SAVING LIVES THROUGH INCREASING AVAILABLE DONOR KIDNEYS: THE POSITIVE EFFECT OF ALTRUISTIC KIDNEY PAIRED DONOR CHAINS

A Thesis submitted to the Faculty of The School of Continuing Studies and of The Graduate School of Arts and Sciences in partial fulfillment of the requirements for the degree of Master of Arts in Liberal Studies

By

Nikita Denise Harmon, B.A.

Georgetown University
Washington, D.C.
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Nikita Denise Harmon, B.A.

MALS Mentor: Gladys White, Ph.D.

ABSTRACT

This thesis will propose that altruistic kidney paired donor chains will save more lives of end-stage renal disease (ESRD) patients by increasing the number of available donor kidneys for kidney transplantation in the United States. Altruistic kidney paired donor chains make the most of a living, healthy and willing potential kidney donor who is immunologically incompatible to his or her directed end-stage renal disease patient. These donor chains enable the potential immunologically incompatible living kidney donor to donate to another ESRD patient, who is immunologically compatible, while their directed patient can receive a kidney from another living donor that is immunologically compatible. This thesis will explain in detail the importance of the kidneys via their physical functions in order to sustain life. It will elaborate on the fact that an ESRD patient is limited to two therapeutic choices in order to live. Kidney transplantation is deemed the ideal therapeutic option for providing standard renal functions for ESRD patients. After all, another kidney can provide identical functions, while dialysis on a machine can only mimic a small fraction of what a kidney can do within the body in a twenty-four hour timeframe. Medical data will be probed which illustrate a profound status of disproportionate sums between the higher numbers of end-stage renal patients in need of a kidney for transplantation and the lower numbers of donor kidneys available for transplantation. The main motive for the development of kidney paired donation.
DEDICATION

This thesis is dedicated to my kidney donor.

Wado Ne-ee-mat.
(Thank you Brother, Nanticoke Language)
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I would like to thank Robert Small, PhD., for being my informal mentor throughout my graduate program at Georgetown. He understood what it meant to me to attend graduate school after a difficult thirteen year period. His optimistic viewpoint was unwavering.

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INTRODUCTION

Kidney paired donation is becoming a more common technique utilized in living kidney donor transplantations in the United States. It is an exciting and innovative option for someone who would like to donate a kidney to a loved one, but cannot because they are immunologically incompatible to their chosen recipient. In the past, when a person with kidney failure had a willing living kidney donor that was incompatible, that person could not benefit from the donor’s gift and receive a transplant. Today, kidney paired donation is making the circumstances of incompatible living donors work. Transplant centers across the country have developed incompatible kidney transplant programs specifically dedicated to this endeavor, which significantly impacts on expanding the options of living kidney transplantation. This thesis will examine the circumstances surrounding kidney paired donation, examine the various modes that have been developed to increase the chances that willing donors will find suitable recipients, and argue for the benefits of the most pioneering advances in living donor kidney paired donation.

For those with end-stage renal disease (ESRD), kidney failure, there are only two types of lifesaving therapeutic treatment options available: dialysis or kidney transplantation. Most nephrologists and ESRD patients prefer kidney transplantation because it can offer a higher quality of life for the patient. With kidney transplantation, the patient would be exchanging the physically debilitating 3 to 4 hour treatment sessions three times a week on a dialysis machine with the use of immunosuppressant drug therapy that is taken at home. More importantly, dialysis treatments cannot fully substitute or mimic the kidneys’ renal functions. Dialysis patients remain unwell and continue with symptoms of fatigue and malaise, while some patients experience physical complications that require
additional medication or surgery for relief. In addition, ESRD patients on dialysis may become dependent on family and friends for physical, emotional and financial assistance. Kidney transplantation has the greater potential for restoring a healthy life to the patient.

Kidney transplantation, compared to dialysis, provides increased longevity and a decidedly improved quality of life to a patient. A transplanted kidney offers identical renal functions as the original kidneys because it too is a human kidney. Physically, patients feel like their average selves and are able to return to a normal lifestyle, which includes work, school, and social or community activities. Patients are far less likely to require any assistance from others. The key factor for the success of kidney transplantation has been the formulation and introduction of several anti-rejection medications, which contribute to the improvements in the patient’s graft survival rate, while decreasing morbidity. In order to achieve more successful outcomes through kidney transplantation, more donor kidneys must be made available.

The need for donor kidneys for transplantation in the United States has substantially increased in just the past decade. In 2011, the United Network of Organ Sharing’s transplant trend reported that 83,000 to 90,000 people were awaiting a kidney transplant in the U.S. at a given time. Due to the lack of available donor kidneys and the sharp rise in end-stage renal disease patients, 4,500 patients die each year waiting for a kidney, while another 1,900 patients are downgraded as inactive on the national registered waiting list. Inactive patients are those who become too sick to receive a kidney transplant, and face certain death. Originally, only deceased donor kidneys were utilized in kidney transplantation. Presently, the use of living donor kidneys is on the rise and continues to grow. However, the supply is still disproportionate to the demand because the number of
ESRD patients continues to escalate and surpass the number of available donor kidneys. With a severe national organ shortage, alternative solutions for extending donor kidney availability have been explored.

While deceased kidney donations have reached a plateau, living kidney donations are going up, and have become a crucial factor in this progressive national health crisis. Most living kidney donations originate from the patient’s pool of family and friends. Unfortunately, there is a sizeable percentage of living kidney donors who are willing to donate, but do not match their intended recipient. The main barriers being incompatible blood type, HLA (antibodies) crossmatch, or both. This circumstance is deemed an incompatible donor-recipient pair. An innovative approach termed kidney paired donation is an evolving strategy for overcoming these barriers between an incompatible donor-recipient pair. The basic form of kidney paired donation is the kidney paired exchange. The barrier of incompatibility is resolved with two or more incompatible donor-recipient pairs exchanging compatible donor kidneys. From the kidney paired exchange, two types of kidney paired chains have been developed with the addition of an altruistic donor. The Domino Chain, which is performed on a simultaneous timeframe, and the NEAD (Non-simultaneous, Extended, Altruistic-Donor) Chain are initiated by an altruistic donor and end when the last donor in the chain donates a kidney to someone on the deceased kidney donor waiting list. This thesis will propose that kidney paired donation, especially the kidney paired donor chains, will save more lives of end-stage renal disease patients by increasing available donor kidneys.

As an end-stage renal disease patient myself, who suffered on hemodialysis for eight agonizing years before transplantation, this thesis is a testament to medical ingenuity,
the generosity of altruistic kidney donors, and the fortitude of ESRD patients throughout the U.S.
CHAPTER 1

KIDNEY TRANSPLANTATION:
THE BEST THERAPEUTIC ALTERNATIVE FOR END-STAGE RENAL DISEASE

Chronic kidney disease is on a sharp rise in the United States.\(^1\) Some major contributing factors are an aging population, diabetes, uncontrolled high blood pressure, and obesity. In addition, there are the standard kidney diseases, which are characterized as hereditary (polycystic kidney disease), congenital (malformation of the genitourinary tract) or acquired (nephritis, inflammation of the kidney). In each of these cases, chronic kidney disease leads to what is termed end-stage renal disease or ESRD—complete kidney failure.

When someone is diagnosed with ESRD, he or she must seek immediate treatment in order to survive. Before 1970, therapeutic options for ESRD patients were very limited. Due to the lack of dialysis facilities and expense, only a minute number of patients actually received treatment. The passage of the Medicare entitlement legislation in 1972, contributed to a vast increase in ESRD patients who received hemodialysis. Nonetheless, despite continued medical and technical advances in dialysis treatment, ESRD patients remained in poor health. Dialysis was not adequate to replace all the kidneys’ renal functions. An alternative treatment, kidney transplantation, had the greatest potential for restoring a healthy, productive life to ESRD patients. The down side was that initially only

deceased donor kidneys were available. With the increasing number of those needing a kidney surpassing the number of available deceased donor kidneys, living donor kidneys began to be utilized. Although living donor kidneys had made a dent in the kidney shortage, it was still not enough. Living donor kidneys, which were pooled mostly from among the patient’s family and friends, were often medically incompatible, and could not be used for the patient. What is the best method for increasing available living donor kidneys? The solution may well be an innovative approach that can transform an incompatible living donor kidney into a successful kidney transplant through a series of pairings which this thesis will examine.

To understand the remedial intent of kidney transplantation, referred to as renal transplantation; one must first differentiate between what a kidney transplant is, and what it is not. Most significantly, a kidney transplant is not a cure for kidney disease or kidney failure. The concept that a kidney transplant is an all-out cure for someone who has lost their renal functions is a misunderstanding often held by lay people. On the other hand, a kidney transplant is a therapeutic alternative, i.e. a medicinal treatment for kidney failure, which can be caused by kidney disease or kidney damage through some type of physical trauma. If someone receives a healthy transplanted donor kidney, it undertakes all the renal functions of the originally impaired kidneys, and is judged the most beneficial restorative option for what is called kidney replacement therapy (KRT) for people with ESRD. ESRD equates to the loss of glomerular filtration or loss of renal functions in the body. Although other replacement therapies are available, such as, hemodialysis dialysis and peritoneal dialysis (both are machine-driven processes designed to partially execute renal functions), kidney transplantation offers the most effective treatment for ESRD patients by providing a
better quality of life through greater health benefits and physical freedom from dialysis machines. Likewise, it offers a higher life expectancy rate to ESRD patients. For children especially with ESRD, a kidney transplant offers countless prospects for growth, development, and achievement as in a normal healthy adolescent life.

For this thesis, the principal cause for kidney failure will be considered to be kidney disease, which is the primary catalyst for ESRD, as opposed to physical kidney damage. The word renal is a fundamental term that denotes the kidneys and their functions, i.e. having to do with the kidneys, while the technical word kidney denotes a tangible organ in the body. A decade ago, in an effort to better assist the non-medical public with understanding what renal signifies in a diagnosis or treatment option, the National Kidney Foundation directed the health care community to substitute the term renal with kidney; therefore, the two terms—renal and kidney--became interchangeable in dialogue and in print.² The two terms will be utilized throughout this thesis accordingly. Prior to further exploring kidney transplantation as a treatment, let us momentarily examine the kidneys and why renal functions are vital to sustaining life.

The average healthy person is born with two bean-shaped organs called kidneys, which are located in the middle of the back just below the lower rib cage. One kidney resides on each side of the spine. Even so, there are those who have been born with one kidney, three or even four due to unusual and sometimes inexplicable circumstances. Although not the average, these people lead normal, healthy lives. Each adult kidney is approximately 4 inches in length. This is roughly the size of an adult fist. Some kidneys

² Edward Kraus, MD., e-mail message to author, September 28, 2011.
may be larger or smaller in size, which can be determined by the uncommon physical proportions of an individual, a medical circumstance, a malformation, or a mishap. When the kidneys are healthy, they act as a filtration system cleaning the body of toxic waste products—chemical, drug by-products, and toxins—and excess fluids via the body’s bloodstream. Blood filtration through the kidneys is a two-step process.

First, blood enters the kidneys and is filtered through capillary tufts called glomeruli. Here excess fluids and soluble waste in the blood are forced out from the capillaries. Second, millions of tubules called nephrons remove waste excretion, and then, reabsorb beneficial substances back into the body. Each day, approximately 200 quarts of blood pass through the kidneys for purification. The kidneys remove about 2 quarts of toxic waste excretion and excess fluid through their production of urine. Ureters carry the urine from the kidneys to the bladder. Then the bladder stores the urine until it passes out of the body by means of urination.

Kidneys have supplementary key functions outside of filtration, such as, stabilizing electrolytes and chemicals in the body. Furthermore, kidneys produce three essential hormones for good health. They produce renin that regulates fluid levels in the circulatory system, which controls blood pressure, calcitriol (active Vitamin D) to absorb calcium from foodstuff to promote strong bones, and erythropoietin, or EPO, to stimulate bone marrow

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which makes red blood cells to thwart anemia.  

**KIDNEY DIAGRAM**

![Kidney Diagram](http://www.comprehensive-kidney-facts.com/kidney-anatomy.html)

FIGURE 1: Kidney Diagram.

A quick summary of the kidneys’ renal functions:

*Acts as a filter system.*

*Gets rid of waste products.
*Balances the body's fluid content.
*Produces hormones that control blood pressure.
*Produces the hormone Erythropoietin to help make red blood cells.
*Activates vitamin D to maintain healthy bones.\(^5\)

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**FIGURE 2: Actual Kidney Size**

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Structures of the kidney and their functions:

1. **Renal pyramid** – One of multiple cone-shaped portions of the kidney where urine is removed from blood and drained into the renal calices.

2. **Interlobar artery** – One of the mid-sized blood vessels that bring blood to the nephron to be filtered.

3. **Renal artery** - The main blood vessel that brings blood to the kidney from the aorta.

4. Renal vein – The main blood vessel that brings blood away from the kidney back to the interior vena cava.

5. **Renal hylum** - This is where tubes enter and leave the kidney.

6. **Renal pelvis** - This is where urine collects prior to leaving the kidney.

7. **Ureter**- This is the tube where urine drains from the kidney to the bladder.

8. **Minor calyx**- This is one of the mid-sized tubes that collects urine to be drained from the kidney.

9. **Renal capsule**- This is the outer covering of the kidney.

10. **Inferior renal capsule**- This is the bottom part of the outer covering the kidney.

11. **Superior renal capsule**- This is the top part of the outer covering of the kidney.

12. **Interlobar vein**- One of the mid-sized blood vessels that brings blood away from the nephron.

13. **Nephron**- This is the working unit of the kidney.

14. **Minor calyx**- This is one of the mid-sized tubes that collects urine to be drained from the kidney.

15. **Major calyx**- This is one of the large tubes that collects urine to be drained from the kidney.

16. **Renal papilla**- This is the pointed end of a renal pyramid.

17. **Renal column**- This is a solid portion of the kidney where blood vessels travel to and
from the nephron.\textsuperscript{6}

By the time someone is diagnosed with ESRD, kidney failure has become so advanced that it cannot be reversed. Renal functions are determined by what is called the Glomerular Filtration Rate or GFR. The GFR defines the efficiency of the kidneys’ ability to filter the blood. In total, there are 5 stages that characterize the GFR. At stage 4, renal functions have severely decreased to a minimum of 30 percent, and are in permanent decline. Kidney failure is imminent. At this point, kidney replacement therapy must be deliberated about by the patient and his or her nephrologist—renal physician. When renal functions fall between 15 and 10 percent, the patient has reached stage 5 and is diagnosed with ESRD.\textsuperscript{7} Here, kidney replacement therapy is obligatory in order to sustain the patient’s life. When the body becomes unable to clear waste excretions and excess fluid, this is a condition known as uremia. Uremia that is untreated leads to certain death. Some of the common causes that can lead to kidney failure are heredity, such as, polycystic kidney disease. Others are infection, drug abuse—cocaine and heroin, HIV, high blood pressure (hypertension), diabetes (the #1 cause), lupus, cancer—lymphoma or myeloma, renal artery thrombosis--blood clots, sickle cell anemia, surgical consequence, glomerular


disease and physical injury. The list goes on. Let us return to the development and practice of kidney transplantation.

In medical jargon, a renal transplant (kidney transplant) is an organ transplant of the kidney. During the 3 to 4 hour operation procedure, renal transplant surgeons place a healthy donated kidney in the lower abdominal region of the body as opposed to the normal anatomical location of the diseased kidneys in the lower-middle of the body in an ESRD patient, i.e. the healthy donated kidney is placed on either the right or left side of the lower abdominal region versus being placed in the same location as the original kidneys in the middle of the body. The transplanted kidney will undertake the renal functions of the failed kidneys. Although there are two diseased kidneys, only one healthy kidney is required and transplanted from a donor to the recipient. Unless the diseased kidneys are malignant or infectious, they are left in place. Over time, those kidneys will shrink in size and become dormant. The key factor for success in the kidney transplantation process lies within the ESRD patient’s immune system. The donated kidney must be an appropriate antigen (molecule) match to that of the ESRD patient. When an antigen (donor) is introduced into the body (patient), it triggers the patient’s immune system to generate antibodies, which will eradicate the antigen as a recognizable harmful, foreign invader. There are six antigens that are assessed and matched between the donor and the ESRD patient prior to any transplant. The greater the antigen match out of six, the higher the success rate of the transplant and the less anti-rejection medication required for the

transplant patient. As with all organ transplantations, ESRD patients will be required to take immunosuppressant (anti-rejection) medication in order to trick their immune system from rejecting the new donated kidney. These specialty drugs are required for the entire life span of the donated kidney. There is one exception; an identical twin is not required to take any anti-rejection medication, when receiving a kidney from the other identical twin. Identical twins have identical tissue types. Granting that most donated kidneys come from recently deceased donors (anonymous cadaveric), living kidney donation is a viable alternative, but the use of live donors continues to rise in the U.S. In 1950, the first kidney transplant utilizing a cadaveric donor took place in Evergreen Park, Illinois. The donated kidney did reject within 10 months due to the absence of immunosuppressant drug therapy. By 1954, the first living donor kidney transplant took place between identical twin brothers. As mentioned, an identical twin pairing does not require immunosuppressant therapy. This is a perfect point to assess the two sources of available kidneys—deceased and living donors.

