Proposed Implementation of a Deceased Organ Donor Program to Address the Critical Shortage of Donor Organs in Wisconsin

by

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Abstract

In 2017, for the first time in organ procurement history, the total number of deceased organ donors in the United States exceeded 10,000, representing a total increment of 3% more organs transplanted compared to the year prior. Despite this milestone and positive improvements in recent decades, around 20 people die each day waiting for a transplant, and a new patient is added to the national transplant waiting list every ten minutes. As the organ shortage crisis continues, each year the number of individuals on the waiting list far exceeds the number of available donors and organs. This project focused on identifying possible deficiencies and root causes of the organ shortage crisis in Wisconsin, and identified the resources for the implementation of an improved organ procurement system. Finally, it resulted in a detailed and viable implementation plan that would increase the number of organs available for transplantation in the state of Wisconsin.

To create a viable implementation plan of an improved organ donation model, this project reviewed various data reported from national and international organizations in order to evaluate variations and trends among successful organ donation programs around the world, and develop an accurate understanding of the current state of organ donation in the U.S. In addition, the project reviewed the total number of deaths and the major causes of deaths in 2017 in Wisconsin to estimate the number of potential deceased donors and define the gap between estimated potential deceased donors and the actual total deceased donors in 2017. Additionally, research was conducted on the current organ transplant programs in Wisconsin to identify how they could be leveraged in the new model.

The project resulted in the recommendation of a transport topology that should optimize the availability and management of organ procurement, transport and transplant. This hub-and-spoke model has been used in various geographies throughout the world with suitable success. Based on the hospital distribution in Wisconsin, this state should be suitable for this model in a manner that connects primary urban hub hospitals in southern Wisconsin with suburban and rural hospitals throughout the state. If implemented, it is expected that this system would improve transplant numbers.

Acknowledgments

I would like to thank the members of my thesis committee, Dr. Ron Gerrits, Kirsten Kallies, and Shannon Anderson, for their support during the development of this project. I would like to thank each of the perfusionists at Aurora St. Luke's hospital for their guidance throughout this course.

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1.0 Introduction

The process of organ transplantation is considered by many to be one of the most significant advancements that has occurred in the medical field. Some of the most complex diseases that once ended in certain death are now being halted, thanks to the advancements in organ donation and transplantation. Unfortunately, many people who qualify for organ transplants are not able to obtain one because of severe donor shortages [1]. Currently, twenty people die each day while waiting for a transplant, illustrating the severe lack of supply regarding the demand for donated organs [2].

Most transplanted organs originate from deceased donors [1, 2]. In 2015, the United States crossed the 30,000 annual transplant threshold with over 80% of donations deriving from deceased donors [2]. The importance of deceased donors is in part because very few organs and tissues can be donated from a living donor, thus further underlying the crucially of organ donation via deceased donors [3]. However, there are significant challenges that accompany organ transplantation via deceased donors, not limited to ethical and legal considerations [4]. In addition, organs are not always viable after death, at least not to the point in which physicians are comfortable using them in transplants [3]. This creates a tenuous situation between supply and demand for transplantable organs and causes many to rethink the status that organs need to be in for viable transplantation.

There are two ways that organ procurement can occur at the end of a patient's life: the most common and longstanding method is donation after neurological determination of brain death (DBD), and a second and newer method is called donation after circulatory determination of death (DCDD), previously known as donation after cardiac death (DCD) [2]. Several studies show the importance of the development of regional DCD programs in order to reduce the recipient waiting list and increase the overall success of transplantation [5, 6]. In addition, some of these studies also recommend the creation of a designated team within clinical or hospital settings to support such programs [6]. Overall, a well-defined protocol that both explores the challenges of organ donation and provides solid solutions has the potential to greatly improve transplant rates and overall organ donation program success.

Perhaps the most compelling method to illustrate the gravity of the organ shortage, with particular focus on the state of Wisconsin, is through statistics. In the last year alone, 36,529 transplants were performed in the United States, thanks to 17,568 donors, of which 10,721 were deceased donors [2]. Today, 1,868 organ recipient candidates are waiting for an organ in Wisconsin, and approximately one of them dies every three days [2]. In the state of Wisconsin, there are only four transplant centers, two organ procurement organizations, and there is no presence whatsoever of non-heart beating donor programs. Given that all historical attempts to replace the functionality of human organs have failed, the state of Wisconsin must take action in further developing its transplant capacity, specifically through the development of non-heart beating donor programs. The goal of this project is to propose a detailed implementation of a Deceased Organ Donation Program for Southeast Wisconsin.

2.0 Background

2.1 From the Legends to the Twentieth Century

2.1.1 *History of Organ Transplantation*

The fascination with the idea of organ transplantation began far before it was even scientifically possible. For example, one Chinese folktale recounts the story of physician Pien Chi'ao who allegedly swapped hearts between two men, as he believed this would have corrected a spiritual imbalance between them. In addition, there are Roman Catholic accounts reporting that third century Saints Damian and Cosmas had replaced the cancerous leg of the Roman Deacon Justinian with the healthy leg of a recently deceased Ethiopian [7]. Perhaps inspired by these accounts, the first successful skin autografts were performed in the late 16th century by Italian surgeon Gaspare Tagliacozzi, thus advancing the field one step closer to total organ transplantation. In contrast to his success with autografts, Tagliacozzi consistently failed in his attempts at allografts, consequently providing the first documentation of the process of organ rejection [7].

Many experts consider the second half of the twentieth century as the new era of organ transplant. During the year 1954, Dr. Joseph Murray performed the first successful kidney transplant, bypassing the barrier of rejection by using the kidney of the patient’s twin [7]. During the successive years, many surgical goals were achieved, such as the world’s first human-to-human heart transplant performed by Dr. Christin Barnard in 1967 in South Africa [7]. Unfortunately, these early transplants were rejected soon after due to immune incompatibility. Such results highlighted the importance of finding a solution to post-transplant organ rejection in nom-matching tissues. Toward this goal, the first breakthrough in immunosuppression occurred during the 1970s thanks to Jean Borel and his colleagues [7]. They discovered cyclosporine, the first single drug able to control organ rejection. This, and the discovery of additional immunosuppressive agents, have formed the foundation of today's existing transplant treatment regiments.

Along with the surgical and scientific achievements, many scientific organizations were also formed with the purpose of improving medical aspects of the transplant process and the overall management of organ donation. One of these, the Southeast Organ Procurement Foundation (SEOPF), was formed in 1968 with the goal of increasing the efficacy of organ placement [8]. This organization introduced the first computer-based organ matching system called the United Network for Organ Sharing (UNOS), which is still in use today [8].

Yet none of these advancements have been able to overcome the critical shortage of organs available for transplant. In 1984, Congress proposed its solution to the crisis in the form of the National Organ Transplant Act [8]. This legislation attempted to address the existing shortages as well as optimize the placement and matching of donated organs. The act established a national registry network for organ matching, called the Organ Procurement and Transplantation Network (OPTN), which was to be operated under federal contract by a private, non–profit organization [8]. In 1987, UNOS began collecting medical data on donor and transplant recipients and in the 1990s introduced innovations such as an electronic data record and internet-based transplant information database system [8]. These vast improvements in the organizational aspect of organ donation, coupled with improvements in surgical and pharmacological knowledge, paved the way for organ donation as we know it today.

2.1.2 *Organ Transplant Crisis*

In the United States, 114,000 patients are listed in the national organ recipient waiting list. In 2018, a total of 36,527 transplants were performed. Although this is an increase of 5% over 2017, there are still around 7,000 patients that die each year as they wait for a transplant because the supply is still far short of the demand [3]. It is unlikely that there will be any near-term decrease in demand, leaving transplant scientists to investigate ways to solve the organ shortage. New and creative strategies to expand the national donor pool include increasing the living donor pool for transplants, using kidneys from donors with hepatitis C, implementing the *ex-vivo* lung perfusion system, and using an organ perfusion system in order to recover discarded organs [9].

There are other possible sources of organs for donation, but they are more grotesque. One of these would be using organs from donors who passed from opioid or other drug overdose [1]. In the United States, the growing opioid epidemic has led to increased deaths, constituting a total of 33,000 in 2015 [1]. In addition, the opioid crisis also marks the first instance of drug overdose representing the most common accidental cause of death among adults, which has previously been motor vehicle trauma and firearms [1]. Drug overdoses have a direct impact on organ donation, with 12% of all recent organ donations derived from this group (a doubling since 2010) [1]. In the New England Organ Bank alone, organs procured from overdose patients accounted for a total of 27% of the region’s donations in 2016, representing a 4% increase overall since 2010 [1]. While it would seem that procuring organs from overdose victims could at least provide some form of positive outcome to the crisis, these transplantations are not without challenges. Organs from drug overdose donors are often underused due to concerns regarding disease transmission via organ donation, including risk of transmission of HIV and hepatitis B and C [1]. In fact, organs from overdose patients are so underused that a patient on the national organ recipient waitlist is more likely to die while waiting for a transplant than to receive an organ from this category of higher risk donors. Despite the barriers to organ donation and great need for higher supply, nearly one hundred life-saving organ transplants are performed daily and more than 34,000 transplants are performed each year via the two forms of donation: living donors and deceased donors [2].

2.2 Types of Organ Donation

2.2.1 *Living Donors*

Living organ donation occurs when a living person donates an organ or portion of an organ. The most commonly donated organs among living donors include kidneys or a portion of the liver [8]. More rarely do living donors give a portion of their lung, intestine, or pancreas [8]. Interestingly, a kidney donated by a living donor has been shown to function longer than one donated by deceased donor, and more than 98% of transplanted kidneys from living donors are still functioning successfully one year after transplant [2].

Another interesting aspect of living donation is the possibility to create paired-organ donation chains, also known as paired exchange, which is a form of living donation that can be utilized when the donor and intended recipient are not compatible [10]. This process brings additional donors and recipients into the chain to ensure all recipients eventually receive a compatible organ. In addition, it allows physicians to approach transplantation more strategically and create compatible pairings to optimize transplant outcomes. This process is frequently used in kidney paired donation (KPD), and allows hundreds of people to receive a well-matched transplant each year. In 2016, 642 KPD cases were performed, which is equivalent to 11% of all living donor kidney transplants in the US [10]. Given its success, the Organ Procurement and Transplantation Network (OPTN) is working to increase the overall number of KPD transplants by proposing the introduction of deceased donors into the donor-recipient pairings [10]. Should the OPTN have success in their proposal, the result would reduce waiting times for recipients, as well as naturally increase the number of KPD pairings to allow more individuals to be matched. Moreover, this would allow deceased donors to make a difference in programs that were previously strictly for living donors.

2.2.2 *Deceased Donors*

Traditionally, both medical and legal communities defined death as the permanent cessation of respiratory or heartbeat functions [11]. This changed in the 1970s when many countries updated the concept of death by defining it as brain death. In the early 1990s, European physicians coined the term *Nonheart-Beating Donor* (NHBD), which was initially used to describe an organ donor after cardio-respiratory arrest [11]. In 1995, the Eurotransplant Working Group proposed a new classification aiming to avoid misunderstandings from both a legal and healthcare perspective. Today, organ transplants from deceased donors can occur in two ways: donated organs may derive from a donor who has been declared brain dead (Donation after Brain Death – DBD), or from a donor who had a circulatory collapse (Donation after Cardiac Death) [11].

During a global consultation on organ donation and transplantation, the World Health Organization (WHO) introduced the *"critical pathway for deceased organ donors"* (Figure 1) [3].

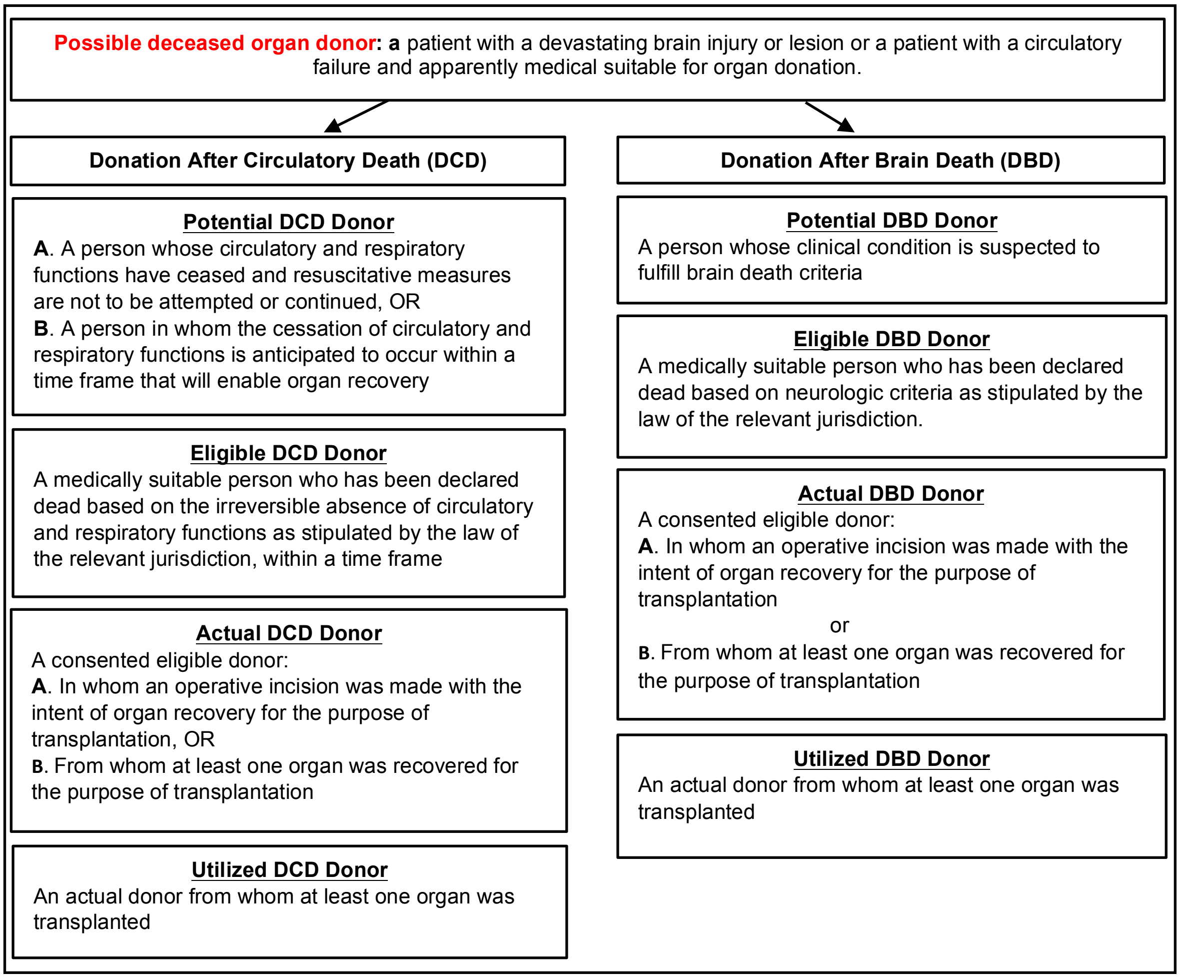


Figure 1: The Critical Pathways for DBD and DCD [3]. DBD = donation after brain death, DCD = donation after circulatory death.

The critical pathway for deceased organ donors aims to help clinicians identify possible donors and outlines stages a patient goes through from donor classification to be a utilized donor. It also provides a systematic approach to the organ donation process, illustrating the two key methods of donation: donation after cardiac death and donation after brain death. Additionally, the pathway provides a useful tool that becomes a guide during the assessment and identification of potential deceased donors.

2.2.3 *Donation after Brain Death (DBD) Donors*

DBD is a complex process that involves many health professionals and generally takes place in the intensive care unit (ICU) [3]. DBD begins when a patient has been diagnosed as brain dead, and thus he or she becomes a potential brain dead donor [12]. To ensure successful and compliant DBD procedures, all healthcare professionals involved in the process must undergo continuous training. It is also important the protocol must be frequently evaluated to ensure a successful transplant program (Figure 2) [13].

