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THE OPTIMIZATION OF ORGAN TRANSPLANTATION

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## **ABSTRACT**

The purpose of this thesis is to give a high level overview of the supply chain process associated with organ transplantation in the United States. Using information on organ transplantation programs from other areas of the world coupled with input from transplant expertise this thesis will highlight areas for logistical improvement to improve the success rate of organ transplantation in the United States. This thesis concluded that while the ultimate solution of improving the success rate of organ transplantation may take legislative action, standardization of transportation by organ is a viable option to save the lives of people waiting for life saving transplants.

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## **Chapter 1**

### **Introduction**

Organ donation is the donation of either biological tissue or an organ from a human to either a living or deceased person to a living person who is in need of a transplant. According to Donate Life America, a nonprofit organization aimed at educating the public on organ donation, another name is added to the national organ transplant waiting list every ten minutes. The issue is the one person being added every ten minutes is being added to an already alarmingly long list of patients awaiting an organ donation. On the website for the United Network for Organ Sharing there is a live update of organ transplant statistics and on March 21, 2015, 116,888 patients were awaiting an organ donation. Eighteen people will die each day while waiting for an organ which amounts to about 7,000 deaths per year. With only 30,000 transplants performed in the United States each year in order to save the lives of those awaiting a transplantation there needs to be a drastic change to the network to increase the amount of transplants each year while also spreading awareness of donation.

The basis of supply chain is balancing the variability associated with supply and demand. It is difficult to reduce this variability in terms of organs because there are simply not enough organ donors, the supply, in the United States to transplant patients awaiting organ donation, the demand. This organ shortage can be largely attributed to a law in the United States requiring citizens to opt-in as organ donors, opposed to opt-out as many European countries are, most notably Spain. Because of this, more than 90 percent of people are organ donors in Europe. It is reported that 67 percent of New York State's residents strongly supported organ and tissue

donation, yet only 13 percent of the state's residents 18 and older were actually on the Donate Life Registry (USA Today Cara Matthews, 2010). The United States has adopted an extensive education campaign and easily expanded the pool of organ donors, however, the amount of donors is still not enough.

This thesis will look into the current network that is in place for organ donation including an in depth overview of the extremely complex process of organ donation. By looking closely into each organization's role and relationships there are clear areas for improvement; specifically highlighting a standardized transport network. It is difficult to quantify the effect such changes could have on the organ transplantation environment, however, small changes to increase the number of successful transplants, coupled with opt-out legislation, open up the opportunity to save the lives of many Americans.

## **Chapter 2**

### **Organ Transplantation Overview in the United States**

#### **Approval for Organ Transplant Waiting List**

The first step for transplant candidates is to obtain approval to be on the Organ Procurement Transplant Network (OPTN) national waiting list. In order for a patient to be eligible to be listed on the national organ transplant waiting list there is a series of screenings set-up by the transplant hospital ending with a final review by the board at the transplant hospital. Due to the amount of time a transplant candidate will wait based on the organ shortage this process is often done earlier than necessary to be sure the patient will be healthy enough for transplant when the time comes.

At the transplant hospital the transplant candidate and their family undergo screenings regarding financial concern, emotional support systems, genetic testing, as well as a full health evaluation. Nurses, physicians, doctors, and the transplant coordinators then join together to discuss their findings from the screening sessions. If the transplant hospital feels the patient and family have the ability to have a successful transplant then they are listed on the OPTN national transplant waiting list. If the transplant candidate is not as lucky as concerns surface such as financial instability or lacking overall health of the patient, the transplant candidate will be denied access to the national transplant waiting list and have the opportunity to transfer hospitals to go through another screening process. Patients may be listed at more than one transplant hospital in the same region but this does not increase the likelihood of transplantation.

## **Becoming a Donor**

In the United States it is required by law to opt-in as an organ donor. In order to become an organ donor there are several ways that person can give consent to their state's donor registry. The most common way of enrolling as an organ donor is by checking a box when obtaining or renewing a driver's license or state ID card. Also, the majority of states offer the opportunity to go on the Internet to register on an online website dedicated to organ donation in the specific state. The second method is by alerting loved ones of the personal decision to become an organ donor. A family has the ability to speak on the deceased behalf to give consent for the deceased organs to be donated.

