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Deceased Donor Potential for Organ Transplantation: A System Dynamics Framework

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Abstract

Organ transplantation is a lifesaving procedure for many people. However, the lack of organs from deceased donors makes it unavailable for many additional people who need it. A commissioned study was undertaken to estimate deceased donor potential in the US. Organ procurement and transplantation take place in the context of a complex system of organizations and policies. This system can both constrain and enhance the realization of deceased donor potential. A system dynamics model is being developed to help identify how that system's behavior affects the availability of deceased donor organs and how particular strategic policy options might increase the number available for transplantation. The version described in this paper utilizes data for kidney procurement and transplantation for the entire US. The structure and data sources for the model are described along with illustrative tests of those strategic options.

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1. Introduction

According to the National Center for Chronic Disease Prevention and Health Promotion, chronic diseases are the leading causes of death and disability in the US (CDC/NCCDPHP, 2012). Seven out of ten (7 of 10) deaths among Americans each year are from chronic diseases. Heart disease, cancer and stroke account for more than 50% of all deaths each year (Kung et al., 2005). Diabetes continues to be one of single largest determinants of kidney failure, non-traumatic lower-extremity amputations, and blindness among adults (CDC, 2008). For many patients in the final stage of these diseases, organ failure, transplantation may be the only option for remaining alive. Even for organ failure where there are alternatives such as dialysis for end stage renal disease, transplantation represents a significant improvement in quality of life and longevity. Once an infrequent event, transplantation has now evolved into everyday procedure supported by an elaborate system that includes interaction of the following elements: organizations seeking organ donations; patient waiting lists; people signing up at motor vehicle and/or state registries to allow use of their organs after death; families reached by other means who consent to the recovery of organs from of loved ones; transplant programs specializing in a reliable and relatively safe transplant procedure; and government agencies that regulate the system to assure efficacy, fairness and promotion of public interest in organ allocation and transplantation.

Some of the transplants performed each year utilize organs from living donors (kidney and liver), but the majority come from patients who are declared dead by either neurologic criteria (brain dead) or circulatory criteria (cardiopulmonary arrest). For kidneys, the organs transplanted in the largest numbers, there were a total of 11,042 transplants from deceased donors and 5,771 from living donors in 2011. (OPTN, 2012). Only a small fraction of the 2.5 million deaths in the US each year occur in a manner that lends itself to retrieval of organs for transplantation. As a result, there are many more organs needed than available and long waiting lists of patients who would benefit from a transplant. At the end of 2011, there were a total of 90,468 patients waiting for kidneys with 62% of those in “active” status ready to receive a transplant. The number of transplants that can be performed is naturally limited by the number willing to be living donors and the number of deceased donors which are, in turn, limited by the number of deaths that take place in settings where organs can be retrieved in a timely manner consistent with clinical requirements.

A study was undertaken in 2010 by the United Network for Organ Sharing’s Center for Transplant System Excellence, under contract to the US Health Resources and Services Administration’s (HRSA) Division of Transplantation, to estimate deceased donor potential for the US and to examine ways in which this potential could be expanded. Recognizing that transplants in the US occur in a complex system, UNOS contracted with two system dynamics modelers to create a model of the donation and transplant system that could be used to understand better

- how that system functions in the context of influencing estimates of deceased donation potential, and
- how various strategic policy options could be employed to enhance the projected availability of deceased donor organs over time.

This application to organ procurement and transplantation was also expected to benefit from experience with extensive system dynamics work in chronic illness and health care delivery. (Homer and Hirsch, 2006; Homer et al, 2004; Hirsch et al, 2010; Homer et al, 2010)

This paper will describe the model and how it was developed, sources of data used, results of initial policy tests¹ of those strategic options, and suggestions for work that could be done in the future.

1.1 The Organ Procurement and Transplantation System

The system in which organ transplants occur has two key parts: organ procurement and transplantation as shown in Figure 1.1. These components work together to determine the numbers and types of transplants done. In the US, there are 58 Organ Procurement Organizations (OPOs) covering defined geographical catchment areas called Donation Service Areas (DSAs). The OPO’s primary responsibility is to work with hospitals within their service area to identify potential donors and arrange for the efficient and safe retrieval of organs in a timely manner. OPO hospital development and clinical procurement staff members are in constant communication with hospitals, are notified when there is a brain death or impending death, work with families to obtain consent for organ donation, and arrange for organ retrieval with transplant program physicians. As indicated in Figure 1.2, OPOs effectively manage a flow of referrals that looks like a funnel, starting with a large number of deaths and shrinking as donors are excluded for various medical reasons. OPOs inform transplant programs of the availability of organs, and participate in an allocation and distribution processes defined by the Organ Procurement Transplant Network (OPTN).

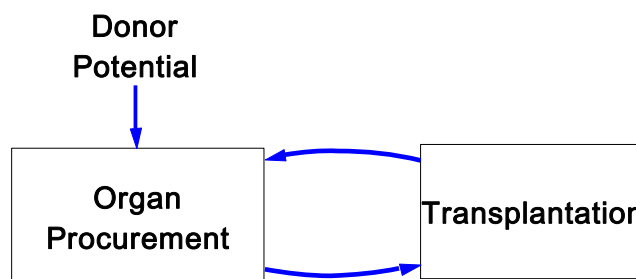


Figure 1.1: Overview of donor potential, organ procurement, and transplantation system

¹ **Policy tests** in this paper refer to the exploration of strategic options that may be considered by the transplant network in setting strategic priorities or for planning purposes. Therefore, policy in this context does not denote specific directives or implications for formulating policies and bylaws via traditional OPTN policy development processes (private rulemaking) or the adoption of additional federal regulations by government agencies with regulatory oversight like HRSA and the Centers for Medicare and Medicaid (CMS).