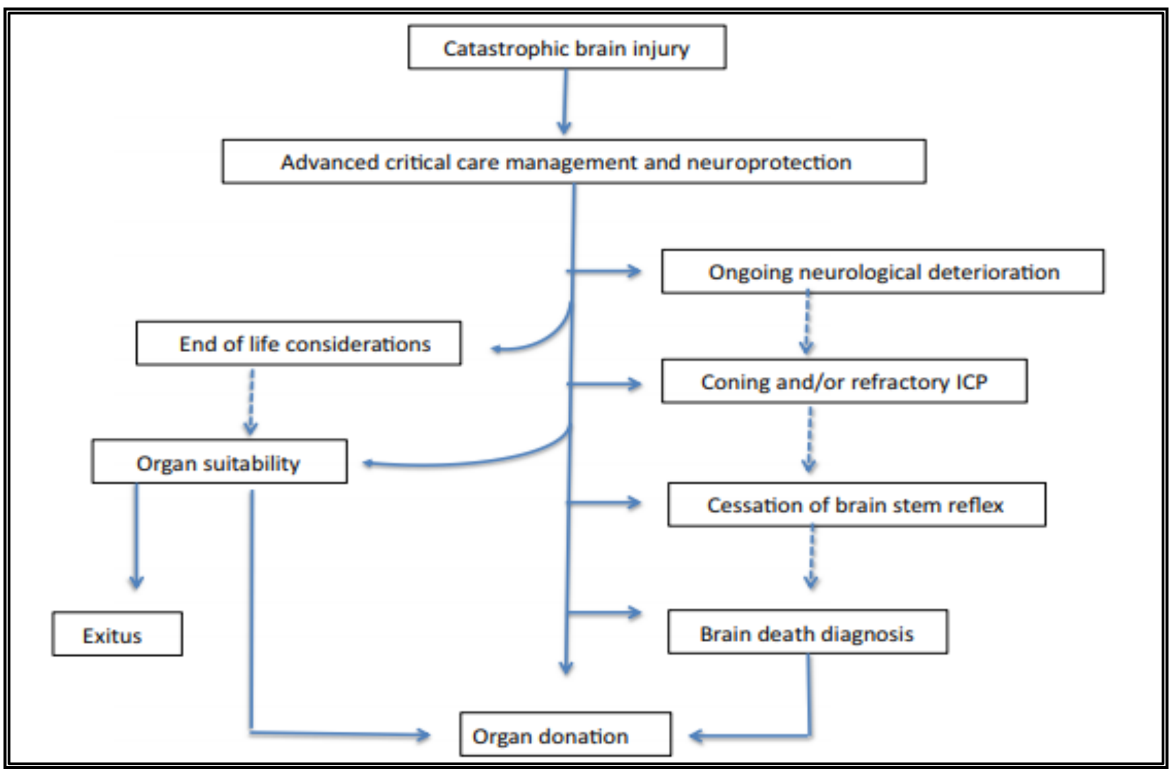


Figure 2: Clinical Pathways for Organ Donation After a Brain Injury [13].

The clinical pathway for organ donation demonstrates the critical passages that a potential DBD donor undergoes from the time of a catastrophic brain injury to being identified as a viable donor. Therefore, it represents a roadmap for clinicians in a decision-making role when it comes to identifying donor candidates in DBD situations.

The early identification and evaluation of a potential brain dead donor is crucial in order to improve the outcomes associated with the use of the harvested organs [13]. Many approaches have been proposed in recent years in order to improve the DBD process, and one of the most common approaches is known as the ABC approach (Figure 3) [13].

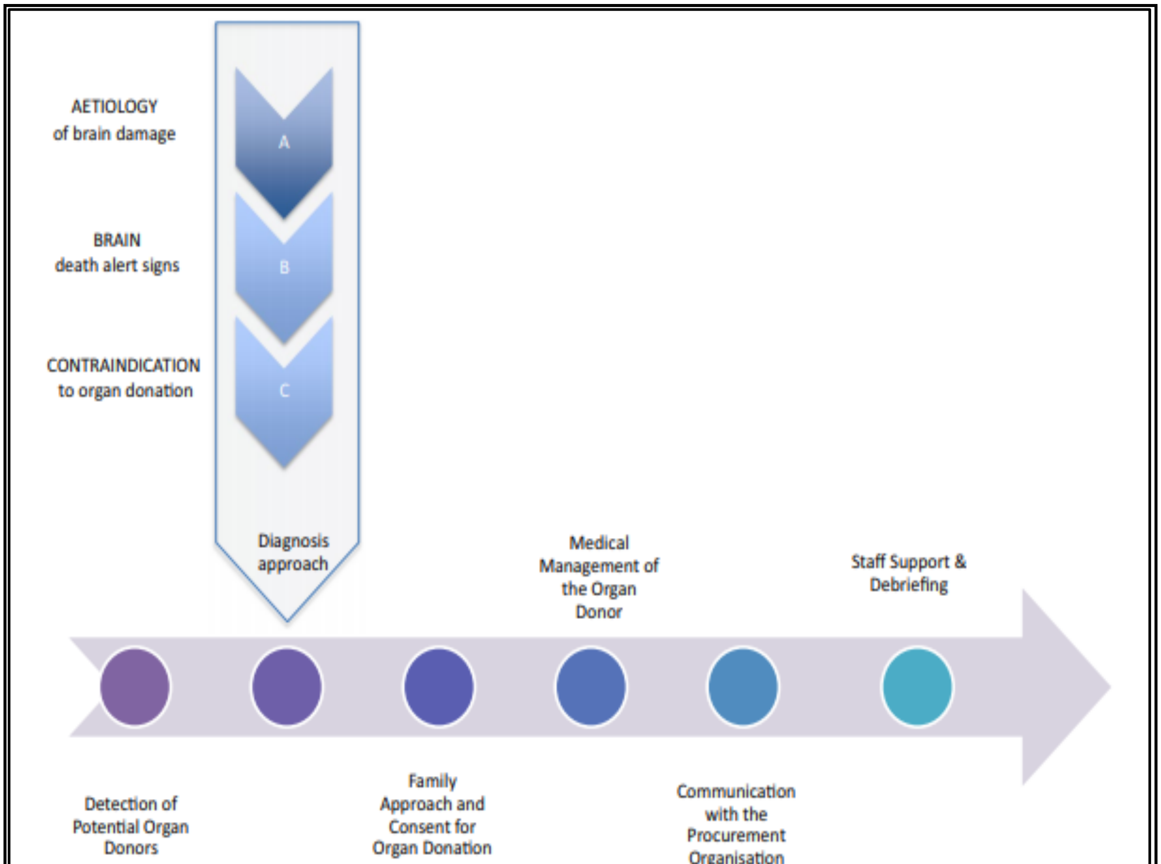


Figure 3: ABC Approach for Organ Donation in DBD Process [13].

The ABC method provides an easy acronym to remind clinicians of important considerations during DBD procedures, which are perhaps the three most initial important steps: A "Aetiology of brain damage", B "Brain death alerts", C "Contraindications" (Table 1) [13].

Table 1: ABC Approach. A detailed description of the ABC approach used to improve the process of donation after brain death.

***Aetiology** of brain damage*	Knowing the aetiology of the potential donor's brain damage is important in order to understand the causes that led to the irreversibility of brain function, and also allows the clinician to exclude other neurological diseases that could prevent the patient from being eligible as a potential donor. It is important to know that in order to create a simplified acronym, the work aetiology was used, rather than the more common spelling of etiology.
***Brain** death alerts*	Generally, the initiation of organ donation starts after the diagnosis of brain death, however there are circumstances in which the signs or alerts of brain death begin before diagnosis is made, for example in situations in which a severe brain injury has occurred or in which clinicians determine brain death is looming. Moreover, it is often difficult for clinicians to identify the precise moment in which the organ donation process can, or perhaps more importantly, should be initiated. To further complicate the decisions regarding the timing of DBD donation, clinicians must also be mindful that the donor must be correctly identified as a potential donor as early as possible in order to preserve the donor's organs for the best possible donation outcome.
Contraindications	There are three primary contraindication categories that must be taken into consideration before proceeding with the donation process: • Absolute contraindications • Organ specific contraindications • Relative contraindications

The pathophysiology of the potential DBD donor is important to consider in order to tailor the treatment of hemodynamic instability and time the organ procurement. Adrenergic hyperactivity, also called autonomic storm, is a classic pathophysiology response that precedes brain death [13]. The autonomic response causes tachycardia, increase in pulmonary vascular resistance and systemic vascular resistance, as well as hypertension [13]. The consequence of these responses can lead to arrhythmias, myocardial ischemia, and a decrease of left ventricular function that can result in regional or systemic ischemia, potent systemic inflammatory response, and circulatory shock [13]. Up to 20% of organs designated to donation are lost due to improper management of potential DBD donors during the early phases of the ischemic brainstem cell response [2]. Therefore, the creation and maintenance of meticulous protocols, guidelines, and checklists is critical in combating these errors and in helping to increase the number of potential DBD patients and ensure organs remain viable to be successfully transplanted.

One of the most well known approaches for the management of the pathophysiologic response in DBD donors is called the VIP approach. The VIP acronym represents three important key aspects of the management of circulatory shock: ventilation, infusion, pumping and pressure (Figure 4) [13].

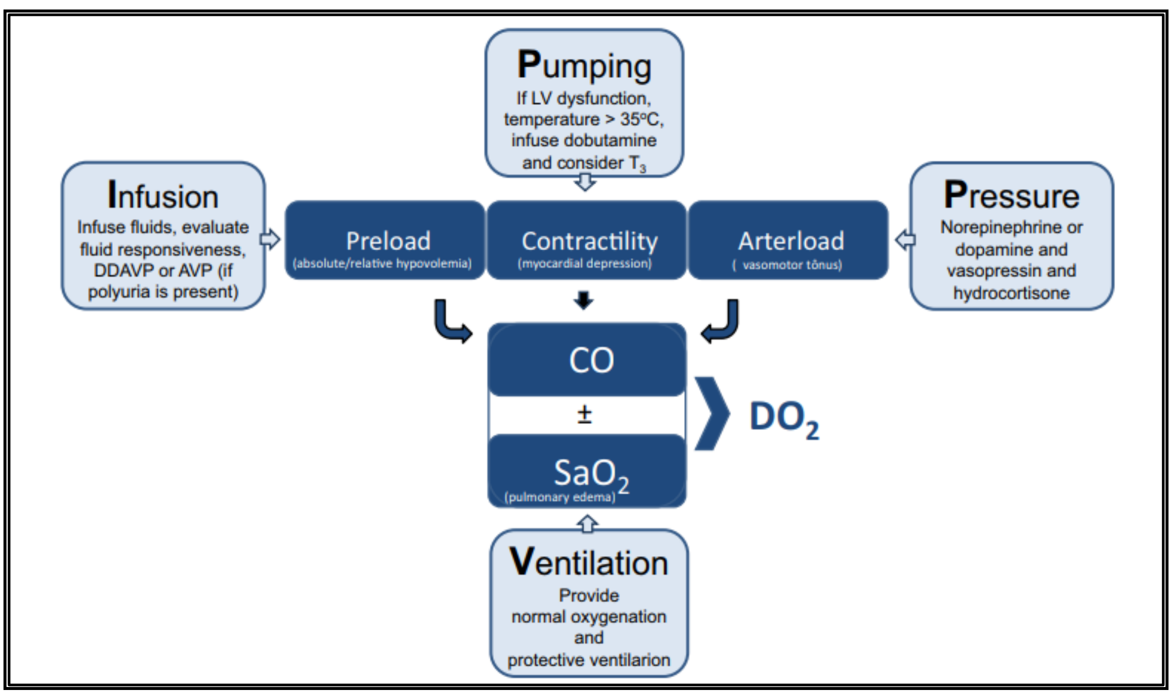


Figure 4: Summary of the VIP Approach [13]. The VIP approach is a mnemonic acronym that summarizes the key aspects of patient management during autonomic storm after brain death.

The VIP approach is a goal-directed protocol used to increase the number of donated organs and to reduce the risk of cardiac arrests or hypo-perfusion periods in potential brain death donors (Table 2) [13].

Table 2: Description of VIP Approach [13]. A detailed description of VIP approach used to reduce the risk of cardiac arrests and hypo-perfusion periods in the potential brain death donors.

Ventilation	Providing normal oxygenation and protective ventilation is crucial in order to maintain adequate arterial oxygen saturation as well as an adequate oxygen delivery (DO_2). The goal is to reduce the risk of hypoxia during adrenergic hyperactivity, which can lead to deprivation of oxygen throughout the body or in a particular region.
Infusion	The infusion of fluids and drugs is critical in maintaining adequate body hydration, preload, contractility, afterload, and improving graft outcome. The donor's blood pressure should be maintained in a sufficient range through the infusion of norepinephrine, or vasopressin. In addition, a randomized trial showed that a low dose dopamine infusion can also improve graft survival.
Pumping	Maintaining adequate cardiac output throughout the donation process is crucial in order to provide sufficient organ perfusion and increase the chances of success of the organ donation. If the left ventricle function starts to decrease subsequent to the autonomic storm, physicians should begin the infusion of dobutamine or evaluate the use of mechanical circulatory support.

Maintaining adequate tissue and organ perfusion during the dynamic phases of organ donation in a patient with devastating brain injuries is essential to ensure a successful graft outcome. The use of the simple VIP acronym helps many healthcare professionals to maintain sufficient oxygen delivery during the long organ donation process, which can vary from 12 to 24 hours [13]. In some circumstances, the use of circulatory support devices can reduce the risk of tissue and organ ischemia and the use of inotropic substances that can cause a decrease in regional blood flow. The use of extracorporeal circulation provides circulatory and ventilatory support, and it also allows for organ recovery after adrenergic hyperactivity as it reduces the use of vasoconstrictors that can decrease regional blood flow and increase peripheral resistances.

The aforementioned treatments begin during the diagnosis of brain death and declaration period until the time of organ harvest. Overall, the entire team of involved healthcare professionals plays a central role in the optimization of organ perfusion and in reducing the possible risk of losing the ability to successfully transplant the organ. This type of treatment is also called High Quality Donor Treatment (HQDT), and leads to a complete heart recovery after autonomic storm, thus making the heart viable for a transplant (Figure 5) [13].

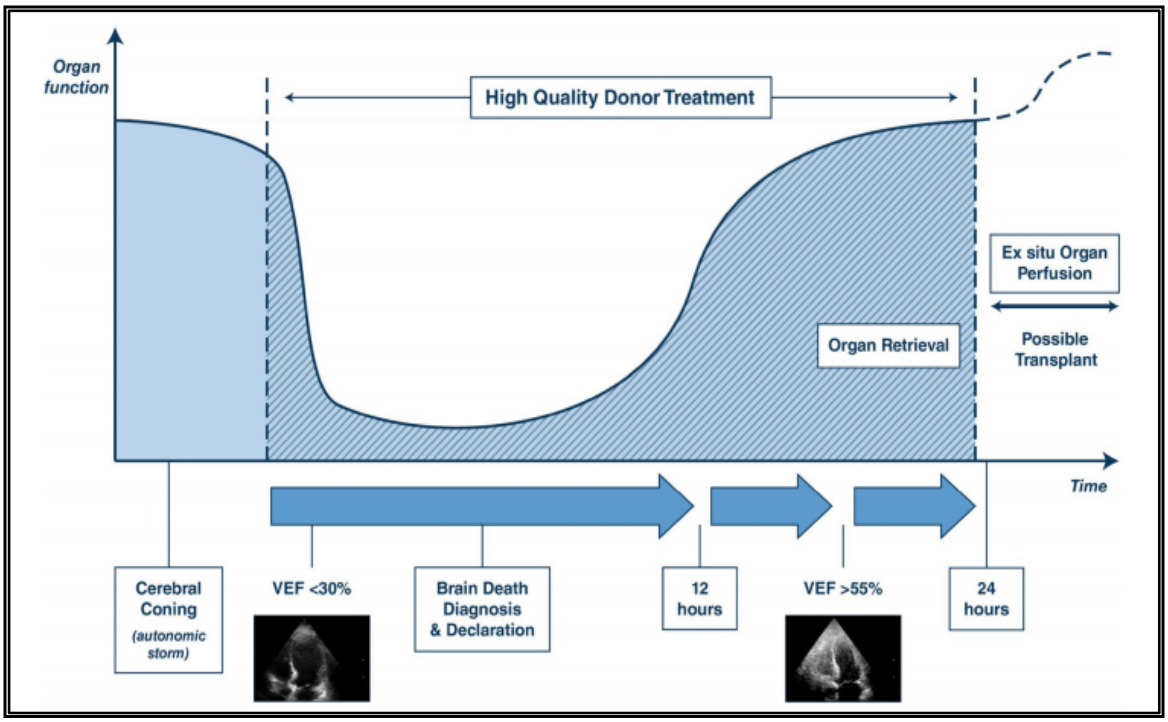


Figure 5: High Quality Donor Treatment [13]. Time-related heart dysfunction caused by autonomic storm, and its recovery during the HQDT treatment.