## **Obtaining Consent**

When a medical team has exhausted their efforts when trying to save a patient, a series of tests is then performed to ensure that a patient can now become a donor. A patient must be deemed brain dead by a neurosurgeon in order to abide by both state law and medical practice policies. It is required for a patient to be brain dead because this means their condition is officially irreversible- eliminating any possibility for a medically induced coma.

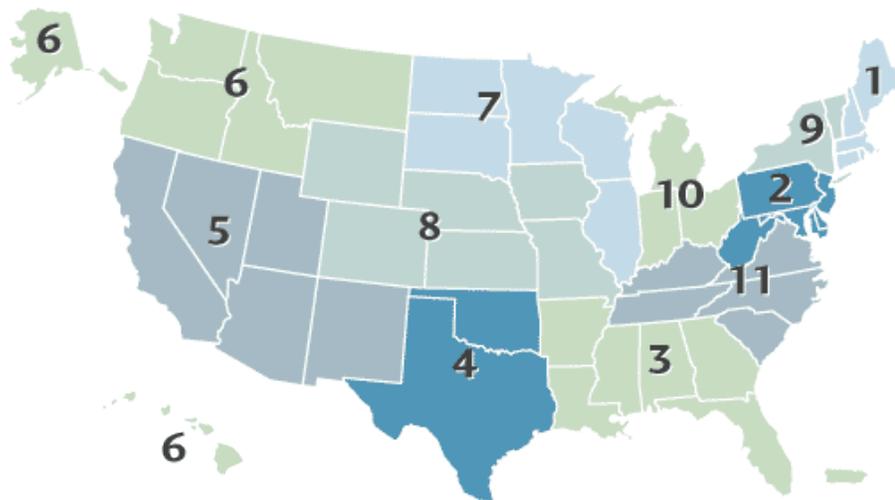
Once the patient is deemed an eligible donor, the hospital where the donor is located must contact their local organ procurement organization (OPO). The hospital is responsible for relaying information about the donor to the OPO who then decides if the patient is a viable donor. An OPO may decide a patient is not donor worthy due to negative aspects of their medical health, such as the presence of HIV. If the local OPO decides the patient is a worthy donor candidate a representative is sent to the donor hospital.

When the representative from the OPO arrives at the donor hospital it is now time to check if the patient has registered as a donor on the state's registry. If the patient is registered this serves as the legal evidence necessary to start the procurement of the organs. If this is not the case then the driver's license or state identification card will be checked. Finally, the OPO representative can ask for consent from the family of the deceased.

### **Matching Donors with Recipient**

Once legal consent has been obtained, the OPO representative at the donor's hospital then contacts the OPTN to begin the search for a matching recipient for the donor. The OPTN has a national database for patients awaiting transplants. The United Network of Organ Sharing (UNOS) under contract by the United States Department of Health and Human Services (HHS) operates this national database. An effective computer program was created in order to match the donor with possible recipients. The computer program looks to compare characteristics of the donor and recipient, such as blood type, tissue type, height, weight, and age. It is also vital for the program to recognize the length of time the recipient has been waiting for a transplant, the severity of the recipient's condition, and their location in the United States in comparison to the location of the donor. The United States is sectioned off into eleven regions and the computer program recognizes that both the donor hospital and recipient hospital must be within the same region for the match to work. These regions can be seen in Figure 1.

**Figure 1. Allocation Regions United States Map**



It is crucial for the computer program to recognize these regions because time is of utmost importance associated with organ transplant. Each organ has a specified amount of time that it is considered viable once the organ has left the donor's body. According to the University of Michigan Transplant Center typical storage times are 30 hours or less for a kidney, less than 12 hours for a pancreas or liver, and less than 6 hours for a heart or lungs. These times vary because of the relative speed at which deterioration begins in the organs' tissues.

UNOS' computer program produces a list of transplant candidates by organ type. The first patient for each organ is offered the organ by contacting the transplant candidate's hospital. The OPO representative contacts the transplant team at the transplant candidate's hospital allowing the transplant surgeon the opportunity to accept or reject the organ. The United States Department of Health and Human Services estimates 75 percent of organs are allocated to the first patient listed. A transplant surgeon may turn down an organ due to the transplant candidate's current health condition or their opinion on the health of the organ being offered.