Deceased kidney donors, formally referred to as cadaveric donors, remain the primary source of kidney donations. Deceased donors are those individuals clinically determined to have irreversible brain damage, i.e. loss of complete brain function. Frequently, deceased donors are unexpected victims of automobile or motorcycle accidents, traumatic falls, physical or chemical brain injury, heart attack or stroke. Presently in the U. S., the next of kin consents to the final decision about organ donation even if the individual had signed an organ donor card prior to death. Deceased kidney donor transplantation does not allow for the preparation time that a living kidney donor transplant can due to the swift turnaround time. Due to advanced techniques in deceased
organ preservation, kidneys can be harvested, kept viable, and transported from greater distances across the country. The traditional technique involved flushing the deceased donor kidney with a distinct solution and then placing the kidney in an ice-filled container. Today, cold infusion machines are used in order to push a steady flow of cool solution through the kidney’s attached blood vessels until the kidney can be tested and placed in the recipient. On average, the kidney can remain out of the body for up to 72 hours before transplantation, although 36 hours is preferred. Roughly, 50 to 60 percent of deceased donor kidneys function immediately after transplantation and have a 50 percent chance of functioning from 10 to 20 years. Deceased donor kidneys are matched to their potential recipients through a national organ registry titled the National Organ Procurement and

Kidney Placement

![Kidney Placement Diagram](http://www.kidney.niddk.nih.gov/KUDiseases/pubs/transplant/index.aspx#how)

Transplantation Network (OPTN), which is operated by the United Network for Organ Sharing (UNOS). Later, we will review these networks and their governing policies of
organ procurement in Chapter 3. Unfortunately, with deceased kidney donation one cannot determine when a suitable kidney will become available for transplantation. The patient will need to remain on dialysis treatments until a kidney becomes available. ESRD patients awaiting a deceased donor kidney must comply with the transplanting center by being bodily on hand, when the deceased donor kidney becomes available.

Living kidney donation is the second source of donor kidneys, and has risen to account for nearly half of all transplantable kidneys. These days, living kidney donations are virtually commonplace. According to UNOS, as of June 2011, living kidney donors contribute approximately 44 percent of all donated kidneys as compared to deceased kidney donors at 56 percent. Living kidney donors are those donors who are alive and donate one of their own two kidneys to an ESRD recipient. In the case of living donation, the donor, the recipient, and the supportive families are provided the flexibility and the convenience to decide when the transplant takes place. If the match can be concluded prior to absolute renal failure in the recipient, the recipient can avoid dialysis treatments altogether. The available kidney waiting time for the recipient is drastically reduced, while the quality of the living donor kidney is likely to be far superior to that from a deceased kidney donor. Though living donors are typically family linked, now, one in four living kidney donors is not biologically related to the kidney recipient. With a full-blooded sibling being one’s closest living relative, living related donors largely have a higher percentage rate for yielding an excellent tissue-type match to the recipient. Subsequently, living related donors possess an emotional investment and gallant interest in saving a family member. Those living donors that are non-biological customarily direct where their donations are going, i. e. identify a specific recipient for their donation. However, there are
exceptions when an altruistic donor decides to donate in order to be a Good Samaritan and save someone in need. Let us review the terminology that is associated with living kidney donation.9

*Living related donation:* a living donor directs their donation to a blood relative recipient.

*Living unrelated donation:* a living donor directs their donation to a non-blood related recipient.

*Living non-directed donation:* a living donor does not direct their donation to a specific recipient. Instead, a recipient is selected from a list of compatible recipients awaiting a kidney. This is also known as an anonymous donation. Anonymous living donation constitutes 1 percent of all living donations.10

Another type of living kidney donation is kidney paired exchange. At the start of kidney paired exchange, there are two pairs of living donors and kidney recipients; however, the living donors are unable to donate directly to the recipient of their choice due to incompatibility—tissue type or positive blood cross match. In the exchange, each living donor will donate a kidney to the other donor’s recipient, i.e. a kidney swap. In selected cases, there can be more than two donor-recipient pairs involved. Kidney paired exchange along with other methods of kidney paired donation will be the focus of this thesis and will be expounded upon in great detail in chapter 4.

Of note, while living kidney donor matches from siblings last on average at the highest rate of 20 to 35 years, living kidney donor matches, overall, begin functioning in the recipient at a rate of 97 percent after transplant. Exactly, who are those non-related

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10 Ibid.
living donors who contribute? Unrelated living donors have included a wide spectrum
from spouses to friends, neighbors to classmates, colleagues to teammates, and perfect
strangers. Half of living donors fall between the ages of 35 and 49 with the majority of
living kidney donors being female.

These days, the key reason why living kidney donation has become so viable is due
to the innovation of laparoscopic surgery. In the past, a technique called an open door
nephrectomy had to be performed in which a living kidney donor would have to endure an
11 to 15 inch flank incision halfway around the body in order to donate a kidney. It was a
major surgery that often required the removal of the 12th rib in order to be able to reach the
kidney. It had involved considerable pain for the donor and extensive time lost—6 weeks
or longer—from returning to a normal schedule, which included a job or social activities.
In 1995, the laparoscopic nephrectomy became available in the U.S., although it took
several years for it to become available in all transplant centers.11

Laparoscopic nephrectomy is considered minimally invasive surgery because it
involves the use of 2 or 3 small 1 centimeter port incisions usually in the abdomen, which
are strategically placed to permit the insertion of surgical instruments. With the use of an
external camera, a scope is placed into the body to seek the kidney’s location. The internal
images are viewed from outside the body on a monitor that guides the hand movements of
the transplant surgeon. After being accurately freed from its attachments, the kidney is
then removed through one of the small incisions. For the living kidney donor, there are far
smaller incisions, less pain, and a faster recovery time. Most living kidney donors need

11 Arthur J. Matas, MD, ed., Manual of Kidney Transplant Medical Care (Minneapolis:
only remain in the hospital 2 days after surgery with an average of 2 weeks recuperation
time at home, while heavy lifting and strenuous activity should be postponed for another 4
to 6 weeks.

What is the prognosis for an ESRD patient after a kidney transplant? For the ESRD
patient, the bottom line is that a kidney transplant is not a cure, but it can extend his or her
life expectancy, while inclusively providing a better quality of life. Characteristically, an
ESRD patient, who receives a kidney transplant, lives on average 10 to 15 years longer
than an ESRD patient who remains on dialysis treatments.\(^\text{12}\) Younger patients, of course,
can benefit the most with an extended life, although elder patients can gain 4 or 5 more
valuable senior years. Kidney transplant patients experience more energy, considerably
fewer diet restrictions, no fluid intake restrictions, and a smaller number of complications
with a transplant as compared to those in conjunction with dialysis treatments. Selected
medical studies have suggested that the longer an ESRD patient continues on dialysis prior
to a kidney transplant, the shorter the amount of time the kidney will function once
transplanted.\(^\text{13}\) But, it is unclear as to why this occurs. It does give added emphasis to the
need for a speedy referral to kidney transplant program. If at all possible, a kidney
transplant should be pre-emptive, i.e. take place before the ESRD patient ever starts
on dialysis.

Regrettably, the waiting list for kidney transplants in the U.S. is long, growing, and

\(^\text{12}\) Beth Israel Deaconess Medical Center, “The Benefits of Transplant versus Dialysis,”

\(^\text{13}\) Arthur J. Matas, MD, ed., Manual of Kidney Transplant Medical Care (Minneapolis:
unlikely to be noticeably reduced by increases in the recovery of deceased donor kidneys.

By year end 2010, there were roughly 93,000 kidney transplant candidates registered with the United Network for Organ Sharing (UNOS) in the U.S.,\textsuperscript{14} while 4,600 patients die each year waiting because they did not receive a kidney transplant in time.\textsuperscript{15} The current American epidemic of obesity along with higher rates of diabetes and hypertension play a greater role in the increase of prevalence of ESRD. The shortage of kidneys for transplantation is restricting the opportunity for realizing any true gains in managing this all-to-familiar disease.


CHAPTER 2

NATIONAL KIDNEY DONOR SHORTAGE: DEMAND EXCEEDS SUPPLY

End-stage renal disease (ESRD) patients that have received a kidney transplant reiterate how a new kidney has not only saved their lives, but has enriched the quality of their lives. They feel better physically; therefore, they have more energy to return to work, to travel, and to do hobbies. They likewise have more time to spend with family and friends instead of time spent away on a dialysis machine. For kidney transplant patients, receiving a new kidney is a liberating, life-changing occurrence. How does a kidney transplant do all of this? Although dialysis is a life-sustaining treatment, it can only mimic approximately 10 percent of what a healthy kidney can do. Dialysis treatments cannot remove fluids and toxins gradually from the body 24 hours a day like a functioning kidney, which is undemanding on the body. A major truth is that ESRD patients cannot survive on dialysis indefinitely. It is tangibly demanding on the body which can cause yet other serious medical complications, such as, high blood pressure, heart disease, nerve damage, bone disease, anemia and various types of infection, which can also lead to premature death. A kidney transplant restores 100 percent of renal functions in an ESRD patient. Because of the donor kidney’s ability to revive renal functions in the body, kidney transplant patients in general experience a longer life expectancy than do ongoing dialysis patients. Regrettably, the number of ESRD patients waiting for a donor kidney for transplantation far exceeds the number of donor kidneys available to them.

Within the last decade, the supply of obtainable deceased donor kidneys has only shown a modest increase, while on the other hand; living kidney donation has experienced substantial growth. Although more living kidney donors are coming forward, they, in
conjunction with deceased kidney donors, still cannot meet the overall kidney donor demand. The bottom line is kidney transplants do save lives, but tragically, tackling an extraordinary demand with an inadequate supply has yet to be reconciled.

The focus of this chapter is the staggering and heartbreaking reality of the human organ shortage in the United States with an application aimed at kidney donation. There are many important questions that need to be brought to light and straightforwardly addressed in order to start constructing plausible solutions to this massive problem, for example, what are the exact numbers of ESRD patients waiting for a kidney on the United Network of Organ Sharing (UNOS) waiting list right now? What are the statistics regarding how many deceased and living kidney donors become available each year? What is being done today in the U.S. to combat the kidney donor shortage? Questions like these and others will be deliberated in order to yield a sound foundation in which to build upon concrete solutions. Various controversial philosophies on how to overcome this numbers discrepancy will be revealed along with information regarding the many organizations that have been created to help assist the process of equating the numbers.

Of particular interest, the National Kidney Foundation, the leading health organization dedicated to the treatment of kidney disease, has established an innovative action oriented initiative to ending the wait for kidney donations completely. In addition, with the accessibility of various media and the internet, ESRD patients in desperation for a kidney transplant seek other outlets in which to locate a donor among the general public bringing forth the altruistic donor.
As of September 21, 2012, there are 100,045 registered candidates on the kidney donor waiting list according to the Organ Procurement and Transplantation Network (OPTN); however, only 93,952 kidney transplant candidates are active, which means able to receive a transplant at the moment.\(^1\) With an overall tally of transplant waiting list candidates equaling 115,666, it is easy to see how the kidney is a most sought after organ. In addition, the number of deceased kidney donors that have been harvested, thus far in 2012, is 3,688, while the number of living kidney donors utilized is 2,756.\(^2\)

The majority of actions employed to combat the shortage of available kidney donors in the U.S. has been undertaken generally by volunteer-led organizations. The participating volunteers often have had some direct involvement with kidney disease, kidney failure, dialysis treatments, kidney donation or kidney transplantation either on a personal level or through an association with a relative, friend, coworker, etc. Most Americans are familiar, at least by name, with the National Kidney Foundation (NKF), whose own initiative to increase the numbers of kidney donors nationwide will be reviewed momentarily, but there are many more organizations in addition to the NKF that contribute to this cause that Americans probably do not recognize. At this time, we will assess three predominant organizations making an impact on increasing the numbers of available


kidney donors and how they do it. Two organizations, the Alliance for Paired Donation and the National Kidney Registry, directly participate with matching donors and recipients for kidney paired donation which is the main topic of this paper. The other, Donate Life America, focuses on increasing donor awareness; therefore, increasing donor numbers and it has partnered recently with a newcomer, Facebook.

The Alliance for Paired Donation (APD) is a non-profit organization devoted to supporting ESRD patients through technology, education and generosity. Its foremost objective is to help those ESRD patients who have a willing but incompatible living kidney donor find another incompatible paired match for a possible kidney donor swap through its paired donation program. The aim of this program is to create more compatible living kidney donor transplantations, i.e. increase living kidney donation through the process of pairing. Each effective pairing would decrease the number of ESRD patients on the deceased kidney donor waiting list. In the process, an incompatible living donor-recipient pair would register in the program and then a computer database is utilized to locate another registered incompatible living donor-recipient pair for a possible kidney donor exchange in order to produce two successful kidney transplants. According to the APD, the medical information for registered pairs is entered into their database and it will search throughout the information of other registered incompatible pairs to find a potential cross-match. If a potential cross-match is found, a team of participating transplant surgeons will determine whether to proceed with advanced medical testing between the two sets of incompatible pairs. If further testing determines an accurate cross-match, the two sets of incompatible pairs will set up a date to undergo simultaneous surgeries to swap kidneys. Travel may be required of the participants though financial assistance for travel expenses is
available from the APD. Kidney donor pairing, known as kidney paired donation, is not a new concept; however, the original semi-manual process of kidney donor pairing had been tedious, slow and geographically limited. The APD’s paired donation program is software driven, has high-speed capacity, and can incorporate all U.S. geographical regions.

Alliance For Paired Donation Emblem

The APD’s pairing system furthermore pioneered and launched what is known as the Non-simultaneous Extended Altruistic Donor (NEAD) Chain. In a NEAD Chain, the system of pairing is present, but with a twist. An altruistic donor makes a non-directed kidney donation to an ESRD patient who is a part of an incompatible living donor-recipient pair. In turn, the living donor of that incompatible pair pays it forward by donating a kidney to another ESRD patient of another incompatible living donor-recipient pair, and so forth and so on. The Chain is non-simultaneous; hence, it can be performed over a span of time and with no geographical limitations. The practice of kidney paired donation and the NEAD Chain will be examined in detail in Chapter 4. Beyond the paired donation
program, the APD provides financial aid to kidney transplant patients, living donors, and their respective families in regards to transplant-related expenses. In addition, the APD supports kidney transplant educational activities for patients and their families while funding educational opportunities for transplant professionals and transplant related research.

Donate Life America is a non-profit alliance of national organizations and state teams across the U.S. dedicated to increasing organ, eye and tissue donation. Its mission is to motivate individuals and communities along with commercial organizations to help increase the number of people who designate themselves as organ, eye and tissue donors to save and heal lives. Its vision is that organ donation should be embraced as a fundamental human responsibility. Donate Life America endorses and administer the national brand for donation entitled Donate Life. Likewise it supports Donate Life state-run teams and other nationwide associates in facilitating high-performing donor registries; constructing and executing effective multi-media donor education programs; and inspiring the American public to register directly as organ, eye and tissue donors. Recently, it was Donate Life California that partnered with Facebook for Facebook’s organ donor initiative, which will be presented momentarily.
In June 2012, Donate Life America unveiled the all-important donor numbers at their fifth annual National Donor Designation Report Card annual meeting. The Report publicized that 101.4 million people had enrolled as organ donors throughout the state sponsored registries in 2011. Nationally that equates to 42.7 percent of Americans 18 years and older are registered organ donors with Alaska and Montana topping the state list registries with 79 percent participation rates each. Continuous organ donor registration is a priority with thousands still waiting for a lifesaving or life-changing transplants. To tackle this perilous need for more organ donations, Donate Life America has launched its initiative known as the 20 Million in 2012 campaign in order to profoundly upturn the numbers of people who register on state organ donor registries. “In 2012 we are making a bold statement about our commitment to save more lives,” says David Fleming, who is the
President and CEO of Donate Life America.³ “With the majority of individuals in the United States wishing to be organ, eye and tissue donors, the biggest challenge to meeting our goal of 20 million will be getting people to take action and register today as an organ, eye and tissue donor at DonateLifeAmerica.org.”⁴ This initiative entails powerful stories of people affected by these donations along with local, state and national events such as Donate Life Flaunt Your Blue and Green (colors of the alliance’s logo), Donate Life Linking Hands, Donate Life Champions and Fan for Life, and Donate Life Flash Mobs to help draw attention to the need for organ donation, but reaching that goal will require the involvement and action of everyone.

**Donate Life 20 Million in 2012 Campaign Design**

![Donate Life 20 Million in 2012 Campaign Design](http://donatelife.net/

The National Kidney Registry’s mission is to facilitate living kidney donor

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⁴ Ibid.
transplants in order to save and enhance the lives of people facing kidney failure by increasing the quality, speed and number of living kidney donor transplants around the world. The Registry will undertake incompatible or poorly matched living kidney donors and recipients and catalog them in a universal pool with other living kidney donors and recipients in the same situation and utilize modern software technology to find compatible matches in less than a six month timeframe. The dilemma of incompatible living kidney donors would become a thing of the past. It had been the Founder and President of the National Kidney Registry’s own dilemma that inspired him to start this non-profit organization that is supported by volunteers, counselors and associates from around the world.

Garet Hil, a businessman of 25 years, became linked with kidney related healthcare issues when his 10 year-old daughter was diagnosed with kidney failure. He wanted to be her directed kidney donor, but his high blood pressure, and two failed cross-matches made it impossible. On his daughter’s behalf, 15 potential directed donors were tested. Fortunately, one 23 year-old cousin cleared all the hurdles and donated his kidney to her. This was back in July 2007. After Hil’s dreadful and frightening experience, he believed that there had to be a better system of finding compatible living donor matches. Then he founded the National Kidney Registry to make that revelation a reality. Through this course of action, Mr. Hil and the National Kidney Registry have helped facilitate several living kidney paired donation matches for transplantation using the Domino Chain which will be examined in detail in Chapter 4.
In May 2012, the American internet giant Facebook, world’s biggest social networking website, made it possible for its American and British members to enroll as organ donors via links on the website, and share publicly that they are registered organ donors in order to raise awareness of those people in need of a life-saving organ transplant. Facebook unveiled its optional organ donor status to the Timeline profile in an effort designed to help the 114,000 plus people in the U.S. and millions more around the world that are still waiting for an organ donor. Facebook decided it was time to do something about the constant organ donor shortage, and that it was time to raise awareness of the people in need. Currently, the more socially conscious network has a membership base of 901 million-strong worldwide and counting. The founder and CEO, Mark Zuckerberg,
created this initiative on behalf of his friendship with the late Apple Inc. co-founder, Steve Jobs, whose life was extended following a liver transplant. In an exclusive interview on ABC’s morning news show Good Morning America, Zuckerberg stated, “What we hope will happen is that by just having this simple tool, we think that people can really help spread awareness of organ donation. We think that can be a big part of helping solve this crisis that’s out there.”

