



## **2016 National Critical Issues Forum: Disrupting the Status Quo** A Process to Facilitate Donor Identification and Utilization

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### **FORUM SUBJECT**

Understanding how to improve information and behavior for better decision making

### **EXECUTIVE SUMMARY**

Decision-making to accept or decline an organ offer is the most important task for a transplant program. This decision-making process defines a program's potential. The decision that follows also determines, in part, the probability of a waitlisted patient dying without a transplant.<sup>1</sup> However, the decision to accept an offer for a particular recipient has influence over the probability of an organ or patient surviving after transplantation. In some instances, the outcomes of poor decisions enter into the public domain.<sup>2</sup> When coupled to the potential to influence a program's resource utilization for any particular case the organ offer acceptance practice is seen to have both positive and negative consequences for a program.<sup>1-3</sup> Therefore, how people may weigh the possibility of the positive or negative consequences of a decision influences how likely they are to accept or decline an organ offer.

The decision to accept an offer is sometimes difficult as the information provided may create uncertainty and perceived risk. However uncertainty deals with possible outcomes that are largely poorly quantifiable while actual risk involves the true likelihood of an event and the scale of negative consequences. When looked at together an accurate and quantifiable possibility of loss is difficult to come to and for the decision maker it is rare that they have available actual risk and probability numbers when the decision is made. Most often their decision occurs in a domain where some degree of uncertainty always exists. Within this domain how information is presented, also known as framing effect, is seen to influence the likelihood of a positive or negative decision.

The most common reason for an organ offer to be declined is quality.<sup>1, 4</sup> Several studies in liver transplantation have outlined how offers declined for quality have been successfully transplanted into other individuals with equivalent results.<sup>1, 4</sup> For the many who have had an organ offer declined for them or by them, a lost opportunity can also be associated increased mortality.<sup>1</sup> Although detailed analyses specific to transplantation have not been performed, a growing field of literature analyzing these "decisions under risk" scenarios has detailed how cognitive bias and personality traits lead to diagnostic inaccuracies, medical errors and inadequate utilization of

resources in medicine.<sup>5, 6</sup> Therefore understanding offer and acceptance behavior is critical to appreciating greater opportunity in organ transplantation.<sup>5, 6</sup> This paper will discuss the concept of “decision under risk” and will focus upon decision making at the OPO, transplant center, physician and patient level in relation to organ offers. For each group we will examine what factors influence a decision to accept or decline an offer and what factors may these in a positive or negative way. We will explore how for any given decision, the degree of certainty varies among individuals analyzing the problem. The difference between uncertainty and risk will be presented. An understanding on how the individual’s degree of variance from actual risk varies based upon circumstance and how the interaction between personality and risk influences whether an offer is accepted or declined will be outlined. Understanding and altering how the framework of risk aversion impacts an individuals’ decision is central to increasing utilization of organ offers. That our decisions are not simply limited to factual knowledge presents an opportunity to disrupt the status quo and to improved offer acceptance. Better decision-making and an understanding of the true risk and potential within the existing donor resource is of infinite value. By addressing inappropriate biases, heuristics and risk averse behaviors it was identified at the recent forum that we will be able to identify greater utilization of existing resource whilst also lessening disparity in access to organs which is driven in part by poor decision-making.<sup>7-13</sup>

## **INTRODUCTION**

Decision-making results in the selection one action or one series of actions. In decision-making one particular path is chosen often from a series of alternatives. In transplantation, decision making surrounding an organ offer defines in part a program’s potential. These decisions also contribute to a patient’s probability of survival on the waiting list and the allograft and donors potential following transplantation. In summary our decisions as custodians of the donor resource determine the probability of listed patients dying, the donor resources utility, our potential to save the greatest number of lives in those awaiting transplantation, and finally a programs’ economic viability.<sup>1</sup> However, our decision to accept an offer for a particular recipient is influenced by how we weight the probability of a particular organ offer having a negative outcome (e.g. delayed or non-function in fatty livers or high PRI kidneys, or a PHS increased risk organ transmitting an infection to a patient) or a recipient experiencing an unwanted outcome (e.g. a recipient in the ICU on vasopressors dying following transplant with a marginal offer, or severe ischemic biliopathy occurring in a DCD offer-acceptance). Often, we are dealing with our concerns when we consider organ offers. Concerns are unquantifiable aspects in a decision that are largely influenced by heuristics related to the characteristics of the donor or recipient. In contrast risk deal with quantifiable probabilities. However another concern that influence decisions are OPTN and CMS bylaws and regulations that designate that all transplant programs maintain patient and allograft outcomes at or above expected should they wish to avoid excessive regulatory oversight or potential loss of participation in the organ transplantation arena. When poor decision-making has occurred, the negative impact upon patients, programs, and institutions can enter the public domain and the economic and

institutional consequences can be enormous.<sup>2, 3</sup> Documented negative outcomes of poor decision making includes significant declines in transplant volume and even transplant center closure.<sup>3</sup>

In considering decision-making it is important to understand the many factors that influence it. How people weigh the possibility of the positive or negative consequences of a decision strongly influences how they choose. In the individual, weighting actual probability and actual facts may not always be considered and people often interpose concerns. Unfortunately, the decision to accept an offer is sometimes made even more difficult by additional and sometimes unfamiliar information that creates uncertainty in the decision maker's mind and, in such circumstances, the decision maker will not uncommonly over-value perceived risk.<sup>4</sup> **Uncertainty** deals with **possible outcomes and is poorly quantifiable**. In contrast, **risk** involves the **true likelihood of an event** and includes the scale of any negative consequences should this event occur. When looked at together, an accurate and quantifiable probability of loss is difficult to assess for most people and decision-makers rarely possess all probability numbers when their decisions are made on donor organs. Some decision-makers however, seek to possess key and critical information whilst also possessing the ability to not overly weight concerns associated with information that has no certainty associated with it. Hence, how some individuals handle information provides them an ability to make better decisions under risk than others. For the others decision under risk is sometimes associated with different decisions on the same organ offers when resented with the same information.<sup>4-6</sup>