## **Recovering and Transporting the Organ**

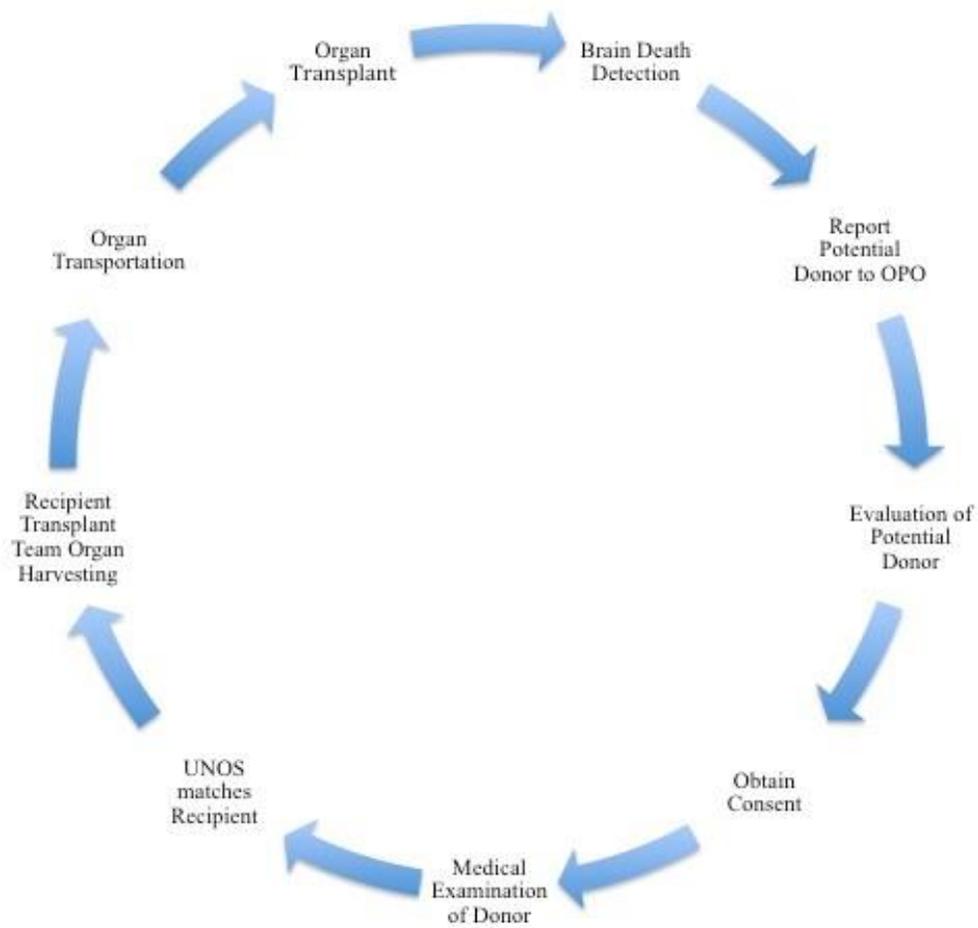
While the allocation of the donors is finalized through the collective efforts of the OPO and UNOS the donor is maintained on artificial support to lengthen the time of viability of the organs. The OPO procurement allocator is in charge of scheduling both the departure and arrival times of the transplant surgical teams from the transplant candidate's hospitals. The transplant patient's surgical team is in charge of the removal and care of the donor organ. Other procedures take place after the removal of all vital organs such as recovering tissues, corneas, skin, and bones.

It is often difficult to schedule the transportation of both the surgical team and the donor organs because of the inability to schedule in advance. This is often where a large amount of money is spent to control the lead-time between the donor and recipient. To help aid in the expense, efforts are made to involve commercial airlines, as well as contracted airlines, helicopters, and ambulatory services. Time is of the essence.

## **Transplanting the Organ**

After the transplant surgical team and the donor organ arrive at the recipient's hospital the operation may take place. It is common that the recipient is already prepped in the operating room awaiting the arrival of the surgical team. An organ transplant surgery may take up to ten hours depending on the degree of complexity of the recipient's condition. The entire organ transplantation process from a brain death diagnosis to organ transplantation can be seen in Figure 2.