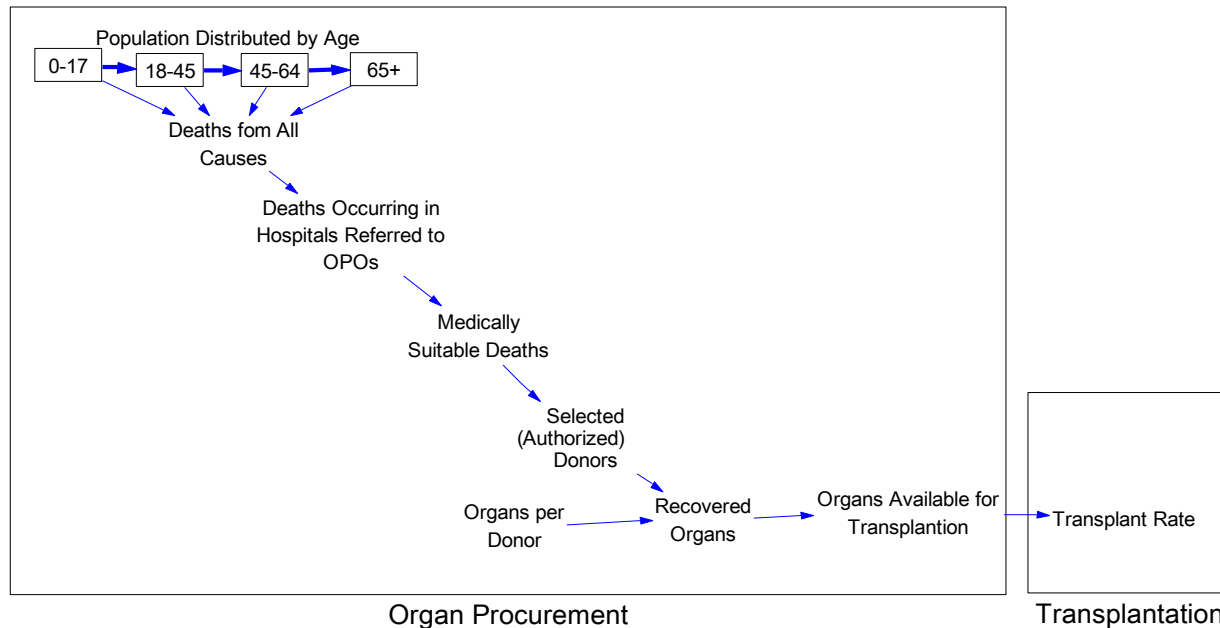


Figure 1.2: Donor potential and organ procurement characterized as a narrowing funnel of deaths

Only 35-38% of deaths occur in hospitals (CDC/NCHS, 2010). All (hospital) deaths are referred to the respective DSA organ procurement organization (OPO). After a thorough, rule-based screening process, only a fraction of those referred will be further evaluated as potential donors. Only a fraction of those referred will be deemed medically suitable and a fraction of those will be selected as donors once OPO’s receive consent from donors’ families and/or find the donor in a state organ donor registry. The number selected as donors together with the number of organs per donor will determine the number of organs that are available to be used in transplants.

Transplant programs evaluate candidates for transplantation, manage waiting lists of those evaluated as medically acceptable candidates, perform transplants as organs become available, and provide follow up care for those who receive transplants. Some deal with only a single organ such as a kidney while others are able to transplant multiple types of organs. Other solid organs that are transplanted include the liver, lungs, heart, pancreas, and intestine. Figure 1.3 shows the critical flows of people through the transplant process. There is a population of patients who develop chronic disease leading to end stage organ failure. (A few patients require transplants as a result of acute conditions.) Some fraction of those patients move on to waiting lists. Some die while waiting for a transplant, some get too sick to have the surgery, and some receive transplants. The rate at which transplants are performed depends on the availability of organs and patients and capacity of the transplant programs. A large fraction of transplants are successful initially, but some patients have grafts that do not survive each year and some die despite having the transplants. Patients whose grafts do not survive may rejoin waiting lists for re-transplantation.

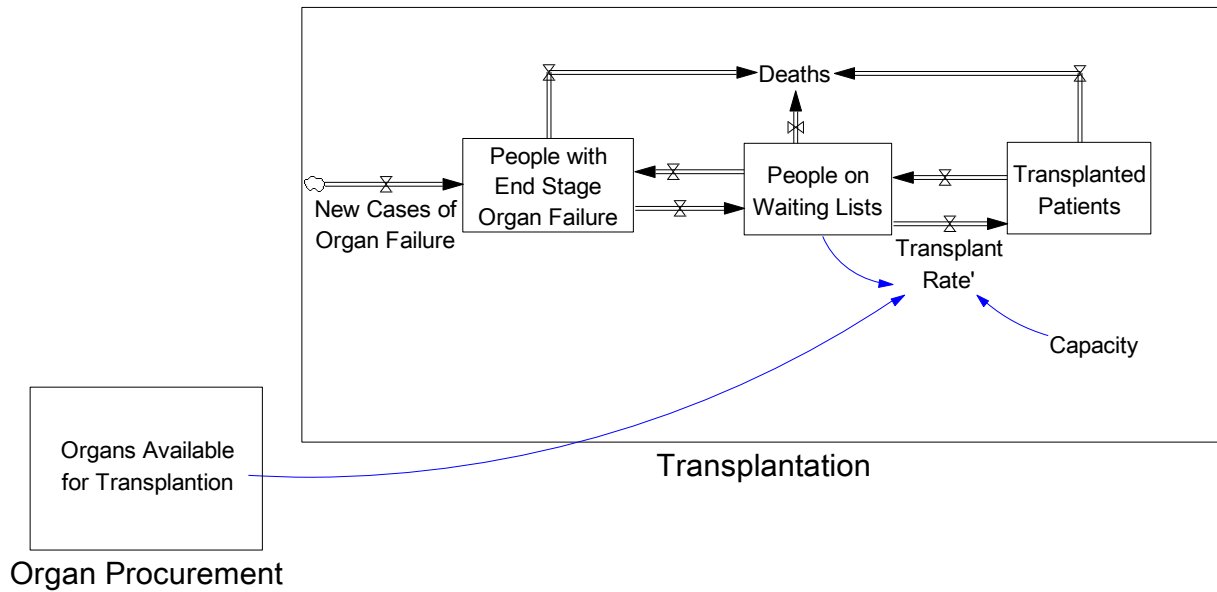


Figure 1.3: Flows of People Associated with Transplantation

The description of the system so far suggests that there is a straightforward flow of organs and patients to transplantation limited only by the number of available deceased donors. However, conversations with those in the transplant world, on both the organ procurement and transplant sides, suggest that there are important feedbacks in the system that can constrain or enhance the numbers of transplants performed. For example, as shown in Figure 1.4, transplant programs decide whether organs from particular donors are acceptable for one of their patients. The volume of transplants done may affect the average medical quality of donors and organs from those donors which can, in turn, affect outcomes such as graft and patient survival. Concern about organ quality and outcomes can then affect criteria for organ acceptability. One transplant program may deem an organ from a particular donor acceptable while another that is more risk averse will not want to accept the organ, even if it means a longer wait for their patients. On the other hand, a more conservative approach may provide more consistent outcomes that encourage more patients to seek transplants and also help to maintain the survival and potential growth of the transplant program. It is important to understand how these feedbacks modify donor potential.