“Medical experts believe that broader awareness about organ donation could go a long way toward solving this crisis.” Facebook provides a video that shows members how to designate themselves as an organ donor. If a member is not presently an organ donor and wishes to become one, Facebook posts a link to the appropriate organ donor registry in order to sign up. The organ donor notice will appear in the member’s Timeline under life events with the likes of college affiliation and marital status information. Organ donor advocates in California are praising Facebook for its action. Donate Life California is a partner with Facebook in this effort. The day before the announcement by Zuckerberg, Donate Life California signed 76 potential organ donors. The next day, the amount jumped

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to 994.7 According to CEO of Donate Life California, Charlene Zettel, “What the Facebook partnership has done is to give hope to all those people on the waiting list that maybe their lives will be changed and they will get a second chance at life.”8

With Facebook, the motivation for organ donation is friendship and trust. In addition to Zuckerberg’s friendship with the late Steve Jobs, Zuckerberg’s then fiancée Priscilla Chan, a medical student, had played a role. Chan, who married Zuckerberg in July 2012, is studying to be a pediatrician. She had relayed to him her experiences with children waiting for transplants. How she would spend weeks upon weeks with a patient to only see them get sicker because they could not get the organ they need. When a patient did receive an organ, she had stated how it was like night and day because all of a sudden the patient was on a path to getting better. The Facebook exposure is a way for people through friendships to receive accurate information regarding organ donation—getting the information, understanding it and making the decision to become an organ donor.

Dr. Art Caplan, a bioethicist, applauds Facebook and states that Facebook can do more to register people for organ donation than any efforts to promote organ donor cards or the Department of Motor Vehicles (DMV) donor registration could ever do. Organ donor cards and driver’s license donor box check-offs do work to notify of a person’s intent to be an organ donor, they just do not work well. Some states have higher percentages of organ donation participants than others. For example, the state of Denver has sixty-two percent


8 Ibid.
participation rate while New York has fewer than fifteen percent. Although a Gallup study found that ninety-five percent of Americans claim they do wish to donate their organs after death, there continues to be a low overall membership participation rate. One setback could be that the DMV is not the most proficient agency to recruit organ donors. Philosophy professors Kyle Whyte and Evan Selinger drove this point home in an article for the American Journal of Bioethics. “Asking people to do something nice for others when they have been stewing in a long line, getting angrier and angrier while they wait is not conducive to altruism.” One professor offered the true story about his experience at the DMV which said it all. He went to the DMV to renew his license in Pennsylvania. While there, he told the official at the counter that he wanted to be an organ donor. Her response was a frown, and she stated that maybe that was not a good idea. She had heard that people who checked off the donate box might not get aggressive treatment at the hospital insinuating the hospital would make you as an organ donor before you were dead. Here was an official giving out wrong information. The point, inquiring about organ donation with someone who does not know the facts or who does not care about them, along with waiting in a gloomy environment is not the best way to identify organ donors. The power of the organ donor card is to let others know your intentions when you die, but what happens if that card cannot be found when you die or your family does not know that one has been signed? Then your desire to donate is unknown and your donation lost.


10 Ibid.
Facebook provides yet another opportunity for others to learn of your aspirations to be an organ donor, and that is all for the good. At least Facebook is trying to find more organ donors for those still waiting. For their sake, let us hope that it succeeds.

There is a hope that in the nearby future organs obtained from animals may help reduce or eliminate the human organ shortage, especially the kidney, but thus far, progress has been agonizingly slow. This concept is called xenotransplantation. In theory, xenotransplantation could save thousands of desperate patients waiting for a donated organ. Although human-to-human organ transplants would always be the first option, animal-to-human transplants may offer a potential treatment option for ESRD patients that remain on the kidney donor waiting list. Xenotransplantation does have support from transplant surgeons, kidney transplant recipients, ESRD patients, patient family members and the general public. The use of pigs or primates would be the most compatible choices; however, cross-species disease transmission is a major obstacle. Scientists would need to find a way to fight animal organ rejection by way of the immune system in the human body, and develop a way to keep animal viruses that could be passed through the animal organs from entering the human population. Nonetheless, medical researchers remain optimistic that science will prevail. There is a moral and social side to this option as well, particularly if animals would be raised for the sole purpose of becoming organ donors. If xenotransplantation turns into a viable forthcoming option, animal rights activists will be sure to heavily protest this measure.

Another scientific experiment is on the hi-tech table, and it is to accurately cultivate human organs in a laboratory. The basis to this mother-of-invention is to use the patient’s own cells to engineer the organ of need. Because the organ is custom engineered from the
patient, the patient’s results will be function better, and last longer. With this process, an organ is developed one layer at a time much like baking a cake, and incubated for several weeks so it can stimulate cell growth like cooking. This technique is also called organ-farming. For organ transplant patients, the use of immunosuppressant drugs would be a thing of the past because the organ would not be seen by the immune system as a foreign object and rejected. This clinical bioengineering of organs has experienced far more positive results than xenotransplantation.

This practice has successfully grown urethras, skin, tracheas, blood vessels, bladders and cartilage. In the works are heart valves, muscle cells, arteries and fingers. At this time, research has faced limits in regards to the formation of livers and kidneys due to the lack of development of a microscopic device capable of supplying oxygen and nutrients to those organs during an entire incubation period of 30 to 50 layers. The current device can sustain viability from 1 to 2 weeks only. If or until science can aid or resolve the lack of available organs for transplantation, expanding the numbers for organ donation will have to rely on continued volunteerism or perhaps government intervention. Let us survey what current proposals are on the table.

The utter most contentiously proposed solution to the kidney donor shortage in the United States is that of legalized payment for human organ donation. In 1984, Congress specifically outlawed the payment of any human organ under the National Organ Transplant Act or NOTA. NOTA will be entirely outlined in Chapter 3. The philosophy behind this viewpoint of payment for human organs lies within practicality. Although organ transplantation is one of the greatest triumphs in medical history, it is a miracle that is out of reach for thousands of patients who die tragically each year waiting for an organ.
The main reasons are these: 1) not enough Americans are signing organ donor cards or denoting organ donation on their driver’s licenses, 2) not enough families are consenting to the donation of their loved ones’ organs after an untimely death (prior donor consent or not), and 3) medical personnel are not approaching the families of potential organ donors often enough in the hospital venue. As a result, the supply of deceased organ donors has been insufficiently flat over the last decade or so. With a person being able to live with one kidney and with kidneys being the most sought organ, the impetus for living kidney donation had begun through the persuasion of relatives, friends, and even total strangers (altruistic donors) to donate one of their own kidneys. Though living kidney donation has made a vital dent in the kidney donor shortage, it has not produced a kidney-for-all in conjunction with the amount of obtainable deceased kidney donations. Hence, for those in favor of payment, there just are not enough organs to go around as the situation stands at this time. That debate has motivated a proposition once considered an unthinkable measure—paying for human organs.

A model deliberation on the topic of the payment for human organs took place in 2008, and the proposition was entitled “We Should Legalize the Market for Human Organs.” Six specialists in fields relating to organ donation and transplantation conducted an Oxford-style debate (a formal, competitive debate format introducing an outlined motion that is proposed by one side and opposed by another) on the sensitive issue of financial incentives for organ donation as part of an event series called Intelligence Squared

U.S. This debate virtually covered the major philosophies for and against this measure. Let us review the highlights of this debate. First, we will examine the credentials of those in favor of the motion and their motives behind their support. Second, we will examine the credentials of those opposed to the motion and their motives behind their absence of support.

Those experts in favor of the measure are as follows:

Sally Satel, MD., a psychiatrist and resident scholar at the American Enterprise Institute for Public Policy Research in Washington, DC, is a kidney recipient and author of kidney transplantation linked articles. She received a kidney from a living donor—friend—in 2006. Dr. Satel’s focus goes beyond the donations from relatives and friends, but towards stimulating appeals for organ donation from the general public. She believes that people need more incentive to donate an organ, but payment should be conducted through a third-party method in order to avoid an organ black market. In her argument, Dr. Satel stated, “Despite decades and decades of public education about the virtues of organ donation, the waiting list just gets longer, and the time to transplantation just gets longer. … It’s past time to face the fact that altruism is just not enough. Many people need more of an incentive to give. And that’s why we need to be able to compensate people who are willing to give a kidney to a stranger, to save a life. … We are not talking about a classic commercial free-for-all, or a free market, or an eBay system. We’re talking about a third-party payer. For example, today you could decide to give a kidney. You’d be called a Good Samaritan donor. … The only difference in a model that I’m thinking about is where
you go and give your organ, and your retirement account is wired $40,000, end of story.”\textsuperscript{12}

Although Dr. Satel had received her kidney from a living donor; therefore, she did not have to wait for her transplant, she does display her compassion for those who remain on the waiting list for a long period of time. Whether or not one agrees with her method to stimulate the general public’s interest in organ donation, her point of a comparatively lesser supply versus an enlarging demand is solid.

Amy Friedman, MD, director of transplantation at SUNY (State University of New York) Upstate Medical University in Syracuse, is a close relative of two transplant recipients and a living organ donor. Dr. Friedman wants organ compensation to be legal and regulated to avoid any black market situation, and wants to ensure the welfare of the living donors as well as the recipients since they would be making an enormous personal sacrifice. In her argument, Dr. Friedman had commented, “I agree with our opponents that the black market must be closed. I disagree with asking patients to accept death gracefully, instead of resorting to the black market. My position is that development of a legal, regulated mechanism for donor compensation is the only means of effectively eliminating the demand for this cover activity, closing down the black market and improving safety for donors and recipients. …Compensation for the organ donor’s time and risks, by providing life insurance, lifelong health insurance and even a direct monetary fee, is more appropriate than for the donation of an egg, the rental of a uterus for a surrogate pregnancy, or the participation in clinical experimentation, all of which are legal.”\textsuperscript{13} Dr. Friedman’s

\textsuperscript{12} Ibid.

\textsuperscript{13} Ibid.
assessments would lift the veil off the black market, where recipients and donors could feel safe and secure in a professional medical environment during the transplantation process. In addition, her statement regarding the provision of lifetime health insurance to living donors could be the key to increasing living donation as an incentive alone with life insurance becoming more difficult to obtain in the current U.S. economy.

Lloyd R. Cohen, law professor at George Mason University in Virginia, has a unique spin on payments for organ donation—that of a contract with the donor prior to death. The amount of payment would be based on a designated sum and totaled for each major organ harvested. Then the payment would be made to the donor’s individual or organization of choice. This method would resemble more of a gift versus an outright payment per say. Professor Cohen has said, “The market I propose is one in which healthy individuals might contract for the sale of their organs and tissue for delivery after their death. If the vendors’ organs are retrieved and transplanted, a payment in the range of $5,000 for each major organ would be made to a person or institution chosen by the donor. …In an options market, organs would only be acquired from the dead. No one need be induced or even permitted to sacrifice his health or bodily integrity for money. The donation of the organs of the deceased by both rich and poor is currently strongly encouraged, precisely because most of us believe that surrendering the organ represents no sacrifice to the donor.”

Professor Cohen’s idea regarding a future donor contract is a grander interpretation of the donor card. The only way this method would work is if the contract is legal and binding, i.e. family members of the contract donor would not be able

14 Ibid.
to decline donation after death, which can be done with signed donor cards or with the designated donor option on a driver’s license.

Those experts against the measure are as follows:

James Childress, PhD, ethics professor at the University of Virginia is the committee chairman of the Institute of Medicine, which produced the 2006 report “Organ Donation: Opportunities for Action.”\(^{15}\) Professor Childress asserts yet another angle on Professor Cohen’s comments. He incorporates the general public’s underlying cynicism towards the medical community’s haste in harvesting organs will result in a premature declarations of death for the sole purpose of obtaining those organs. This is a reality that must be confronted. He states, “Imagine a futures market in organs where individuals contract to provide their organs after their deaths, and in return receive a payment now, or designate the payment to the provided after their deaths to their families or to a charity.

…Well, consider that many people don’t sign donor cards now because of distrust or mistrust. They worry about being declared dead prematurely, or even having their deaths hastened, if they have signed a donor care. Well, they would certainly be reluctant to enter a futures market, to sign a futures contract, when the only barrier to the delivery of their organs is the fact that they’re not dead yet.”\(^{16}\) Whether a valid concern or not, there will always be a percentage of the American population that is wary of organ donation because they do fear that hospital staff would allow them to die under extraordinary circumstances in order to save someone else.

\(^{15}\) Ibid.

\(^{16}\) Ibid.
Francis Delmonico, MD., professor of surgery at the Harvard Medical School, is an advisor to the World Health Organization (WHO) on human organ transplantation. Dr. Delmonico has witnessed first-hand the effects of what is known as medical tourism, i.e. for transplantation purposes, a person, who can afford to do so, travels typically to a third-world country in order to purchase a healthy organ cheap from someone who is in desperate need of money. He says, “What we do here has a profound influence on the rest of the world. Now, I say that because I’ve been to Manila. And … it’s not a matter of balanced thought when a 14-year-old has to sell a kidney to an American that comes there. It’s not a matter of balanced thought in Pakistan, or in Egypt. … About 20 patients a month go from Israel to Manila because of cheap prices. If there’s a market legalized in the United States, in the global context of medical tourism, do you think that the 72-year-old patient on the list would wait for a kidney here, versus going to buy a 20-year-old kidney in Manila?”

17 For those individuals used to buying their way through life, and getting what they want when they want it, medical tourism is a no brainer when it comes to needing a kidney. One would merely find the best market—one with a high supply—regardless of geographical location, pay for a matching kidney, and recover under the care of a local doctor. Once the connection is made between the patient and the host country, more often than not, a package deal can be arranged prior to departure.

David Rothman, PhD, professor of social medicine at Columbia University, is the director of the Center on Medicine as a Profession. Dr. Rothman considers financial incentives as the outright selling of human organs. He states, “What this is really about is 

17 Ibid.
the sale of organs from living donors. … There are very, very good reasons—many drawn from behavioral economics, some drawn from past experience—that suggest that, in fact, to create a market might diminish the supply, not increase it. In the first instance, if I can buy it why should I give it? … In England, where the sale of blood was not allowed, rates of donation were considerably higher than the U.S., where the sale of blood was allowed.”  

Utilizing concrete donation results from outside countries is an effective means of measuring what could happen in the U.S. if the same approaches were applied. Past experience is an excellent teacher as Dr. Rothman pointed out.

The National Kidney Foundation (NKF), the foremost American organization in the battle against kidney diseases, made its final verdict known regarding payment for human organs back in 2002. The NKF Board of Directors unanimously voted to denounce any effort to legalize payment for human organs in the United States. Andrew Baur, the NKF Chairman, stated “the national shortage of organs for transplant is a major concern of the NKF and we will intensify our efforts to encourage people to donate organs when a loved one had died. But we cannot condone or supports paying for organs.” Some people may find irony with this decision because it was the NKF that first broached the subject of financial incentives for organ donation eleven years prior at the Controversies in Organ Donation conference. Since that conference, this issue has been fiercely debated, and continues to be so as the number of people on the kidney donor waiting list increasing each 

18 Ibid. 

year. In the wake of the kidney donor shortage, the NKF issued a call to action.

The NKF, the largest voluntary health organization in the U.S., has diligently strived to improve the health and welfare of ESRD patients along with their families while creating innovative techniques to increase the availability of kidneys for transplantation. At present, the NKF has unveiled a comprehensive plan to address the need to increase the number of donor kidneys available for transplantation. The initiative is called END THE WAIT! The NKF considers this a multi-faceted approach that includes a list of viable recommendations to incorporate financial, educational, and medical practices, which the NKF declares have been tested and proven to be successful in increasing donations.

According to John Davis, who is the NKF CEO, “Most of the people on this list (UNOS) will wait too long for an organ and too many will die while waiting. We’ve decided to meet this core challenge head on and lead a broad-based initiative that will eliminate barriers to donation, institute best practices across the country, cover the cost of donation and increase the pool of living and deceased donors. Instead of debating the merits of untested strategies that may or may not motivate people to donate, we’re unveiling a national plan that combines the ‘best of the best’ tactics that have worked in some regions of the country to increase donation. We are committed to making the disincentives to donation go away.”

The END THE WAIT! initiative does not set out to pursue minor legal changes or single-issue amendments to existing transplantation laws. Over a ten year period, END

THE WAIT! sets out to collaborate with other major kidney care organizations and transplant communities, and to lead the way in working with the U.S. Congress to create legislation that will attend to all the barriers to kidney donation. The aim is to complement, not amend the National Organ Transplant Act (NOTA) of 1984, which banned the sale of all human organs. NOTA will be discussed in Chapter 3. In addition, it wants to supplement the Uniform Anatomical Gifts Act (UAGA), which enables potential organ donors to legally indicate their wishes on their driver’s licenses. In the absence of any known donor wishes at the time of death, the UAGA allows spouses or specific relatives to make the gift. On a wider scale, the UAGA prohibits trafficking of human organs for profit.