Figure 2. Organ Donation Process



## **Chapter 3**

### **Network Optimization Trends in the United States**

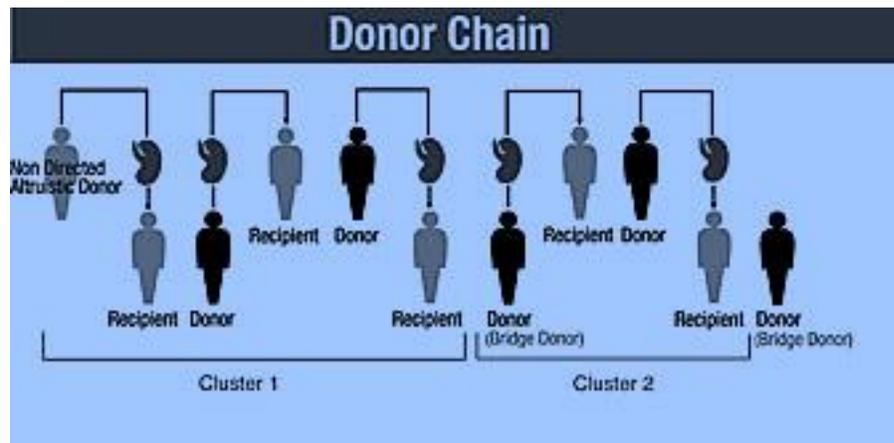
Organ transplantation is a unique procedure continuously looking for areas for improvement. While government and health entities continue to argue over ethical realities associated with adjusting legislation in the United States, there have been improvements to the current program from both a medical and technological standpoint to make-do with the amount of donors currently enrolled in the United States. While some research is still preliminary, there are programs that have already completely transformed the landscape of organ transplantation, especially for kidneys.

#### **Kidney Paired Donation**

There was a program created as a scalable, data-driven method for designing the allocation of donor kidneys to patients on a waiting list in a fair and efficient way. The efficient kidney exchange also known as the Kidney Paired Donation (KPD) created by OPTN and managed by UNOS can be achieved through a paired donation of “never-ending” living donor chain. A traditional, or "closed-loop", paired donation consists of two or more donor/recipient pairs whose blood types are not compatible with each other. It is currently a pilot program that can be enrolled in throughout the United States. Patients must be approved through a similar medical and psychological testing as those who are accepted to the national organ transplant waiting list. The medical information of the enrolled is input in the OPTN KPD database to

search for cases where the donor in the system is a match with a recipient in another pair or in multiple pairs. An example of a donor chain can be seen in Figure 3.

**Figure 3. KPD Donor Chain (CPMC, 2015)**



As can be seen in the donor chain the idea behind this algorithmic database is by exchanging donors where a compatible match for multiple recipients can be found. Because this is a living donation there is extensive medical testing done before a person can enroll in the KPD database. The chain assembles a match that is creating hope for a patient who has been waiting on dialysis, may prevent a patient from ever starting dialysis, and can even decrease the wait time for a kidney. This can be an extremely beneficial program for kidney transplant patients because a living kidney donation has been proven to last longer for the patient with a decreased need for immunosuppressant medication (UNOS, 2015).

### **Organ Preservation**

The largest constraint associated with organ transplantation is the length of time an organ is viable outside of the human body. Due to the fact that an organ only has a few hours outside of the donors body before it will be considered not suitable for transplantation one major effort in

technology for organ transplantation is machines or medicine designed to preserve the organ while outside of the donor's body and Organ Transport Systems (OTS) is leading the way in this effort.

After over ten years of research OTS has released a technology known as The LifeCradle Heart Perfusion System. This technology allows the heart to live outside of a human body for up to twelve hours compared to the maximum time of preservation of four hours in the typical transportation method, a cooler (OTS, 2015). The LifeCradle is incredibly effective because it is able to oxygenate the heart during travel time while also sustaining life by rejuvenating with nutrients meant to sustain life. With this circulation the heart is able to travel longer distances while also remaining healthier compared to a heart transported on ice. This leads to an increased rate of a successful transplantation for the recipient.

### **Xenotransplantation**

The idea of using animal parts to save human lives is no new introduction to the world of medicine. In fact, the idea of replacing valves in human hearts with valves from pig's hearts is a practice that has been occurring for decades. This is perhaps the reason that a new hot topic in organ transplantation is xenotransplantation, the transplantation of living cells, tissues, or organs from one species to another.