Figure 1.5 presents some additional feedback loops that can constrain organ availability. One, indicated as loop B, suggests that transplant programs have particular goals and they may become more selective about organ acceptance once those goals are met. This loop can work in concert with loop A to make transplant programs more risk averse once their goals have been met. Loop C similarly suggests that OPO criteria for the types of donors they will attempt to obtain will depend on their goals and how their performance is measured. Measurement based on variables such as organs per donor and conversion rates may cause them to avoid certain potential donors who are likely to yield fewer organs or be more difficult to convert from potential to actual donors. Past experience with transplant programs not accepting organs from certain types of donors may also discourage them from pursuing those donors.

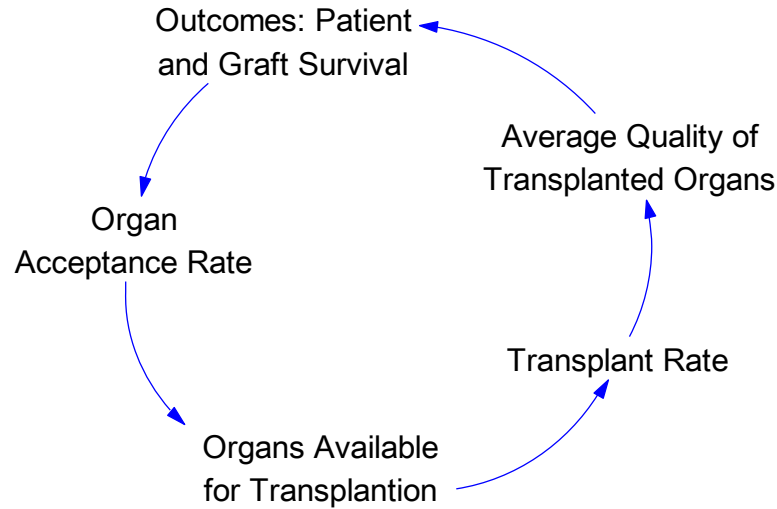


Figure 1.4: Feedback loop affecting organ acceptance through perceived quality

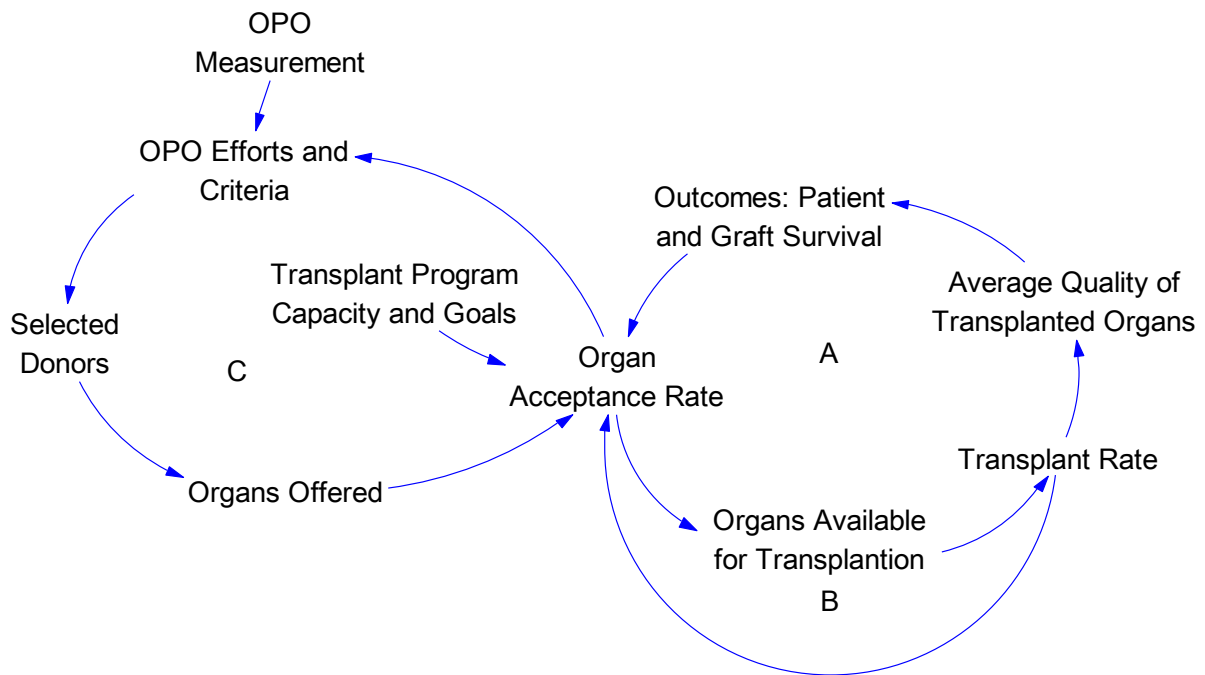


Figure 1.5: Additional feedback loops constraining organ availability and acceptance

The next section describes sources of data used to quantify and validate the model.

2. Sources of Insights and Data for the Model

Forrester (1980) indicates that the causal structure of a system dynamics model should be based in large part on behavioral information that resides in people's experience. The behavior of such a model depends largely on the structure that is elicited from this experience, especially where the structure contains feedback loops that drive a system in a particular direction (reinforcing loops) or that resist change (balancing loops). Behavior patterns produced by the model should hold true over a wide range of different input parameters. We have made a concerted effort to elicit this experiential information as it relates to organ procurement and transplantation and supplement it with quantitative information that allows the model to be validated against historical data.

2.1 Field visits and stakeholder meetings

The modeling effort began with visits to a small number of OPO's and transplant programs to get a basic understanding of the processes involved in organ procurement and transplantation. These were supplemented by interviews with UNOS staff and extensive conversations to get a good overview of organ transplantation in the US. These were supplemented by further visits and phone conferences with additional OPOs and transplant programs to validate the completed model and help apply it in several Donation Service Areas with different demographic characteristics.

Additional inputs about elements to include in the model came from two stakeholder meetings held in March, 2011 and March, 2012 that included a cross-section of 40-50 people from OPO's and transplant programs as well as individuals from academic institutions and government agencies with expertise relevant to questions of donor potential. The Stakeholder Committee consists of thought leaders and key stakeholders from both the transplant and non-transplant community. These stakeholders, selected with input and approval from HRSA, were a diverse group representing the following constituents: OPO leaders and procurement professionals; transplant clinicians (surgeons and physicians), and other clinicians with expertise in critical care, emergency medicine, palliative care, and transplant nursing; and researchers with subject matter expertise in epidemiology, geography, public health, health economics, health services research and statistics, and system dynamics, many of whom hold an interest in transplantation among other health care issues. Exercises at the first meeting identified key variables. Part of the second meeting was devoted to reviewing a draft model and identifying additional concepts to be represented. Validation of the model by these meetings will be supplemented by the small group sessions mentioned above.