Perfusionists frequently play a crucial role during the HQDT phase via the use of extracorporeal circulation. Because HQDT ends with organ retrieval, there is also the possibility that perfusionists will also be involved in perfusion of the organ after procurement, or *ex situ* organ perfusion. It is important to note that circulatory support can be initiated before the patient is declared dead because the use of extracorporeal circulation does not break any dead donor rules (DDR) and overall does not affect or accelerate the diagnosis of brain death [14]. In addition, extracorporeal circulation significantly reduces the use of catecholamines that are necessary in order to maintain adequate blood pressure and heart ejection but can lead to regional hypoperfusion and decrease of heart function [15].

One of the most important goals in DBD management is to preserve and improve cardiac function as much as possible during the diagnosis of brain death, especially given the fact that heart donation and therefore procurement can only occur in DBD cases [13]. Another important aspect that should be taken into consideration during the use of extracorporeal circulation in DBD donors is the possibility to employ lung-protective ventilation strategies, which reduce the risk of ventilator-induced lung injuries such as barotrauma, atelectrauma, and biotrauma [13]. On the other hand, there are many limitations to be aware of during the use of extracorporeal circulation before or during the declaration of death. One such limitation is in regard to potential DBD donors in areas of the world in which local legislation does not accommodate for common brain death criteria, or when a patient does not meet locally defined neurological conditions needed to diagnose brain death. In this scenario, the use of extracorporeal circulation would be considered inappropriate and would significantly prolong the patient's length-of-stay (LOS), thus increasing the healthcare costs and creating false hope in regard to the patient's possible recovery. While often complex and surrounded by political and religious stigmas, DBD donation is the primary source of organs procured for transplantation, and each year allows for thousands of individuals in need to receive a second chance at living a healthy life [2].

2.2.4 *Donation after Cardiac Death (DCD) Donors*

The 2017 Annual Data Report of the U.S. Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR) reported that 81.7% of the 10, 286 transplanted organs are derived from DBD patients, while the remaining donors were DCD patients [2]. Even though donation after cardiac death is not a new concept, the fraction of transplanted organs from this group is still small. Recall that donation after cardiac death (DCD) differs from donation after brain death (DBD) as it provides options for transplant even if the patient still shows minimal brain function; however, consent can only be obtained once life support has been withdrawn [13]. In DCD cases, the patient must cease to have a measurable heartbeat prior to being eligible to donate organs, and most protocols suggest this must occur within 60 minutes of withdrawal of life supporting measures [16].

Similar, to DBD, there are also various protocols and classifications to aid clinicians during DCD cases [11]. The first widely accepted classification for DCD, also known as the Maastricht Classification, was developed during the first International Workshop on Nonheart-Beating donors in 1995 held in Maastricht, Netherlands [10, 16]. The first Maastricht classification contained four major categories, and also introduced several new concepts based on the circumstances of the cardiac arrest (CA), such as uncontrolled DCD (uDCD) or controlled DCD (cDCD) (Table 3) [10, 16].

Table 3: The 1st Maastricht Classification and its Categories of DCD [11]. CA = Cardiac Arrest, and CPR = Cardiopulmonary Resuscitation.

Uncontrolled DCD	
I. Dead on arrival	Includes victims of a sudden death, whether traumatic or not, occurring out of the hospital and who, for obvious reasons, have not been resuscitated.
II. Unsuccessful resuscitation	Includes patients who have a CA and in whom CPR has been applied and was unsuccessful.
Controlled DCD	
III. Awaiting cardiac arrest	Includes patients in whom withdrawal of life-sustaining therapies is applied, as agreed on within the healthcare team and with the relatives or representatives of the patient.
IV. Cardiac arrest while brain-dead	Includes patients who have CA in the process of the determination of death by neurologic criteria or after such determination has been performed but before the transfer to the operating theater. It is likely the restoration of cardiac activity is first attempted, with a switch to the protocol of donation after circulatory death, if it fails.

The uDCD category contains two minor classes, the first one includes all the patients that arrive dead at the hospital, and the second class includes all the patients where CPR was unsuccessful. The cDCD category also contains two classes. The first one includes all the patients where the physicians are waiting cardiac arrest and the second includes all the patients that have a cardiac arrest while they are brain dead [11].

During recent years, the original Maastricht classification was revised several times resulting in an expanded and modified classification released in 2013 [11]. The second version of the classification preserves the skeleton of the original, but also provides more details describing the various types of DCD and adds a new fifth category that outlines patients that request a medically assisted circulatory death, also known as euthanasia (Table 4) [10, 16].

Table 4: The Modified Maastricht Classification of DCD [17]. CA = Cardiac Arrest, and CPR = Cardiopulmonary Resuscitation.

Uncontrolled DCD	
I. Dead on arrival	Includes victims of a sudden death, whether traumatic or not, occurring out of the hospital and who, for obvious reasons, have not been resuscitated.
II. Unsuccessful resuscitation	Includes patients who have a CA and in whom CPR has been applied and was unsuccessful. CA occurs out of or in the hospital, being attended by healthcare personnel with immediate initiation of CPR.
Controlled DCD	
III. Awaiting cardiac arrest	Includes patients in whom withdrawal of life-sustaining therapies is applied, as agreed on within the healthcare team and wit the relatives or representatives of the patient.
IV. Cardiac arrest while brain - dead	Includes patients who have CA during a DBD procedure.
V. Euthanasia	Includes patients who grant access to medically assisted circulatory death.

The modified Maastricht classification also continued to build upon its further classifications of uDCD and cDCD pathways to donation. The uDCD classification is further divided into two different categories: category I which includes victims of sudden death that have not been resuscitated, and category II which includes patients who have a CA in which CPR was unsuccessful [11]. In addition, it is useful to explore the uDCD process which includes four major steps: the asystole period, also called warm ischemia time (WIT), in which there is no circulatory support; the resuscitation period, in which there is a low flow; and the no-touch period, where the physician declares the patient's death; and finally the organ preservation period (Figure 6) [17].

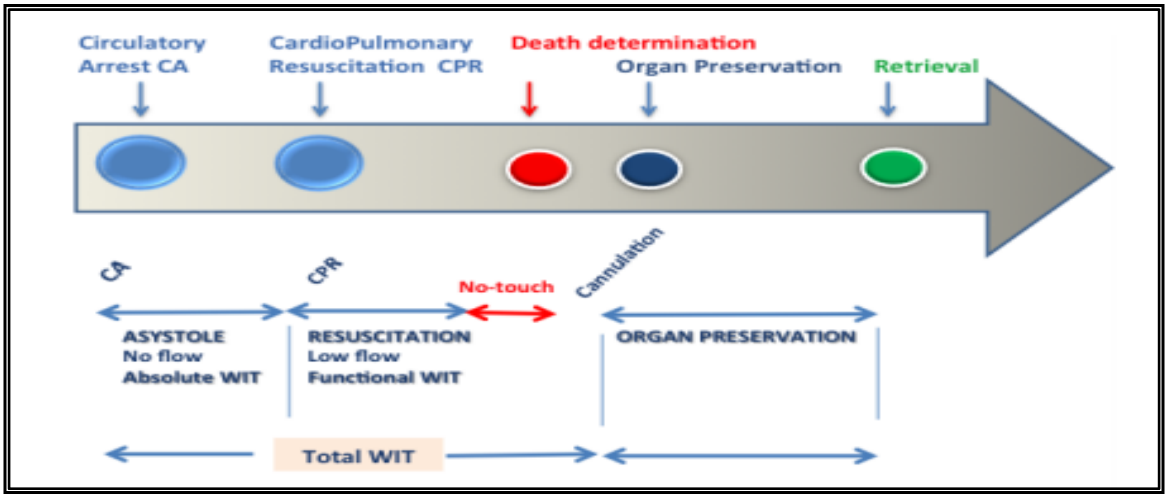


Figure 6: Uncontrolled DCD Process [17]. WIT = Warm Ischemia Time.

Generally, the uDCD process can either occur in or outside of the hospital due to unexpected or emergent cardiac arrest. After it is determined that resuscitation of the patient will not be successful, clinicians switch gears to focus on preserving organs for donation. Upon the declaration of death, which occurs after resuscitation attempts are terminated, there is a subsequent "no touch" period [17]. This period is the period of time between the declaration of death and from when organ preservation may begin. Once the "no touch" period has concluded, attempts to preserve organs using extracorporeal perfusion or *in situ* cooling can be started [7].

The cDCD classification is further divided into three different categories: category III, which includes all patients in which withdrawal of life-sustaining therapies are applied; category IV, which includes all the potential DBD donors who have had a cardiac arrest; and category V, which includes all who have requested medical assisted circulatory death, also known as euthanasia [17]. The cDCD process only includes three steps, the first being the withdrawal phase, also called the agonal phase, the second step is the no-touch period, and the process ends with the organ preservation phase (Figure 7) [17].

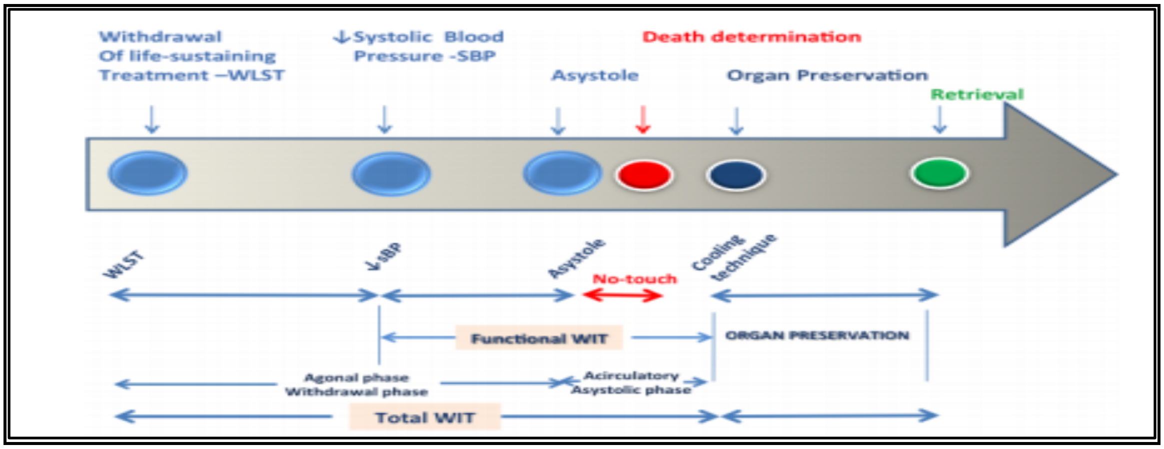


Figure 7: Controlled DCD Process [17].

The cDCD process starts when physicians withdraw life-sustaining treatments, at which time cardiac arrest generally follows shortly after. No resuscitation maneuvers are performed after CA and the no-touch period starts immediately following CA. Generally, the WIT in cDCD cases is shorter than that of uDCD cases, which typically results in better organ function following the transplant [18].

Beyond provided expanded classifications and detail to aid clinicians during complex transplantation processes, the introduction of the second version of the Maastricht classification also attempted to resolve the non-medical ethical, psychological, and legal issues related to cadaver donation [17].

Despite the important advancements made in recent years in DCD donation, there are still some notable limitations that are frequently dependent on local medical societies and authorities. Accepted protocols vary around the world, and one example of this is the variation in the length of the no-touch period in CA cases with unsuccessful resuscitation [17]. The no-touch period is the estimated time after the absence of circulation when brain function is irreversibility and deeply compromised [19]. It occurs between the unsuccessful cardiopulmonary resuscitation (CPR) or the declaration of death and the organ preservation phase. No-touch periods vary around the world depending on the local jurisdiction and range from 2 minutes in the United States to 20 minutes in Italy. Despite the wide range, in most countries a no-touch period of 5 minutes is widely accepted by hospitals and decision-making authorities [17].

The no-touch period is critical from both a clinical and ethical standpoint. Clinically, the general rule of thumb is the longer the duration of the no-touch period, the longer the WIT and worse the organ transplant outcome [20]. Ethically speaking, a longer no-touch period generally results in less opposition and a higher sense of assurance that organs were procured from a patient that was truly dead [19]. Perfusionists play a crucial role across the world during the various phases of both uDCD and cDCD donation. The use of extracorporeal circulation helps to maintain adequate tissue perfusion after the no-touch period and during the organ preservation phase, thus reducing the risk of systemic or regional tissue ischemia and significantly improving the transplant outcome [14, 20].

The OPTN/SRTR 2017 Annual Data Report showed that 18.3% of organs are derived from DCD patients, representing an increase of 8.5% over the last 10 years [2]. There are many contributing factors in the notable increase in DCD donation, including the development of new organ retrieval processes, better transplant outcomes, and overall better organ perfusion strategies after the declaration of death [3]. While it remains the less common donation pathway, a recent meta-analysis evaluated one-year patient survival rates comparing patients that received a liver from a DBD donor without the use of circulatory support, to a DCD donation with the use of extracorporeal circulation [21]. The analysis discovered that there were no significant differences between the two groups, and that the most important factor that led to graft failure was a warm ischemia time longer than 45 minutes during CPR in DCD patients [21]. In addition, a retrospective cohort study compared the survival rate of transplanted kidneys in the three major donor categories: DBD, uDCD, and category III cDCD [21]. The study concluded that there were no differences among the three, suggesting that all organs procured using all three methods should be considered viable and able to provide valid long-term graft outcomes in patient recipients [21]. Therefore, despite the notable differences between the DBD and DCD donation pathways, research continues to show that both methods can result in successful transplants.

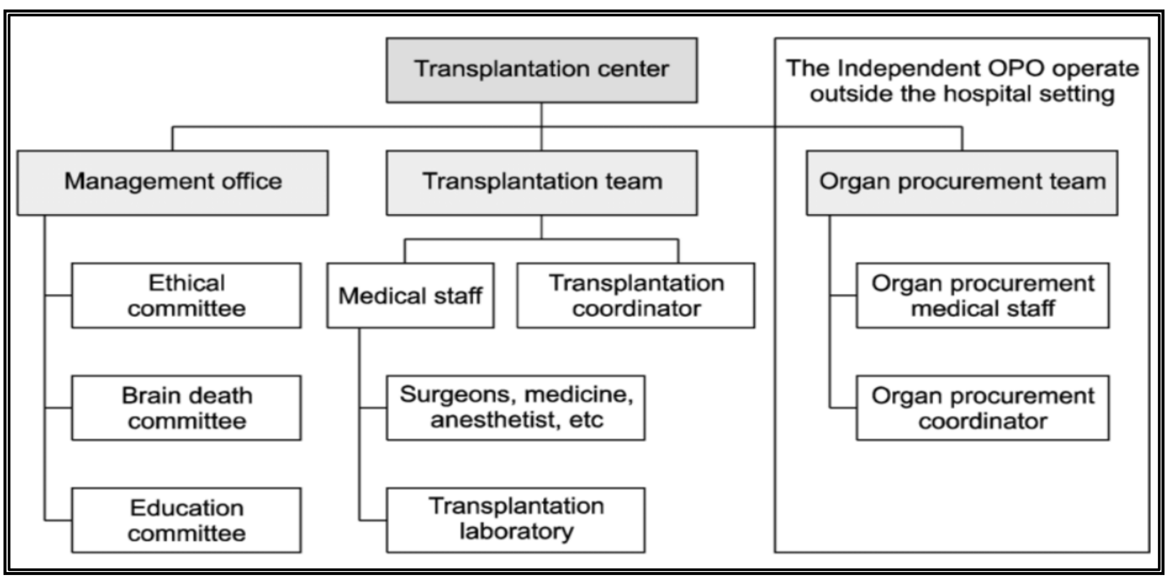
2.3 Organ Procurement, Allocation, and Preservation

2.3.1 *Organ Procurement*

The organ donation process has continued to improve throughout the last several decades due to the dedication of many healthcare professionals and the involvement of governmental and non-profit organizations. Creation and development of new protocols, checklists, and guidelines have improved the organ procurement phase of the donation process, specifically facilitating the passage of deceased donors from the ICU to a regional organ procurement organization (OPO) team [13]. OPOs are defined as non-profit organizations that evaluate and procure organs from deceased donors, and the 58 OPOs throughout the United States each have a specific region for which they are responsible [4]. By law, all OPOs must be members of OPTN and also recognized by UNOS [8]. Additionally, they must have direct contact with hospitals within the region they represent and with the family of the recently deceased donor. The OPO staff collaborates with UNOS to identify the best recipient for the available organs, and coordinates both the harvest and transplant surgical teams [4]. Other responsibilities include determination of organ suitability for transplant, obtain consent from the family for non-registered donors, and management of clinical care and organ recovery [4].