For any decision maker how information is provided, for example whether it is framed in a positive or negative tone, or whether information comes from a known and reliable source, influences the acceptance or decline an offer. In addition, whether information that is valued by the decision maker is available, for instance a biopsy or a Fibroscan reading on an HCV positive donor, also influences the decision to fly out or to openly accept an offer without visualization of a liver. We also see, that if others should decline an organ offer, that others are more likely to decline the same offer within particular regions. Illustrating this is the fact that 10 liver transplant programs nationally accept approximately 80% of national offers. Offer and acceptance rates for subsequently transplanted liver and kidneys varies 4-fold in some instances and but a small number of programs accept repeatedly declined offers. Importantly, the post-transplant patient survival and allograft outcomes is no different to programs who more often decline offers. Critical is these "aggressive" programs have lower pre-transplant mortality rates when compared to comparative programs and provide the best outcome in Intention to Transplant Successfully (ITS) analysis. For these aggressive programs, how the information is framed may be less important than for programs that are less. These potential phenomena, in organ transplantation, have been sadly inadequately studied although this area is well recognized as an opportunity for quality assessment and performance improvement in other areas of healthcare management and the transplant community can learn from this.

The most common reason for an organ offer being declined is quality.<sup>1, 5, 6</sup> Several studies in liver transplantation have outlined how offers declined for quality have been successfully

transplanted into other individuals, with an equivalent acuity of illness, with recipients enjoying post-transplant outcomes at or above expected. For those in whom organs transplant into others were first declined, we appreciate an unfortunate increase in waiting list mortality for them.<sup>1, 5, 6</sup> As mentioned, some centers with the highest acceptance rates enjoy patient survival outcomes both in the waiting list and after transplant consistently better than those predicted by outcome models of SRTR. These centers also enjoy better economic performance and substantially greater out of state referrals. However, for the many who have had an organ offer declined for them or by them, this lost opportunity, as previously mentioned, is associated with increases in pre-transplant mortality and waiting list removal without transplantation.<sup>1</sup> Although detailed analyses specific to transplantation have not been performed, the growing field of study of “decisions under risk” scenarios details how cognitive bias and personality traits lead to diagnostic inaccuracies, medical errors and inadequate utilization of resources in medicine.<sup>6, 7</sup> Therefore, understanding what information is necessary for an appropriate decision, how our cognitive biases and personality traits may negatively influence our decision potential, and how the environment in which the decision is made influences offer and acceptance behavior must be a priority should we seek to honor our commitment to improve donor organ utility and thereby increase the number of successful transplants performed each year.<sup>6, 7</sup>

## **PURPOSE**

This paper will explore the concept of “decision under risk” by focusing upon factors that influence organ acceptance at the transplant center, organ procurement organization (OPO), physician, and patient level. For each group we examine how influence is created, how biases and heuristics influence how we appreciate information, and then what knowledge is needed to enhance our capacity to make the correct decision. We will explore why, for any given decision, the degree of certainty varies among the individuals analyzing the problem and what elements or behaviors might be modified to improve decision-making. The goal of this paper is to influence uncertainty within individuals and to replace concern with actual risk in a decision. An understanding of how the individuals create their variance from actual risk and how personality characteristics influence the perception of risk in offer acceptance practices presents a significant opportunity for the transplant community.

Understanding and altering inappropriate risk aversion is central to increasing the utilization of organ offers. That our decisions are not simply limited to factual knowledge is an opportunity to disrupt the status quo. To better realize the existing opportunities for our programs and our patients we must disrupt what we are doing today and shift to a better decision process should we seek to save the greatest number of lives in those waiting. This change package is a “skills” piece that provides the reader the ability to identify and address their inappropriate biases, heuristics and risk adverse behaviors. Through this realization donor utility will be enhanced in our existing resource.<sup>8-13</sup>

## **DECISION-MAKING BEHAVIOR: OUTCOMES OF THE FORUM AND RECOMMENDATIONS**

Forum participants were charged with identifying recommendations for **transplant centers** that may improve organ utilization. They were asked to identify performance gaps in organ utilization and to provide change recommendations that would increase the likelihood that a transplantable organ offer would be accepted. To develop the recommendations, information and behaviors related to communication (both internal and external to the program), standard practice determination, and risk aversion were to be examined for variability amongst participants. From this participants' have provided a list of recommendations that should close the performance gap in organ utility. The forum participants then provided the “change concepts” and “activities” needed to realize their programs true potential in organ offer and acceptance.

## **BEHAVIOR AND OUR ACTIONS**

### **Risk Aversion**

While risk aversion in response to concerns about adverse regulatory action was a reason for declining an offer, participants learned that this concern is not supported by data and also that, for appropriately made decision on marginal offers, risk is incorporated into prediction model as these include risk adjustments. In fact, an important change concept appreciated was that utilizing perfect offers leads to a prediction model for outcomes that might in fact compromise one's ability to address declining outcomes; perfect organs generate a need for perfect outcomes while extended risk organs and high DRI have the ability to increase the distance between predicted and actual outcomes, in effect creating a better buffer. It is a rational response to under-adjusted factors that may benefit and to overweight risk to a decision when faced with declining outcomes. Indeed, centers have shown reduced volume and reduced utilization of organs with perceived inferior outcomes in response to being flagged for center-specific outcomes, even though patients clearly would benefit from use of these organs and a center, by decreasing volumes and assuming more conservative organ acceptance, actually lessen the opportunity to quickly address the flag that they are face with. Participants unanimously recognized that "Perfect organs requires perfect outcomes" warrants that all centers utilize all appropriate potential offers and accepted that in organ offers with "risks", they often decline because of what were unquantifiable "concerns". In summary when faced with declining outcomes investigate for transplant system and performance issues, address these deficiencies quickly and the consensus favors increasing utilization and increasing transplant volumes concurrent with system improvement so as to optimize patient outcomes on the waiting list while not taking excessively risk recipients to transplant while actually looking to utilize donors with increased risk characteristics that form part of the outcomes prediction models. 8-10