2.2 OPTN data base

The Organ Procurement and Transplantation Network has a very rich data base of donor and recipient characteristics including data on outcomes (graft and patient survival rates). These data were used in the quantification of the model for many of the initial values of stocks and fractions of patients flowing from one status to another each year. As an initial test, the model was parameterized for kidney transplantation for the US as a whole, beginning in 2001 and running through to 2021. The model closely approximated recorded data during the 2001 to 2011 time period. Model parameters were further refined based on more extensive analyses of OPTN data, and supplemented with other data sources that incorporate important population, demographic, epidemiologic and geographic factors from sources such as the US Census and the CDC's National Center for Health Statistics.

2.3 Stakeholder input and causal factors survey

Initial identification of variables to include in the model came at the first stakeholders meeting in March of 2011. As indicated above, stakeholders were presented with simple templates showing flows of patients and organs through the transplant system and asked to identify variables that had an influence on those flows. This process led to the identification of a number of causal factors. It did not, however, provide a sense of the relative influence of these factors. The next step was to do a survey of the stakeholder group to discern relative influence and identify any new factors that the earlier exercise may have missed. There were 37 responses to the causal factors survey, balanced between OPO and transplant program respondents plus third smaller group of knowledgeable observers from transplant community. The survey yielded a number of useful insights and support for adjusting certain model variables as well as some new variables to consider. Analysis of responses by those in the survey revealed some interesting differences in perception between those working in OPO's and those in transplant programs.

Key insights from the stakeholder survey included the following:

- Agreement that transplant capacity is not a fixed constraint and can be somewhat flexible.
- Imports (organs supplied to a DSA from a distant DSA) and exports (organs provided to another DSA from an originating or "local" DSA) are not a large component of available organs in most DSA's.
- Volumes of transplants required to meet program goals, regulatory requirements to maintain certification by Federal agencies and private payers are not as important in determining transplant program capacity and volume as number of qualified surgeons and medical support available

- Differences in perceptions between OPOs and transplant programs in at least two areas:
 - Perceived importance of organs per donor available and the numbers of people on waiting lists on transplant rates
 - Effect of concern about poor outcomes on transplant program capacity and volume in a counterintuitive direction

More extensive analyses of the data will be performed to derive more insights and value from the survey. This effort will be pursued concurrently with other proposed model validation activities. .

3. Detailed Model Structure

The deceased donor model is organized into several subsystems. Figure 3.1 provides an overview that shows how these subsystems relate to each other.

Demographics affect both the donor potential and people entering the patient (transplant candidate) queue. Potential donors become actual donors through a conversion process that depends on the OPO's ability to gain the consent of donors' families if the deceased donor is not already registered as an organ donor via various state-based donor registries. Its success is influenced by OPO capacity and effectiveness and results in organs being available for transplantation. OPO capacity can respond to multiple factors that affect the demand for organs including the length of the patient queue (on waiting lists) and transplant rate. An OPO's revenues affect its ability to expand its own capacity to obtain organs.

Available organs and, to a lesser extent, transplant program capacity, determine the transplant rate and the wait to receive a transplant. Available organs may not be recovered. This is often true for organs other than kidneys. Most organs recovered are transplanted and the fraction not transplanted are discarded or used for other purposes such as research. Average organ quality is affected by the volume of organs accepted by transplant programs. A larger pool of organs may imply a larger fraction with less-than-ideal characteristics. Accepting more organs may imply less selectivity over a continuum about donors' condition and medical history and the condition of organs to be transplanted. Centers with greater tendencies to accept organs may be responding to longer wait lists and waiting times and competition for organs within a region. (Garonzik-Wang, James, Weatherspoon et al., 2012) Alternately, accepting fewer organs may denote surgeon/clinician preferences and comfort (experience, established protocols, etc.) in dealing with suboptimal organs in their transplant market areas. Current evidence suggests underutilization of the organ acceptance criteria system that could make matching of donors and recipients more uniform. Many transplant centers are thought to use the same overly broad criteria for almost all of their waitlist registrants, causing them to overestimate their actual use of these organs in their clinical practice. (Massie, Stewart, Dagher et al., 2010). Organ quality has a strong influence on transplant success and, in turn, on risk tolerance by surgeons and patients' willingness to enroll in waiting lists for transplants.

Each of these subsystems is designed to function in a certain way. However, the interactions among major subsystems can lead to outcomes that may not be intended by the bounded

rational decisions made in each subsystem as outlined in Morecroft (1985). Each subsystem is described in the following sections.

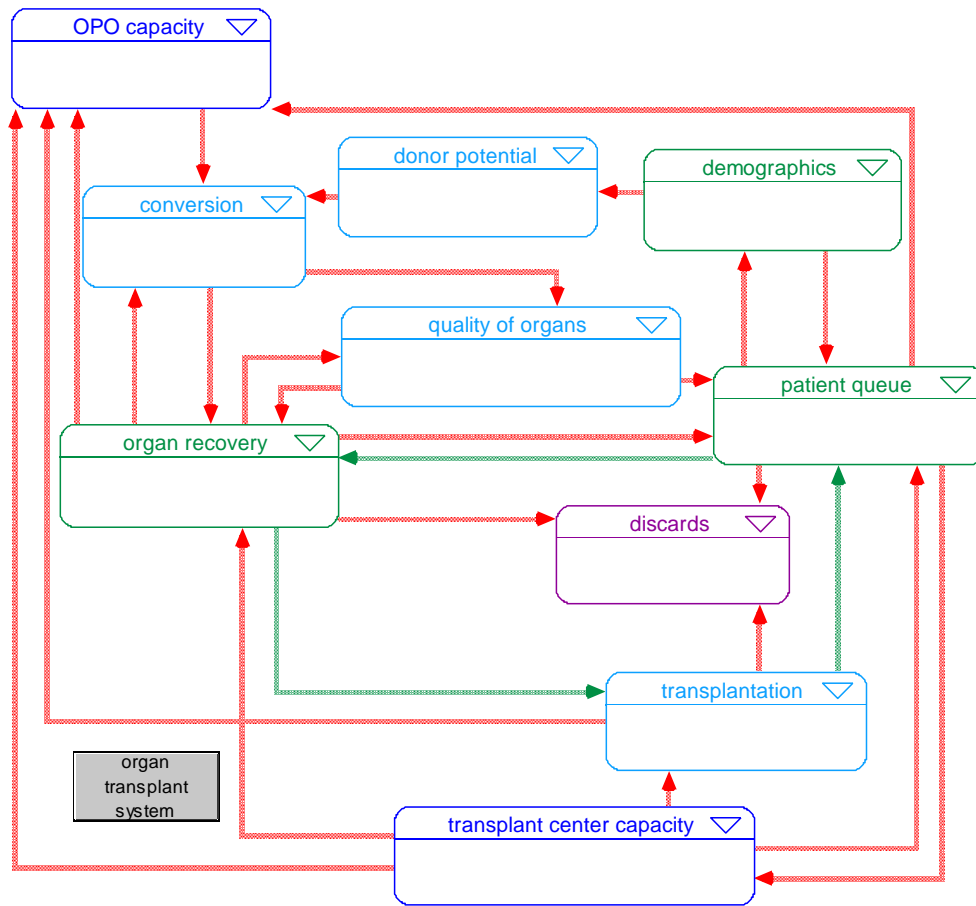


Figure 3.1: Subsystems in the model and their interplay

3.1 Donor potential

Figure 3.2 illustrates how donor potential is determined. It begins with a fraction of all deaths occurring at the medical centers. The fraction currently used in the model is a placeholder pending more accurate numbers awaited from the data subcommittee of the project. A fraction of the potential donors become referred deaths, a fraction of which are deemed medically suitable/eligible deaths depending on OPO screening process and expediting efforts.