Research has shown that there are high rates of rejection with this type of organ transplantation from the immune system due to the cross-species. Ultimately for this to be a reasonable solution for future organ transplantation there needs to be improvements in medications to prevent organ rejection. One current effort used often with pig valve replacements

is genetically engineering tissues of animals to make their tissues more resistant to the human immune response (Cooper, 2012). There have been attempts at chimpanzee kidney xenotransplantation, chimpanzee heart xenotransplantation, and even a baboon heart xenotransplantation. Unfortunately, a patient often agrees to this organ donation due to their quickly declining health and likelihood of not living long enough for a human organ to become available. Due to these factors there has not been any evidence of sustained life with xenotransplantation past eight weeks. Although no success can be proven, this revolutionary idea, combined with tremendous medical advancements, could one day save the lives of many patients awaiting organ transplantation.

## Chapter 4

### Organ Transplantation Optimization in Europe

Organ transplantation is a sensitive topic dealt with differently throughout the European Union to adhere to the cultural values, legal, administrative, and organizational issues. Although all of the European Union is under opt-out legislation for organ transplantation, the most successful organ transplantation program in the European Union is in Spain. In 2014 there were 4,360 transplants carried out in Spain with the deceased organ donation rate standing at 36 per one million inhabitants. In France and the United States this figure is only 26 (Badcock, 2015). The Spanish model has been optimized by the director of their National Transplant Organization program known as Organización Nacional de Transplantes (ONT) as a part of Spain's Health Ministry, Dr. Rafael Matesanz. Spain is not necessarily revolutionizing organ transplantation due to efforts put towards improvement of distribution but rather putting a heavier emphasis on the importance of improving donation rates.

#### Organización Nacional de Transplantes (ONT)

The National Transplant Organization (ONT) was created in 1989 belonging to the Spanish Ministry of Health, Social Services, and Equality. This organization is similar to the United Network of Organ Sharing (UNOS) in the United States because ONT is also in charge of overseeing extraction, preservation, distribution, and exchange of both organs and tissue throughout the Spanish Health Care System. The primary difference is that ONT takes on one primary role that in the United States the organization Donate Life America leads: promotion of organ transplantation.

As Spain is already under opt-out legislation, presuming consent unless otherwise stated, ONT is responsible for maintaining the organ donors. ONT's provides a feel of professionalism along with encouragement for the families losing a loved one. The director of the program, Dr. Matesanz, has attempted to spread this program into areas such as Germany. However, the complexity of the web of insurance providers and private hospitals make the environment not compatible for such a network. On the other hand areas with public health insurance such as the United Kingdom have had trouble maintaining their organ donors in an opt-out systems because there are a small number of well-paid doctors who can afford a transplant coordinator, in Matesanz's view the heart of the success of the transplant program.

### **Transplant Coordinators**

Organ donation is an incredibly complex process with a variety of emotions depending on the cause of death of the donor. In every hospital in Spain there is a transplant coordinator who is in charge of maintaining professionalism from a legal aspect of organ donation while also catering to the emotional needs of families while in the hospital. There is also a transplant coordinator in most hospitals in the United States; however, in Spain transplant coordinators are intensive care specialists as opposed to technicians or nurses.

The position is considered emotionally daunting and often has a high rate of psychological burnout. Since the beginning of ONT Spain has trained over 16,000 transplant coordinators, averaging 600 transplant coordinators each year. The special training given to transplant coordinators is both physiological and medical. Transplant coordinators are aware of

the appropriate information to deliver families based on the cause of death to be sure they will continue supporting the reality of their loved one becoming an organ donor.

## Chapter 5

### Standardized Transportation Network

Although it is difficult to standardize a practice as inconsistent as organ transplantation, the standardization of transportation has the possibility to increase the success rate of organ transplantation despite the lack in organs available. The success rate could be improved by delivering the organ on standardized routes between hospitals, avoiding the added step of finding transportation that is available at the time an organ becomes viable, and possibly expanding the regions where organs can be allocated based on timesaving.

In order to create a standardized transportation network there would need to be a computer program available to each OPO. The computer program would allow the OPO representative at the donor hospital to select the location of both the donor and recipient hospital, then be presented with options for transportation. Based on the organ that is being transported the OPO representative would have the ability to look for either a reliable route for an organ that has a longer viable window or to look for the quickest option for transportation for an organ with a shorter window of viable time, such as for the heart. After selecting the best option for transportation the computer program would then have the ability to send notifications to the parties involved, for example contacting an airline if such a method was selected. That entity, for example the airline, would then call to confirm with the OPO representative. In Table 1 a SWOT analysis is shown to outline all positive as well as negative aspects associated with a standardized transportation network, both internally and externally.