END THE WAIT! has established preset recommendations in four key areas with regards to the shortage of kidneys for transplantation:

1) Improve the outcomes of first transplants. If the first transplant is successful, it eliminates the need for a second transplant; therefore, a maximum utilization of kidneys available.

Financial – Cover the cost of immunosuppressive drugs for life.

Education - Educate CKD (Chronic Kidney Disease) Stage 4 patients about:

- Staying as healthy as they can.
- The opportunities for and benefits of having an early transplant.
- The possibility of living kidney donation.
- Identifying potential living kidney donors.

Medical Practice - Evaluate Stage 4 CKD patients for a transplant prior to the initiation of dialysis.

2) Increase deceased kidney donation through specialized training of hospital personnel in regards to optimal care of potential donor families at the time of death. In addition, recover and utilize extended criteria donors, such as, those individuals who are older or have experienced illness prior to death. Include donors who experienced a cardiac death (and not just donors with brain death).
**Financial** - Ensure that OPOs (Organ Procurement Organization) have the discretion and funding to assist donor families with expenses directly related to the donation, which may include some funeral expenses.

**Education** - Facilitate awareness of all appropriate hospital personnel about the optimal care for potential donor families.

**Medical Practice** – Renew criteria at Transplant Centers to:

- Minimize discard and maximize utilization of donated organs.
- Identify, recover and utilize organs from Extended Criteria Donors and from donation after cardiac death donors nationwide.

3) Increase living kidney donation by ensuring donors that they will be reimbursed financially for all expenses related to their donation. Provide donors with health care and life insurance coverage.

**Financial** -

- Guarantee that all living donors, without restriction, are reimbursed for all their expenses involved in the donation process, including lost wages. This includes non-directed (altruistic) donors and potential donors who are evaluated but do not ultimately donate.
- Guarantee all living donors access to health care coverage for any medical expense or disability related to the donation.
- Guarantee all living donors life insurance coverage for any would-be death related to the donation.
- Guarantee that all living donors get their jobs, or equivalent jobs, back upon recovery from donation.
- Guarantee that all living donors will not be discriminated against in obtaining future health and life insurance (predetermined condition).
- Establish a specific billing code for post-donation care expenses of all living donors.

**Education** -

- Create a NKF Living Donor Council (support group) to support the needs of living donors and address the questions of potential donors.
- Create a "Living Donation Breakthrough Collaborative" to encourage best practices for living donation.
- Update the general public about new technological developments in living donation and transplantation.

**Medical Practice** -
o Build up medical staff and expand the physical resources at all transplant centers in the nation in order to minimize the wait time for living donations.
o Evaluate more than one potential living donor for a single recipient when possible.
o Collect, maintain and analyze data on living donors each year, comprising a minimum of blood pressure, eGFR (Estimated Glomerular Filtration Rate-lab test used to screen for and detect early kidney damage), proteinuria, and Hb A1C (lab test used to show average level of sugar in the blood over 3 months in order to detect diabetes).

4) Improve the donation and transplantation system throughout the U.S. to make it more efficient and equitable.

Medical Practice -

a. Eradicate all regional variations in the rates of donor consent, living donations, access to early transplantation, access to transplantation and follow-up care.
b. Eradicate all racial and supplemental disparities in donating, listing, remaining active on the UNOS waiting list and receiving a transplant.
c. Uphold uniform organ donation laws across the United States.21

The fact that there are more patients in need of an organ for transplantation in the United States then there are human organs available is clearly a black and white issue. The numbers speak for themselves. On the other hand, regrettably, exactly how to resolve this discrepancy is very much undecided. Because of the critical organ donor shortage, it is imperative to identify new sources, techniques, and initiatives in gaining more transplantable organs. Let us evaluate what science has to offer with an estimated timeline.

With respect to xenotransplantation, this process has been funded since the early 1990’s, and few positive results have been experienced thus far. This may become an option further in the future in say about another 20 plus years at the rate it is progressing.

Research in xenotransplantation will rigorously endure with available private and governmental funding, but with the current pace for the increasing need for organs, it should not be heavily relied upon to assist or solve the deficiency in the near future. Therefore, this option cannot be counted upon at this time. Organ farming shows tremendous promise since it has already experienced concrete success. Although limited to which organs can be replicated, it should only be a matter of years before additional organs can be added to the present list. It is with great anticipation that kidneys will be able to be replicated within the next 10 or so year timeframe. Although organ farming may be closer to comprehensive success than xenotransplantation, it too can only be considered as a future option towards the kidney shortage. There is an additional project involving kidney engineering taking place in the U.S. that combines xenotransplantation and organ farming. Regenerative medical researchers are trying to build replacement kidneys by using pig kidneys to make scaffolds—support structures—that could theoretically one day be used to form new kidneys for human ESRD patients. The concept is to remove all the animal cells from the pig kidney leaving only the kidney structure or a skeleton. Then the patient’s own cells would be deposited into the scaffold to make a kidney that a patient’s immune system would hypothetically not reject. Nonetheless, this endeavor is still in its infancy. Once more, this is a potential future solution. Until science can offer solid organs for transplantation, ESRD patients would need to depend on the non-scientifically inspired initiatives on the table to increase the numbers of transplantable kidneys.

In the past, organ advocacy groups out-and-out asking for organ donations from the general public did not yield a sufficient increase in kidney donations in order to solve the kidney shortage. Therefore, the novel notion of financial incentives including making
outright cash payments available to individuals or families for giving organ donations in order to increase the number of human organs available came to light. This controversial method to proliferate organ donations undoubtedly faces moral obstacles along with legal entanglements. Any initiative linking human organs with any amount of money reeks of a black market environment where the wealthiest people would benefit most. Whether soliciting voluntary organ donations or making payments for them, human nature must be taken into account as the motivational force for donating. Human nature equates to a kaleidoscope of varying degrees of compassion and greed, conviction and skepticism, selfishness and self-sacrifice, valor and fear, and the list goes on. It is true, not all people would be willing to give an organ unless something is in it for them no matter how slight that something may be. It is also true, that there are people who would donate an organ just because someone is in need whether they know the person or not. In order to devise a successful outcome to resolving the kidney donor shortage, a variety of concerns from the perspective of the donor or donor’s family must be incorporated into the strategy. The donor is, first and foremost, the key factor. For a living donor, providing appreciation through concrete measures guaranteeing safety and security would be paramount. For a deceased donor’s family, a strong message of heroism and remembrance would foster emotions of great respect and honor during a time of their darkest hour.

People cannot be coerced into giving an organ donation based on moral duty, but people can be called to action in helping another human being survive a deadly consequence. Channels of communication must be open for discussion in order to make potential living donors aware that giving a kidney can be done safely, and that only one kidney is needed to live so giving the other kidney is not detrimental to one’s own health.
For those individuals potentially willing to sign an organ donor card, they must be made aware that they will not face a premature death in a hospital for the sole purpose of procuring their organs. In the case of a deceased donation, family members need to be reassured that the body of their loved one will be handled with the utmost care during the harvesting of the organs, and not handled like a car in a chop shop as some may visualize.

Payment for organ donation would not be an ideal initiative for several reasons. If the U.S. Congress made payment for organ donation legal, whether it was successful or not, it would be virtually impossible to reverse the decision and stop altogether. Money would be an insult to a deceased donor’s family by putting a price tag on their loved one’s organs like a commodity. In other words, making payments for organ donations would go against the values of the American society. It would be an unethical medical practice. It would set a dangerous precedent that the U.S. condones or endorses an organ trade that does exist in some countries today. For example, the worst case scenario of organ harvesting in the world exists in China where Chinese officials sell the harvested organs of executed prisoners. Giving an organ needs to be a voluntary system free of coercion or commercialization; otherwise, it would not be a donation. On the other hand, some stipulations need to be incorporated. For example, a living donor, who has health and life insurance, may lose both in donating a kidney. In place is the Affordable Care Act to protect people from being denied health insurance due to organ donation, which can be deemed a pre-existing condition, but this does not take effect until 2014. However, the Affordable Care Act does not prevent insurance companies from raising health insurance premiums for those they consider high risk, which includes kidney donors. Without legal protect for living kidney donors, only those who have a direct relationship with someone
facing kidney failure would donate. This would drastically limit living kidney donation in the U.S. It appears that American healthcare insurance companies do not take into consideration that promoting living kidney donation would save money for them in the long run. Overall, the costs associated with kidney dialysis over a period of years along with dialysis related medications, side effects medications and periodic hospitalization for one ESRD patient would be far more expensive than the costs associated with a kidney transplant and immunosuppressant drugs for one ESRD patient. Individual insurance companies should do the math. They would see that it would equate to a win-win situation.

In order to increase kidney donation in the U.S., Congress should immediately mandate a kidney donation Act that would guarantee no forfeiture of healthcare insurance or increases to insurance premiums under the guise of pre-existing condition for living kidney donation. For potential living donors without healthcare insurance, guarantee government subsidize healthcare for a period of ten years post donation. For, the insured and non-insured, a free annual physical from a post-transplant facility for ten years. In the framework of the United Network for Organ Sharing (UNOS), establish and manage a non-profit organization entitled the United Network of Registered Organ Donors (UNROD) where potential organ donors would formally register as organ donors vice the current systems of organ donor cards or driver’s licenses. Donor intent and registration would not have to be made known to the next of kin. It would be done quickly and easily through electronic signature over the internet. For those without the internet, a wet signature would be mailed in on a donor registration form. There would be a multitude of advantages with a legalized nationwide organ donor registry. UNROD would allow immediate access to donation registration information nationwide to all Organ Procurement Centers (OPC).
would take the guesswork away from hospitals as to organ registration status of a
terminated patient. Likewise, a patient from New York could terminate in California;
UNROD would allow the gift of life to be utilized on the other side of the country.
Equally, the individual’s family would not be able to recall the individual’s decision to be
an organ donor. With these steps, valuable organ harvesting time would be greatly
reduced. An UNROD website would provide a donor sign-up, donor-related—living and
deceased—information and transplant statistics to potential organ donors along with
personal stories of those willing to share their experiences.
CHAPTER 3

THE LEGAL FRAMEWORK FOR ORGAN DONATION:
GOVERNING TRANSPLANT POLICIES AND PROMOTING ORGAN
TRANSPLANTATION

Organ shortages are not exclusive to the United States. Countries all over the world are experiencing an identical crisis. Though, each country’s government determines how it will handle its organ shortages, some countries lack medical regulations regarding organ donation triggering organ trades and organ trafficking, while other countries brand it legal to sell one’s organs for profit producing a legalized organ market. With or without detailed legislation, results can vary. For example, in Iran kidney sales are not only legal, but regulated by the state. On the other hand, Iran has no kidney donor waiting list. In Jordan, organ trade is illegal. However, living donors are brought over the boarder to Iran to perform the transplantation. Extreme poverty in India, along with legal loopholes, has led to many flourishing organ markets where the poor are taken advantage of by organ brokers. Organ prices there are based on location and available supply. In the U.S., ethical principles play a heavy role in such matters as organ donation. Americans know, for instance, that legal ambiguities plus low incomes plus a high demand for organs, especially kidneys, can easy equal an illicit black market for organs. The American federal government resolves to make its mark regarding organ donation and transplantation through its oversight in the organ transplant process to include refining the organ allocation system in order to effectively and equitably distribute organs, improving the regulatory management of transplant centers to ensure the safety of organ donors and recipients, and increasing the national organ supply through nationwide educational programs.

With human organ transplantation becoming more and more conventional in the
United States, and with the number of patients in need growing day-by-day, the Federal Government initiated legal processes to focus on the nation’s emergent organ shortage along with constructing refinements to the existing organ procurement, matching and allocation criteria. Equal in importance, the United States Congress sought to create its own specific legislative guidelines that would guarantee an ethical organ procurement system all the while safeguarding equitability in the distribution of available organs and wiping out any monetary gains being acquired in conjunction with the human organ allocation process. Although most organs are still being harvested from deceased donors, living organ donation has been on the rise and needs to be legally addressed. With regard to living human organ donation, Congress had to balance the needs of those desperate patients seeking organs with the moral requirements and safety of potential living organ donors. In what became the principal federal law governing human organ transplantation in the U.S., the 1984 National Organ Transplantation Act (NOTA) legalized living as well as deceased organ donation while prohibiting the sale of any human organ for the sole purpose of transplantation. At this precise time, we will further explore the particulars of NOTA along with other U.S. laws and organizations that were created by the federal government to attend to the detailed issues encompassing human organ transplantation, which are not kidney specific. Further along; however, we will examine legislation exclusive to the application of human paired organ donation as it reflects the main topic of this paper living kidney paired donation.

The core dilemma for Congress in organ transplantation was trying to increase organ donation while keeping within an ethical and equitable boundary as long as organ transplantation was a viable means of saving lives. Essentially, there are thousands upon
thousands of desperate patients throughout the U.S. competing against one another on a national waiting list for a limited number of existing transplantable organs. These patients are literally fighting for their lives. On the other hand, with the Congressional initiative to be ethical and equitable, some methods to increase organ donation have had to be rejected. For example, Congress refuses to make monetary offers of any kind to the general public in exchange for an organ donation as this would be considered the buying and selling of human organs. If this type of offer were to become legal, there would be those willing to buy and sell organs on their own accord. Consequently, the end result could take advantage of those with lower incomes, those with a lesser formal education and could certainly recruit unscrupulous scams and scam artists by way of organ bidding wars creating a form of legal underground market. In the long run, authorized monetary offers may well benefit those who are the wealthiest Americans or even privileged foreigners in obtaining a healthy organ in a quicker time frame. Of course, there would be those who are less fortunate financially and willing to sell anything and everything they have to obtain an organ for themselves or someone they love. Nonetheless, the demand for transplantable organs continues to outpace the supply.

On October 19, 1984, the 98th Congress took formal measures in developing policy management for human organ transplantation in the United States. Public Law 98-507, entitled the National Organ Transplant Act or NOTA, banned the sale of human organs, while issuing federal funds to create a qualified criterion for organ transplantation designated as the U.S. organ procurement system.\(^1\) It was NOTA Section 301 that

explicitly outlawed the exchange of what is deemed valuable consideration (money or the

equivalent) for a human organ,\(^2\) i.e. barred the buying or selling of human organs “for
valuable consideration for the use in human transplantation.”\(^3\) The lone monetary exchange
recorded in NOTA was that of reasonable payments to compensate living organ donors as
it relates to lost wages, travel expenses, and hotel accommodations in connection with
donating an organ.\(^4\) In addition, NOTA launched a Task Force exclusively devoted to organ
transplantation and organ procurement. This Task Force was to conduct comprehensive
assessments and generate resolutions on the medical, ethical, legal, economic, and social
issues raised by human organ procurement and transplantation, and report directly to the
U.S. Secretary of Health and Human Services. Objectives included safety, effectiveness,
and costs associated with organ transplantation, the advantages of and access to
immunosuppressant drug therapy, the education and training of health care professionals,
equitable access to organs by all patients, the education of the general public, etc.
Furthermore, it authorized the U.S. Department of Health and Human Services to establish
fiscal grants towards the creation, development, and operation of qualified Organ
Procurement Organizations known as OPOs, along with the formation of the Organ
Procurement and Transplantation Network (OPTN).

On April 5, 2004, legislation continued under the 108\(^{th}\) Congress, which enacted

\(^2\) Erin Williams, Bernice Reyes-Akinbileje, and Kathleen S. Swendiman, “Living Donation
and Valuable Consideration,” Congressional Research Service, no. RL33902 [March 25, 2010],
http://0-www.lexisnexis.com.library.lausys.georgetown.edu/congcomp/getdoc?CRDC-

\(^3\) Ibid.

\(^4\) Ibid.
Public Law 108-216, entitled the Organ Donation and Recovery Improvement Act (ODRIA).\(^5\) In part, this federal law was wholly applicable to living donors (i.e., “living people who donate either an organ they can survive without, such as one of their two kidneys, or a portion of an organ, such as a liver”)\(^6\) as living donation became preferable due to living donations outlasting cadaver donations. Congress wanted to carry out public programs to educate the public on the significance of being an organ donor, how it saves lives, and making your personal choice to be an organ donor known to family members. A crucial factor for the use of live kidney donors was the acknowledgement of a cutting-edge transplantation technology called laparoscopic nephrectomy (referenced in Chapter 1), which enabled living donation to be a viable therapeutic treatment option. The law outlined how the U.S. Secretary of Health and Human Services would make available grants to states, transplant centers, and authorized organ procurement organizations to reimburse subsistence expenses including travel costs to those willing to become living donors. What is more, the Secretary was permitted to distribute grants to states for the purpose of educating the public by means of donor awareness programs and outreach activities. Furthermore, the Secretary was sanctioned to establish and maintain processes for gauging the long-term effects connected with living organ donation. All in all, the laws together expounded upon numerous imperative and qualifying issues surrounding organ


transplantation in the U.S., and in time, amendments to these laws would be implemented to keep pace with present-day medical policies, evolving technologies and donor education.

In order to better organize and upgrade the organ matching and placement process in the U.S., the NOTA originated the Organ Procurement and Transplantation Network or the OPTN. This network would concentrate on organ shortages and maintain the national organ registry or waiting list, which matches donated organs with potential recipients. The NOTA contended that the OPTN be managed by a private, non-profit organization under federal contract. That organization became the United Network for Organ Sharing or better known as UNOS. Located in Richmond, Virginia, UNOS received the OPTN contract under the Health Resources and Services Administration within the Department of Health and Human Services in September 1986. Thus far, it has been the only organization to manage the OPTN by providing a well-designed, operative management system, which includes a Board of Directors, functioning committees, and regional membership. UNOS reviews and improves transplant policies that govern organ procurement, allocation and transportation of deceased donor organs. In addition, it monitors professional compliance with those policies for patient safety.