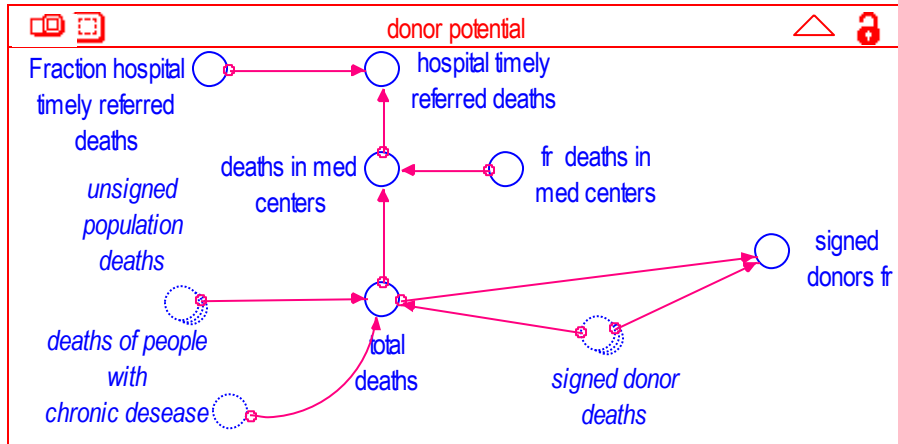


Figure 3.2: The donor potential sector

3.2 Conversion to actual donors

The conversion sector, shown in Figure 3.3, calculates the fraction of potential donors who will become actual donors. It contains the multistage process outlined earlier in Figure 1.2

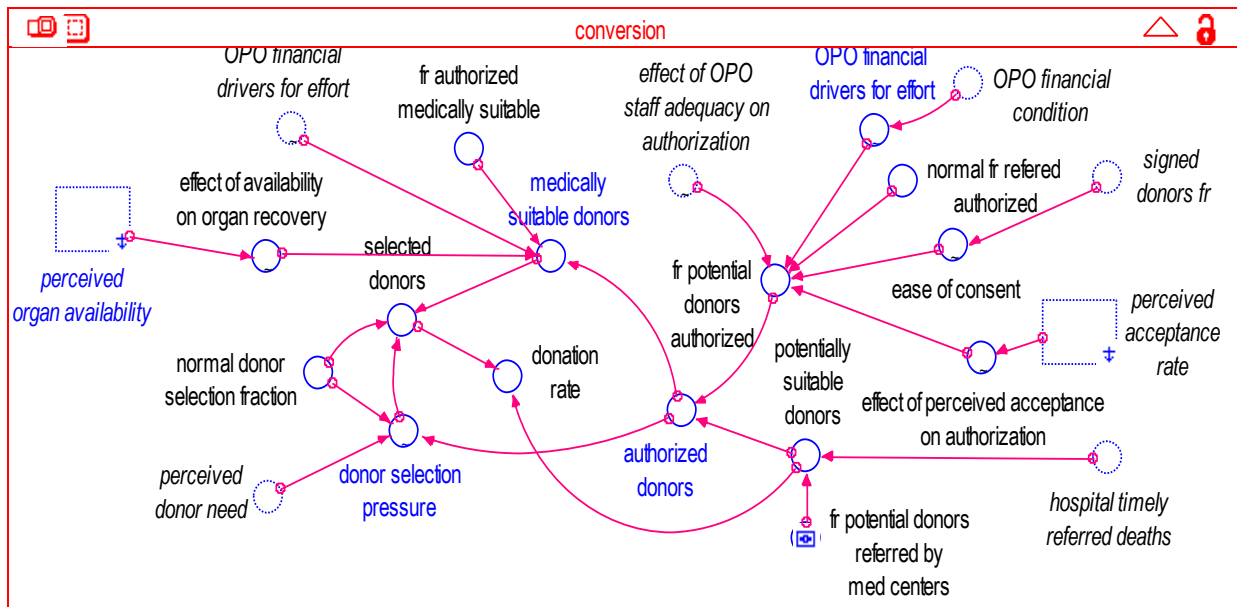


Figure 3.3: Conversion sector

A fraction of referred deaths are deemed potentially suitable for donation and become authorized donors once the consent of families is obtained and/or donors are found to be enrolled in registries. The fraction that become authorized depends on OPO staff capabilities and incentives, OPO perceptions of donors likely to be accepted by transplant programs, and the ease of obtaining consent which is affected by the fraction of the population signed up on donor registries. Medically suitable authorized donors become selected donors at a rate based on a normal fraction and a donor selection pressure that reflects perceived need.

3.3 Demographics

The demographic sector of the model keeps track of the general population in terms of its distribution between healthy people who are not registered for organ donation, healthy people who are registered, and the population afflicted with chronic disease. In the current version of the model, the chronic population represents those with chronic kidney disease. The subsystem representing this sector is shown in Figure 3.4. Deaths occur from each of the three categories and their sum constitutes total deaths in the donor potential sector. Births and immigration add to the healthy population not yet signed up on donor registries. This inflow is assumed to be exogenous and in our tentative model is taken from the US Census data.

“Unsigned” healthy donors can sign up at motor vehicle registries and other sites to become “signed” healthy donors. Currently, over 100 million individuals are registered as organ donors in the U.S. with efforts underway to register an additional 20 million individuals in 2012 (Donate Life America, 2012). Even with increasing registrations, a time lag between registration and eventual death results in a delay before benefits are realized in the form of increased numbers of organs available.

Both the unsigned and signed populations are disaggregated into six age groups: 0-6, 7-14, 15-35, 36-59, 60-69 and 70+. Both groups of healthy people can become afflicted with chronic disease, chronic kidney disease in the current version. This chronic population feeds the patient flow that ultimately develops end-stage renal disease (ESRD) and requires kidney transplants. (A small fraction of patients requiring transplants may come directly from the healthy population as a result of an acute illness or injury.) The model can accommodate other types of organs and transplant procedures either by creating arrays or creating separate models as the one presented here for kidneys.