Generally, OPOs are not affiliated with hospitals and are considered independent, which allows them to serve various acute care centers, transplant hospitals, as well as provide a well-equipped and complete organ procurement team, organ procurement medical staff, and organ procurement coordinator (Table 5) [4].

Table 5: Organizational Structure of an Independent OPO [4].



The donation and transplant process is much like a complex machine, and involves many healthcare professionals and administrative staff from various organizations in order to function properly. The success of the procurement process is strictly correlated with organ allocation and distribution phases of transplantation [22]. Even when an organ is perfectly procured from a donor, the sophisticated algorithms and distribution models that are responsible for creating optimal organs-candidates matches can result in overall transplantation failure during organ allocation.

2.3.2 *Organ Allocation*

Thousands of successfully procured organs are discarded each year, and a significant portion of these are discarded due to issues in organ allocation, specifically organs that are missing a designated recipient once procured [2]. The United Network for Organ Sharing (UNOS) matches lifesaving organs from registered donors to recipients following matching criteria that were developed from the transplant community and then approved by UNOS [22]. The matching system considers only medical and logistical factors, while the UNOS matches people on the waiting list with donors by considering additional factors including blood type, body size, severity of patient condition, distance from donor and recipient, tissue type, and total time on the donor list. In addition, there are many other factors in organ allocation that are unique to each organ type (Figure 8) [22].

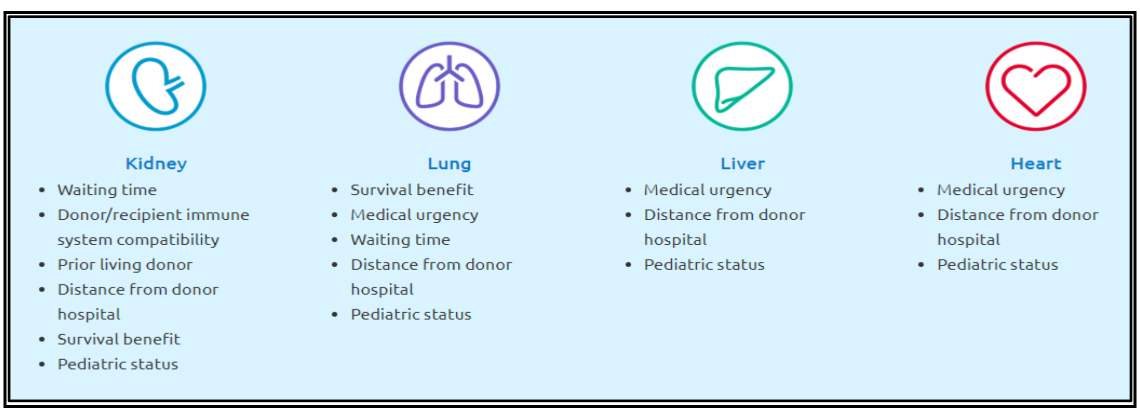


Figure 8: Overview of the Primary and Unique Organ Allocation Factors that Must be Taken into Consideration for Each Respective Organ [22].

In order to create a successful match, both donor and candidate information are necessary and must be thoroughly evaluated. This also allows for the creation of a ranked-order list to categorize candidates based on medical urgency and best chance of survival [22]. The UNOS computerized system is able to perform thousands of donor and candidate information matches in minutes; however, UNOS must also consider ischemia time between the time of procurement and transplantation before giving permission for the transplant [22]. In addition, in 2018 OPTN and UNOS proposed three new frameworks in order to optimize organ distribution for a specific organ in a specific area. The three proposed frameworks are outlined in Table 6 [22].

Table 6: OPTN/UNOS Proposed Frameworks [22].

Fixed Distance from Donor Hospital	Optimization framework that creates defined geographic areas based on the distance between the donor's hospital and that of the recipient candidate. This framework can widen distribution areas in medical emergencies, although local matches often take precedence.
Mathematically Optimized Boundaries	Use of mathematics to define and optimize boundaries of organ distribution. A statistical formula is used to identify best distribution outcomes dependent on the given goals, for example that of having an equal ratio of recipients to donors within a given area.
Continuous Distribution	Use of a statistical formula that takes clinical factors into consideration, such as medical urgency and likelihood of success, as well as distance to the donor hospital. In this framework potential recipients are given a distribution score that determines who is chosen to receive an organ, and there are no fixed geographical boundaries.

In the beginning of 2019, OPTN and UNOS approved the continuous distribution model as a framework for future policy development for organ distribution in the United States [4]. Therefore, the continuous distribution model will replace the fixed geographic boundaries model that has been in use for more than 20 years [22]. Using the new model, each candidate will receive a relative score based on biological match, medical urgency, and proximity to the donor location hospital. The combination of these three factors will identify the best candidate for a specific donated organ without any fixed boundaries between donor hospital and transplant hospital (Figure 9) [22].

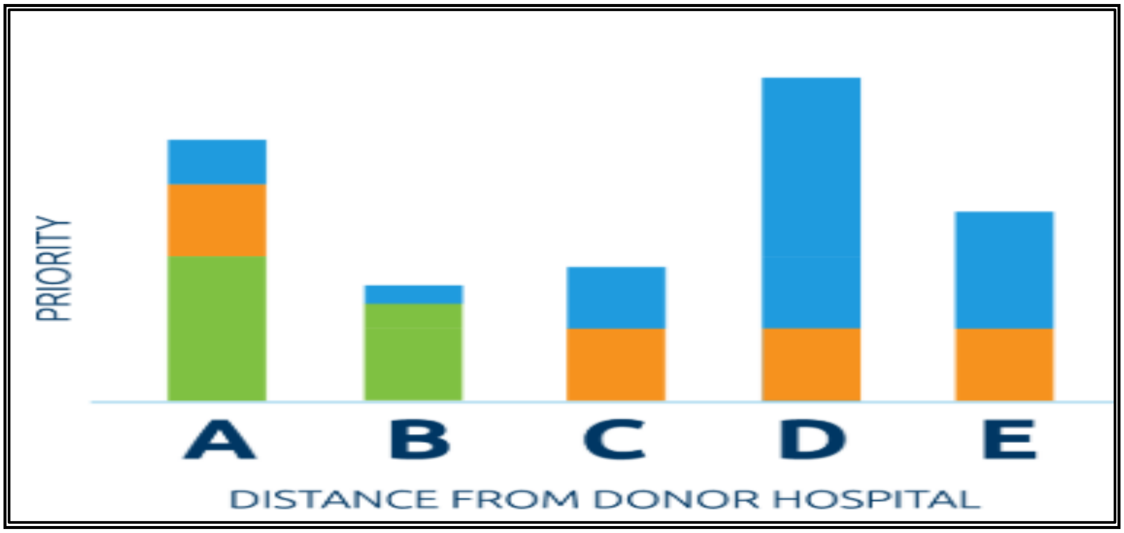


Figure 9: Continuous Organ Distribution Example [22]. A candidate at hospital D would appear first on the match even though he or she did not receive any proximity points (green area), but ranks strongly based on medical urgency (blue area) and biologic compatibility (green area).

With the development of the Continuous Distribution Model, OPTN and UNOS committees tried to solve the issues and restrictions of organ allocation caused by the previous system, specifically those based on the possibility to allocate an organ only within a specified area or fixed boundary. Improved organ preservation techniques now allow more time for geographic travel [4].

2.3.3 *Organ Preservation*

As outlined during the organ allocation phase, the distance between donor and transplant hospitals plays a crucial role in the transplant process. The organ preservation technique and type of organ transport are the two most critical factors in ensuring a successful organ transplant outcome. In order to deliver organs of high quality, healthcare professionals have developed specific organ preservation protocols that reduce the risk of developing a hypoxic injury and the associated risk of developing ischemia, as well as reperfusion injuries, in donated organs [22, 23]. Currently, there are two approaches for the preservation for transplantable organs: static and dynamic [23]. The static approach consists of perfusing the harvested organ using a cold preservation solution and topical cooling systems (i.e., ice or a cold saline solution) that reduce cellular metabolism and oxygen demand [24]. The dynamic approach includes two systems: hypothermic machine perfusion (HMP) and normothermic machine perfusion (NMP) [23]. The dynamic system not only preserves organs and extends preservation time, but it also assesses organ function and viability throughout the entire process [23].

Today, the cooling approach is frequently called simple static cold storage (SCS) and is the most common strategy used by harvest and transplant teams. The popularity of SCS is due to its low cost and ease of use, and it allows clinicians to keep organs viable from procurement to transplantation and for up to several hours depending on the organ that is harvested (Figure 10) [4].

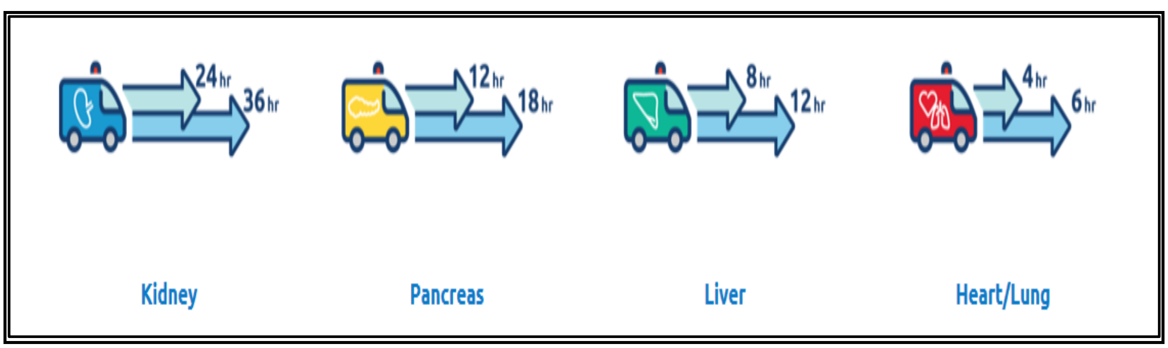


Figure 10: Common Maximum Organ Preservation Times [4]. The upper arrow represents the maximum length of time for successful organ transplant using the hypothermic static crystalloid system, and the lower arrow represents the maximum length of time for successful organ transplant using the hypothermic dynamic system.

Continual improvement in preservation strategies is crucial for reducing discarded organs. The practice of SCS, for example, can lead to an organ placed in ice for too long, which can lead to poor overall function or eventual discarding of the organ [24]. The newer dynamic systems increase preservation time and reduces risk of organ injury and provides a viable strategy for today's clinicians to ensure organs successfully pass through the final phase of transplantation [23]. However, there is always room for improvement, and it will be exciting to follow future clinical studies, which are currently working to determine a method to use the system to convert a discarded organ with poor organ function into a recovered and transplantable organ.

2.4 Project Goals

Despite the introduction of new technologies and organ distribution models, there is still a continuous organ shortage that results in thousands of deaths each year. The purpose of this project was to craft a potential implementation plan for a Deceased Organ Donation Program in Southeast Wisconsin as a means to increase the number of organs available for transplant. To this end, the project focused on identifying possible deficiencies that are the root cause of the organ shortage crisis in Wisconsin. Second, it identified the possible strategies that could eliminate the causes of the organ shortage crisis. Finally, it detailed an implementation plan that would increase the number of organs available for transplantation in the state of Wisconsin.

3.0 Methods

The steps in Table 7 were followed as a means to identify the scope of the Wisconsin transplant organ shortage and to develop recommendations for an improved, organ procurement system.

Table 7: Processes Utilized to Develop an Implementation Plan of an Organ Procurement System. Brief description of the steps followed in order to identify possible deficiencies within the organ shortage crisis in Wisconsin and the resources that can result useful for the implementation of an organ procurement system.

Step 1	Data review of the OPTN/SRTR 2017 Annual Data Report to determine the state of deceased organ donation in the U.S and in Wisconsin.
Step 2	Data review of the OPTN/SRTR 2017 Annual Data Report to determine the various reasons that led to harvested organs being discarded.
Step 3	Data review of the 2017 Annual Wisconsin Death Report to determine all deaths that occurred among Wisconsin residents in 2017 and to make useful comparisons with national data.
Step 4	Estimation of the number of potential organ donors in Wisconsin.
Step 5	Identification of the most significant organ donor programs, OPOs, and transplant programs in Wisconsin. Identification of all hospitals with a perfusion service, and all hospitals without a perfusion service but with an intensive care unit.
Step 6	Creation of a multi-center system model: 1. Identification of hub hospitals 2. Identification of spoke hospitals 3. Identification of radius of action

Many of the steps outlined in Table 7 were based upon the analysis of data published by the Department of Health and Human Services, which maintains precise records in regard to United States organ transplantation. Since 1987, the OPTN has maintained and collected data on all waitlist registrants and transplant recipients, including both living and deceased donors. They use a separate form, and data are collected differently, for each organ involved. Data are also divided amongst adult and pediatric patients. Additionally, the form for data collection also varies depending on whether the donor is living or deceased. The Deceased Donor Registration (DDR) is submitted by the respective OPO, while the Living Donor Registration (LDR) paperwork is procured by the patient's hospital [2]. At the time of donation, information such as general demographics, diseases, infections, comorbidities, and either the cause of death or post-operative information is collected depending upon the type of donation.

Another important source of data used was the global observatory of donation and transplantation register (GODT). The GODT is the most comprehensive source of worldwide data within the field of organ transplantation and donation and includes data intelligence from verified official sources and information on legal and organizational components of transplantation [25]. All data taken into consideration and forming the basis of this project were derived from the most recent resources available and used 2017 as the reference period.

3.1 Review of *OPTN/SRTR 2017 Annual Data Report*: Deceased Organ Donation

In order to calculate metrics including donation rate, rate of organs recovered for transplant but not transplanted, and organ yield, the SRTR uses data collected by the OPTN to generate its annual data report. These metrics are further broken down and provide counts of deceased donors, including both DBD and DCD donors [2].

By thoroughly reviewing the OPTN/SRTR 2017 Annual Data Report*,* it was also possible to analyze the various reasons that led to organs being discarded, either in situations in which the organ was recovered for transplant, and also in cases in which the organ was not recovered. In instances in which an organ was recovered for transplant but not transplanted, the report identified three major causes of this occurrence including poor organ function, too long of a WIT, or the organ being “too old on ice”. In the scenario in which the organ was not recovered for transplant but discarded, leading causes included time constraints, poor organ function, a patient ejection fraction lower than 50%, unstable patient hemodynamics during the donor procedure, and PO2 < 200 mmHg in lung donations.

3.2 Review of the *Annual Wisconsin Death Report, 2017*

The Department of Health Services requires the state of Wisconsin to prepare annual reporting on vital statistics, thus resulting in the *Annual Wisconsin Death Report.* The State Vital Records Office collects the information included in this report along with technical notes. The report presents information regarding all deaths that occurred among Wisconsin residents in the given year, and also further categorizes deaths by common demographic characteristics such as age or rate. Furthermore, data are also provided on the location in which the death occurred and the deceased’s legal residence [26].