UNOS manages a number of factors of the donation process and organ transplantation, which include the following:

* Manages the national organ transplant waiting list, which matches donors to recipients 24 hours a day, 365 days a year.


*Maintains the organ transplant database, which tracks every transplant that occurs in the U. S.

*Develops policies that best make use of limited organ availability, while providing nondiscriminatory access to all patients irrespective of sex, age, race, religion or social economic position.

*Monitors organ allocation policies for accuracy.

*Offers support to patients and caregivers.

*Educates organ transplant medical professionals on updated donation and transplant practices.

*Educates the public on the significance of organ donation.  

The UNOS mission is to save lives through the advancement of organ transplantation along with organ availability. It advocates and unites the transplant communities for the benefit of patients by means of continued educational methods, technological improvements, and policy developments. In the area of policy, UNOS maintains a policy staff with expertise in and dedication to organ transplantation. UNOS members have countless years of experience in public health policy management and analytical practices. They play a fundamental role in instituting and refining the operating policies that govern the OPTN. These policies include organ procurement and distribution along with the obligations and rights of the contributing members. Members are divided into committees, and each committee carries out and supervises a specific responsibility devoted to improving a range of policy. UNOS is headed by a Board of Directors, which

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9 Ibid.
oversees the organizational management. The Board of Directors guides UNOS on corporate-like principles that are outlined in a series of governing documents implemented and revised periodically to guarantee they meet the standard requirements of UNOS and reflect present-day industry best practices. UNOS has two major roles relevant to national transplant policymaking. UNOS originates, evaluates and upgrades transplant policy to offset equity with utility. In addition, UNOS censors transplant professionals’ compliance with policy and issuances that affect patients’ safety, living donors’ safety, and value-added practical innovations. In its ongoing efforts to promote organ donation, UNOS reaches out directly to the general public through events and exhibits held at community centers, church groups, colleges, civic organizations, etc. It conducts organ donor presentations at such organizational functions as the American Transplant Congress Annual Meeting, International Society of Heart and Lung Transplantation Annual Meeting, National Medical Association Annual Conference, National Black Nurses’ Association Annual Conference, National Donor Sabbath, Retailer 4 Life within the Retail Merchants Association, etc.

To reiterate, UNOS is the Federal Government’s managing contractor for the Organ Procurement and Transplantation Network, denoted as the OPTN. Likewise, the OPTN is a private non-profit entity, whose expertise lies in the field of organ procurement and

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transplantation. It has a Board of Directors that governs by means of a Charter. Members of the OPTN are volunteers, and each is required to comply with the provisions transcribed, and amended to the NOTA. In order to remain true to the cause, at least, 50% of the Board’s members consist of transplant surgeons and physicians while, at least, 25% comprise transplant candidates, transplant recipients, organ donors, and transplant linked family members. The OPTN implements ongoing and periodic analyses and assessments of each Member Organ Procurement Organization (OPO) and Transplant Hospital Program for compliance with the OPTN Final Rule, which is the NOTA amendment, 42 U.S.C 273. We will revisit this NOTA amendment and its subject matter further along in this chapter.

The OPTN encompasses several key commitments in organ transplantation practices. Its purpose is to operate and monitor an equitable system for distributing donated organs among transplant patients; establish measures to guarantee a safe and efficient acquisition and transplantation of donated organs; maintain a national waiting list of potential recipients; match organ donors with potential recipients in accordance with conventional transplant medical criteria; register potential recipients and remove those recipients with successful transplants from the national waiting list; facilitate effective and efficient placement of organs for transplantation; and increase organ donation. In concurrence with its practices, the OPTN gathers, analyzes and publishes pre-transplant and post-transplant data in order to expand the fields of organ procurement, organ transplantation, organ preservation, and immunogenetics.

In order to take full advantage of all organ donations and heighten more fruitful transplant recipient outcomes, an Organ Procurement Organization, or OPO, complies to standard policies regarding organ harvesting from deceased individuals, such as, the evaluation of would-be donors—verifying the pronounced death of a donor in accordance with applicable laws, and attaining the donor’s medical and behavioral history; screening would-be donors for hemodilution by means of blood samples obtained (only a non-hemodiluted specimen qualifies as a viable donor); gaining legal consent for donation; and initiating organ procurement and placement through tissue typing and crossmatching between would-be donor and would-be recipient along with proper packaging of organs for transport. In other words, an OPO is an institute explicitly accountable for the procurement of organs for transplantation. Each OPO receives a geographical territory defined by the Centers for Medicare and Medicaid Services (CMS) in which to focus its procurement efforts. However, no one OPO is limited to or limited by an exclusive territory in which to procure organs. OPOs work in conjunction with transplant centers also referred to as transplant hospitals.\textsuperscript{14}

A transplant center, or transplant hospital, is one that performs the organ transplants. It may have one or more transplant programs available supervising one or more organ types. It is the sole responsibility of the receiving transplant center’s transplant surgeon on-call to take delivery of the organ type for his or her organ candidate, and make certain the donor organ is medical suitable for transplantation into the prospective recipient,

which consists of ABO blood type compatibility between the donor organ and the candidate. On the other hand, it is the responsibility of the transplant center to authenticate the donor’s recorded ABO blood type along with the candidate’s recorded ABO blood type, and the UNOS Donor ID number upon acceptance of the organ preceding transplantation. Each action calls for mandatory documentation and is subject to medical review upon audit.\textsuperscript{15} As of October 2011, the U.S. organ procurement system comprises of 58 OPOs that provide deceased organs to the 250 transplant centers across the nation.\textsuperscript{16}

When Congress was developing laws on how to structure and govern the organ transplantation system in the United States, living organ donation was limited to the traditional sense of a family member (parent, sibling, or cousin), spouse, or friend being the organ donor if biologically compatible with the patient. However, in a continued effort by the medical community to increase living organ donation, non-traditional programs were developed in conjunction with the OPOs. These programs involved multiple living donors along with multiple recipients in a multiple organ exchange. The first such programs were located in the Washington, DC metro area and New England. One program was the list donation exchange, and the other was the human organ paired exchange. Both types of exchanges involved kidneys alone and were being implemented with only NOTA in place. Due to timing, these exchanges were not recorded within NOTA’s guidelines. However, with NOTA using the terminology of valuable consideration, were these exchanges illegal in any way? The statute for valuable consideration carried a criminal penalty with fines up

\textsuperscript{15} Ibid.

to $50,000 and imprisonment up to five years or both if violated, but the statute did not define valuable consideration in exact detail. NOTA simply acknowledged that the term “does not include the reasonable payments associated with the removal, transplantation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ.”17 Since NOTA could not foresee the development of non-traditional living donation, it did not proclaim that either exchange was a violation of its guiding principles; therefore, neither was illegal per say. Through NOTA, Congress’ main objective was to convey its determination to criminalize the buying and selling of organs for profit.

Briefly, let us review these two non-traditional techniques, their risks, and their upcoming consequences. A list donation involves a living donor who wishes to donate a kidney to an identified recipient, but is biologically incompatible. The living donor will make a kidney donation to a compatible recipient on the waiting list so that his or her identified recipient can advance on the waiting list to receive a kidney from a deceased compatible donor. The risk associated with this type of exchange is that the identified recipient could die prior to receiving a compatible kidney, while the living donor has already made an exchange. This is the extent to which list donation will be addressed, while the remainder will emphasize kidney paired exchange. In the kidney paired exchange, there are two living donors who each have an identified recipient; however, each

donor is biologically incompatible with their identified recipient. Through a matching process, a living donor is found who is compatible to the other donor’s identified recipient and vice versa. With two incompatible pairs, the living kidney donors make kidney swaps with one another’s pair recipient. To minimize the risks associated with this type of exchange, where a donor may opt out last minute, the exchanges are performed simultaneously. These innovative non-traditional approaches to living organ donation were facilitating increases in living kidney donation, but the usual moral questions of post-operative issues for the living donors, such as, prolonged health risks, impacts on social activities and financial effects had arisen once again. This required the intervention of both the House and Senate doing their part in contributing to and supporting the efforts to increase living organ donation.

Below is the Senate floor statement that was made by U.S. Democratic Michigan Senator Carl Levin on Living Kidney Organ Donation in February 2007. He was proposing legislation that was aimed at modifying NOTA in order to clarify that kidney paired donation does not violate the act’s prohibition of “valuable consideration.”

Mr. President, I am pleased today to be joined by Senators Bond, Dorgan, Graham, Durbin, Mikulski, Pryor, and Cardin in introducing legislation that will save lives by increasing the number of kidneys available for transplantation through a process call paired organ donation. Our bill, the Living Kidney Organ Donation Clarification Act, addresses this relatively new procedure, which is supported by numerous medical organizations, including the United Network for Organ Sharing, the American Society of Transplant Surgeons, the American Society of Transplantation, the National Kidney Foundation and the American Society of Pediatric Nephrology. Paired organ donation, which did not exist when the National Organ Transplant Act (NOTA) was enacted more than two decades ago, will make it possible for thousands of people who wish to donate a kidney to a spouse, family member or friend, but find that they are medically incompatible, to still become living kidney donors.
Our legislation is necessary because the National Organ Transplant Act (NOTA), which contains a prohibition intended by Congress to preclude purchasing organs, is unintentionally impeding development of a national registry that would facilitate matching incompatible pairs. This legislation would simply add kidney paired donation to the list of other living-related donation exemptions that Congress originally placed in NOTA, and would permit establishment of a registry for paired organ donors. No Federal dollars are needed to implement it. And, for each patient who receives a kidney, Medicare will save roughly $200,000 in dialysis costs.

In the process of kidney paired donor transplants, a pair consisting of a kidney transplant candidate and a biologically incompatible living donor is matched with another such pair to enable two transplants that otherwise would not occur. In other words, the intended recipient of each donor is incompatible with the intended donor but compatible with the other donor in the arrangement.

The legislation we are introducing removes an unintended impediment to kidney paired donations by clarifying ambiguous language in Section 301 of the National Organ Transplant Act (NOTA). That section has been interpreted by a number of Transplant Centers to prohibit such donation. In Section 301 of NOTA, Congress prohibited the buying and selling of organs. Subsection (a), titled “Prohibition of organ purchases,” says: “It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration…” The legislation we are introducing does not remove or alter any current provision of NOTA, but simply adds a line to Section 301 which states that paired donations do not violate it. Congress surely never intended that the living donation arrangements that permit kidney paired donation be impeded by NOTA. Our bill simply makes that clear. Some transplant professionals involved in these and other innovative living kidney donation arrangements have proceeded in the reasonable belief that these arrangements do not violate Section 301 of NOTA, but they contend that they are doing so under a cloud.

Mr. President, there is no known opposition to this legislation. It is essential that we make the intent of Congress explicit so that transplant centers which have hesitated to implement incompatible living kidney donation programs can feel free to do so; and in order that the Organ Procurement and Transplant Network, which is operated by UNOS under contract with the U.S. Department of
Health and Human Services, may implement a national registry of pairs who need to find other compatible pairs so that their loved ones can get the transplant they so desperately need. It is our hope that the Senate will promptly act on this bipartisan legislation. Time is of the essence. Patients waiting for a life-saving kidney transplant could have that wait significantly shorten with the enactment of this legislation. I am very pleased that companion legislation has been introduced in the House by Representative Charles Norwood and Representative Jay Inslee.\textsuperscript{18}

Legislation S.487: Living Kidney Organ Donation Clarification Act of 2007 states that “kidney paired donation shall not be considered to involve the transfer of a human organ for valuable consideration.”\textsuperscript{19} The bill passed unanimously in the Senate on February 15, 2007. Matching Congressional legislation would continue the support for kidney paired donation and amend NOTA.

On March 7, 2007, the House of Representatives unanimously passed H.R.710: Charlie W. Norwood Living Organ Donation Act. This Act also states that NOTA’s prohibition on the exchange of valuable consideration for organs does not extend to paired organ donation.\textsuperscript{20} Republican Georgia Representative Charles Norwood was the sponsor of this act and soon died after it was introduced. On December 21, 2007, U.S. President George W. Bush signed this Act into law. It became Public Law 110-144. As part of P.L. 110-144, the U.S. Secretary of Health and Human Service is required to put forward yearly


a report, which details the progress made toward understanding the long-term health effect of living organ donation to the applicable Congressional committees.

12/21/2007—Public Law. Charlie W. Norwood Living Organ Donation Act – Amends the National Organ Transplant Act to provide that for the purpose of provisions that prohibit the transfer of any human organ for use in human transplantation for valuable consideration, human organ paired donation does not involve such a transfer. Defines “human organ paired donation” as the donation and receipt of a human organ under the following circumstances: (1) an individual (the first donor) desires to make a living donation of a human organ specifically to a particular patient (the first patient), but such donor is biologically incompatible with such patient; (2) a second individual (the second donor) desire to make such a donation to a second patient, but is biologically incompatible with such patient; (3) the first donor is biologically compatible to the second patient, and the second donor is biologically compatible to the first patient; (4) all donors and patients enter into a single agreement to donate and receive such organs; and (5) no valuable consideration is knowingly acquired, received, or otherwise transferred with respect to the organs.

Requires the Secretary of Health and Human Services to report to Congress on the progress made toward understanding the long-term health effects of living organ donation. 21

P.L 110-144 contains the following definition of human paired organ donation:

(A) An individual (referred to in this paragraph as the ‘first donor’) desires to make a living donation of a human organ specifically to a particular patient (referred to in this paragraph as the ‘first patient’), but such donor is biologically incompatible as a donor for such patient.

(B) A second individual (referred to in this paragraph as the ‘second donor’) desires to make a living donation of a human organ specifically to a second particular patient (referred to in this paragraph as the ‘second patient’), but such donor is biologically incompatible as a donor for such patient.

(C) Subject to subparagraph (D), the first donor is biologically compatible as a donor of a human organ for the second patient, and the second donor is biologically compatible as a donor of a human organ for the first patient.

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21 Ibid.
If there is any additional donor-patient pair as described in subparagraph (A) or (B), each donor in the group of donor-patient pairs is biologically compatible as a donor of a human organ for a patient in such group.

All donors and patients in the group of donor-patient pairs (whether 2 pairs or more than 2 pairs) enter into a single agreement to donate and receive such human organs, respectively, according to such biological compatibility in the group. 22

In January 2008, the Charlie W. Norwood Living Organ Donation Act amended the National Organ Transplantation Act (NOTA) via U.S. Code Title 42, Section 273. Publicly, this new organ transplantation technique confronted the unintended restrictions set forth in the original NOTA, and earned the opportunity to venture forward in saving more lives through living kidney paired exchange. In the future, the main question will be how far will Congress need to intervene with regard to impending, ever evolving organ transplantation systems? Irrespective of what systems are developed or how beneficial they are to saving lives, Congress must ensure that ethical and equitable guidelines are preserved, that the fundamental components in the organ transplantation structure remain sound, that the safety needs of the patients and living organ donors are met, and that federal laws be addressed promptly and accurately to keep pace with the organ donor shortage crisis faced by thousands each day in the United States.

With the NOTA amended to close the legal loophole stating that valuable consideration does not apply to kidney paired donation, the number of living kidneys available for transplantation will increase. The U.S. House and Senate have openly recognized the life-saving benefits of paired organ donation. Kidney paired donation is not

considered something that is done for financial gain, but considered a gift from the living donor. All legal questions regarding the types of kidney paired donation are made clear in the legislation; therefore, no medical facility or staff can be accused of unethical practice while performing live kidney transplants under their kidney paired donation programs. In addition, the OPTN can move faster towards establishing a national registry for incompatible pairs, and transplant centers can begin to implement them straightaway. The reformed NOTA has opened the door wide for kidney paired donation to thrive by saving more lives each year, while it defends living donors and recipients from maltreatment.
CHAPTER 4

KIDNEY PAIRED DONATION:
PAIRED EXCHANGE AND DONOR CHAINS

The transplant organizations responsible for the allocation of organs, in this case kidney, in the United States have adhered to the federal mandate detailed in the National Organ Transplant Act (NOTA), which demands the practice of a fair and equitable system for distributing those allocated donated organs among transplant patients in accordance with established medical criteria. The United Network of Organ Sharing (UNOS) has interpreted the term equitable as meaning balanced between justice and utility. Until 2007, those doctors and transplant centers playing critical roles in the living kidney donor innovations of paired donation did so under a reasonable presumption that no laws were being violated under the NOTA. Even though, they did contend that they felt as if they were practicing under a veil of criticism and possible moral contempt. The terminology of valuable consideration in NOTA’s Section 301 was too vague. What was clear relating to paired donation was that no one was selling or buying a kidney for profit. On the other hand, NOTA had not explicitly cited paired donation, but it was not available in 1984 when NOTA was originally written. Therefore, paired donation was not legally protected by NOTA. With the added provision in NOTA affirming that paired donation does not violate Section 301’s valuable consideration statement, paired donation has been able to continue and to thrive in a positive approach by steadily increasing the number of end-stage renal disease (ESRD) patients saved each year in the United States. The officially legalized innovations of paired donation, its techniques, its strategies, its objectives, and its outcomes have been brought together to provide an informative synopsis of how paired donation benefits and will continue to benefit the healthcare of ESRD patients in the U.S.
With 90,000-plus people in the U.S., and counting, on the UNOS national deceased kidney donor waiting list, kidney paired donation (KPD), also referred to as paired kidney donation, significantly increases the number of ESRD patients saved each year who have a willing and medically suitable, but immunologically incompatible living kidney donor. Kidney transplantation has arisen as the therapeutic treatment of choice for medically suitable patients with ESRD. With living donor kidney transplantation being the most favorable solution to closing the gap between organ supply and demand, KDP has the ability to optimize the availability of viable donor kidneys. Positive results from KDP include the broadening of the accessible living kidney donor pool, the extension of the post-transplant kidney (graft) survival rate as compared to that of a deceased kidney donation, and the enhancement of long-term health outcomes for ESRD patients with far less remedial complications than is the case with dialysis treatments. In addition, paired donation offers a lower cost alternative in relation to the expense of dialysis treatments per patient per year, a wide-ranging reduction of waiting time for ESRD patients on the UNOS national deceased kidney donor waiting list, and a profound emotional satisfaction for the caregiving family and friends by allowing them to be able to donate a kidney to a loved-one although indirectly.