**Table 1. SWOT Analysis Standardized Transportation Network**

|                 | <i>Positive</i>  | <i>Negative</i>   |
|-----------------|--|---|
| <i>Internal</i> | <b><u>S</u>trengths</b>  | <b><u>W</u>eaknesses</b>  |
|                 | <ul style="list-style-type: none"> <li>• Transportation readily available</li> <li>• Contracted prices</li> <li>• Specialization in organ transplantation transportation</li> <li>• Reduced lead time for organs once available</li> </ul> | <ul style="list-style-type: none"> <li>• Limited resources for funding</li> <li>• Unplanned supply and demand</li> </ul>  |
| <i>External</i> | <b><u>O</u>pportunities</b>  | <b><u>T</u>hreats</b>   |
|                 | <ul style="list-style-type: none"> <li>• Focus on research and development</li> <li>• Surgeons have extended time for surgical procedure</li> </ul>  | <ul style="list-style-type: none"> <li>• Rising fixed costs</li> <li>• Increased regulation</li> <li>• Decreased push to increase the organ donor pool</li> <li>• Opt-out legislation not enforced</li> </ul> |

### **Strengths**

If UNOS is to set-up a standardized transportation network there would be many benefits for the organization as well as for the OPO. From Table 1 it can be observed that the first strength for UNOS would be readily available transportation. In the current state of organ transplantation it is up to the OPO to schedule and arrange transportation for the organs ready for

organ transplantation. This is not ideal because there is no guarantee that there will be a flight departing for the destination at a certain time or that an ambulance will be available to transfer the organ. Also, by contracting prices with transportation organizations it is possible that UNOS could help insurance companies avoid high transportation costs. Rates would vary based upon gas and oil prices, however, a flat rate for services could put UNOS and insurance companies in a more stable position.

In order to set-up this standardized transportation network it would take the collaboration of experts in logistics combined with experts in organ transplantation. When these two forces come together to create a transportation network there will then be people who are specialized in the area of transportation for organ transplantation. This specialization could help in future situations to plan for future occurrences in the event of a natural disaster. If these experts are contacted in the event then there would be a decreased amount of organs sacrificed due to the disaster disrupting transportation methods.

Ultimately, the most important factor in creating this standardized transportation network is to decrease the lead times for viable organs. The map for optimal routes from hospital to hospital would consider factors such as traffic and weather conditions to decrease the time between the organ donor and the recipient. Organs only have a certain time period that they are viable for use after extracted from a human body. While technology continues to improve to lengthen organ viability times, lead time reduction will be key to raising the success rates of organ transplantation.

## **Weaknesses**

With the implementation of a standardized transportation network there will be clear risks UNOS will need to take into account. The first issue at hand is the issue of funding. There will need to be collaboration from both logistics experts and organ transplantation efforts to come to a final decision for the transportation network. During the collaboration there will be time spent away from usual work, however, it is important to understand the cost in comparison to the benefit. It is difficult to put a price on a human's life when considering the amount of time that could be taken to create this standardized transportation network. With the combination of fundraising efforts, adjustments to budgets, and voluntary efforts towards a good cause this is an initiative for a network that could be created.

If funding is able to be discovered to make the effort possible one major challenge will occur for the experts creating the network: the uncertainty of supply and demand. Unfortunately no system will ever be able to predict when and where an organ will be available. It can almost be guaranteed that while under the opt-in legislation there will be a demand for the organ, it is just a matter of the location of the demand in comparison to the supply. To optimize this risk it will be important to focus on decreasing lead times and having transportation methods readily available.

## **Opportunities**

After the creation of the standardized transportation network there will be two main areas for opportunity for external parties. The first is the opportunity for research and development. With a standardized network there will be time available to focus on creating technology to

improve organ transplantation. The OPO will no longer have the responsibility of setting up the transportation for the organ from a blank slate allowing this organization to focus on finding the best option for the best recipient, and if it is not a clear match, focusing on finding the next best organ recipient.