The 2017 Annual Wisconsin Death Report provides detailed insights into the top three causes of death within the year, also making useful comparisons with national data. In addition, it contains a chapter that reports upon deaths caused by drug overdoses divided in three major causes: illicit drugs, prescription drugs, and other drugs. One of the most significant challenges of a donation program is to estimate the potential number of deceased organ donors in order to develop specific strategies to increase the total amount of organs donated each year [26, 27]. Using datasets from the National Center of Health Statistics (NCHS) and a specific filtering strategy provided by the OPTN, it was possible to estimate the potential number of deceased organ donors in Wisconsin [28].

3.3 Data Comparison

3.3.1 *Data Comparisons Between the Global Database on Donation and Transplantation and The Top 10 Donation Programs in the U.S.*

Data comparison was performed considering the annual donation activities of the ten most advanced countries in the world and their databases on organ donation and transplantation. The primary data source was derived from the collaboration between the World Health Organization (WHO) and the Spanish Transplant Organization, Organización Nacional de Trasplantes (ONT), in a joint initiative in the collection of global data. This collaborative database is also known as the joint ONT-WHO Global Observatory on Donation and Transplantation [29]. Two main classes of data were considered: actual deceased organ donors and utilized deceased organ donors. Each of these classes includes two minor categories, which were analyzed and compared in this thesis.

Additionally, data comparison was performed through an analysis of the information provided by the OPTN/SRTR in the 2017 Annual Data Report. The analysis considered the ten best donation programs in the U.S., specifically considering the ratio between the total deceased organ donors in 2017 against the respective state's population [30].

3.4 Transplant Program Comparisons

Comparisons were made among transplant programs in the state of Wisconsin to uncover transplant statistics in the year 2017 as well as the donor types the transplants were derived from. Data found within the SRTR databases are mainly collected by the

OPTN and are also provided by OPOs and histocompatibility laboratories [31]. The database contains useful insight regarding transplant waiting lists, the donor and recipient matching process, as well as donor type and transplant recipients. Overall, this database outlines the organ shortage and crisis on a national and state level and can be used as a baseline for the implementation of a deceased organ donor program.

3.5 Multicenter System Model

During the last several decades, the healthcare industry has started to utilize complex organizational models and optimization modeling in order to confront crises and improve and optimize medical support and resources [32]. Interestingly, optimization modeling was first introduced in the 1970s in maritime emergencies and disasters and has now branched into other parallel fields such as the airline industry, transport market, and in this example within the healthcare field. Using these tools to review Wisconsin's major organ donation programs would provide a thorough analysis of the location and structure of transplant centers, as well as available resources [31].

In order to develop a hub-and-spoke model for organ donation, principal hubs were identified based on specific characteristics such as the presence of adequate resources with the ability to support the spoke hospitals, as well as extensive experience in donation and transplantation processes [33]. The second step of the hub-and-spoke model was to identify all hospitals within the region that have a valid organ donation program, as well as all hospitals that have an intensive care unit and sophisticated life support machines and intensive monitoring capable of managing DBD and DCD donors [33]. The third step in the creation of a hub-and-spoke model was to map a radius of action that represents the total area involved in the model. The radius of action depends on many factors including type of deceased donor, distance between hub and spoke hospitals, and type of transport [33].

4.0 Results

4.1 Deceased Organ Donations

4.1.1 *Deceased Donor Recovered in the U.S.*

The U.S. Department of Health & Human Services (HHS) annually publishes data collected by OPTN to describe the relationship between deaths, donations, and transplants performed in the United States and in each individual state. One of the purposes of this report was to establish a relationship between potential donors, types of potential donors, donors, and total transplants. Between 2006 and 2017 there was a continuous increase in donors both living donors and deceased donors, and the total amount of deceased donors in 2017 was 10,286, of which 8,403 were DBDs and 1,883 were DCDs (Figure 11) [2].

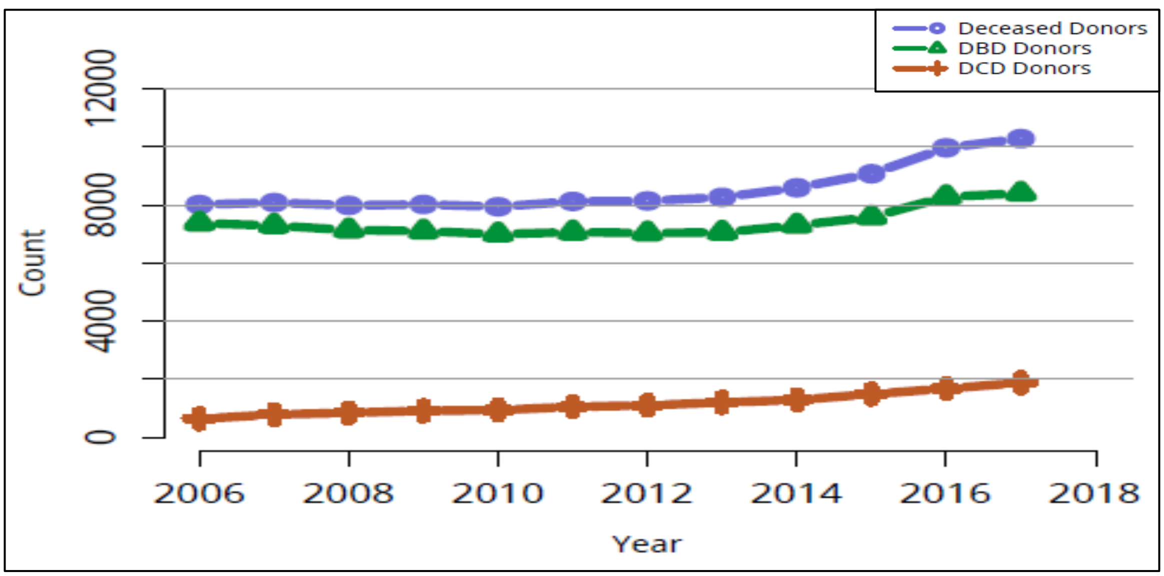


Figure 11: Overall Counts of Deceased Donors, DBD and DCD Donors, 2006-2017 [2].

The number of organs authorized for recovery from deceased donors continued to increase to 73,660 in 2017, and the number of organs recovered for transplants and total transplanted organs increased to 29,435 in 2017 as well (Figure 12) [2]. Potential reasons for the growth in organs authorized for recovery, donors, and the number of deceased donor transplants include the rising number of deaths in young individuals due to the opioid epidemic, and an increased use of organs deriving from DBD donors.

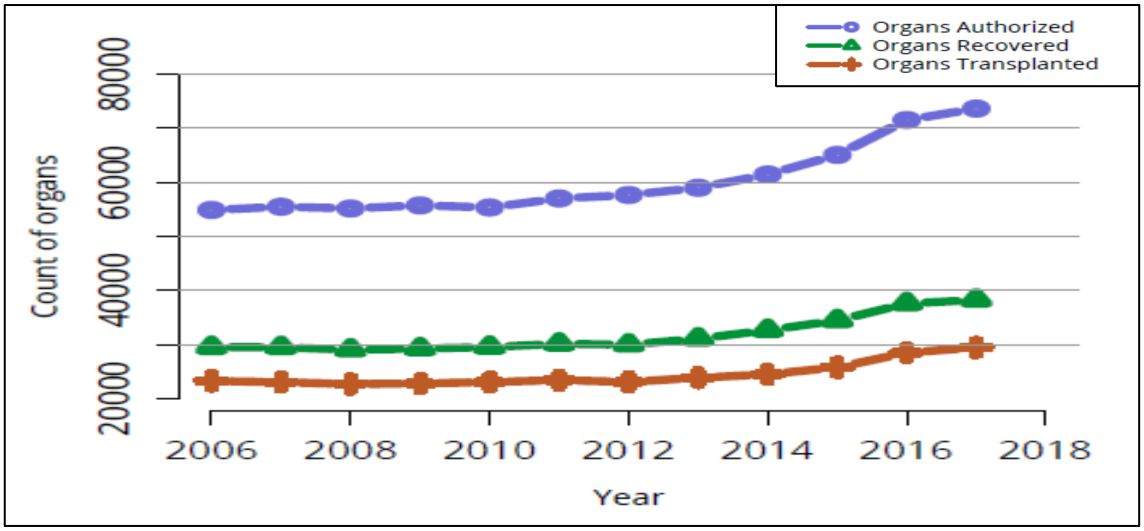


Figure 12: Overall Counts of Authorized, Recovered and Transplanted Organs, 2006-2017 [2].

4.1.2 *Disposition of Organs*

Every year, the HHS publishes a summary of the total number of donors for each organ, the total amount of organs recovered for transplant but not transplanted, and the total number of organs that were not recovered (Table 8) [2].

Table 8: Overview of Donated Organs in 2017 [2]. A summary of the donors, recovered donor for transplant but not transplanted, and the organ not recovered in 2017.

Organ	Donors	Recovered for Transplant but not transplanted	Organs not Recovered
Heart	10,286	33 (0.3%)	5,304 (51.6%)
Lungs	10,286	101 (1.1%)	6,364 (61.9%)
Kidneys	9,824	1,629 (16%)	755 (7.7%)
Liver	10,286	743 (7.2%)	1,458 (14.2%)

In addition, the HHS describes the reasoning behind why an organ was recovered for transplant but not transplanted, and the reasons why the OPO did not recover an organ despite receiving consent for the donation [2]. In regard to organs recovered but not transplanted, the causes and aspects that must be carefully investigated in order to implement a deceased organ donor program include organs that are too old on ice, those with poor function, and cases in which the warm ischemia time is too long (Table 9) [2].

Table 9: 2017 Organs Recovered for Transplant but Not Transplanted [2]. A summary of the main categories under investigation of the organs recovered for transplant but not transplanted in the U.S.

Organs Recovered for Transplant but Not Transplanted			
	Too old on ice	Poor organ function	Warm ischemia time too long
Heart	1	7	0
Lungs	1	44	1
Kidneys	40	195	19
Liver	20	34	66

On the other hand, when organs are not recovered at all, it is critical to investigate factors such as time constraints, poor organ function, an ejection fraction (EF) of less than 50%, hemodynamically unstable donors, and cases in which PO2 < 200 mmHg (Table 10) [2].

Table 10: 2017 Organs Not Recovered [2]. A summary of the main categories under investigation for organs not recovered in the U.S.

Organs Not Recovered					
	Time constraints	Poor organ function	EF < 50%	Hemodynamically unstable donor	$PO_2 < 200$ mmHg
Heart	85	1,404	250	76	-
Lungs	258	2,285	1	75	562
Kidneys	2	506	0	0	-
Liver	133	164	0	50	-

4.1.3 *Annual Wisconsin Death Report*

The 2017 Annual Wisconsin Death Report was released by the Wisconsin Department of Health Services in May 2019 and indicates that there were 52,679 deaths among Wisconsin residents, representing a 2% increase from the year prior [26]. The three major causes of death in Wisconsin during 2017 were heart disease, accounting for 22% of deaths; cancer, accounting for 21% of deaths; and unintentional injury, accounting for 7% of all deaths. Of the deaths attributed to heart disease, the leading cause was ischemic disease, representing 54.8% of cases; followed by hypertensive heart disease, representing 7.4% of cases; and pulmonary heart disease, representing 3.4% of cases (Table 11) [26].

Table 11: Overview of Deaths Caused by Heart Disease in Wisconsin in 2017 [26]. Number of heart disease deaths and percentage distribution by heart disease type and gender in 2017 in Wisconsin.

Heart disease types	Male	Female	Total deaths
Ischemic heart	4,048	2,513	6,561
Hypertensive heart	393	441	834
Pulmonary heart	154	236	390
Other types	1,846	2,184	4,030
Total	**6,441**	**5,374**	**11,815**

In 2017, the leading causes of unintentional injuries that caused death in Wisconsin were falls, poisoning, motor vehicle crashes, suffocation, drowning, and fire (Table 12) [26].

Table 12: Overview of Unintentional Deaths in 2017 in Wisconsin [26]. Total number of unintentional injury deaths separated by injury type in 2017 in Wisconsin.

Cause of Injury	2017
Fall	1,539
Poisoning	1,092
Motor Vehicle Crash	599
Suffocation	100
Drowning	54
Fire/Flame	44
All Others	279
Total	**3,707**

In addition, the Wisconsin Department of Health Services (DHS) also collected data based on the five major regions of the state, and the annual report provides the total number of deaths in each region divided by the cause of death (Table 13) [26].

Table 13: Overview of Total Deaths by Region in 2017 in Wisconsin [26]. Number of total deaths in 2017 provided by the Wisconsin Department of Health Services (DHS), represented by region and cause of death.

DHS Region	Total Deaths	Heart Disease Deaths	Unintentional Death
Northeastern	11,882 (22.6%)	2,726 (23.1%)	724 (19.5%)
Northern	5,108 (9.7)	1,222 (10.3%)	274 (7.4%)
Southeastern	18,900 (35.9%)	4,245 (35,9%)	1,520 (41%)
Southern	9,446 (17.9%)	2,039 (17.3%)	742 (20%)
Western	7,326 (13.9%)	1,583 (13.4%)	447 (12%)
Total Deaths	**52,769 (100%)**	**11,815 (100%)**	**3,707 (100%)**

It is important to note that deaths attributed to drug overdose are included in the overall counts for unintentional deaths and form a specific subcategory of this group. Most of overdoses not intentional, and only approximately 12% of overdose deaths are thought to be self-inflicted or purposely carried out. Notably, in Wisconsin more than half of all drug overdose deaths occur solely within the Southeastern region of the state (Table 14) [26].

Table 14: Overview of Drug Overdose Deaths by Region in 2017 in Wisconsin [26]. Number of total drug overdose deaths by Wisconsin Department of Health Services (DHS) Region in 2017.

DHS Region	Total Deaths
Northeastern	176 (15.1%)
Northern	58 (5.0%)
Southeastern	608 (51.9%)
Southern	227 (19.4%)
Western	102 (8.6%)
Total Deaths	**1,171**

In 2017 alone, deaths caused by drug overdose increased over 14% since 2016 with a total count of 1,171 deaths. Illicit drugs such as heroin and cocaine are the leading cause of drug overdose deaths, causing 568 deaths per year; followed by fentanyl and synthetic opioids, leading to 353 deaths per year; and prescribed drugs such as natural and semi-synthetic opioids, representing 250 deaths per year [26].

4.1.4 *Deceased Donors in Wisconsin*

The OPTN/SRTR reported that in 2017 there were 384 donors in the state of Wisconsin, of which 151 were living donors and 233 were deceased donors [2]. Of the deceased donors, 191 donors were DBD cases and 42 donors were DCD cases. All the deceased donors donated a combined total of 590 organs, while the living donors donated a total of 151 organs (Table 15) [2].

Table 15: Overview of Organs Recovered from Deceased Donors in 2017 in Wisconsin [2]. A summary of the type and number of organs recovered from deceased donors in Wisconsin in 2017.

OPTN/SRTR Deceased Donors Data Report 2017			
Type of Deceased Donor	**Number of Donors**	**Type of Organ Recovered**	**Number of Organs Recovered**
DBD	191	Kidney	169
		Liver	176
		Heart	74
		Lung	56
		Others	40
		Total	**515**
DCD	42	Kidney	40
		Liver	27
		Heart	0
		Lung	2
		Others	6
		Total	**75**

In addition, in 2017 the OPTN/SRTR reported that a total of 112 organs were discarded in Wisconsin alone, including 80 kidneys, 13 livers, and 12 lungs. Unfortunately, the information provided does not indicate the reason that the organs were discarded.

4.2 Estimation of the Number of Potential Organ Donors in Wisconsin

The NCHS–Multiple Cause Mortality database contains records on more than 99% of deaths in the United States. Through a comparison of this database with the data reported in the 2017 Annual Wisconsin Death Report, it is possible to make an initial identification of the potential deceased organ donors and those that are not eligible to be deceased donors. To identify the potential deceased donors, specific data filters are adopted including for an age ≤ 75 years, in-hospital death status, exclusionary diagnostic codes, illness score which includes donor's conditions and donor's LOS, and the percentage of registered Wisconsin donors (Figure 13) [28].