### **Living Donors and Enhancing Operational Performance**

Living donor transplantation provides the greatest benefit to the recipient, and benefits those on the waiting list by removing a potentially competing candidate that will not compete with those awaiting an organ from the deceased donor pool. To maximize organs available for transplantation living donation remains an under-utilized resource for many transplant programs. To maximize utility within living donation avenues include better messaging on the to the community of the values and actual risks to living donation, the use of good Samaritan donors, and the novel practice of paired-donor exchange and the national paired donor registry. Through living donation and with utilization of all the opportunities that exist for identifying appropriate donors for waitlisted recipients, centers are able to maximize the number of transplants, the survival with a living donor kidney and to diminish the risk for allograft loss by better matching wit listed patients with donor organs that they are less likely to reject and hereby less likely to lose. By favoring an exchange for ABO-incompatible pair by creating a compatible through the national registry, DSA desensitization of recipients can be reduced and allograft outcomes improved, For those waitlist patients that are highly sensitized, we can reduce the degree of risk for late kidney allograft loss, we can reduce the time waiting for an organ offer

and we will thereby improve the utility of the resource whilst shortening the period waiting for an organ and risk for dying on a waiting list.<sup>11-14</sup>

**To be successful the attitude and approach requires:**

- Remember why we are doing this
- Be creative in your approach to barriers
- Challenge the status quo
- Stay hungry – strive to continuously improve and find an edge
- Ask the next question
- Have a crisis response and include in this solutions and novel approaches to mitigate the impact

**DISCUSSION OF AND RECOMMENDATIONS FOR PHYSICIAN BEHAVIOR**

While many factors influence the complex process that facilitates utilization of deceased donor organs for transplant, physician and transplant center decision-making clearly is a lynch pin in the series of transactions that extends from organ offer to a successful transplant. Offer acceptance decisions are complex episodes, influenced by multiple factors including but not limited to: recent physician and center outcomes, characteristics of the recipients on the waiting list, incomplete information about specific donor characteristics, logistical challenges such as travel and timing of donor and recipient operations, familiarity with the OPO or hospital of the offer, recent transplant activity, and physician fatigue or personal conflicts. Furthermore, the current regulatory environment surrounding transplant, with its emphasis on one-year graft and patient survival following transplant, has pressured transplant physicians to primarily consider post-transplant outcomes in organ acceptance decisions. This perceived pressure to achieve essentially perfect post-transplant outcomes can distract from the critical mission of transplant, which is to provide life-saving donor organs to as many appropriate candidates as possible.

At the National Critical Issues Forum sponsored by the Alliance, multiple strategies were discussed to optimize physician behavior as it relates to organ utilization. While a myriad of strategies may be effective, those discussed at the forum fell into categories summarized as optimizing listing and transplant practices to take advantage of “low-hanging fruit” to increase organ utilization, identifying processes that optimize decision-making at the time of the organ offer, increasing collaboration with OPO partners and transplant centers, and creating a culture within transplant centers that values all providers and maximizes efforts to increase organ utilization.

While transplant is perhaps the most rapidly evolving and innovative field in modern medicine, the propagation of proven strategies to increase organ utilization can be inconsistent. Significant variation exists among transplant centers in listing and organ acceptance practices, even when validated “low-hanging fruit” strategies are considered. Darren Stewart of United Network for Organ Sharing (UNOS) summarized this variation dramatically, documenting that transplant

centers vary dramatically in the listing of patients expected to benefit from transplant with an extended criteria donor (ECD) kidney (candidates over age 40 with diabetes and/or long waiting times), with listing rates of 0 to 100%. This variation in listing practice deprives up to 50% of patients nationally who might benefit from an ECD kidney from receiving such offers. In the case of living donor kidney transplantation, which consistently offers superior survival benefit to patients awaiting renal transplant, several opportunities exist to maximize available living donor-recipient pairs. Adam Bingaman of Methodist Specialty and Transplant Hospital in San Antonio summarized these opportunities including: subtyping blood type A donors, entering compatible pairs into kidney paired donation pools, performing low risk desensitization, and maximizing use of O donors among recipients with panel reactive antibody (PRA) <95%. Use of these strategies can translate to increased living donor transplants, even among smaller transplant programs without extensive experience in kidney paired donation (KPD) or desensitization protocols.

Improving the organ acceptance decision-making event is critical to increasing organ utilization. As described nicely by Bryan Lima of Baylor University Medical Center's heart transplant program, excessive "noise" exists around the organ acceptance decision-making process. Insulating the responsible physician(s) from these diverse and distracting pressures is critical to optimizing organ acceptance decisions, and thus organ utilization. Such external pressures, combined with regulatory scrutiny that values post-transplant outcomes over waitlist outcomes, often leads to a "presumption of NO" when considering organ offers. Programs who have experienced marked growth and increased organ utilization have effectively converted to a "presumption of YES". Such strategies require a commitment of resources and flexibility to procure and/or transport more donor organs, and thus accept more "false alarms" when organs are turned down after procurement due to quality concerns. In addition, programs with more aggressive acceptance practices must have providers considering organ offers who have mastery of their waiting list, thus allowing flexibility in matching of donor organs to recipient characteristics. There are no industry standards in organ acceptance practices, and transplant centers use a variety of models in considering organ offers. However, it appears that the centers who have accelerated organ offers often have a more centralized system of organ offer consideration, with either a single individual (often program leader) having final say in organ acceptance decisions, or a system that creates opportunity for review of organ offers by multiple individuals before organs are turned down. Such practices can centralize decision-making to individuals that know the waiting list, and insulate on-call providers from decision-making that can be influenced by other clinical demands.

Collaborative partnerships between transplant centers and OPOs also appear to increase organ utilization. One perverse consequence of broader regional and national sharing of donor organs is that relationships between centers and local OPOs appear to have degraded to some degree. It is now essential for centers to interact with multiple OPOs, without the benefit of personal relationships and trust that have historically developed between local transplant center providers and OPO staff. Interaction with non-local OPOs, with personnel and protocols that are not familiar, can be an additional disincentive to organ acceptance. As it is unlikely that broader



sharing will diminish (in fact it will likely further increase based upon policy changes), the only antidote to this challenge is direct efforts by transplant center providers to interact directly with OPO personnel. Eliminating the “telephone game” that often exists in organ offer discussions (surgeon to transplant center coordinator to OPO coordinator to onsite coordinator etc.) is critical both to obtaining accurate information about donor characteristics and to creating trust between centers and OPOs with which they are not familiar. Furthermore, increasing standardization among OPO practices and protocols will eliminate some of the mystery and uncertainty that can cloud organ acceptance decisions due to variation in donor management and procurement practices.