A major component to creating this standardized transportation network is decreasing lead times. If the organ is able to arrive to the recipient's hospital in a shorter amount of time than usual then surgeons have the opportunity to take their time with the surgery and concentrate during difficult cases. A successful surgery is the key to increasing the success rate of organ transplantations, and added time for a surgeon would increase the likelihood of a successful transplant.

### **Threats**

By outsourcing transportation to contracted carriers this unfortunately opens areas for threats towards UNOS and overall the transportation of organs. By contracting with large transportation companies the result is a high fixed cost upfront. While UNOS will be the company who is initially paying the price to contract the carriers it is important for UNOS to know they will be compensated by the insurance companies throughout the year for the upfront contracted cost. There is also a threat to UNOS as these contracted carriers may put into place regulations for transportation such as creating a container that is acceptable for transportation by the carriers. This could become expensive for research development reasons as well as exceeding the cost of a typical cooler that is used in transportation in organ transplantation transportation's current state.

The idea of creating a standardized transportation network is to increase the success rates of organ transplants as well as increasing the amount of organ transplants performed each year. With the implementation of this network there is a risk that people would not be as apt to become an organ donor because there are being efforts made to function with the amount of organ donors currently enrolled. Therefore, there could be less focus on the idea of switching to an opt-out legislation to expand the organ donor pool. This is a problem because education on organ donation to increase the number of organ donors should never be an option. It is critical to keep organ donation in the spotlight and to highlight the need for organ donors in the United States.

## Chapter 6

### Opt In Versus Opt Out Legislation

The United States currently follows an opt-in system regarding organ donation. With new legislative action the process to becoming an organ donor could be easier and therefore increase the availability of organ donation. An opt-out policy, or also called “presumed consent”, could be put in place in the United States to ensure this crisis does not continue. The opt-out policy says if there is no explicit objection to the donation of an organ or tissues, consent should be presumed.

However, there are doubts associated with the policy. Lawmakers in New York, Illinois and Delaware have proposed versions of the European model — called “presumed consent” — with the goals of increasing the supply of donated organs and shrinking waiting lists (Mantel, 2011). But all bills have died in committee amid the public's concerns that such programs are coercive. With any new legal policy there is bound to be opposition.

The main concern for the general public, not including those of religious opposition, is patients believe if there is a possibility their organs would be viable for donation, then when there is a near death situation then doctors will not help them survive but will rather use their organs to save multiple lives. With the opt-out policy the public must maintain a high level of trust in medical practitioners, and in particular, confidence that medical treatment would never be compromised for the sake of harvesting their organs.

The Hippocratic Oath states that, above all, a doctor will prevent harm and injustice. It is a given that a physician will and must follow the Hippocratic Oath and not harm or endanger the life of any patient. It is important to recognize that countries that currently operate under

presumed consent policies have no recorded instances of doctors providing inadequate treatment because of a potential conflict of interest between potential donor and potential recipient (Cameron, 2005).

## **Chapter 7**

### **Conclusion**

Organ donation is an important topic worldwide. In the United States there are people every day who die awaiting the gift of life. Although there is constant research in the United States to transplant as many patients possible with the current donor pool, other areas of the world have been able to improve upon a system that is clearly broken in the United States by switching to an opt-out legislation. It could take years for such legislation to be put into place in the United States so an intermediary plan such as a standardized transportation network for organ transplantation is a viable option at the current time to decrease lead times and increase the success rate of organ transplantation.

In countries like the United States where individual rights are of great importance, it is vital that our policies should reflect public opinion. A presumed consent policy could directly address the defect in the current opt-in policy, as the failure to procure organs is generally due to failure to obtain permission and not due to the lack of general public support for organ donation.

Overall, opt-out legislation has a positive and sizeable effect on organ donation rates. Countries enforcing an opt-out policy have 25 percent to 30 percent higher donation rates compared to the United States. This level of increase would greatly ease, though not completely eliminate, the organ shortage in the United States.

It is often the smaller things in life that can make the greatest impact. Although the deed in becoming an organ donor will not be given to those in need for years to come, it is empowering to know that such an admirable decision has been made to turn a loss into a beautiful future for many people. The need for organ donors is inevitable. A decision today and

commitment to spreading the word of the need for organs in hopes of recruitment could lead to the survival of a loved one. Share your life, and share your decision.

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