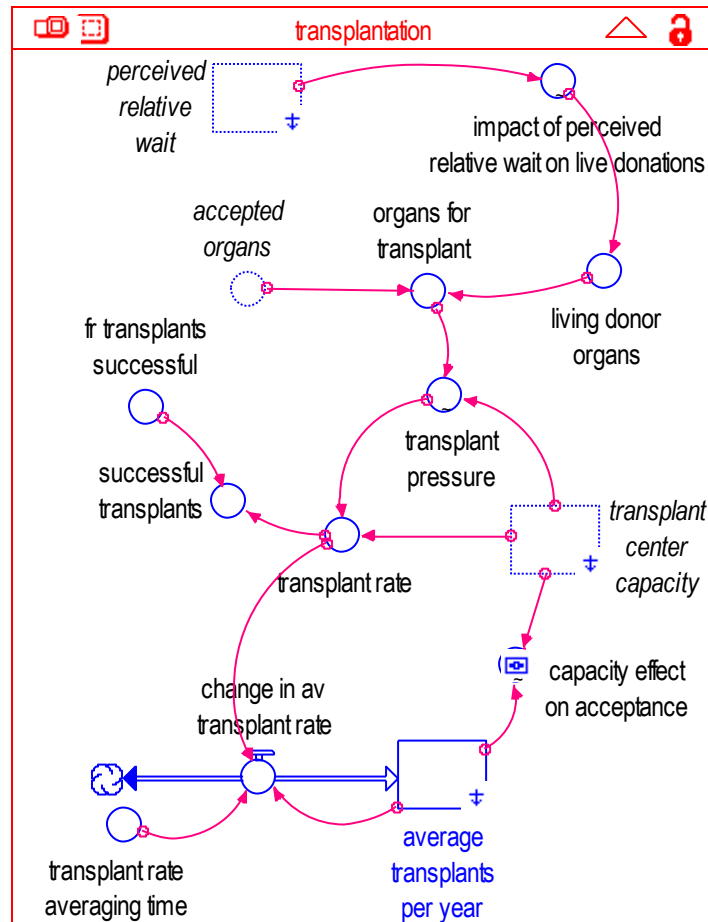


Figure 3.6: The transplant rate

3.6 Organ Recovery

The organ recovery sector, shown in Figure 3.7, addresses the process that starts with selected (authorized) donors and determines the number of organs available for transplantation. A fraction of medically suitable donors are selected based on acceptability criteria utilized by the OPOs, the perception of need based on length of the wait list, and an average volume of transplants based on past experience. OPOs will obtain consent for as many donors as possible once potential donors are identified. Then the OPO gets more information on the donor and offers organs to transplant programs based on wait list rank order (i.e., which patients have the highest priority). Transplant centers accept or decline the "offer" based on their assessment of the suitability of each organ for the intended recipient.

The normal rate of organs recovered per donor, known as "yield" (1.7 for kidneys, about 3 for all organs), is modified by the perceived availability of organs. Lower perceived availability of organs will create pressure to recover more organs per donor. The likelihood of organs being accepted by transplant programs and volume of organs accepted are affected by the length of waitlist and quality of the organs being offered, and, to a lesser extent, transplant program

capacity. A lengthy waitlist will make it more likely that organs will be accepted and that OPOs will place more organs. Poor quality will limit the fraction of offered organs that become accepted organs.

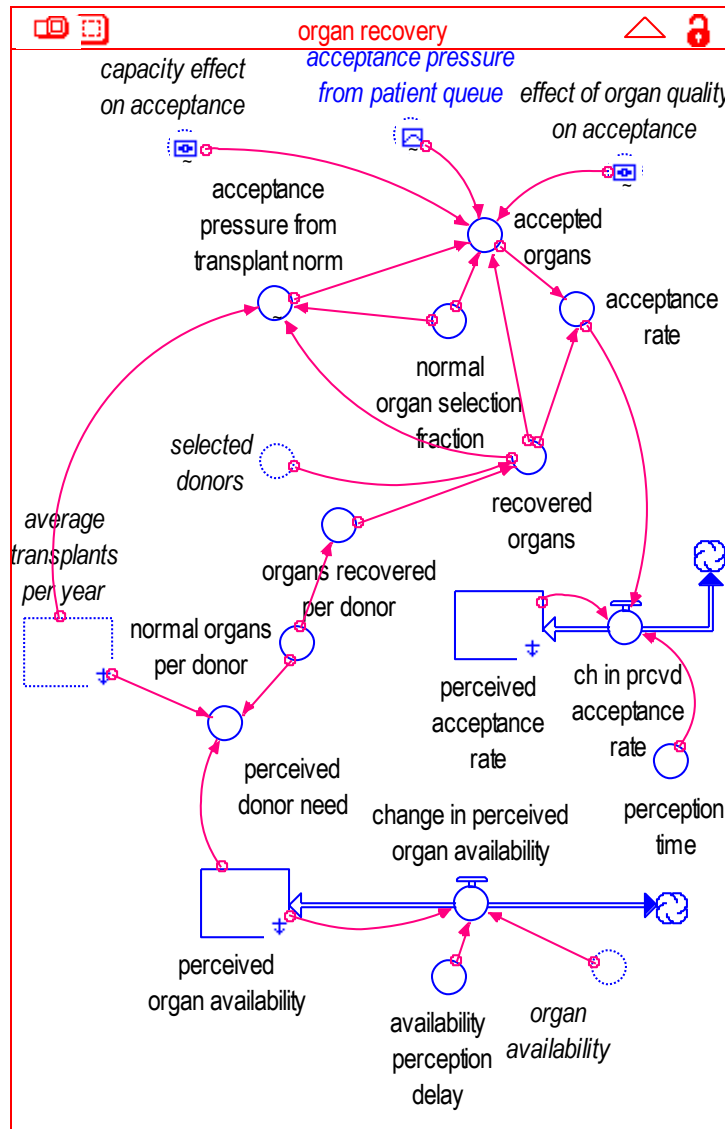


Figure 3.7 Organ Recovery Sector

3.7 Transplant Center Capacity

Transplant center capacity has been described to us as a flexible factor that can be adjusted as needed in response to the availability of organs. However, over the long term, it can be an important factor that ultimately affects the number of transplants. The capacity adjustment process is therefore an important part of the dynamics we are trying to understand. Transplant capacity has proven to be a hard concept to visualize. We have expressed it as the ability to

deliver a certain volume of transplantation and have represented the factors that impinge upon the decision to change capacity over time. Figure 3.8 shows the transplant center capacity sector of the model.