Finally, as in all cases of organizational leadership, culture always trumps strategy. Transplant surgeons and providers must create cultures within their centers that value organ utilization as our most important mission. Again, regulatory pressures seem to have shifted the mission of many transplant centers to achieving perfect one-year outcomes, rather than to save more lives through transplant. Creating an imperative for organ utilization, such as reminding center providers that 20-25% of patients listed for liver transplant die while waiting, is critical to focusing efforts on increasing organ utilization. Ochsner Multi-Organ Transplant Institute in New Orleans has experienced exceptional growth in liver transplant volume while maintaining outstanding outcomes – a phenomenon that program leader George Loss attributes to having created a culture of trust and teamwork focused on the mission of decreasing waitlist mortality. Building a robust and highly functioning team requires enough committed providers that surgeons are not making organ acceptance decisions or performing complex operations when tired. All modifiable risk factors, such as cold ischemia time and operative efficiency, must be optimized. Transparency about decision-making and outcomes must exist, such that failures are dealt with openly and collaboratively to strengthen the entire team. Individuals must be treated and reimbursed equally and fairly, without personal gain tied to individual transplant events (i.e. incentivize quality, not volume). Ultimately, the most effective cultures appear to be driven by passion, particularly the passion of a committed leader dedicated to the team and center over individual.

## **DISCUSSION OF AND RECOMMENDATIONS FOR PATIENT BEHAVIOR**

Central to patient offer an acceptance is our role as a transplant community to educate. The forum identified that, in line with those recommendations above, national guidelines should be established and best practices established for providing patient education on what will be a difficult decision for some.

The following are recommended:

1. During the initial transplant evaluation the various donation opportunities must be discussed including those associated with living donation, deceased donation and with deceased donation education specifically on the domain of PHS increased risk and donation after cardiac death should be performed.

2. Confirmation of an understanding of this should be obtained from the patient and the care partners at the end of the transplant evaluation.
3. Best practices would suggest that consent for PHS increased risk donors should be attained at the time of listing for transplantation.
4. Continuing patient education should occur with each clinical encounter.
5. Data should be made available to the patients to access through and education portal.
6. Patient should be provided information on the potential outcomes of particular offers as part of the educational process and prior to consent.

If we are seeking to enhance utilization without creating uncertainty in patients, it was the consensus of this meeting that the sharing of information and establishing best practices for the communication of information to patients is essential.

### **DISCUSSION OF AND RECOMMENDATIONS FOR OPO BEHAVIOR**

OPOs function within a complex system of interdependent relationships and system-level behaviors involving<sup>15</sup>:

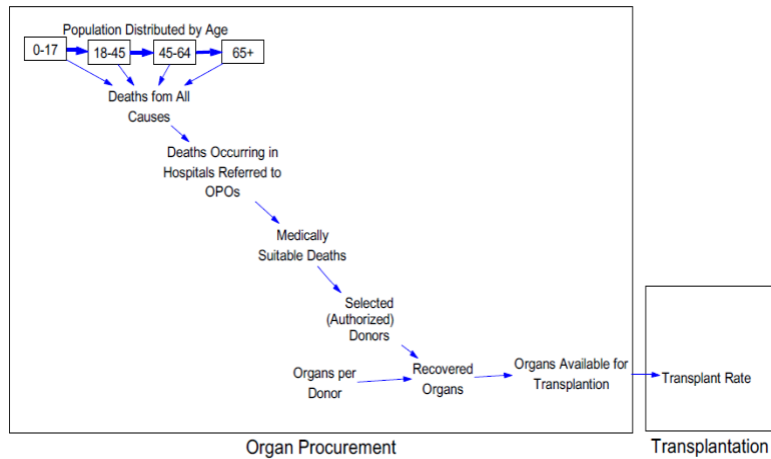
1. OPO and assigned DSA hospitals where patients die and may meet clinical criteria for organ procurement for transplantation.
2. OPO and DSA community made up of various demographic populations willing or not willing to donate organs.
3. OPO and DSA-located hospitals that provide organ transplantation services.
4. OPO and non DSA-located hospitals that provide organ transplantation services in geographically dispersed areas.
5. OPO and Organ Procurement Transplant Network (OPTN) policy and compliance framework (organ allocation per required allocation algorithms, data reporting, performance analysis, policy compliance, patient safety practices compliance).
6. OPO within a community of 58 OPOs with varying levels of providing organs for transplantation anywhere in the United States (U.S.).

These relationships and interdependent behaviors create both intended and unintended consequences that impact the overall transplant system performance ultimately based on organs donated and recovered, organs made available for transplant utilization, accepted, and transplanted and with suitable clinical and economic outcomes. As discussed during the forum, aligning each of these key steps results in an efficient and effective donation and transplant system with performance rates that range from lower to higher across the geography of the U.S.

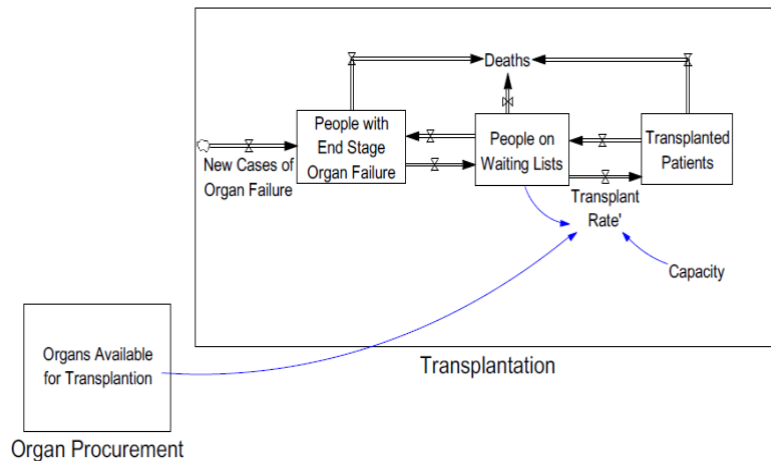
Multiple published studies have demonstrated variation in performance and outcomes for both OPO and transplant programs while ongoing monitoring highlights a spectrum of performance outcomes over time. In isolation, various components of the system seem to have solutions to challenges in performance, yet when focused upon, unintended consequences in the overall system actually negatively impact these areas such as organ acceptance because of assumed

negative impact on transplant outcome measurement and subsequent risk averse acceptance behaviors. Such behaviors then impact organ acceptance patterns, reduced organ utilization rates and increases in organs discarded, and subsequent OPO behaviors that may impact pursuit of similar organ donors in the future.