KPD through the processes of kidney paired exchange and two types of kidney paired donor chains will be explained in simple terms and examined in precise detail in order to demonstrate its effectiveness and achievements as an outstanding advancement in living kidney donation, resulting in more life-saving kidney transplants. In order to provide visual support in comprehending how pairs are utilized, diagrams of each type of KPD will be presented and assessed for the reader’s clarity. Authentic examples will be cited to
expand on the importance of KPD to those individuals in need of kidney transplants, and to those loved-ones who desperately want to help. As with all noble innovations, there are disillusionments, technical hitches, and obstacles that require addressing. These issues will be incorporated as well to reveal how adjustments can be and are being made while still validating the undeniable potential of KPD. Although all statistics provided in this text are based on U.S. data, KPD has a global outreach that can advance kidney transplantation to benefit all who need it.

As is customary with living kidney donation, ESRD patients reach out to a minor group of family and friends to find a compatible donor match. If no well-suited match becomes available within that group, those ESRD patients generally wait on the UNOS national deceased kidney donor waiting list on an average of five years, while remaining on some form of dialysis treatment before ever receiving a lifesaving deceased donor kidney. The ultimate sad truth is that approximately twelve ESRD patients die each day in the U.S., while still waiting for a kidney. There are an estimated 6,000 ESRD patients on the national deceased kidney donor waiting list, who actually have a willing medically fit donor, but that donor is immunologically or blood type incompatible. This circumstance yields an incompatible donor-recipient pair. For approximately 1 in 5 ESRD patients with an incompatible living donor, a suitable match can be obtained through what is called a kidney paired exchange with another incompatible, but a suitable cross match donor-recipient pair. Kidney paired exchange—the original kidney paired alignment—in its basic structure can match one incompatible donor-recipient pair, for example, with blood types A & B to another incompatible donor-recipient pair with blood types B & A, so that the donor (A) of the first pair gives a kidney to the recipient (A) of the second pair, and vice versa. In
other words, the two pairs exchange kidneys during the time of transplantation. Therefore, the kidney paired exchange makes two living kidney donor transplants possible while freeing up two more vital spots on the deceased kidney donor waiting list for those remaining ESRD patients still waiting. On the whole, ESRD patients with either an identified incompatible living donor or with no identified living kidney donor can benefit from KPD in one of its three available approaches by increasing their chances of receiving a healthy kidney prior to suffering the irrevocable detrimental health issues, set-backs or side-effects of prolonged dialysis treatments or even death.

At this time, there are three approaches to living kidney paired donations being performed in the U.S. The first is the original or traditional kidney paired exchange, which remains the fundamental foundation for all paired donation. It occurs when there is a directed simultaneous living kidney donor exchange between two (or three) donor-recipient incompatible pairs in order to make two (or three) compatible pairs all of which are ordinarily, but not necessarily performed in the same transplant center. The second is the domino kidney paired donation or domino chain. It is a variation of the original kidney paired exchange with the inclusion of a non-directed living kidney donor being matched to a recipient of an incompatible donor-recipient pair then that incompatible living donor donates a kidney to the next compatible recipient on the deceased kidney donor waiting list. This approach can extend beyond the use of one incompatible donor-recipient pair. The surgeries are also performed simultaneously, once accomplished in the same transplant center and now, can be performed across multi-transplant centers during a corresponding timeframe. The third is the non-simultaneous, extended, altruistic-donor (NEAD) chain occasionally referred to as the never ending altruistic donor chain or NEAD chain. It is a
variation of the domino chain. Again, a non-directed donor is included and matched to a recipient of an incompatible donor-recipient pair and that incompatible donor agrees to donate a kidney to the first compatible recipient of another incompatible pair and so forth and so on continuing the chain indefinitely in principle. The NEAD chain is altered from the domino chain in that it is performed over a period of time—days, weeks, months, or even years and can involve the use of multi-transplant centers across the country. The key to being able to stretch the NEAD chain over time is the use of a “bridge” donor. A bridge donor is the living donor in an incompatible pair that continues the chain by donating a kidney at a later time. The domino chain and the NEAD chain conclude when the last recipient in the chain is one without a co-registered living donor. The present-day goal of KPD is to perform 1500 to 3000 more living kidney donor transplants each year in the U.S. As living donor participation increases, the number of lives saved increases. The definitive goal for KPD would be to eliminate the need for a UNOS national deceased kidney donor waiting list. Donor kidneys would become readily available through the KPD process. In that case, when an ESRD patient requires a kidney transplant, a health kidney would be available within weeks versus years. A patient’s new and healthy life would begin almost immediately.

Basic outline of KPD:

1) Kidney Paired Exchange:
   - Matches two or three incompatible donor-recipient pairs.
   - Performed simultaneously or in an equitable timeframe.

2) Domino Kidney Paired Donation Chain:
   - Utilizes a non-directed living kidney donor.
• Matches one or more incompatible donor-recipient pairs.

• The final recipient derives from the UNOS waiting list.

• Performed simultaneously or in an equitable timeframe.

3) NEAD Kidney Paired Donation Chain:

• Utilizes a non-directed living kidney donor.

• Utilizes a bridge donor.

• Matches an unlimited number of incompatible donor-recipient pairs.

• The final recipient derives from the UNOS waiting list.

• Performed over a period of time—days, weeks, months and years.

The origins for the concept of kidney paired exchange are uncertain; nonetheless, the idea that two incompatible donor-recipient pairs could exchange kidneys as a viable means to circumvent any immunologic incompatibility in living kidney transplantation may have been under ideological development in the international transplant community as early as 1970. By 1986, Dr. Felix Rapaport, a pioneer in global transplantation development, had composed the first publication dedicated to kidney paired exchange. The first kidney paired exchange program in the world was launched in South Korea in 1999. By 2000, the U.S. had its own kidney paired exchange program established at the Johns Hopkins Hospital in Baltimore, Maryland. It is accurate to say that the use of KPD is not exclusive to the U.S., granting that Johns Hopkins Hospital is one of the most prominent pioneering transplant centers for state-of-the-art kidney transplant procedures worldwide. Likewise in 2000, the U.S. did record its first kidney paired exchange although it was performed at the Rhode Island Hospital in Providence where little media attention was given. In that particular case, two adult living kidney donors wanted to donate to their
respective, but blood type incompatible recipient mothers. With this primary paired 
exchange’s historic success, kidney paired donation has become the fastest growing source 
in the U.S. of transplantable kidneys in the past decade by overcoming the obstacle of 
living donor incompatibility with the intended recipient.¹

To outline a graphic example of kidney paired exchange, below, is a clear-cut 
configuration in a comprehensive format. In this illustration, there are two sets of living 
kidney donor-recipient pairs—donor 1 and recipient 1 along with donor 2 and recipient 2. 
In each cooperative pair, the living donors are incompatible to their directed patient 
recipients. Through a paired exchange matching process, the living donor from pair 1 
(donor 1) is immunologically compatible to the recipient from pair 2 (recipient 2), and the 
living donor from pair 2 (donor 2) is immunologically compatible to the recipient from pair 
1 (recipient 1). In the paired exchange, the two pairs simultaneously switch donor kidneys 
during the time of transplantation, i.e. a two-way concurrent kidney swap.

¹ Jeffrey Veale and Garet Hil, “The National Kidney Registry: Transplant Chains— 
Beyond Paired Kidney Donation,” Chapter 21, pages 253-254, 
16, 2011).
As one can see from this illustration, this kidney paired exchange had presented the opportunity to perform two successful kidney transplants where it otherwise would not have been possible. Recipient 1 and recipient 2 were able to receive life-saving kidney transplants without having to turn to or remain on dialysis treatments, or turn to or remain on the UNOS national decease kidney donor waiting list. The living donors were able to save the lives of their directed recipient in an indirect approach. In addition, the average living kidney donation lasts twice as long as a deceased kidney donation with better renal function and less chance of rejection. By the living donors’ agreeing to exchange recipients, they are providing two patients with healthy kidneys thus creating two successful matching pairs. Now, the two recipients are able to lead healthier lives away from daily affliction, dialysis treatments and constricting limitations, such as, diet restrictions, in-home confinement, travel incapability, social activity limits, and the list goes on. Imagine the countless opportunities for one’s recipient to not only survive, but
thrive in a normal life again.

In order to highlight the two-way kidney swap in a specific incompatibility format, this added diagram is being provided. In this particular example, one can envision the kidney paired exchange even more clearly through the nature of the incompatibility being one of blood type between the donor-recipient pairs. Donor 1 (blood type A) gives a kidney to recipient 2 (blood type A), while donor 2 (blood type B) gives a kidney to recipient 1 (blood type B). In KPD, the exchange enables the two incompatible recipients to receive healthy, more compatible kidneys. Any donor-recipient incompatible pair that is medically suitable can participate in a KPD program.

As mentioned earlier, the paired kidney exchange format can also be applied with three donor-recipient incompatible pairs in a multi-pair swap as was the case for Katrine and Ed Conroy of British Columbia, Canada. It meant that Ed would receive a much
needed kidney that Katrine could not provide. Katrine, a politician, had wanted to give her husband Ed a kidney, but they were an incompatible match. Their four adult children were incompatible to Ed as well. Instead, Katrine would donate a kidney to another recipient in an incompatible pair, then the second donor would donate a kidney to yet another recipient in an incompatible pair, and the third donor would donate to Ed. Altogether, there were six people involved in this large-scale exchange that took place in multiple transplant centers across Canada. Three successful kidney transplants were accomplished. Three more lives were saved. Katrine Conroy said that she was incredibly grateful that such a program existed, and that it was a great benefit to her family. Furthermore, Conroy had stated to the Canadian media that she was sure that this amazing program was virtually unknown by most people. For Ed, he no longer had to endure dialysis, which caused him to have four surgeries to deal with complications associated with dialysis. Being a public figure in Canada, Katrine Conroy and her family had decided to go public with their success story in order to help raise awareness of KPD. She has the hope that if others know about the program, they may want to participate.²

Although the next diagram does not recount Katrine and Ed’s particular three-way kidney exchange transplant, it does provide a visual comparative of a three-way kidney paired exchange. A three-way kidney exchange is a bit more of a complex case than the two-way exchange due to the use of an additional incompatible donor-recipient pair.

Prior to examining the other two methods of KPD—donor chains, the domino chain and the NEAD chain and how they work, let us focus on the key to any donor chain by addressing the matter of who is a non-directed living kidney donor and why this particular donor is so important. Although most living kidney donors have an identified recipient, a non-directed kidney donor, also referred to as an altruistic donor or a Good Samaritan donor, is an individual who wants to donate one of his or her kidneys for the exclusive benefit for someone in need. Hence, the non-directed donor does not have an existing identified recipient in mind to receive their potential donation. Non-directed donors begin
the process through contact with a transplant center in regards to their interest and intent. The transplant center will determine and instruct how best to utilize the non-directed donor’s lifesaving gift. The non-directed donor would donate to a recipient in an incompatible donor-recipient pair; while the living kidney donor in that incompatible donor-recipient pair would “pay it forward” by donating a kidney to another recipient in an incompatible donor-recipient pair either at the same time in a cluster procedure or once their recipient receives a kidney. While the non-directed donor is the key component in any donor chain, he or she receives no obvious gains other than the emotional reward of giving.

In 2006, Dr. Robert Montgomery, Chief of the Division of Transplantation, Director of the Comprehensive Transplant Center, and the Director of the Incompatible Kidney Transplant Program at Johns Hopkins Hospital, and his transplant associates offered a variation on the traditional kidney paired exchange calling it the domino kidney paired donation or domino chain. This chain begins with a non-directed living donor giving a kidney to a recipient in an incompatible donor-recipient pair, and that incompatible living donor gives a kidney to another recipient of an incompatible pair and so on ending the chain when the last paired living donor in the chain gives a kidney to an unpaired recipient on the deceased kidney donor waiting list. These kidney transplants are performed either simultaneously in one transplant center or incorporate multi-transplant centers in a corresponding timeframe.

The basis of the domino kidney paired donation was to develop a strategy that would best make use of any living non-directed (LND) kidney donation. Since there is no comprehensively established uniform system in the U.S. for allocating kidneys from LND
donors, recipient selection had been wholly based on the discretion of the transplant center in which the LND donor acknowledged their intent. Yet, transplant centers are guided by one of three accredited models of LND allocation: donor-centric, recipient-centric or socio-centric. Every model has a positive and negative side to patient care outcomes. Each transplant center chooses the model in which it believes will operate best for its particular circumstances and resources, such as, facility size, geographical location, financial status and staff numbers. Briefly, to review each, donor-centric allocation is directed to ensure the successful outcome for the recipient, and it provides a medical justification for transplant centers to put a healthy person in harm’s way in an effort to save another. A positive outcome gives the LND donor a sense of worth and triumph in bestowing a life-saving gift. On the flip side of this allocation, only the healthiest patients on the waiting list are taken, who are the very patients who can manage well on dialysis or with deceased kidneys. With recipient-centric allocation, the belief is that society is responsible to look after its’ most vulnerable and disadvantaged citizens. In this scheme, LND donor organs would be given to those patients most in need—those who require a kidney transplant for immediate survival or those who would be disadvantaged in any way on the UNOS national deceased donor waiting list. The positive side would be that younger patients, such as children or teenagers, would be able to receive a kidney sooner and possibly avoid dialysis. In addition, critical patients with hardly any therapeutic options, such as those with no viable vascular accesses—artificial vein portals, those with high antibody counts—high kidney rejection rate, and those with life-threatening medical complications linked to dialysis, would be moved to the top of the transplant center’s list. The down side to this method is one of poor transplant outcomes due to the use of high-risk
patients, which in turn, unfortunately, lead to a negative public perception of LND donation. The risk is one of deterring other people from donating a kidney if they believe that their kidney will essentially be squandered. And last of all, the socio-centric model dictates that the LND donation be regarded as a public resource to be allocated in the fairest and most equitable fashion regardless of outcome or need. What this scheme boils down to is the concept of first come first served. The patient on the top of the UNOS waiting list would receive the next matching kidney. The challenges to this method are that those who have already made it to the top of the UNOS waiting list will indeed receive a deceased kidney donation prior to receiving a live donation, and that they have already incurred medical costs and exposure to comorbidity—presence of one or more medical disorders—from dialysis treatments.

As has previously been noted in this text, the presence of a willing living donor does not guarantee that an ESRD patient can circumvent the usage of UNOS national deceased kidney donor waiting list due to immunological incompatibilities with their directed donor. A mathematical technique is applied to optimize the best outcome between two incompatible donor-recipient pairs in order to perform a positive kidney paired exchange: however, for those pairs that are unable to be matched, it is most likely due to the patients having a hard to match blood type or HLA sensitivity--antibodies. It is at this cross road where the domino kidney paired donation combines the LND donor kidney with hard to match donor-recipient pairs resulting in a gift that can be multiplied. Essentially, the LND donor’s kidney initiates a chain of matches.

In this course of action, the LND donor’s kidney is matched to a compatible recipient, who is part of an incompatible donor-recipient pair. In turn, the incompatible
donor agrees to give a kidney to the next compatible recipient on the UNOS deceased kidney donor waiting list, thus, creating a domino effect. The positive result equates to two living kidney donor transplants where the LND donor’s gift was multiplied.

Below, is an encompassing diagram showing the expansion towards making use of living donor kidneys including the use of LND donor kidneys. Letter A is a one-to-one example of a compatible donor-recipient pair. Letter B is a paired exchange between two incompatible donor-recipient pairs. Letter C is the domino paired donation where the LND donor, one incompatible donor-recipient pair and a patient on the kidney transplant waiting list are combined.

Examples of Living Donor Matches

FIGURE 11: Examples of Living Donor Matches
Source: http://www.thelancet.com/journals/lancet/article/PIIS0140673606691150/images?imageId=gr1&sectionType=green&hasDownloadImagesLink=true
Brad Dean is an exceptional person and example of a LND donor who made a momentous impact on the lives of others in need by initiating a domino chain. The president of the Myrtle Beach, South Carolina, Chamber of Commerce, Brad is 43 years-old man in perfect health. As altruistic donor, he had offered his kidney to an unknown individual simply because he thought it was the right thing to do. Brad’s kidney went to Sue Gommer, a 67 year-old retired Navy nurse, who suffered from a genetic kidney disease for decades. Sue’s daughter, Jennifer Gommer, a 39 year-old Duke pharmacist, wanted to donate a kidney to her mother, but they were blood type incompatible. So Jennifer gave her kidney to Jeffrey Rogers, a 42 year-old former construction worker.³

In December 2011, this domino kidney paired donation was the first ever performed in the state of North Carolina at the Duke University Medical Center. Officials at Duke and other transplant centers within North Carolina want to spread the word about the success of this domino kidney paired donation in order to attract more donor-recipients pairs to sign up for their living donor programs. Pitt Memorial Hospital in Greensville is gearing up for its own six-person living donor operation, while UNC Health Care, which extends across the state, is among a host of other medical centers interested in participating in such an endeavor.