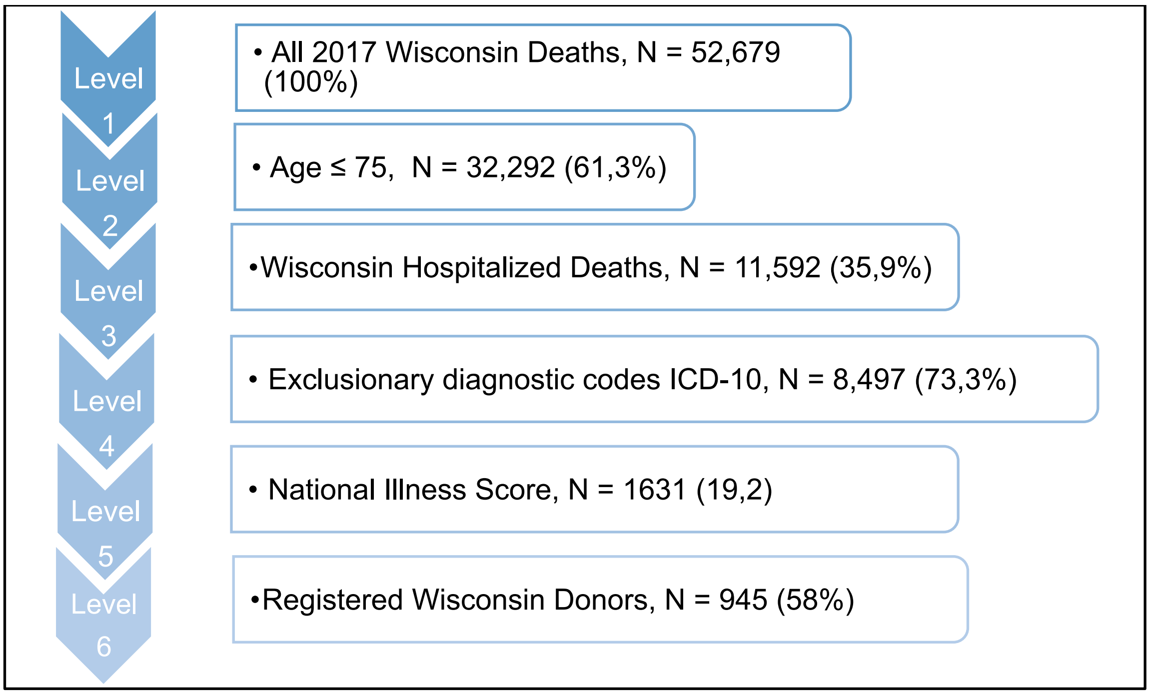


Figure 13: Data Filters Utilized to Estimate Potential Deceased Donors in Wisconsin in 2017 [28].

Based on the 2017 OPTN/SRTR Deceased Donors Data Report, it is possible to estimate the number of potential DBD and DCD donors during that particular year in Wisconsin, which amount to 774 (82%) potential DBD donors and 171 potential DCD donors (18%). Given that there were an estimated 945 potential deceased organ donors in Wisconsin, it is quite alarming to consider that only 233 deceased individuals actually donated.

4.3 Global Observatory on Donation and Transplantation Data

The Global Observatory on Donation and Transplantation (GODT) is the most complete and detailed data source on a worldwide scale in regard to organ donation and transplantation [29]. The GODT represents a joint initiative in the collection of global data as the World Health Organization (WHO) and the Spanish Transplant Organization, Organización Nacional de Trasplantes (ONT) join forces. All data are presented in absolute number and rate per million inhabitants (pmp) [29].

4.3.1 *Deceased Organ Donors throughout the World*

The deceased organ donor category is one of the two major categories that is summarized by the GODT and it includes two minor categories that are the number of DBD donors, and number of DCD donors (Table 16).

Table 16: Global Total Number Deceased Organ Donors in 2017 [29]. A summary of the Total Number of Deceased Organ Donors, Number of DBD donors, and Number of DCD donors.

Nation	Total Number Deceased Organ Donors (pmp)	Number of DBD Donors (pmp)	Number of DCD Donors (pmp)
Spain	2,183 (47.05)	1,610 (34.7)	573 (12.35)
Portugal	351 (34.08)	330 (32.04)	21 (12.04)
Croatia	140 (33.33)	140 (33.33)	0 (0)
USA	10,286 (31.7)	8,403 (25.9)	1,883 (5.8)
Belgium	348 (30.53)	245 (21.49)	103 (9.04)
France	1,933 (29.74)	1,796 (27.63)	137 (2.11)
Italy	1,714 (28.86)	1,661 (27.96)	53 (0.89)
Czech Republic	269 (25.38)	256 (24.15)	13 (1.23)
Austria	213 (24.48)	206 (23.68)	7 (0.8)
United Kingdom	1,492 (22.54)	898 (13.56)	594 (8.97)

The nation with the highest number of donors in the world is the United States; however, in order to get a complete and exhaustive overview on donation throughout the world, it is more accurate to consider the ratio between deceased organ donors and population that can donate. As shown in Figure 14, Spain has the highest ratio, and it is the only county in the world with a ratio over 40 pmp [29].

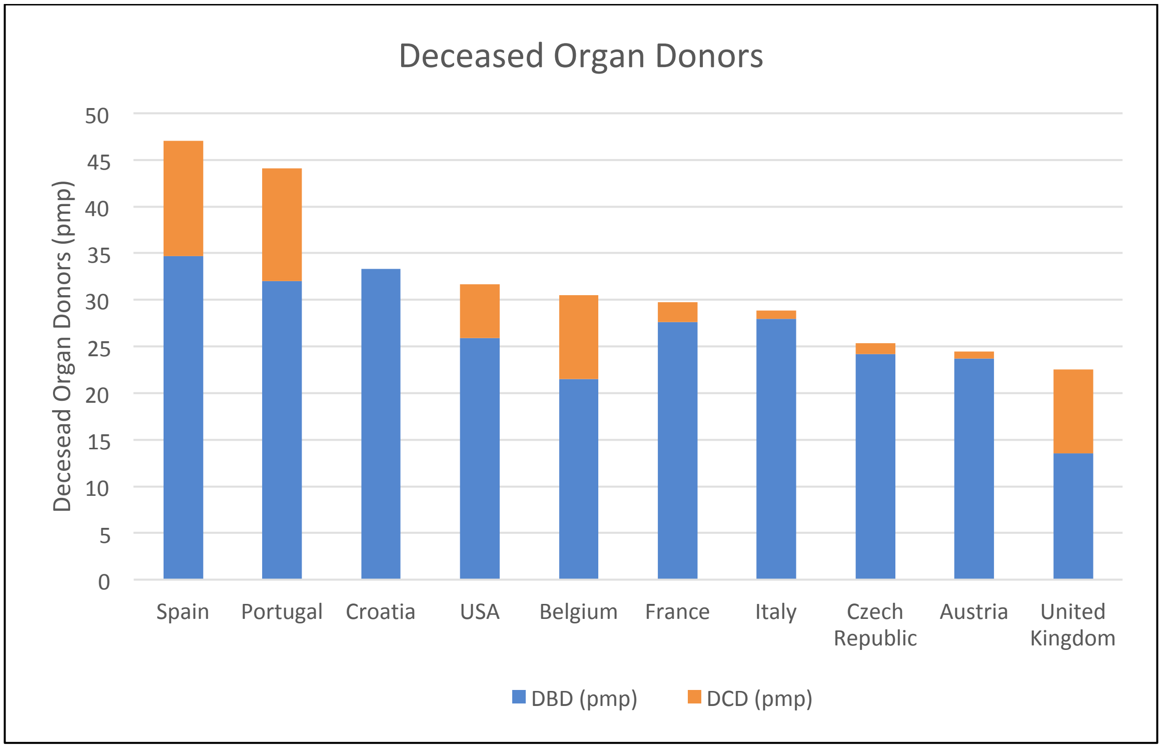


Figure 14: Total Number of Deceased Organ Donors, DBD Donors, and DCD Donors in Top Ten Countries in 2017 [29].

4.3.2 *Utilized Deceased Organ Donors*

The second category that is summarized by the GODT is the total number of utilized deceased Organ Donors and it includes two minor categories that are the number of DBD donors, and number of DCD donors (Table 17) [29].

Table 17: Total Number of Utilized Deceased Organ Donors [29]. A summary of the Total Number of Utilized Deceased Organ Donors, Number of Utilized DBD donor organs, and Number of Utilized DCD donor organs in 2017.

Nation	Total Number of Utilized Deceased Organ Donors (pmp)	Number of Utilized Organs from DBD Donors (pmp)	Number of Utilized Organs from DCD Donors (pmp)
Spain	1,906 (41.08)	1,421 (30.63)	485 (10.45)
Portugal	322 (31.26)	308 (29.9)	14 (1.36)
Croatia	132 (31.43)	132 (31.43)	0 (0)
USA	9,706 (29.91)	8,073 (24.88)	1,631 (5.03)
Belgium	348 (30.53)	245 (21.49)	103 (9.04)
France	1,882 (28.95))	1752 (26.95)	130 (2)
Italy	1,437 (24.19)	1,407 (23.69)	30 (0.50)
Czech Republic	244 (23.49)	239 (22.55)	10 (0.94)
Austria	206 (23.68)	199 (22.87)	7 (0.8)
United Kingdom	1,413 (21.34)	873 (13.19)	540 (8.16)

The nation with the highest number of utilized deceased organ donors in the world is the United States; however, it is more accurate to consider the ratio between deceased organ donors and the population. As shown in Figure 15, Spain has the highest ratio, and it is the only county in the world with a ratio over 40 pmp (Figure 15) [29].

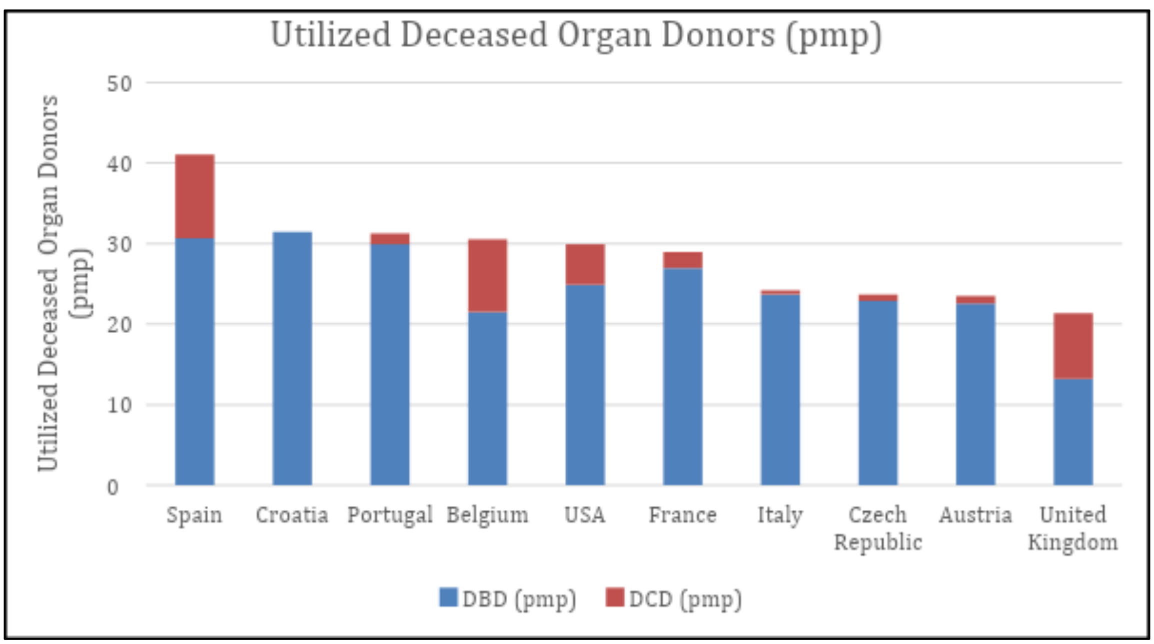


Figure 15: Total Number of Utilized Deceased Donor Organs [29]. Number of utilized DBD donor organs, and number of utilized DCD donor organs in the top ten countries in 2017.

4.3.3 *Deceased Organ Donors by State*

The OPTN reports data about deceased organ donors for each state and compares the total amount of deceased organ donors and the ratio of deceased organ donors to the respective state's population. Table 18 shows the ten U.S. states with the highest ratio [2, 30].

Table 18: 2017 U.S. States with Highest Per Capita Deceased Donors [30]. Ten U.S. states with highest ratio of deceased organ donors per capita in 2017.

	Total Number of Deceased Organ Donors (pmp)	**Number of Organs from DBD Donors (pmp)**	**Number of Organs from DCD Donors (pmp)**
USA	9,753 (29.84)	8,003 (24.48)	1,753 (5.36)
District of Columbia	142 (202.85)	117 (167.14)	25 (35.71)
Kansas	245 (84.19)	200 (68.72)	45 (15.46)
Pennsylvania	789 (61.64)	622 (48.59)	167 (13.04)
Tennessee	372 (54.94)	321(47.41)	51 (7.53)
Massachusetts	292 (42.31)	230 (33.33)	62 (8.98)
Louisiana	187 (40.21)	182 (39.13)	5 (1.07)
Wisconsin	233 (40.17)	191 (32.93)	42 (7.24)
Arizona	267 (37.23)	181 (25.24)	86 (11.99)
Nebraska	68 (35.21)	52 (30.25)	16 (4.95)

It is important to note that using a ratio that also considers the population of a specific state results in a more meaningful and accurate measurement, rather than simply comparing the number of deceased organ donors. Naturally, the ratio does not necessarily include the states with the highest number of deceased donors, such as California, which is the state with the highest overall number of deceased organ donors, but not per capita. In fact, when population is factored into the equation, the District of Columbia has the highest ratio of deceased organ donors per capita, while California is not even in the top ten states (Figure 16) [2].

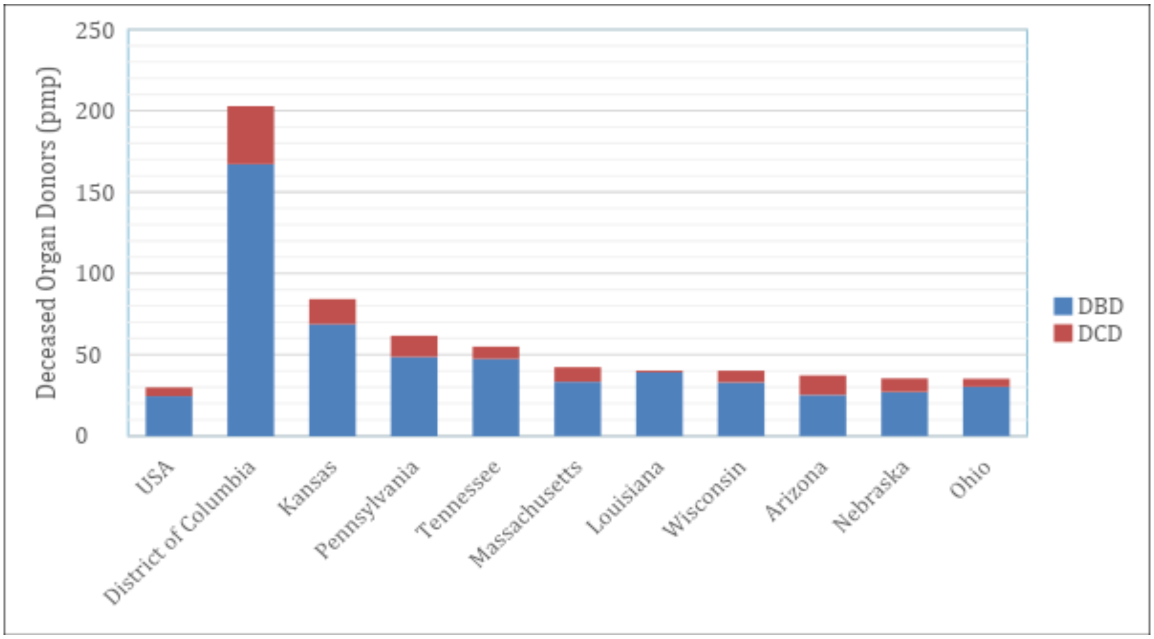


Figure 16: **Graphical Representation of the Ten U.S. States with the Highest Ratio of Deceased Organ Donors per Capita in 2017 [2].**

4.4 Organ Donation and Transplantation Programs Overview and Creation of a Multicenter System Model

4.4.1 *Transplant Programs in Wisconsin*

In Wisconsin, there are only four transplant programs, comprised of three that perform transplants on adults and only one which performs transplants on children. Each of the four hospitals is located in the Southeastern region of the state between Madison and Milwaukee (Table 19).