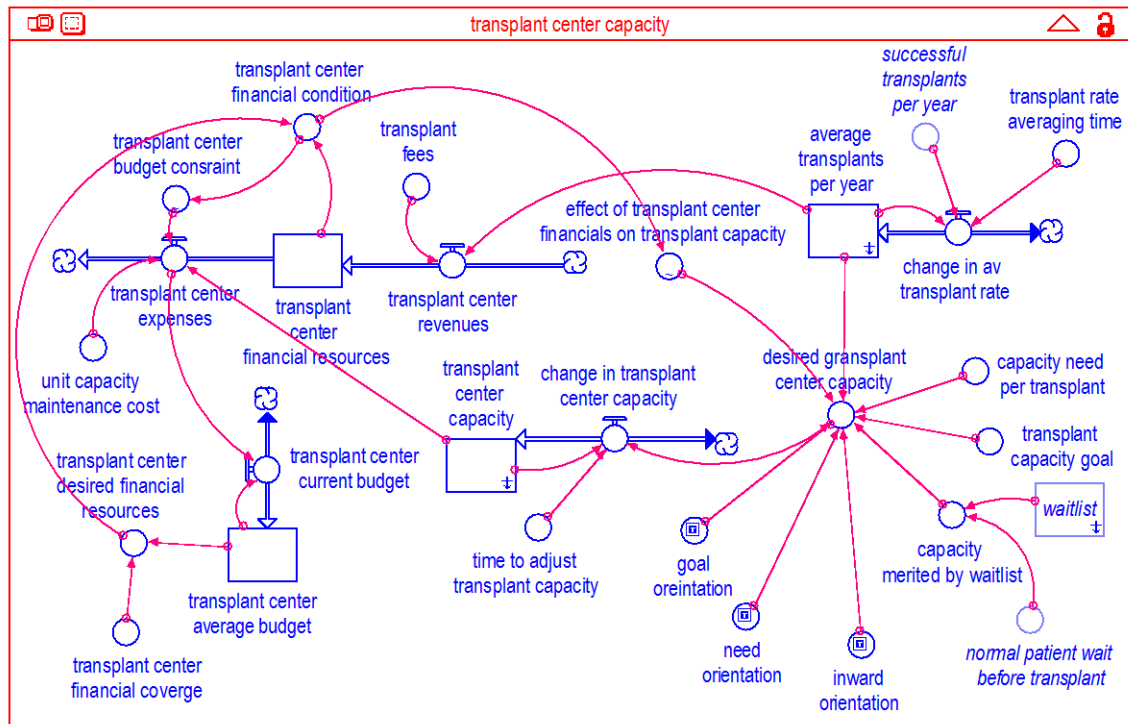


Figure 3.8: Transplant center capacity

Transplant center capacity adjusts toward any of three targets that can be chosen by the user of the model: 1) a desired value that is determined by past performance which is determined both by the past capacity and organ availability, 2) the transplant need created by the waitlist, or 3) exogenously determined targets. In all cases, this goal is modulated by financial considerations that reflect past performance as well as the revenues derived from transplantation and the costs of maintaining transplant capacity.

3.8 OPO capacity

OPO capacity affects donor selection and organ recovery. It is expressed in the model in terms of OPO staff and is assumed to adjust towards a desired value through recruitment and attrition processes. The OPO capacity sector is shown in Figure 3.9. The desired number of staff is determined primarily by the DSA size and level of activity in terms of number of hospitals in its DSA, numbers of potential organ donor referrals, other activities such as tissue and eye donation (not addressed in this project), and geographic size of the DSA. OPO capacity can respond to organ need and is further modulated by financial considerations. Rising or falling revenues as a result of changes in the volume of organs procured can lead to adjustments in OPO capacity.