The waiting list for kidney donation is longer than that for any other organ, and of the 90,000-plus patients on the UNOS waiting list, 3,000 reside in North Carolina. According to Dr. Matthew Ellis, the Medical Director of Duke’s Kidney Transplant

Program, kidney paired donation will not completely fill the void, but it sure would make a nice dent in it. Dr. Robert Harland, Chief of the Division of Transplant Surgery at East Carolina University’s Brody School of Medicine and the Director of Transplantation at Pitt Memorial, hopes Duke’s success along with his upcoming three-pair domino version will increase interest in forming a statewide consortium. A centralized state databank comprised of potential donor-recipient pairs would make complex matches easier and quicker. In addition, it would open the door to further chain-type donations, and it would free up operating room space in any one transplant center by utilizing multiple operating rooms in various centers.4

All should recognize that Brad Dean did not come to his decision to be an altruistic donor lightly. He had studied the ins and outs of donating a kidney for a year while speaking with his family and praying over his decision. He is proud that his gift helped change not only one life, but two. He does not know of many things in life that could top his donation. For Jennifer Gommer, she had learned about the kidney paired donor program through the Duke website. Although Jennifer works on the Duke abdominal transplant team, she did not know about the program. She had signed up immediately knowing that her mother would probably die while waiting for a deceased donor kidney. As for the recipients, Sue Gommer lives with her two daughters, and her transplant has freed her from a life that surrounded four-hour dialysis treatments, three days a week. She is optimistic and enthusiastic regarding her new kidney and her new lease on life. Jeffrey Rogers, who had spent 10 long years of dialysis, relates that dialysis treatments had

4 Ibid.
dominated his life and he was not able to work. Now, Jeffrey cannot wait to get back to work, go on a vacation, eat what he wants, i.e. live a normal life.\footnote{Ibid.}

Below, is a diagram of a three-way domino kidney paired donation, also known as the domino chain. Please note that the domino chain is initiated with a LND donor (altruistic donor) and filters through the incompatible donor-recipient pairs. As we proceed with the domino chain, one will see by example how this chain has been expanded even further.

\textbf{Three-way Domino Kidney Chain}

\begin{figure}[h]
\centering
\includegraphics[width=0.7\textwidth]{three-way_domino_kidney_chain.png}
\caption{Three-way Domino Kidney Chain}
\label{fig:three-way_domino_kidney_chain}
\end{figure}

On November 14, 2006, the kidney transplant team at John Hopkins Hospital successfully achieved the first domino “quintuple” chain.\footnote{Eric Vohr, “Hopkins Performs Historic ‘Domino Donor’ “Quintuple” Kidney Transplant,” \url{http://hopkinsmedicine.org/Press_releases/2006/Transplant/11_20_06.html} (accessed January 5, 2012).} This five-way living kidney

\begin{thebibliography}{1}
\bibitem{Ibid} Ibid.
\end{thebibliography}
donor swap was the first of its kind incurring 10-hour surgeries while occupying 6 operating rooms. It was yet another groundbreaking KPD triumph for a transplant team that continues to pioneer innovative strategies especially in this matter of incompatible donor-recipient pairs. Initially, four kidney transplant candidates, who had willing donors, were evaluated at Hopkins separately. Each donor-recipient pair was found to be incompatible. Utilizing their foregoing paired matching system along with the generous offer of a LND donor, each recipient was able to receive a compatible kidney from someone they did not know. In addition, a fifth recipient stemming from the UNOS national deceased kidney donor waiting list received a kidney as well. Due to the magnitude of this endeavor, the transplant team consisted of 12 surgeons, 11 anesthesiologists, and 18 nurses. All in all, the transplant team extracted 5 kidneys from 5 female living donors and transplanted them into 5 unrelated recipients, whose ages ranged from 40 to 77 years-old, and hailed from 5 states and Canada.

For Honore Rothstein, a 48 year-old computer programmer, being the altruistic donor for this particular domino chain was motivated by the loss of her husband and her daughter in separate occurrences. According to Dr. Montgomery, “It has been a privilege to help Ms. Rothstein fully realize her altruism by placing her into a domino transplant where her gift has made five transplants possible that would not have occurred.” In addition, Dr. Montgomery says, “With domino paired donation, all three ethical tenets are satisfied. The likelihood of a good outcome is increased by spreading the risk of recipient graft loss across more people. The neediest are served, since in many cases incompatible

7 Ibid.
donor-recipient pools have a high proportion of patients who are hard to match. And fairness is served because the last paired donor’s kidney in the chain is allocated to the next compatible patient on the deceased donor waiting list.”

Dr. Montgomery shares and echoes the view of Dr. Robert Harland in North Carolina. He states that without a universal style system for pair matching in place, altruistic donor kidneys may end up on a random internet donation site or may become subjected to inconsistent allocation systems. Either way, only a single patient would benefit. To further the cause, Dr. Montgomery had composed a paper in the British Journal “Lancet” that set out his blueprints for an extensive system for pairing altruistic donors with incompatible donor-recipient pairs to significantly increase the numbers of available organs and to better support the interests of both transplant donors and recipients.

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8 Ibid.
By April 5, 2008, Dr. Montgomery and the John Hopkins transplant team were at it again. This time, the first six-way domino chain was performed among 12 individuals using nine surgical teams and 6 operating rooms. Five donor-recipients pairs were evaluated separately and all were found incompatible. An altruistic donor was introduced to the mix, and a six-way swap was arranged.

The very next year in June, the domino chain soared to yet another new pinnacle in medical history. The first eight-way domino kidney transplant was performed utilizing multiple transplant centers—Johns Hopkins Hospital (Baltimore), Barnes-Jewish Hospital (St. Louis), INTEGRIS Baptist Medical Center (Oklahoma City), and Henry Ford Hospital (Detroit). Three male and five female donors provided kidneys to another grouping of three male and five female recipients. By adding more recipients to the chain, logistics
became the challenge for any one transplant center and staff on the same day; therefore, it was decided that this domino chain of 16 surgeries would be performed in four transplant centers incorporating four days—June 15th, June 16th, June 22nd, and July 6th. As a part of this complex domino chain, Johns Hopkins Hospital flew one kidney each to Barnes-Jewish, INTEGRIS, and Henry Ford, while each of these thee transplant centers flew one kidney each to Johns Hopkins Hospital.

The altruistic donor of this extraordinary domino chain was Thomas F. Koontz, a 54 year-old Marine. One Sunday, Koontz read his church bulletin that a person in his parish needed a kidney. He volunteered, but another fellow parishioner was a more suitable match so Koontz contacted Johns Hopkins to see if anyone else needed a kidney. He was expressing his gratitude to God for saving his teenage daughter from brain cancer. “God helped me, so I was trying to give something back to God. You only need one kidney.” Koontz’s gift set off a chain that allowed eight—yes, eight—people to get new kidneys, aiding them in surviving and thriving against kidney failure and other life-threatening kidney complications.

Another participating donor in this chain, Pamela Paulk, is the vice president of human resources at Johns Hopkins Hospital and its Health System. She had long been a supporter of living kidney donation, and decided to donate a kidney to a fellow Johns Hopkins colleague who had lost his renal functions three years earlier. According to Paulk, “I always knew I was going to donate. I was just waiting for the right time, and this was...”

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the right time.” Paulk has even created her own blog—pameladonates.blogspot.com—documenting her perspective regarding her kidney donation, which can give others insight into living kidney donation. On the lighter side, Paulk states, “My kidney lives and pees in St. Louis right now.”

While all the participating donors and recipients were delighted to be a part of history, one of the transplant surgeons specified that this type of unprecedented eight-way kidney swap can drastically reduce the number of patients on the waiting list. Dr. Montgomery added, “We hope this creates a movement that encourages other transplant centers to adopt the model we used.” There is yet another exciting KPD chain that helps reduce the number of patients on the waiting list. Next, we uncover the non-simultaneous kidney donor chain.

The non-simultaneous, extended, altruistic-donor (NEAD) chain takes the innovation and success of the domino chain one-step further and multiplies its configuration with the use of a living incompatible donor as a “bridge donor” in the chain. Where in the basic domino chain, a non-directed living donor is matched with a compatible recipient who has a willing incompatible donor, and that incompatible donor agrees to give their kidney to the first compatible recipient on the deceased kidney donor waiting list with the exchanges occurring simultaneously, the NEAD chain uses that incompatible donor as a


12 Ibid.
bridge to another incompatible donor-recipient pair at a later time and conceivable location change. The non-directed kidney donor initiates a cluster of kidney transplants incorporating those recipients that have an incompatible living donor; therefore, forming of a chain. The bridge donor can continue the chain by donating a kidney to the next available incompatible donor-recipient pair or depending on the circumstances, donate a kidney to the next compatible match on the deceased kidney donor list ending a particular chain. Either way, the use of a bridge donor makes it possible to take advantage of a healthy, willing, but incompatible living donor’s gift. It provides greater outcomes for incompatible pairs. The NEAD chain concept is the creation of Dr. Michael Rees, Director of Renal Transplantation at the University of Toledo Medical Center in Toledo, Ohio. Dr. Rees had pioneered the NEAD chain in order to create a new way of utilizing non-directed donor kidneys where kidney paired exchanges no longer had to be performed simultaneously.

To elaborate and demonstration the NEAD chain using the bridge donor, the below diagram displays two clusters of simultaneously performed kidney transplants with Cluster 1 being initiated by a non-directed donor blood type “A”, and Cluster 2 being initiated by a bridge donor blood type “O” at a different interval. Also utilized in single kidney transplantations, the incompatible living donor at the end of each cluster or single transplantation serves as the bridge donor to the next cluster or single transplantation thus extending the chain at a later time.

To elaborate and demonstration the NEAD chain using the bridge donor, the below diagram displays two clusters of simultaneously performed kidney transplants with Cluster 1 being initiated by a non-directed donor blood type “A”, and Cluster 2 being initiated by a
bridge donor blood type “O” at a different interval. Also utilized in single kidney transplantations, the incompatible living donor at the end of each cluster or single transplantation serves as the bridge donor to the next cluster or single transplantation thus extending the chain at a later time.

**NEAD Chain Clusters**


In order to evaluate a NEAD chain, let us start at the beginning with the very first NEAD chain in history. In 2006, when Matthew Jones, a 28 year-old Michigan man and father of five, had decided to donate a kidney to a perfect stranger little did he realize that
he would be starting a lifesaving “pay-it-forward” chain that would provide 10 people with new kidneys. The coordination effort would incorporate two paired donation registries, take place over an eight month period, and involve six transplant centers in five states.

Five recipients had received their kidneys simultaneously in organ exchanges. In the other five exchanges, the five living donors became “bridge” donors and had to wait until an appropriate matching recipient was located with the longest stretch of time being five months. The woman, who received Matthew Jones’ kidney, had lived in Phoenix. Her husband had wanted to donate to her, but was incompatible; therefore, he had donated his kidney to a young woman whose mother was willing, but did not match, and so on, it continued through the chain. At this point, to simplify the complex process involved in a NEAD chain, a condensed version of this first NEAD chain will be revised for the reader’s overall comprehension. Some participants will be referred to merely as donor or recipient and a number due to participants’ privacy.

Once more, Matthew Jones, a 28 year-old male, was the altruistic donor who was registered with a transplant center that partners with the Alliance for Paired Donation (APD) in 2006. The APD is a 25-state coalition of 70 transplant centers that pool patients into a sole registry with the purpose of increasing opportunities for paired donation. In April 2007, the ADP found a match, and the NEAD chain was begun. On July 18, 2007, Jones (donor 1) flew to Phoenix, Arizona to donate his kidney to a 53 year-old female (recipient 1) who suffered from the genetic polycystic kidney disease. Her husband was

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willing to donate to her, but was incompatible through a positive crossmatch. Eight days later, the Arizona woman’s husband (donor 2) flew to Toledo, Ohio to donate his kidney to a 32 year-old female (recipient 2) with blood incompatibilities to her mother. Two months later, the mother (donor 3) traveled to Columbus, Ohio to donate a kidney to someone at Ohio State University (recipient 3). Recipient 3’s co-registered donor (donor 4) simultaneously donated a kidney to a male recipient (recipient 4) at the same transplant center. Recipient 4’s sister (donor 5) became the bridge donor; however, she was blood type B, which was hard to match.  

It took 5 months to match donor 5 with recipient 6 at Johns Hopkins Hospital in Baltimore, Maryland. Recipient 6’s donor (donor 6) became a bridge donor, and was matched a woman (recipient 7) from Johns Hopkins Hospital, while recipient 7’s donor (donor 7) was matched to yet another recipient (recipient 8) at Johns Hopkins Hospital. On February 29, 2008, simultaneously, donors 6, 7 and 8 received laparoscopic nephrectomies. In this threesome, one kidney was shipped by commercial airline to Wake Forest University Hospital in North Carolina. During this mass pairing, The Johns Hopkins Hospital pairing system also found a match for recipient 8’s donor, a bridge donor (donor 9), at Johns Hopkins Hospital. On March 18, 2008, donor 9 was removed at Wake Forest University Hospital, flown to Baltimore, and transplanted in recipient 9. Recipient 9’s co-registered donor (donor 10) was a 40 year-old male who was matched to a recipient in Toledo, Ohio. Donor 10’s kidney was removed the same day that his co-registered donor

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received a kidney, and the kidney was flown to the Toledo Medical Center for recipient 10, a 60 year-old woman. Recipient 10’s co-registered donor, her daughter, became another bridge donor. Here is where this particular NEAD chain was placed on hold.\textsuperscript{15} Below, a figure is provided to display a visual arrangement of this first NEAD chain. It has references to the transplant timeframes, transplant center locations, co-registered donor-recipient relationships, blood type compatibilities, donor and recipient genders, and recipients’ race.

\textbf{The First NEAD Chain}

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{NEAD_chain.png}
\caption{The First NEAD Chain}
\end{figure}

\begin{itemize}
\item Source: \url{http://www.nejm.org/doi/pdf/10.1056/NEJMoa0803645}
\end{itemize}

In the case of the NEAD chain, the main concern is whether or not paired donors can or should be trusted to donate a kidney after their own co-registered recipients have

\begin{itemize}
\item \textsuperscript{15} Ibid.
\end{itemize}
received a transplant. This is why traditional paired donations were performed simultaneously to eliminate that prospect. On the other hand, a chain that is initiated with an altruistic donor can safeguard against negative outcomes resulting in any reneging complications. In a paired exchange, for example, there are two donor-recipient pairs, if one donor in a pair decides to renege, then another compatible donor-recipient pair would need to be found and matched in order to carry on with an exchange. In addition, no one would receive a kidney at that time. In a chain, for example, the two donor-recipient pairs remain the same, but with an altruistic donor that is compatible to the recipient in say pair 1, if the donor in pair 1 decides to renege on donating to the recipient in pair 2, after their recipient received a kidney, pair 2 is not irreparably harmed. Although unfair to pair 2, they have theoretically not lost anything, and can be re-matched in another paired exchange or chain. All the while, at least, one recipient did receive a kidney. Risk assessment for a living donor in a chain is based on two main criteria: one, if the donor’s co-registered recipient receives a negative result after transplantation, and two, if the donor as a bridge donor has to wait a very long time in order to donate. Even with unforeseen complications, if the NEAD chain were broken, the chain could be extended again by finding another recipient or donor-recipient pair. Largely, the NEAD chain allows a greater number of difficult to match kidney candidates to be transplanted than the other two methods of KPD.

With the lifesaving advancement and achievement of KPD that is literally transforming the lives of Americans, what would be the natural next step? There is a worldwide shortage of kidneys for transplantation. As pointed out, the U.S. maintains a deceased donor kidney waiting list with approximately 90,000 people alone. In the U.S., the addition of living kidney donors has made an impressive indentation in this sizeable
list. In order to facilitate more living kidney donations, the strategy is one of simple communication and educational coordination with the public. It is essential that the public understands how dire the kidney shortage is presently and how the basic form of the KPD method (paired exchange) makes it possible for two incompatible living donors to swap kidneys with their intended recipients to make two compatible kidney transplants. To further elaborate on this strategy, inform them that incompatible donor-recipient pairs may participate in donor transplant chains that are initiated by an altruistic donor and terminated with a final donation to someone on the national waiting list. Optimized algorithms can calculate all possible variation of matches within a registry by means of criteria based on chain length, HLA (antibodies) match, equity of candidates, patient preference and estimated cold-ischemia time (transportation of donor kidney). Other advances in KPD include the creation of nationwide paired exchange registries that have already enabled hundreds of kidney transplants in the U.S., and now, UNOS has developed a pilot program for paired exchange with the goal of consolidating KPD across all 250 kidney transplant programs. The outcome of a large national consolidated registry would be more matches, and higher-quality matches, especially for highly sensitized (hard to match) candidates. And the natural next step would be to develop international exchange channels. Six hour coast-to-coast flights carrying shipments of cryopreserved living donor kidneys are now routine. Within that same timeframe, Western European countries with established KPD programs, such as, the Netherlands, Spain, and the United Kingdom, could exchange kidneys with the U.S. and vice versa. It has been found that a cold-ischemia time up to 18 hours has no adverse effect on graft survival. Of course, a living donor kidney would be able to tolerate the preservation better than a deceased donor kidney. All the domestic and
international KPD programs that adhere to the ethical standards of the Amsterdam Forum and the Declaration of Istanbul may well impart best practices of KPD and work toward conjoint standards for oversight, HLA along with laboratory values, algorithm software, and surgical policies. Logistical barriers, such as cross-border exchanges, can be overcome, much like those cooperating international registries for bone marrow donation. Transnational exchange challenges are inconsequential in comparison to the potential advantage for patients who might receive a kidney transplant as a result of internationally expanded KPD.\textsuperscript{16}

CHAPTER 5

ETHICAL AND MORAL ISSUES AS RELATED TO ORGAN TRANSPLANTATION

The medical practice of human organ transplantation, aptly referred to as clinical organ transplantation, has been acknowledged in the United States as one of the most significant health advancements in the last one-hundred years. It has the extraordinary impact of saving the lives of patients who face or who have faced, in the case of kidney failure, terminal vital organ failure. In spite of the initial cause or causes for organ failure, medical issues or environmental triggers, the occurrences of vital organ failure continue to rise each and every year in the U.S. Alongside an inadequate quantity of obtainable human organs for transplantation, principally from deceased organ donors, the disparity continues to widen between organ supply and organ demand. In other words, every patient that requires an organ for transplantation does not receive one. The consequences have been an ever extensive waiting period for ailing patients on the deceased organ donor waiting list to receive an organ as well as an increase in the numbers of patients who die each year while still waiting for an organ. In order to expand this gift of life, genuine involvement from the American people is essential through their unswerving devotion to donate organs through deceased organ donation in conjunction with a substantial quantity of organs donated from living donors. It is precisely these corporal and societal factors that surround organ supply versus organ demand that comprise the success or failure of organ transplantation in the U.S. and that have prompted an assortment of ethical anxieties pertaining to organ availability, organ allocation methods, and the appropriate use of living donors.