Table 19: Wisconsin Transplant Programs. A summary of the four transplants programs in Wisconsin divided by type of patient, type of organ, and type of donor.

<table>
<tr><th>Hospital</th><th>Patients</th><th>Transplant Programs</th><th colspan="2">Transplants Performed in 2017 and Donor Type</th></tr>
<tr><td rowspan="8">UW Hospital (Madison)</td><td rowspan="8">Adults/Pediatrics</td><td>Heart
(19 Transplants)</td><td>19 Adults</td><td>19 DD</td></tr>
<tr><td rowspan="4">Kidney
(280 Transplants)</td><td rowspan="2">272 Adults</td><td>168 DD</td></tr>
<tr><td>105 LD</td></tr>
<tr><td rowspan="2">8 Pediatrics</td><td>6 DD</td></tr>
<tr><td>2 LD</td></tr>
<tr><td rowspan="2">Lung
(20 Transplants)</td><td>19 Adults</td><td>19 DD</td></tr>
<tr><td>1 Pediatric</td><td>1 DD</td></tr>
<tr><td>Liver
(112 Transplants)</td><td>112 Adults</td><td>112 DD</td></tr>
<tr><td rowspan="4">Aurora St. Luke’s (Milwaukee)</td><td rowspan="4">Adults</td><td>Heart
(26 Transplants)</td><td>26 Adults</td><td>26 DD</td></tr>
<tr><td rowspan="2">Kidney
(35 Transplants)</td><td rowspan="2">35 Adults</td><td>17 DD</td></tr>
<tr><td>18 DD</td></tr>
<tr><td>Liver
(24 Transplants)</td><td>24 Adults</td><td>24 DD</td></tr>
<tr><td rowspan="5">Froedtert Hospital (Milwaukee)</td><td rowspan="5">Adults</td><td>Heart
(12 Transplants)</td><td>12 Adults</td><td>12 DD</td></tr>
<tr><td rowspan="2">Kidney
(66 Transplants)</td><td rowspan="2">66 Adults</td><td>40 DD</td></tr>
<tr><td>26 LD</td></tr>
<tr><td>Lung
(13 Transplants)</td><td>13 Adults</td><td>13 DD</td></tr>
<tr><td>Liver
(28 Transplants)</td><td>28 Adults</td><td>28 DD</td></tr>
<tr><td rowspan="4">Children’s Hospital (Milwaukee)</td><td rowspan="4">Pediatrics</td><td>Heart
(9 Transplants)</td><td>9 Pediatrics</td><td>9 DD</td></tr>
<tr><td rowspan="2">Kidney
(7 transplants)</td><td rowspan="2">7 Pediatrics</td><td>2 DD</td></tr>
<tr><td>5 DD</td></tr>
<tr><td>Liver
(3 Transplants)</td><td>3 Pediatrics</td><td>3 DD</td></tr>
</table>

Following a detailed review of Wisconsin transplant centers, three potential “hub” hospitals were identified including the University of Wisconsin Hospital in Madison, Aurora St. Luke’s Hospital in Milwaukee, and Froedtert Hospital in Milwaukee (Figure 17).

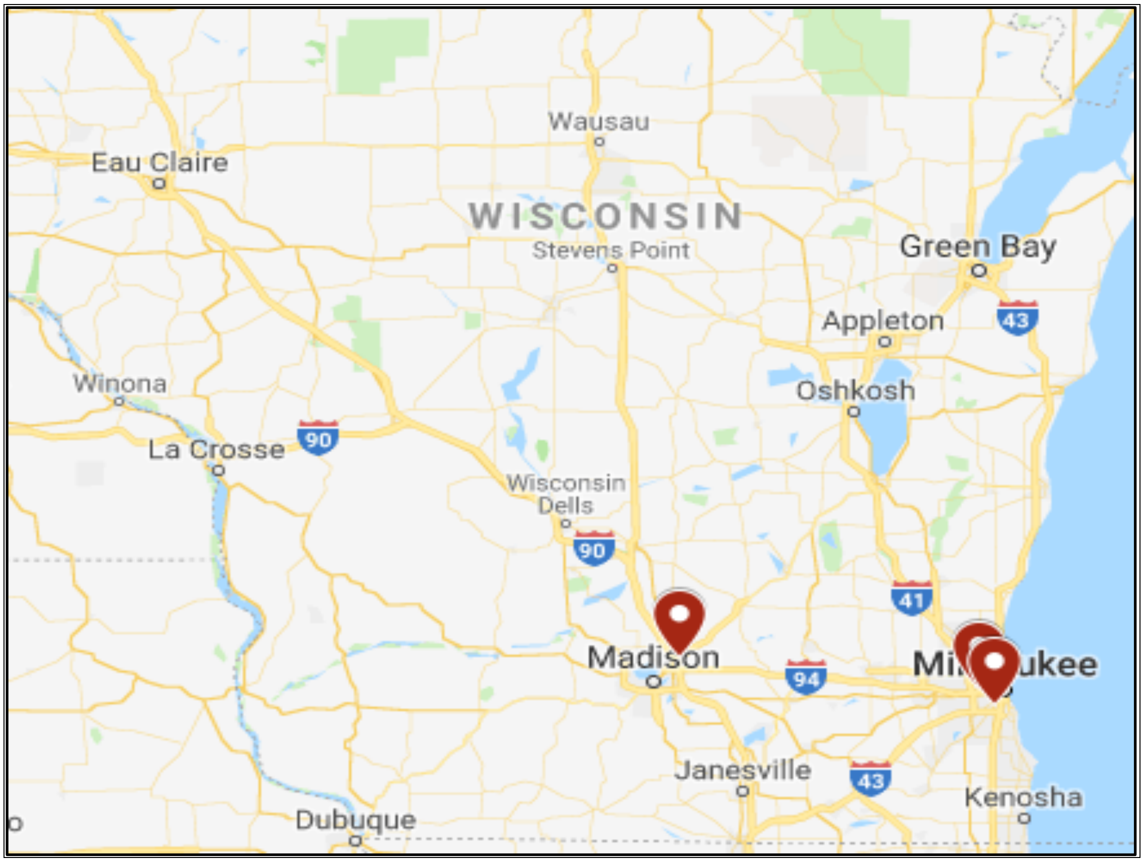


Figure 17: Hub Hospitals Map. The map shows the three hospitals identified as hub hospitals (red pennant).

In addition, University of Wisconsin Hospital in Madison and Froedtert Hospital in Milwaukee have the potential to provide normothermic *ex-vivo* perfusion, which could significantly increase the number of organs available and successfully transplanted.

4.4.2 *Organ Donation Programs in Wisconsin*

To support organ transplantation throughout the state, there are only 10 centers with a valid organ donation program in Wisconsin, and just two OPOs that collaborate with these centers in order to improve the total number of organs available each year (Table 20).

Table 20: **OPOs and Organ Donation Programs in Wisconsin.** A summary of the OPOs and Organ Donation Programs in Wisconsin.

Organ Procurement Organizations (OPOs)	
Wisconsin Donor Network	Milwaukee
UW Organ and Tissue Donation	Madison
Organ Donation Programs	
Luther Hospital	Eau Claire
Theda Clark Regional Medical Center	Neenah
St. Vincent Hospital	Green Bay
Mercy Hospital	Janesville
Gundersen Lutheran Hospital	La Crosse
St. Mary's Hospital	Madison
UW Hospital	Madison
St. Joseph Hospital	Marshfield
Aurora St. Luke's Medical Center	Milwaukee
Children's Hospital of Wisconsin	Milwaukee
Froedtert Memorial Lutheran Hospital	Milwaukee
WFH St. Joseph	Milwaukee
WFH All Saints St. Mary's Campus	Racine
Waukesha Memorial Hospital	Waukesha
Aspirus Wausau Hospitals Inc	Wausau

The second step of the hub-and-spoke model is to identify all hospitals within the region that have a valid organ donation program, as well as all hospitals that have an intensive care unit and sophisticated life support machines and intensive monitoring capable of managing DBD and DCD donors (Figure 18).

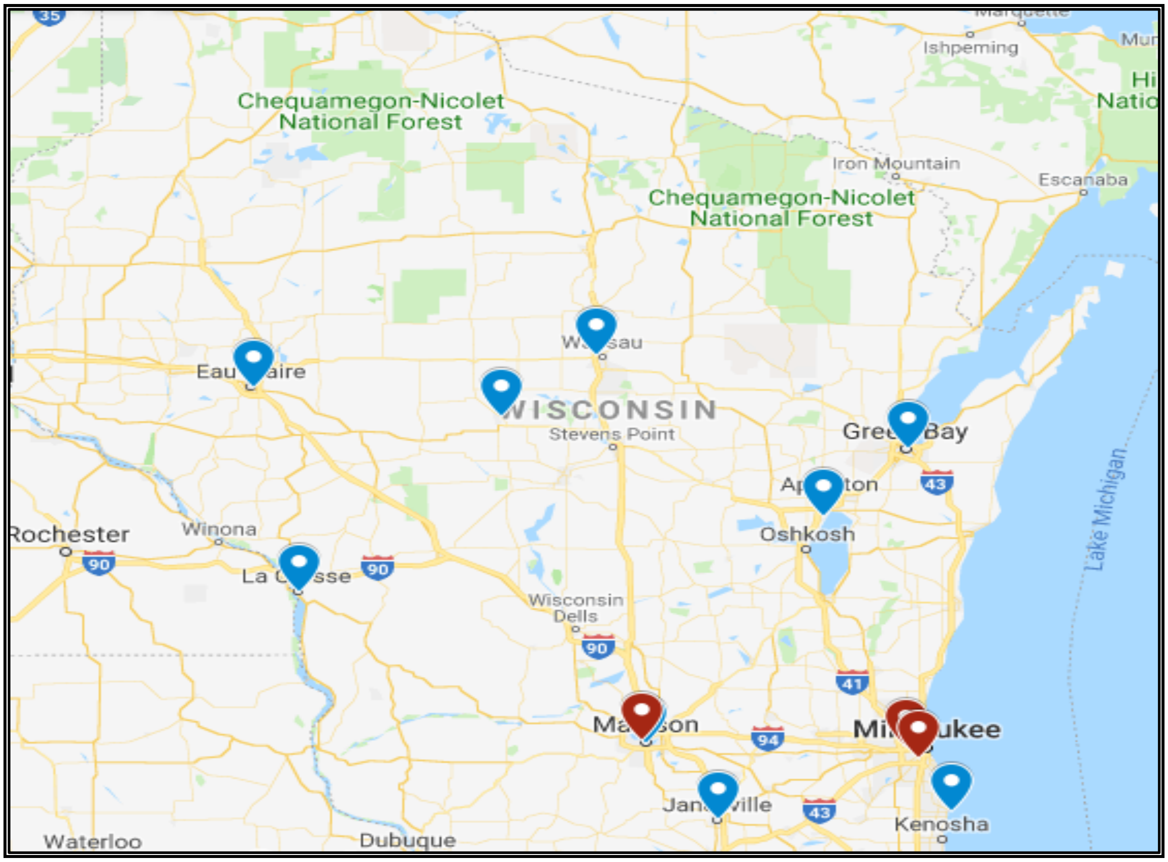


Figure 18: Hub-and-Spoke Hospitals Map. The map shows the hub hospitals (red pennant) and the spoke hospitals with a valid organ donation program (blue pennant).

Next, this group of hospitals is further categorized by those that could only effectively and safely manage DBD donors, and those than can manage both DCD and DBD donors. The presence of a perfusion service within spoke hospitals can result useful in order to support extracorporeal circulation in DBD donors and is absolutely critical in order to support DCD donations (Figure19).

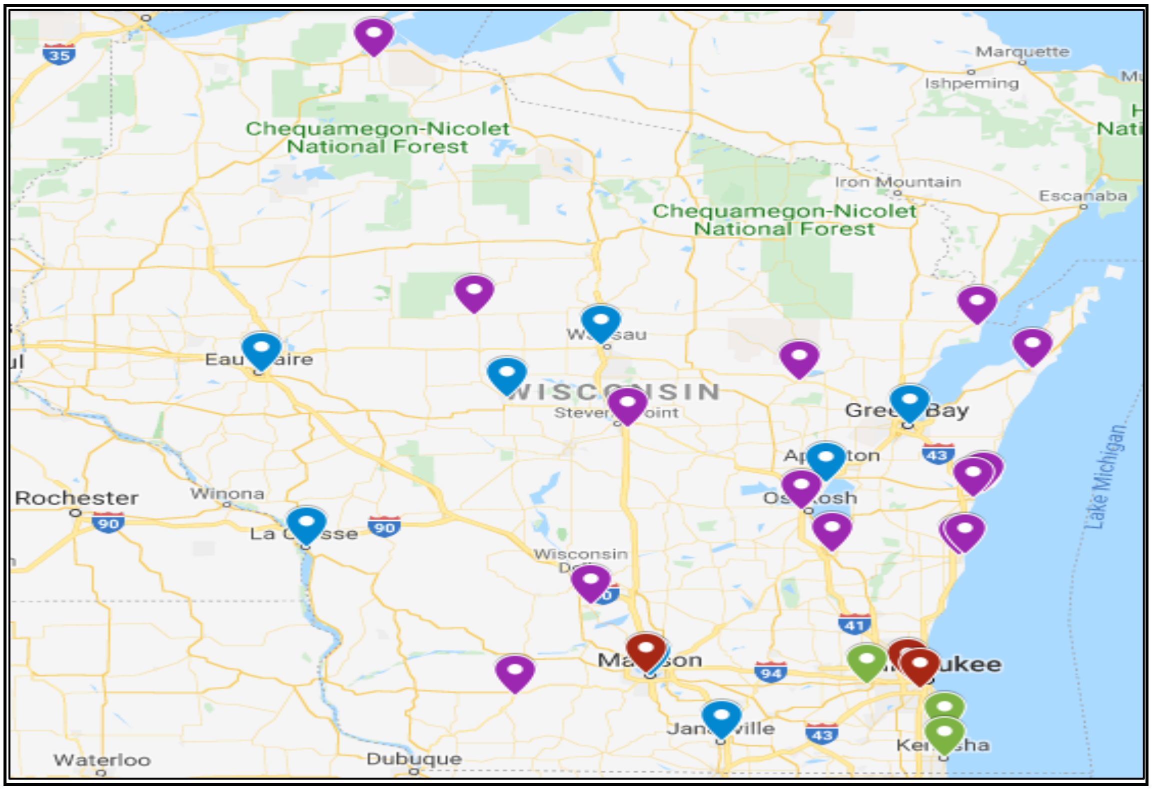


Figure 19: Hub-and-Spoke Map. The map shows hub hospitals (red pennant), spoke hospitals with a valid organ donation program (blue pennant), spoke hospitals with the presence of a perfusion service (green pennant), and spoke hospitals without a perfusion service but with an ICU (purple pennant).

Hospitals without a perfusion service were not considered as potential locations to perform DCD donations for the scope of this project, given that the WIT would be far too long and efforts to preserve organ function would be futile. However, hospitals without a perfusion service were considered for DBD donors.

4.4.3 *Radius of Action*

The third step in the creation of a hub-and-spoke model is to map a radius of action that represents the total area involved in the model. The radius of action depends on many factors including type of deceased donor, distance between hub and spoke hospitals, and type of transport. The distance between the hub and spoke hospitals and the type of transport is critical both in starting the donation process and in organ preservation. The type of transport chosen not only depends on the distance between the two hospitals, but it also depends on the circulatory instability of the donor and the weather conditions. The biggest limitation in starting an extracorporeal procedure is time, and generally the limit depends on the patient's conditions and the status of advancement of the diagnosis of brain death. For these reasons, the maximum radius of action that an ambulance or a medical motor vehicle can cover is 100 miles, and for a helicopter the maximum distance that can be traveled is 200 miles. As shown in Figure 18, the hub-and-spoke model could cover a large portion of the state of Wisconsin, assuming that the primary hub hospitals are Milwaukee's Froedtert Hospital and Aurora St. Luke's hospital (Figure 20).