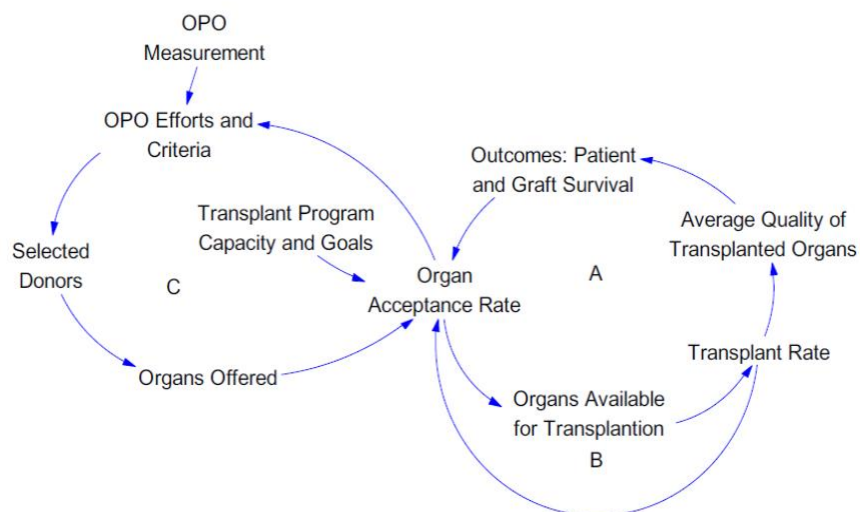
A graphical representation of organ procurement relationships is shown below in Figure 1.



A graphical representation of transplant program relationships is shown below in Figure 2.



A graphical representation of OPO-Transplant program interdependent relationships is shown below in Figure 3.



1. OPOs are designated to provide donation services in assigned DSA hospitals where patients die and may meet clinical criteria for organ procurement for transplantation. The OPO-hospital

relationship influences the degree to which hospital staff are educated about organ donation, recognize potential donors, refer them to the OPO for donor potential evaluation, support potential donors with clinical management and then develop and optimal donation environment where authorization for donation is granted. The concept of developing and maintaining a “culture of donation” is a universal goal of OPOs that is aimed at increasing the donation rate of each hospital and thus the OPO to provide the maximum numbers of organs available for transplantation. This donation rate includes two major types of donors; most frequently, those declared dead by neurologic criteria and less frequently, those declared dead by circulatory criteria. Within this framework, OPOs and hospitals work together to balance service to hospitals, hospital client families experiencing loss, and through the OPO, to patients waiting for transplantation anywhere. Behaviors with known challenges and suggested opportunities for improvement are highlighted below:

OPO resources limit staff presence & service responsiveness to all hospitals	Increase resources, create more collaboration between hospital and OPO, educate for more involvement by hospitals
OPO resources limit aggressive pursuit of potential donors with assumed lower yield of organs for transplant	Adapt practices from higher performing OPOs to spread practices that maximize all donation opportunities
Observed donation rate is lower than expected	OPOs seek learn more effective practices and implement those
Leadership / culture of OPO resists change	Spread more effective practices
OPO is influenced by DSA transplant programs that may not accept organs from donors that are less than “ideal”	OPO provides feedback to local transplant programs about utility of these organs and works to place these organs at centers outside local DSA

2. OPO and DSA community made up of various demographic populations willing or not willing to donate results in regional geographic variation impacting the initial supply of transplantable organs. The degree to which OPOs can influence these rates of donation has been a long-standing debate among procurement professionals. The establishment of donor registries and more importantly, the willingness of OPOs to consistently honor the donor’s wishes have made an important impact on driving up donation of organs, eyes and tissue (reference). Many states report donor registry enrollment rates greater than 50%, some reporting above 80%. Numerous other states are rapidly increasing their donor registry rates (reference Texas > 1 million per year). The role of community outreach and advertising on the local, regional and national basis has recently become more market-research based using national campaigns designed by Donate Life America and others. There are emerging patterns of evidence that these campaigns, especially in social media do gain attention and increased donor registration.
3. OPO and DSA-located hospitals that provide organ transplantation services is the traditional and fundamental relationship in the historic structure of OPOs traditionally focused on local DSA with a bias for locally recovered and locally transplanted organs. As variation in practice patterns

across centers and regions has accelerated (reference acceptance patterns, paper by Jesse Schold), local acceptance patterns which primarily influence organ utilization has transitioned dramatically following Organ Donation Breakthrough Collaborative (2003-2010) efforts to a more nationally based system. In fact, major efforts to reduce geographic variation in organ availability and patient mortality while waiting is driving wider organ allocation systems and more complex organ placement efforts by OPOs to maximize organ utilization. The conflict between best use of the organ on various definitions of outcome other than simply “offered, placed, transplanted” creates a tension between ideal recipient in some location versus extended organ preservation times and likely reduced function. Balancing these competing goals is difficult and current organ allocation systems and compliance requirements to ensure every candidate on the “list” is offered the matched organ, and efforts to use each recovered organ do not include critically needed and regulated alternate pathways to help increase organ utilization. Each available organ, even those with predicted shorter graft survival, likely has a transplant benefit compared to not being transplanted in the first place (reference Volk, Segev, others).

