399	1561	3306
2001 QI	50	300	1452	1526	3328
2001 QII	77	279	1519	1779	3654
2001 QIII	58	288	1570	1820	3736
2001 QIV	60	310	1494	1684	3548
2002 QI	71	287	1432	1699	3489
2002 QII	81	340	1579	1719	3719
2002 QIII	72	293	1658	1888	3911
2002 QIV	67	310	1571	1712	3660
2003 QI	84	329	1555	1741	3709
2003 QII	101	325	1629	1674	3729
2003 QIII	95	310	1651	1836	3892
2003 QIV	112	384	1635	1676	3807
2004 QI	117	386	1593	1780	3876
2004 QII	133	321	1662	1837	3953
2004 QIII	136	328	1774	1959	4197
2004 QIV	151	350	1618	1859	3978
2005 QI	212	392	1593	1831	4028
2005 QII	172	420	1689	1929	4210
2005 QIII	172	367	1697	2006	4242

2005 QIV	198	440	1589	1774	4001
2006 QI	218	421	1637	1832	4108
2006 QII	273	417	1641	2221	4552
2006 QIII	270	375	1643	2072	4360
2006 QIV	221	437	1511	1902	4071
2007 QI	265	445	1475	1821	4006
2007 QII	311	426	1542	2026	4305
2007 QIII	287	396	1594	1989	4266
2007 QIV	267	414	1426	1940	4047

Log to level conversion:

(#Transplants = $e^{(\ln \bar{x} - \theta) - \bar{x}}$) where θ is the *POLICY* coefficient