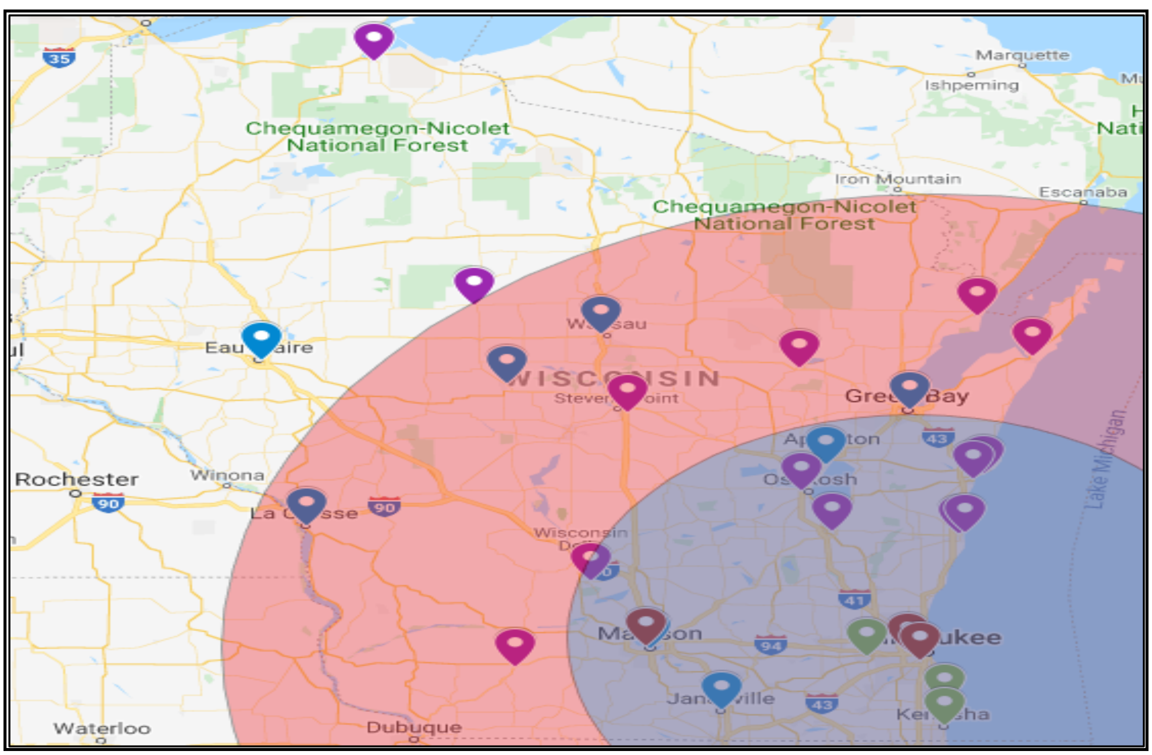


Figure 20: Radius of Action Map. The map shows the radius of action that an ambulance can cover (shaded in blue) and the radius of action that a helicopter can cover (shaded in red), considering that both hub hospitals are in Milwaukee.

If the University of Wisconsin Hospital in Madison was selected as the primary hub hospital instead of the hospitals in Milwaukee, the radius of action would include all the cities that were previously included with the Milwaukee hospitals acting as primary hubs, as well as additional hospitals in the northwestern region of the state that were previously excluded (Figure 21).

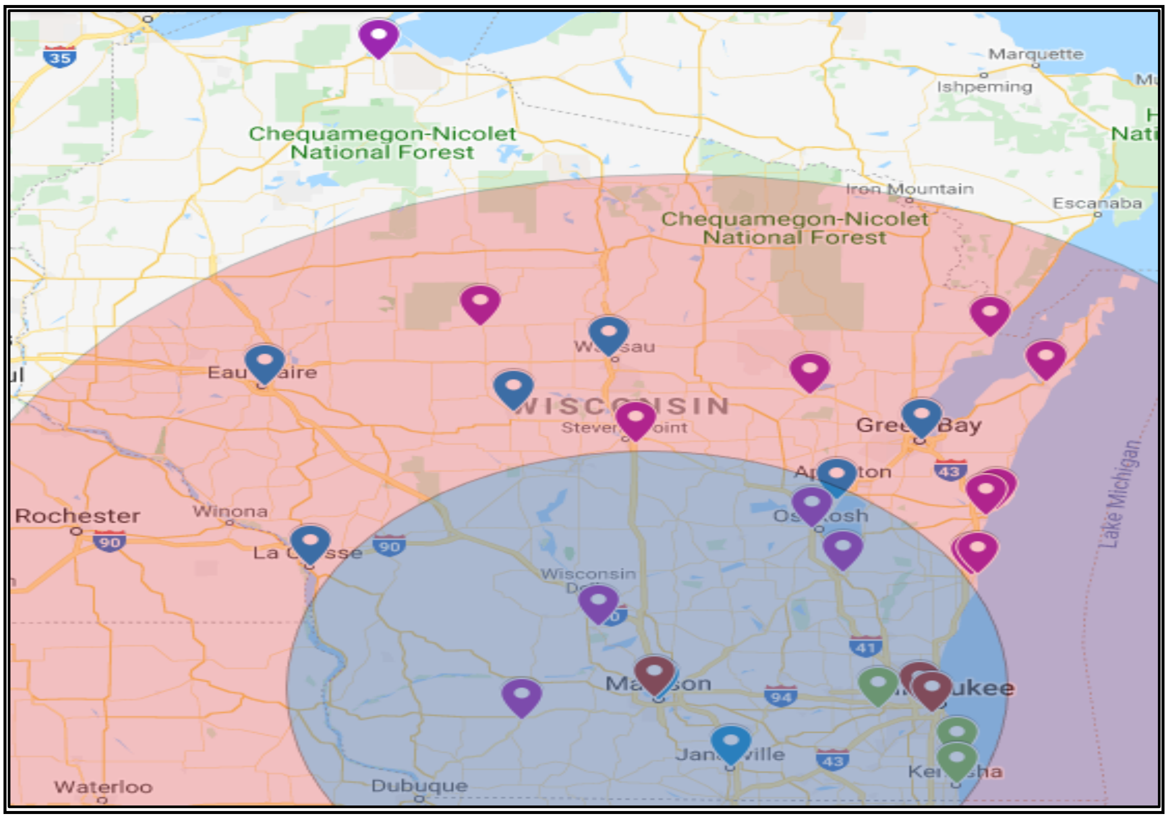


Figure 21: Radius of Action Map. The map shows the radius of action that an ambulance can cover (shaded in blue) and the radius of action that a helicopter can cover (shaded in red), considering that the hub hospital is located in Madison.

The identification of the most optimal primary hub hospital is crucial in order to cover as much geographical area as possible, as well as to optimize available resources in order to increase the number of donors and improve the quality of organs donated.

5.0 Discussion

Over the last decade, the number of DCD and DBD donors has continued to increase, while the number of organs authorized for recovery as well as the total number of organs recovered and transplanted have also increased [2]. These increments have been primarily due to both clinical and social aspects, and on a clinical level the most notable contributing factor has been the opioid epidemic crisis that led to a 12% increment in drug overdose deaths in 2017 alone [2]. Additionally, a significant clinical contributing factor to the overall increase in donors, organs available for donation, and number of organs actually retrieved and transplanted was the introduction of the Organ Policy Equity Act (HOPE), which modified the rules regarding donated organs deriving from HIV-positive individuals and the authorized use of these organs in clinical research. Notable social aspects that have contributed to the increase in the number of deceased donors include the continuous growth of the U.S. population, a country in which the rate of registered organ donors is high relative to its population [3].

Despite the innumerable efforts by many government and private organizations and the development of new donation and allocation strategies, the rate of deceased organ donors over the past ten years has only slightly improved [2]. In 2007, there were 26.6 deceased donors per one million persons (pmp), while in 2017 there were to 31.7 deceased donors per one million persons (pmp) [2]. In addition, the gap between organs authorized for transplant and organs recovered, as well as the gap between organs recovered and transplanted has not changed in the recent decades. Furthermore, the data published in 2017 by the HHS indicate that a significant percentage of the organs viable for transplant were never actually recovered, and a large number of organs recovered for transplant were never actually transplanted [2]. The percentage of lost organs in these categories represents 25% overall, at times reaching a peak of 63% [2]. Moreover, there is much room for continued improvement and unfortunately only few advances have been made in the last decade. Specifically, improvements must be made in the management of brain dead donors in the ICU, as well as in the organ recovery system for the circulatory dead donors [13].

This work estimated the number of potential organ donors in Wisconsin to be a total of 945 potential organ donors in Wisconsin for the year 2017. Notably, there was a difference of 712 donors between actual donors and those who could have potentially donated via deceased donation.

The United States of America has the highest number of donors in any country worldwide and reached a total of 10,000 deceased donors 2017 [2]. However, despite this single statistic, the U.S. is fourth worldwide in the ratio between deceased donors and population, and fifth for utilized organ donors behind Spain, Portugal, Croatia, and Belgium. Despite this placement, some U.S. states boast a ratio of deceased organ donors to the respective state's population that exceeded 40 pmp, and the District of Columbia's ratio exceeded 200 pmp [2]. These states were able to maintain a higher ratio due to many factors including highest countrywide rate of registered donors, and the presence of many organ donor programs in high-density areas.

In 2017, the ratio between deceased donors and overall population in Wisconsin was 40.1 pmp, mainly due to a high percentage of registered donors (58%). In addition, it is important to note that the highest number of statewide deaths occurred in the

Southeastern region of Wisconsin, which is also where the state's major hospitals and donor organizations are located. Unfortunately, there are no available data that provides a comprehensive overview of the number of deceased donors from each Wisconsin hospital or county. However, it is possible to conclude that there is great opportunity to increase the ratio between deceased donors and the population, given that only 35% of Wisconsin deaths occur in the region in which the state's organ donor programs are concentrated.

The healthcare industry is characterized by continuous change on a multitude of fronts, and the success in this environment requires healthcare providers to be proficient in a myriad of areas, including the way they organize and deliver services. In 2008, a specific framework for the practice of organ donation was developed in Spain in order to achieve 40 donors per million inhabitants (pmp) in each region throughout the country [34]. The use of a transport model optimization system, specifically the hub-and-spoke model, was used in order to achieve this goal. Part of the program's success and overall efficacy was due to its ability to connect urban and suburban healthcare providers through a strategic centralization of the most advanced medical services in the region, otherwise known as the "hub", which offers support during the donation process to the secondary and less organized hospital nearby, also known as the "spoke".

The identification of the most optimal primary hub hospital is crucial in order to cover as much geographical area as possible, as well as to optimize available resources in order to increase the number of donors and improve the quality of organs donated. The University of Wisconsin Hospital would be the strongest contender to be the primary hub, given that its location would allow it to cover a greater area than the hospitals present in Milwaukee. In addition, the University of Wisconsin also owns an *ex-vivo* perfusion device for the heart (TransMedics – OCS), which would be useful in recovery of hearts that might normally be considered unfit for transplant [35]. It is important to consider that a crucial aspect in the process of increasing the number of organs available for transplant is time. The sooner extracorporeal support begins after a donor is identified, the higher the possibility to harvest organs with adequate organ function that can be successfully transplanted. For this reason, if there are enough available economical resources, it would be possible to consider using two independent primary hubs, with one being in Madison and the other being in Milwaukee. In this scenario, each primary hub would cover a specific area and specific hospitals within that area, which would lead to a higher number of potential transplants.

There are many benefits and risks that should be considered in the implementation of the hub-and-spoke model. All these benefits and risks listed in Table 21 are intrinsic to this type of organizational model [36].

Table 21: Benefits and Risks Associated with the Hub-and-Spoke Organization Model [36].

Benefits	Risks
• Reduce costs • Enhance quality • Optimize resources • Enhance service coverage • Increase efficiencies	• Congestion of hubs • Overextension of spokes • Staff dissatisfaction at spokes • Transportation disruptions

One specific limitation that must be considered in order to create an efficient hub-and-spoke model is the private healthcare system that currently exists in the U.S. In European countries with nationalized healthcare in which the hub-and-spoke model has been implemented, once the government supported the project it was implemented nationwide and was not at the choice of individual hospitals or health systems. Differently in the U.S., each individual private system involved would need to agree to participate in the project. While a nationalized health system generally results in government distributed funds and national employment contracts, the formation of such a program could be slightly more complex in the U.S. considering that all parties involved would need to agree on the payment and organization of implementation and ongoing costs.

An additional aspect that should be considered for a complete implementation of a deceased donor hub-and-spoke system is the possibility to include hospitals that are not in Wisconsin in the radius of action, such as hospitals in Illinois, Minnesota, Iowa, and Michigan. In addition, considering that few counties in the Midwest have a population density higher than 3,300 people per mile square, the project could be taken a step further to create a Midwest hub-and-spoke system that would have the capacity to cover all rural hospitals and facilities that would be excluded when considering only hubs present in Wisconsin.

Formulating an effective hub-and-spoke network ultimately requires that all clinicians within the network gain a deep understanding of the network's organizational structure, operational protocols, and methods of delivering care to the communities it serves [36]. To foster this process, it is critical to build and maintain relationships between the hospitals and facilities within the network, so that open and accurate communication occurs even in emergent situations. With the foundation of strong communication and shared knowledge of structure and protocols, the teams involved can collaborate to prevent hub congestion and overextension of the spoke hospitals. Once the model has been adequately structured and if relationships are maintained, hub-and-spoke models can be highly adaptable and scalable [36].

Certainly, a successive step in this project would be to create a mathematical model that is able to consider all human, technological, and economical resources that are necessary in order to optimize the hub-and-spoke model. Another successive action that would further improve the model would be that of creating new protocols and programs to increase the number of organs and donors available. For example, other countries have also implemented protocols that promote the identification and early referral of possible organ donors from outside of the ICU, expanded criteria donors, or have developed advanced normothermic regional perfusion protocols. Once a successful hub-and-spoke model is in place, its continued success should also be measured in the implementation of parallel programs and protocols such as those utilized by other countries in order to continue to combat the organ shortage crisis.

The use of specific transport topology optimization in the healthcare field transformed the management of available resources in a given area, and also extended healthcare options to hospitals and facilities that normally could not afford them [36]. Undoubtedly, achieving an increased number of donors and the number of organs available does not only depend on the implementation of the logistic phases of the donation processes, but it is also dependent on many other factors such as the early identification and referral of potential DBD donors, strong cooperation between hub-and-spoke hospitals, and development of detailed protocols in order to request and activate the hub hospitals in order to begin extracorporeal circulation as soon as possible.

6.0 Conclusion

The continuous growing demand for organs has motivated many countries throughout the world to maximize donations by capitalizing on an often-untapped source of donors and implement more innovative and strategic organ donation programs. This project demonstrated the possibility to increase the number of organs available in the state of Wisconsin through a new organ donation program focused primarily on deceased donors. Through targeted research of 2017 data available within the field of organ donation, the number of potential organ donors was estimated in order to calculate the gap between actual and potential deceased organ donors. In order to propose a solution to close this gap which results in far too many lives lost each year, this project explored a viable and effective organizational model that would focus on the creation of a strategic network of hub-and-spoke hospitals able to increase the area within the state that can support safe and successful organ donation. This implementation plan would serve as a first step toward innovating the deceased organ donation process in the state of Wisconsin and would have the potential to form the basis of additional programs capable of greatly improving the field of organ donation through the Midwest United States.

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Thesis Approval Form

Master of Science in Perfusion – MSP

Milwaukee School of Engineering

This thesis, entitled "Proposed Implementation of a Deceased Organ Donor Program to Address the Critical Shortage of Donor Organs in Wisconsin," submitted by the student Flavio Cavallari, has been approved by the following committee:

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