4. OPO and non DSA-located hospitals that provide organ transplantation services in geographically dispersed areas become known by professionals working in the field and though data that are more willing to accept organs on the margin. While it may be common wisdom that based on experience (behavioral economics, bias), a certain distant center will accept an organ not commonly or never accepted locally, the OPO today must still proceed per allocation policies and offer the organ through the list while preservation time builds. This frustrating situation creates an opportunity for an evidence-based alternative allocation system for organs of some certain degree of quality threshold that could allow the organ to be placed in parallel systems or in a system that identifies the most accepting of centers.
5. OPO and Organ Procurement Transplant Network (OPTN) policy and compliance framework (organ allocation per required allocation algorithms, data reporting, performance analysis, policy compliance, patient safety practices, compliance) create intended and unintended consequences. The unintended consequences with the goal of ensuring equal access to available organs regardless of geography, most likely drives up organ discard and limits utilization that could be afforded by a more flexible system. Some examples of alternate systems are the current Collaborative Improvement & Innovation Networks (COIIN) research project, proxies of the European allocation system that accelerates older organ allocation for older patients and the possibility of a facilitated allocation process for high KDPI kidneys for example.
6. OPO within a community of 58 OPOs with varying levels of providing organs for transplantation anywhere in the United States. Organ donation rates vary by geography (include graphs from DDPS) and for various reasons. SRTR data illustrates this variation and specific reasons for the range of performance is subjective (leadership, culture, resources) and difficult to isolate (population variation, multicultural factors, impact of donor registry). Regardless, multiple OPOs have demonstrated significant improvement in volume of organ donors recovered and organs

made available for transplantation anywhere. These facts (reference 2016, 38/59 OPOs increased organ donor volume) highlight the opportunities for system wide improvement.

## **FUTURE OPPORTUNITIES**

There are a lot of great ideas to improve utilization of organs that can be implemented relatively quickly and easily, many of which are outlined in this paper. These opportunities will no doubt have a positive effect on the number of patients transplanted. There are however additional opportunities for future improvement that should be explored and discussed within the transplant community:

### **Honor the Donor**

For the most part, our entire allocation and transplant system is designed for the benefit of transplant recipients. As in all medicine, transplant professionals have the best interests of their particular patient as their main focus. This has led to a system that allocates organs not to maximize use or benefit to society, but rather to be fair to all patients and give the sickest patients, the most and best opportunities to receive a transplant. The value of the gift of donation is not part of the equation when utilization decisions are made. Possibly the single greatest opportunity to increase utilization is to change the paradigm and make “Honoring the Gift of Donation” a major consideration for the entire transplant community. “Honoring the Gift” is not a specific recommendation, rather a change in our collective thinking, goal setting and definition of success. Below are a few specific examples of how including “Honoring the Gift” in our thinking might change transplant policy and practice.

### **Design New Allocation System for Marginal Organs**

Instead of allocating marginal organs to the sickest patients, allocation would start with the patients and programs most likely to use the organ. “Targeted Lists” could be used within a DSA to start allocation. If not used for a targeted list, organs could be offered to programs nationally that consistently successfully transplant marginal organs for any patient they wish.

### **Reward High Acceptance and Transplant Rates**

Instead of (or in addition to) using survival rates to compare programs, use acceptance and transplant rates as a measure of success, and reward programs who achieve high rates of acceptance or low rates of offer turndown.

### **Compare Transplant Outcomes to “No Transplant” Alternative**

Currently we compare transplant outcomes to all other transplant outcomes. This misrepresents the true alternatives for patients. The real question is what is a patient’s result compared to no transplant at all? If we accepted for example that a XX% improvement in 5-year survival is “good” comparing no transplant to transplant of a specific organ, for a specific patient, then the decision to accept an organ could be based on consistent science.

### **Transplant Program Staff Expansions**

Organ donation has expanded nationally for the last 4 years, a trend that seems likely to continue as registries continue to expand and OPOs continue to innovate to increase organ availability. In nearly every OPO that has seen significant donation increases, staff has been expanded dramatically. Unfortunately, a corresponding increase in transplant staffing has not materialized



across the country. Administrations are focused almost exclusively on cost control; qualified transplant professionals are difficult to recruit and programs are reluctant to dilute their teams for fear of reduced quality. There needs to be an increase in surgeons and coordinators to fully utilize the increased number of organs if we are going to properly honor all donors.

### **Increased Efficiency of the Transplant System**

The current system of organ recovery and allocation is fundamentally based on the way organ transplant happened circa 1995. Surgeons routinely recover what they will transplant, allocation is top down, evaluation of organs is inconsistent, communication of information imperfect. In some cases, surgeons performing recovery are not well trained or simply overworked with the result being surgical errors and errors in judgement. Using professional recovery surgeons and modern telemedicine instead of having programs send teams to recover organs would improve the quality of recoveries and make the system more efficient, thus allowing better utilization and better use of resources.

### **SUMMARY AND CONCLUSIONS**

In 2016, 54,260 were added to a waitlist of approximately 118,000 people. In that same year 27,630 deceased donor transplant and 5,980 living donor transplants were performed. Both at the beginning and end of that year, approximately 115,000 people were awaiting transplantation and, in that year, approximately 15,000 people were removed from the waitlist for mortality or becoming too sick.

If we seek to address this unacceptably high failure in our intent to transplant we must appreciate every potential opportunity for our patients. This article seeks to provide all participants and the transplant process with an understanding that our decisions impact our potential and that our resource may be much greater than we currently realized. Through change comes opportunity.

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## APPENDIX: CHANGE CONCEPTS

The following questions, change concepts, activities, and potential expected outcomes provide the basis for a greater discernment across transplant centers to advance the common goal of increased organ utilization:

## **GENERAL PRINCIPLES**

### **Overcoming barriers:**

- Establish a clear mission and vision
- Eliminate any perception that your actions or those of your team are for personal gain.
- Consider a salary-based compensation package with some performance incentives that drive the correct behaviors that align with the programs mission and vision.
- Incentivize quality – patient survival, graft survival, decreasing death on the list, increasing utility of the resource in a judicious manner.
- Do not tie bonuses to transplant volumes and tie incentives to the behaviors and actions that benefit the patient, the program and the population you serve,

### **Generating growth in organ utilization:**

- Perform a good operation and have enough staffing per case and for redo transplants.
- Know the data surrounding every aspect of your operations
- Identify and address performance gaps
- Look for opportunities to improve and also to develop your program through innovative concepts and the best practices of others
- Analyze organ turn down and track the outcomes for refused offers subsequently transplanted and consider reports and weekly conference calls with your OPO.
- Establish annual meetings between OPOs and transplant program and develop annual reports that include and analysis of the transplant center partners of the OPOs
- Create improvement plans at the annual meetings with the OPOs.
- Organ acceptance practices – formalize a decline process with minimally 2 people being involved in an organ offer being declined and consider a formal process and a published guideline for the assessment of ever organ offer and tracking of donor factors and the decision process prospectively
- Should organ declines of subsequently transplanted and realized offers exceeding 30% consider inviting these programs to your program to present on their approach on organ utilization: SHARE BEST PRACTICES
- Standardization of biopsy reads (minimize organs lost due to the misinterpretation of biopsies).
- Consider attaining resources that allow for the personal interpretation of biopsies (adaptor for phones to allow photographs to be taken of actual biopsies and shared.
- Provide pathologists a quality assurance (QA) process on pathology reads and outcomes of organs that they have reviewed.