This final chapter will investigate and expound upon the ethical qualms that have arisen from human organ transplantation in the U.S. Ethical issues that have developed
from such factors as the technological advancements of surgical techniques and immunosuppressant therapy that sustain graft (organ) life making organ transplantation viable, the tribulations linked between organ supply versus organ demand which poses the question of priority in who should receive an organ, and the risks and benefits related to living organ donation for the living donor himself. In addition, the ethical disparities that exist in relation to initiatives to increase organ donation will be addressed. This chapter will illustrate approaches deemed proper and suitable to utilize in order to increase organ donation through the U.S.’s potential recognition of an organ donation method termed “presumed consent,” the acknowledgment of correct measures to be provided for what is known as acceptable appreciation and compensation to the deceased donor’s family or the living donor, and the perception of humanitarian responsibilities of the American society along with those of medical professionals to aid their fellow human beings. To close, there will be a short consideration of proposed views on the subject of the use of organs from executed prisoners and modified animal organs.

The field of transplant ethics is a specialty within the practice of clinical ethics. The goals of transplant ethics are to promote the integrity of transplant medicine, and the welfare of living donors and organ recipients. Because organs are very scarce and a precious gift, transplant ethics aims for organ allocation to those with the capacity to benefit from it.

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Sixty years ago, any individual person diagnosed with imminent organ failure or multiple organ failure would come to suffer enormous bodily pain, crippling physical debility, and frailty over a course of time followed by certain death. A second chance at life along with a reprieve from horrendous affliction came in the health-giving practice of human organ transplantation particularly with its remedial advancements in the last thirty years such as its surgical techniques (laparoscopic surgery for living donation) and immunosuppressive therapies (prevention of organ rejection). While this great medical marvel is in principle accessible to those in need, human organs cannot merely be acquired at will, found among the dead in the hospital morgue or obtained upon plea. As previously noted in Chapter 2, those who need a surrogate organ must register on the deceased organ donor waiting list. Human organs are primary sought through the availability of deceased donor organs. For organs such as the kidney, liver, lung and pancreas, a living donor may be considered. In any case, the number of people that are facing organ failure continues to far outpace the number of organs that become available for transplantation, and this is where ethical boundaries are being made and tested every day. In other words, how far would we or should we as Americans go to save a life? Let us gain a quick preview on what can occur outside of the U.S. at the moment.

In certain foreign countries—mostly in the third world—human organs are a commodity like anything else that can be procured with no ethical attachments made. For example, there are businesspersons that arrange the sale of organs that can be obtained from living organ donors. These organ sales do exploit the poor while aiding the rich. This type of behavior is readily tolerable on a societal level in these arduous locations. There are only a few wealthy people who need an organ, who can afford to pay for one like they
do an automobile. On the other hand, there are numerous poor although fit people, who need money to buy very basic necessities such as food. As a result, in order to feed their families, the poor cannot afford not to sell their organs on ethical grounds. This style of organ purchase or exchange would be deemed a black market sale in the U.S. and would be very much deemed unacceptable by the American society from its customary ethical point of view.

In the U.S., the desperate dilemma of a human organ shortage has forced medical professionals and institutions to reflect on new practice policies, strategies and reforms in order to increase the organ supply within American implicit and unbiased margins. With organ transplantation being widely acknowledged as a life-saving procedure which not only demonstrates profoundly longer living survival rates for patients, but also improves their overall quality of life, in addition to the decrease in health care costs to society, Americans should be morally and humanistically beholden to discover ways of obtaining more organs and allocating those organs. Accordingly we must develop a set of ethical rules and guidelines with which most Americans can concur.

The explosion in organ transplant technology has resulted in a tremendous shortage of available organs. Over 6,500 patients died in 2011 while they were waiting for an organ transplant.19

When organ supply does not measure up to organ demand, and thousands of lives are at stake with a time constraint involved, fundamental ethical implications such as organ distribution equality and medical suitability standards can arise in regards to organ

allocation methods. This process would regard the dispersal of organs that become available from deceased organ donors and how organ recipients on the deceased organ donor waiting list are selected to receive an organ. As the old sayings go, “all is fair in love and war” and “all things being equal,” when life is on the line, it is war, and equality becomes less a necessity on a personal level. This train of thought is normal and instinctive for basic individual survival. In rational thought, fair is fair, but what is considered fair to one person is not inevitably deemed fair to another person during such a critical organ shortage. It would only be human nature for each individual patient to see his or her situation as being the most critical, and thus far, needing an organ without delay. Deciding who receives a lifesaving organ and who does not—deferred—can more or less resemble playing God. To make the process of organ allocation as equitable as possible in the U.S. in both distribution and medical appropriateness, the United Network for Organ Sharing (UNOS), described in Chapter 3, was handed the responsibility for developing the American national criteria for the allotment of all deceased donor organs.

The UNOS criteria are initiated in this arrangement. First criterion, the geographical location of the deceased donor is equated to that of the potential recipient, i.e. local recipients are given primary accessibility of local organs that become available. If no suitable match is found among the local recipients, then the organ is offered to potential recipients within the state, then the designated region and then, finally, the entire nation. Second criterion, a donor-to-recipient match is made through blood type group compatibility and histocompatibility matching. And the third criterion, a time accumulation point system that is based on each patient’s accrued wait time on the national deceased organ donor waiting list. The subsequent variables that apply: a) patient’s
waiting time on the UNOS donor list, b) immunological match between donor and recipient, c) patient’s present-day standing of medical urgency, and d) patient’s existing age—priority is given to pediatric patients eleven years-old or younger.²⁰

Ethical implications on the topic of living donation originate from the identified drawbacks associated with becoming a living donor, and are the root causes for its critics. After all, living donors are putting their lives on hold and in physical and emotional jeopardy to save the lives of others in need. Those drawbacks take account of potential health risks—post-surgical pain or complications, risk of infection, bleeding, and possible future health concerns; psychological factors—personal guilt or familial resentment if choosing not to donate an organ; family pressure—pressure to donate if a family member requires an organ; and absence of a living donor advocate—unlike patients who have advocates such as transplant centers and surgeons along with medical teams looking out for their best interests. The living donor has no one individual or institution to turn to for information or counseling in such an overwhelming and complex process. In spite of the drawbacks, living donation continues to be a major source of organs and a major means to reducing the organ shortage in the U.S. The benefits of living donation include such factors as pre-arranged transplants which reduce the patient waiting time, produce better genetic matches between donors and recipients which increase graft success rates, and emotional satisfaction for both the donor (saving a life) and the recipient (receiving a new

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The ethical implications encompassing living organ donation can be justified when the appropriate actions are observed prior to any living donor transplant taking place.

Living organ donation may derive from a related, non-related, a.k.a. emotional related or altruistic donor. On humanistic grounds, each is justifiable and therefore, ethical provided that a medical and a psychological evaluation is conducted on the potential living donor in accordance with nationwide established transplant protocols, the donor is fully versed in all physical, medical, emotional and fiscal consequences linked with living organ donation, and the donor provides a copiously signed consent. In addition, the rate of living kidney donor complications after transplantation is very minute while the success rate of living kidney donor transplantation is significantly superior to that of a deceased donor.22 The American Medical Association’s Consensus Committee stresses the benefits to the patient as well as the living donor outweigh the risks associated with the donation and transplantation, and the living donation should exclusively be for altruistic and humanitarian reasons.23

Ever-increasing the availability of deceased organ donations is imperative to adequately providing organs for everyone in need. To begin, along with the vital organs, tissue, skin, intestines, bone, and corneas can all be harvested from a deceased donor. One

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23 Ibid.
deceased donor can save up to seven lives with the donated organs while enhancing the lives of those who have suffered burn injuries, internal injuries or blindness. The familiar methods have been utilized over the years with only marginal increases in deceased donations thus far—educating the public on the importance of organ donation, donor consent on organ donor cards or driver’s licenses, and outright civic appeals for organ donor registration. The time has come for the U.S. to recognize and consider a very effective method used in various cultivated countries in order to increase their supply of deceased donor organs called presumed consent. The implementation of presumed consent has proven highly effective by almost doubling the amount of deceased donor organs that become available annually in those countries that have implemented it, such as, Spain, Australia, France, Sweden, Portugal, Italy, Norway, Greece, Finland, Turkey, Belgium, etc. Let us examine the workings of presumed consent.

The method of presumed consent works when a society as a whole reasons that every adult individual (18 years and older) is a potential organ donor unless that individual has indicated an objection prior to death also known as an opt-out. This would also exempt the wishes of the family to donate the organs of the deceased if an objection was documented. This method is seen as a compassionate solution to saving the lives of those who need organs. Presently, in the U.S., the procurement of deceased donor organs embraces the default conjecture that individuals prefer not to donate their organs for transplantation after death unless they have specified otherwise. It is the mission of presumed consent advocates to make lifesaving organ transplants available to all who need them. It is seen as a moral duty of all individual adults to help those in need. Although this may be a moral improvement to the current American system of organ procurement,
Americans will perhaps view presumed consent as a detriment to personal autonomy which underlies the American concept of informed consent. It is an underlined western philosophy that control over one’s own body is a fundamental right, which would extend to the consent (non-presumed) of organ donation. Equally, presumed consent does not supersede one’s individual right to opt-out of organ donation which would safeguard the right to control one’s own body. From a religious perspective, the major religions—Christianity, Judaism, and Islam—do not object to presumed consent as made known by Pope John Paul II in 1992, by the Jewish Rabbinical Council of America in 1991, and the Islamic Fatwa Committee of Kuwait in 1979 which stated that “organ transplantation can take place from a dead donor providing that there was a necessity to save a human life and that permission of the family is not required since human organs belong to God and not to the family.”

Another method for the U.S. to contemplate in regards to increasing organ donation from deceased organ donors is called objective appreciation. This method falls in line with the idea of financial support which is already on the table in America outlined in Chapter 2. Through objective appreciation, the family of the deceased organ donor would not receive a direct cash payment, but would receive financial assistance in relation to


funeral, travel and other miscellaneous expenditures encompassing the deceased donor’s state of affairs. To avoid ethical problems, the funding would go straight to the funeral home, hotel and/or travel agency. In 1994, the state of Pennsylvania did implement such a system with a maximum amount of reimbursement set at $3,000.00. This set amount would appear reasonable in relation to the thousands or even hundreds of thousands of dollars expensed in medications, hospitalizations, therapies, etc. that can be utilized in the treatment of one patient with organ failure. Nevertheless, the other 49 American states have not chosen to participate in objective appreciation.26

A distant, but possible third method to increase organ donation from deceased organ donors would incorporate the use of marginal or suboptimal donors, i.e. ordinarily discarded donors. This method would be in reference to kidney donations typically with the kidney being the utmost critical organ. In general, many transplant institutions will not accept organs, for example, from donors less than 5 years old or older than 60 years, donors with diabetes, donor with HIV or deceased kidneys preserved over a forty hour period. This has raised an ethical dilemma since the refusal to use these types of organs will deprive a number of patients from receiving a transplant. A way in which to utilize marginal organs objectively would be to obtain prior consent from patients to use them in a transplant. Patients would need to be fully informed regarding the use of marginal organs prior to transplantation due to the fact that the use of marginal organs may result in more instances of delayed function or non-function. The patient would need to weigh this option cautiously. By chance, if the current rate of human organ donation doubles, there will still be an insufficient amount of organs to meet the overwhelming need. Let us survey the

26 Ibid.
main two types of non-traditional organ donations that have been deliberated.

Although this practice has since been ceased as of October 2012, it was a common practice in China to take the organs of executed prisoners and give them to various Chinese transplant institutions or sell them to other countries for transplantation. To the extreme viewpoint of increasing organ donation by any means possible, the usage of organs from executed prisoners has been considered in the U.S. For those Americans who agree to use organs from executed prisoners, they merely agree to the practice in regards to living donation versus deceased donation. These individuals find the process of executing prisoners itself ethically unsound and not the use of the organs themselves. Back in 1999, noted lawyer and ethicist, John Robertson spoke and contended that obtaining organs from a condemned prisoner should be permitted if the prisoner or their next of kin consents to the donation, as long as organ donation is not the means by which the prisoner is executed which would violate the ethical principles of deceased organ donation. In other words, if a prisoner wishes to become an organ donor upon their death or their family consents to the donation after death, it can be considered to be ethically equated with any deceased organ donation. On the other hand, it would be ethically justified to use organs from executed prisoners if the method of presumed consent donation was authorized in the U.S. to include all adult Americans.

Xenotransplantation (transplantation of an animal organ into a human), referenced in Chapter 2, is another form of non-traditional organ donation that has been considered in the U.S. Although its future potential is vast, at present, this type of non-traditional

donation is limited in scope, not an exact science or completely viable as an option. Therefore, theoretically, ethical implications would lie within concerns of health complications for the recipient resulting from animal bacteria and viruses transferring to humans, lack of immunological therapies for xenotransplantation, and the farming of animals as an organ source. Three key guidelines have been established to coincide with constructive medical and ethical outcomes for xenotransplantation. To begin, restrict the use of organs to domestic animals such as pigs, sheep and calves. Many animal rights organizations are opposed to the use of primates, which have been used in the past, as an organ source. Next, breed animals in a special environment while they are being tested for any infectious organisms, for example, in order to avoid retroviral infection from pigs to humans. Lastly, any transplant experiments or trials using animal organs should be reviewed and supervised by an Institutional Ethics Committee. In the future, if animal organs can be utilized recurrently for transplantation under the subsequent guidelines, thousands of patients can be saved and removed for the deceased organ donor waiting list.

Identical to the practice of marginal or suboptimal donors in organ transplantation, prospective patients of xenotransplantation would need to be fully informed regarding the use of animal organs with the patient’s consent being sought in advance of any transplantation. Patient consent would need to incorporate medical as well as the psychological aspects. On the medical side, the patient requires a thorough understanding

of the immunosuppressant therapies available with xenotransplantation and all its possible side effects. On the psychological side, the patient must be able to emotionally handle the mental facets of receiving an animal organ. One imperative ethical factor for the American society regarding the impending use of xenotransplantation is the acceptance of its use by such individuals as patient candidates themselves, post-transplant recipients, transplant surgeons, primary care physicians and religious leaders.\textsuperscript{29} This acceptance, along with the imminent success of xenotransplantation, would make xenotransplantation the most viable option for reducing the numbers of patients on the deceased organ donor waiting list, and in turn, be provided with further government and foundation funding for research and clinical trials.

The very nature of clinical organ transplantation creates profound issues and dilemmas within medical ethics since the benefits of organ transplantation have yet to be efficiently maximized. The advances in transplant technologies and immunosuppressant therapies have enabled more and more patients suffering from organ failure to be considered for transplantation. Nonetheless, the persistent shortage of available organs makes it impossible for everyone who needs an organ to receive one. It is the scarcity of available organs in the U.S., and the methods established to manage those implications that have presented the greatest ethical challenges. It is imperative that the utility of what donated organs do become available be maximized until or when an effective solution is found to profoundly increase or match the number of available organs to the number of those in need of an organ.

In order for us, as a nation, to help the sick and the dying, we must take

\textsuperscript{29} Ibid, 67.
responsibility for their welfare as fellow human beings. Organ transplantation can be wholly advantageous and life-saving for all those who need an organ if every last one of us as a society from the conscientious individuals through civic and altruistic duty donate an organ either after death or whilst living, the government officials through the creation of applicable laws to protect the patient and donor’s rights, and the physicians along with medical institutions through enduring research to advance this pursuit do so with the utmost respect and consideration for what is in the best interest of the patient all the while respecting and upholding the ethical tenets of our society. Regrettably, the world of medicine is a business, and more often than not, the business profits guide the outcomes versus patient requirements. For that reason, personal recognition for virtuous deeds and financial advantage through commercial gain need to be set aside. In addition to increasing available organs, we must furthermore safeguard the patient’s dignity and optimal care through proper pre-transplant patient consent. This key procedure ensures the patient’s rights of autonomy, human integrity, end-of-life declaration, and comprehensive facts regarding the values and consequences of medical technology, and social equity in the allocation of organs. As Americans, we can overcome the ethical glitches involved in organ transplantation in order to save the thousands of patients with organ failure still waiting on the deceased organ donor waiting list. The use of volunteer living donors can provide additional medical advantages to patients, and heighten public education and awareness to giving the gift of life on purely benevolent grounds with no personal gains. The fact is that the gap between organ demand and organ supply in the U.S. continues to widen each and every year with no end in sight. Providing and increasing the gift of life to those patients in need is an honorable humanitarian act.


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