- When increased supply decreases waitlist size look to expand waitlist additions of candidates with the same qualities that were associated with appropriate outcomes.
- Consider novel technologies like a Fibroscan of the organ to enhance the utilization of HCV positive donors and donor that are obese.

### **Recipient selection and education practices to facilitate and optimize organ utilization:**

- Change concept (Efficiency): Identify best practices for organ acceptance for individual patients through waitlist management with:
  - identification of waitlist subsets, sub-lists, or top 10 to have better efficiency of organ offers,
  - risk mitigation through better education of staff and patients before an organ offer acceptance occurs,
  - look to pro-actively match before organ offer and acceptance those who might accept and any particular offer safely (HCV NAT positive into HCV NAT positive or HIV positive organs into HIV positive recipients),
  - establish standards for patient education and patient consent for Public Health Service (PHS) increased risk offers,
  - share established standards between programs to facilitate greater adoption of best practice and thereby organ utilization,
  - establish standards for patient expectations and preparedness so as to improve efficiency and outcomes in patient satisfaction whilst waiting and following organ acceptance.
- Change concept (Acceptance): Identify best practices for organ acceptance for individual patients through data utilization communication and transparency with:
  - immediate notification of organ offer usage for better decision making,
  - user friendly dashboards to change organ acceptance patterns,
  - real time organ usage and outcomes for better informed organ acceptance,
  - consider limiting the total number of offers seen by a center at any one time for a particular candidate to lessen decision fatigue.

### **Overcoming geographic barriers to increase organ utilization:**

- Change concept (Allocation): Identify best practices for reducing time constraints, and thereby to create greater certainty, when sharing over large distances:
  - consider revisions to the organ offer time limit,
  - standardizing the meaning/practice of a provisional “yes” to provide uniformity of expedited match run and reduced interval of time to allocation,
  - requesting from the OPO an organ donor alert or early communication to shorten interval time,
  - increase utilization of parallel offers to expedite the match run,

- revising the organ allocation process post recovery (expediting the match run) to decrease the amount of ischemic time.
- Change concept (Efficiency): Identify best practices for reducing time constraints of sharing over large distances through shifting towards local recoveries by:
  - hiring local specialized procurement surgeons to increase utilization and increase DCDD,
  - improved imaging prior to recovery for better presentation of the organ
  - OPOs having the ability to pump kidneys to decrease delayed graft function (DGF),
  - optimizing the scheduling of the recovery / transportation of the organ for increased organ utilization.

**Organ evaluation practices to facilitate effective placement and utilization of donor organs:**

- Change concept (Priority): Provide standardized, accurate and comprehensive donor information to ensure efficient, consistent and successful organ placement and thereby utilization through:
  - sharing of evaluation data with accepting physicians/surgeons on the placement platform of DonorNet,
  - review and rapidly update the minimum information needed for organ offers to be accepted and thereby potentially enhance utilization. These data should be monitored periodically for ways to further enhance offer data.
  - ensure that information provided is framed objectively and without personal bias,
  - ensuring the donor information entered is accurate and as complete as possible (OPO standardization),
  - implementing DonorNet enhancements to increase efficiency – notifications pushed when donor info changes, program is now 1° or on deck and having IM capability,
  - true oversight and ownership of the DonorNet system (currently an orphan child).
- Change concept (Efficiency): Provide standardized, accurate and comprehensive donor information to ensure efficient, consistent and successful organ utilization through the development of a methodology for expedited or facilitated organ placement by:
  - defining the parameters and mechanism for facilitated/expedited placement by organ system to enhanced utilization,
  - ensuring transplant centers have a process in place to respond to expedited offers,
  - exploring the concept of offering to a center vs patient (open offer) and increase the number of centers who can get the offer,
  - developing expedited placement list based on past offer acceptance and utilization data.
- Change concept (Demography): Provide standardized, accurate and comprehensive donor information to ensure efficient, consistent and successful organ utilization through the

development of a mechanism for standardized biopsy interpretation and dissemination with:

- standardized regional/national parameters,
- capacity to share digital images.
- Change concept (Opportunity): Provide standardized, accurate and comprehensive donor information to ensure efficient, consistent and successful organ utilization through the use of technology to provide transplant centers with data to facilitate organ offer and acceptance with:
  - revision of data reports of center turndown and outcome reviews (timelier)
  - revision of refusal codes,
  - enhancing data points w/in UNets<sup>SM</sup> to help with risk stratification for outcome adjustment.

### **Communication practices and strategies to increase organ utilization:**

- Change concept (Increasing potential): Develop communication strategies designed to maximize organ utilization by identifying organs most at risk for discard by providing:
  - extra-renal post cross-clamp: intra-operative declines enable OPOs to use expedited allocation,
  - transparency for situations when the transplant centers are handling multi-offers for a patient,
  - effective communication plan for managing primary back-up offers,
  - Scientific Registry for Transplant Recipients (SRTR) definition of organs meeting increased risk for discard: move to predictive allocation.
- Change concept (Communication): Develop communication strategies to maximize organ utilization by collecting and reporting granular data in organ declines and discards and contrasting these to offers accepted and utilized:
  - develop more granular data submission related to decline codes so that we might better understand the rationale of the declining of a later accepted offer,
  - communicate with centers who declined an offer that was subsequently transplanted the outcome of the offer,
  - compile a comprehensive behavioral assessment of transplant center discard and/or decline activity through the SRTR platform and share best practices,
  - develop a reporting portal for intra-operative and post-operative organ declines with reasons,
  - develop a reporting portal for activities related to facilitated placement of offers declined by others and circulate the best practices of the accepting centers.

### **Organ offer data to facilitate organ utilization practices:**

- Change concept (Information/Data): To improve organ utilization by providing targeted data that facilitates successful transplants by packaging the data to the transplant centers to optimize the efficiency of organ evaluation to:

- provide simulation with transplant center decision makers to understand what organ specific data they use and what organ specific data high performing centers use when accepting offers,
- assess OPO performance for clues to utility through similar simulation exercises,
- redesign how the information is packaged based on the evidence/results of the simulation,
- have real-time recipient information available in UNets<sup>SM</sup> at the time of organ offer.
- Change concept (Performance Metrics): To improve organ utilization by providing targeted data that facilitates successful transplants through new performance metrics for both transplant centers and OPOs by:
  - developing new data sets that better reflect patient outcomes for patients who have been listed for transplant within a donation service area (DSA),
  - developing standardized process for which OPO donation rates are measured,
  - Consider offer and acceptance of successfully transplanted organs as a performance metric.

**Actions to improve the public’s understanding of organ quality and principals associated with appropriate acceptance:**

- Change concept (Community): Create a consistent and transparent national message that builds the public’s trust by uniting OPOs, transplant centers, hospitals, legislature, regulatory and community leaders to create a unified patient-centered message that emphasizes urgent need to save lives and dispel myths by:
  - coordinating joint participation at society meetings to facilitate organ utilization and public trust,
  - developing a unified local and national message, recognizing the power in numbers, through partnerships by stakeholders, and the media,
  - holding national donor/transplant 5K race on same day each year, while honoring donors via a national donor memorial,
  - providing every transplant candidate with the same packet of info via print and social media, re: living donor and deceased donor rates,
  - using personal stories to increase public trust.
- Change concept (Community): Create a consistent and transparent national message that builds the public’s trust by uniting OPOs, transplant centers, hospitals, legislature, regulatory and community leaders to convene statewide summits (in all 50 states) to develop a consensus on strategies to expand donation and increase rates of transplants by:
  - identifying key participants from transplant centers, OPOs, the industry, and the community,
  - identifying and engaging high level sponsors,
  - identifying statewide initiatives currently in place to identify gaps,



- holding a summit to solve disparity between rates of donation & transplant needs.

### **Ethical considerations and the implication of these upon organ allocation and utilization:**

- Change concept (Ethics): Develop key ethical practices and expectations that improve organ allocation and utilization by creating an industry-wide expectation agreement for transplant patients to:
  - reset patient expectations in the setting of worsening donor quality,
  - increase organ utilization of marginal organs.
- Change concept (Expectations): Develop key ethical practices and expectations that improve organ allocation and utilization by modifying organ allocation policy to balance ethical considerations:
  - Consider developing models that might predict for a program what offers they should use and consider allocating specific offers to centers.
- Change concept (Transparency): Develop key ethical practices and expectations that improve organ allocation and utilization by increasing transparency and consider publishing transplant program organ acceptance practices.

### **Ethical considerations and the implication of these upon high kidney donor profile index (KDPI) kidney organ allocation and utilization:**

- Change concept (Eliminate Barriers): Reduce barriers to using high KDPI kidneys by bridging the ethical gap between the benefit to an individual patient and the benefit to the waiting list by:
  - Producing a document that can be distributed to patients with end-stage renal disease (ESRD) at nephrologist offices, and in transplant center waiting rooms, authored by a trusted non-medical / non-transplant society, such as the American Association of Retired Persons (AARP). This needs to be written in a concise manner that does not play to the concerns of ageism, but presents the current state of organ shortage and waitlist mortality, making high KDPI kidneys more of an opt-out option for patients that would benefit. The expected outcome is to reset expectations of recipients by increased understanding of organ shortage, waitlist mortality and the advantage of high KDPI kidneys.

**Economic considerations when managing patients who have received the higher risk organs and how to guide decisions to mitigate economic consequence:**

- Change concept (Economics): Define high risk organ – those where cost is significantly higher related to increased LOS, DFG, or need for ICU stay (quantifiable, objective, simple, applied nationally) by:
  - creating multi-disciplinary workgroup to define high risk that leads to high cost.
- Change concept (Economics): Establish funding for new technologies to assess grafts or improve function (ex vivo lung perfusion (EVLP), kidney and liver pumping, etc.) by:
  - identifying major payor to model extra-renal cost savings,
  - creating a cost benefit analysis – transplant earlier and more organs,
  - identifying funding sources to cover direct sources of technology.

**What factors are of concern from a cost perspective, either from the OPO or transplant center, that impact decision making that hinder organ utilization and which approach and/or perspective could help to facilitate organ utilization?**

- Change concept (Finance): Costs can be contained or offset and utilization improved, through standardization with flexibility, and alignment of regulatory policies between OPOs and transplant centers to balance and align transplant center and OPO practices focused on improved utilization by:
  - revising outcomes regulations to honor every organ every time,
  - align decisions with a developing system to save the greatest net number of lives
  - using data analytics to revise processes; i.e. acceptance and listing criteria.
- Change concept (Finance): Costs can be contained or offset and utilization improved, through standardization with flexibility, and alignment of regulatory policies between OPOs and transplant centers through collaboration and coordination of processes by:
  - communication of OPO process to transplant centers to actualize better time utilization and lower costs,
  - improving relationships between OPO and transplant centers, e.g. add new position of Director of Transplant Center Relations to optimize relationship,
  - reviewing utility models in all domains of organ allocation to mitigate future loss with organs matched to recipients for factors like age, recipient life expectancy, etc.,
  - with new allocation systems and with changes to transport times commence discussions and analyses between OPOs and transplant centers should occur to mitigate costs,
  - consider organ procurement centers within DSAs to optimize efficiency.

**What opportunity exists to have different reimbursement models that would allow for cost and risk sharing with insurance carriers for higher organ utilization with higher risk organs?**

- Change concept: Assemble all the stakeholders (transplant centers, OPOs and insurers) to explore shared risks (incentive alignment) by piloting projects that can be accomplished with transplant centers and OPOs such as:
  - guidelines to track and standardize waivers,
  - reduce centers procuring their own organs (tech, waive, etc.),
  - pass-through OAC (extra-renal organs align to kidney),
  - sliding scale - organ cost,
  - incentivize live donors (insurance for donors),
  - pay for performance on getting patients transplanted sooner.