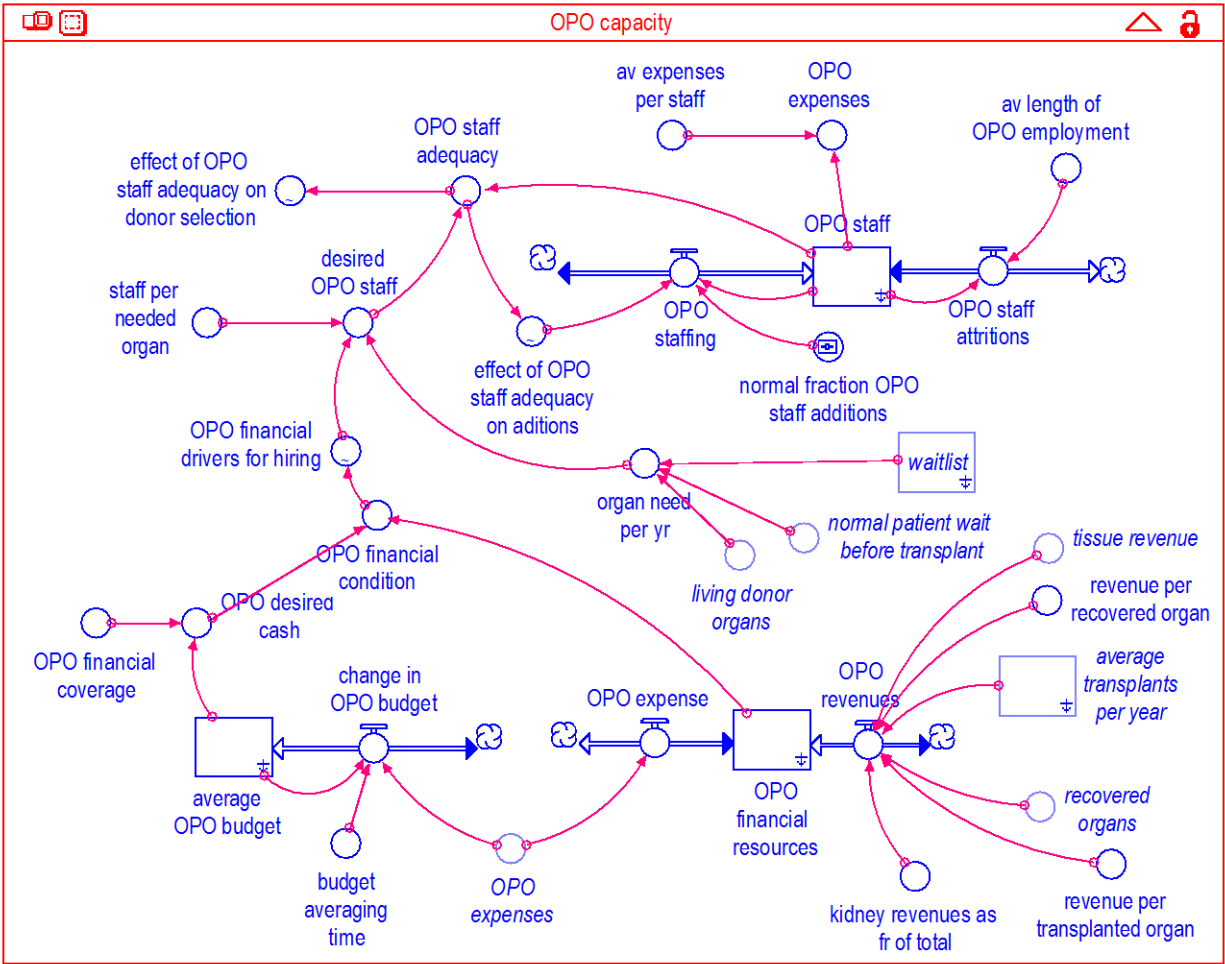


Figure: 3.9 OPO capacity

3.9 Quality of organs

The average quality of organs recovered and implanted depends on a number of factors as shown in Figure 3.10. A larger number of consented donors allows matches with recipients to be made more readily and allows organs to be recovered and placed more quickly, helping to assure higher quality. On the other hand, a higher donation rate may imply widening donor selection criteria that may result in diminished quality. Similarly, an increase in organs recovered per donor can also imply lower average quality if it results from loosening the organ recovery criteria. Higher organ yield could result without lowering quality if a larger fraction of donors are younger and healthier. A perception of quality is a key determinant of organs accepted for transplant. Recovered organs not transplanted yield discards, which have been rising along with the transplantation activity. Finally, the quality of the transplanted organs affects the potential for graft failure and mortality rates of transplanted patients and, as indicated above, risk tolerance of patients deciding whether to enter waiting lists.

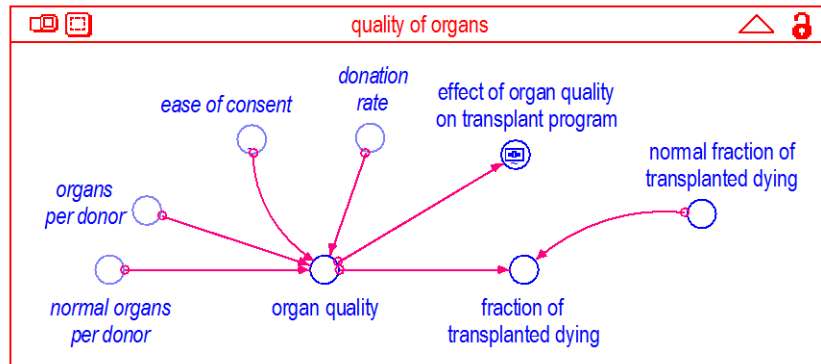


Figure 3.10 Quality of Organs

The next section describes the process of model validation and some initial strategic policy experiments.

4. Model Validation and Policy Analyses

4.1 Validation

There are a number of methods for validating a system dynamics model. (Sterman, 2000) One is reviewing the structure with people who are familiar with the real-world system and ascertaining that it accurately represents the underlying causal structure responsible for a system's behavior of interest. As mentioned earlier, the model has been presented and critiqued at two meetings of stakeholders representing a good cross section of the organ procurement and transplant community. We have also had additional meetings to go deeper and review the model in detail with smaller groups of stakeholders from the field. These were meetings with staffs of OPO's and a transplant programs separately and one meeting with both represented. These were interesting, not only for model validation, but to see differences in perceptions between OPO's and transplant programs. It was possible to arrive at a shared sense of how the system works.

Starting the model at an earlier point in time and comparing results to actual historical data is another approach to validation. Data from the OPTN data base was used to evaluate the model in this manner. The model was parameterized to represent kidney transplantation for the US as a whole with initial values from 2001. Figures 4.1 and 4.2 show results of a baseline simulation of the model with time zero corresponding to 2001 and the (annual) kidney transplant rate and size of the active waiting list for kidney transplants (number of people waiting) plotted against their historical values taken from the OPTN data base. The transplant rate includes those done with both living and deceased donor organs. (By transplant rate, we mean the number of transplants done per year which is different from how the transplant community uses the term transplant rate.) Simulations over the 2001-2009 time period suggest that the model tracks these historical values well in terms of similar growth observed over the 2001 to 2011 time period. The simulation does not reflect the relative change or increase that

occurred in the transplant rate around 2005-2006 which occurred as a result of a HRSA sponsored Institute for Healthcare Improvement (IHI)-based national collaborative for performance improvement effort to improve system performance from earlier efforts of that initiative (Howard, Siminoff, McBride, and Lin, 2007). However, the model does duplicate the longer term change in the real-world transplant rate that occurred over the period 2001-2009. The size of the active waiting list is a stock variable that is affected by a number of inflows and outflows. The size of the waiting list produced by the model tracks its historical value over the 2001-2011 time period.

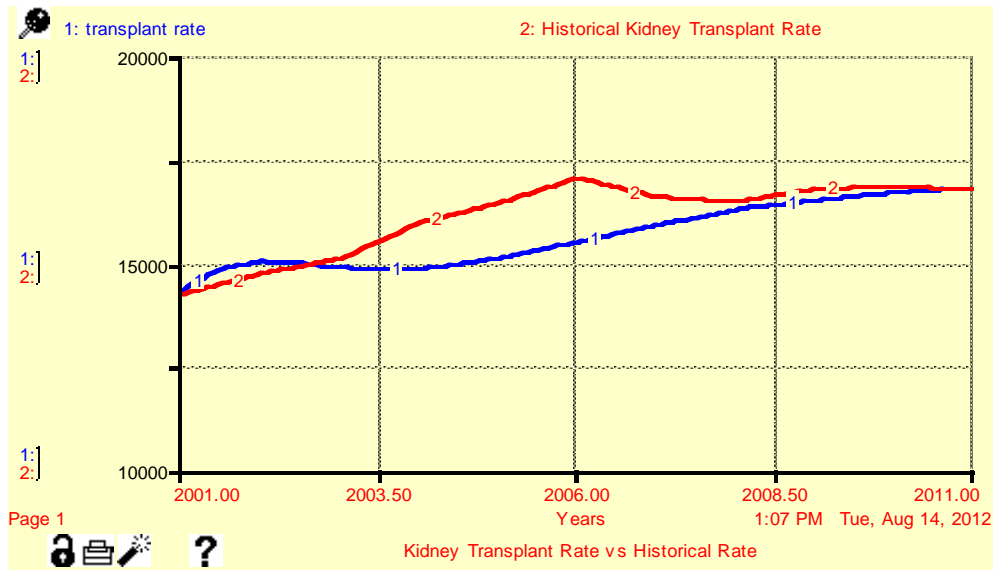


Figure 4.1: Kidney Transplant Rate vs. Historical Values

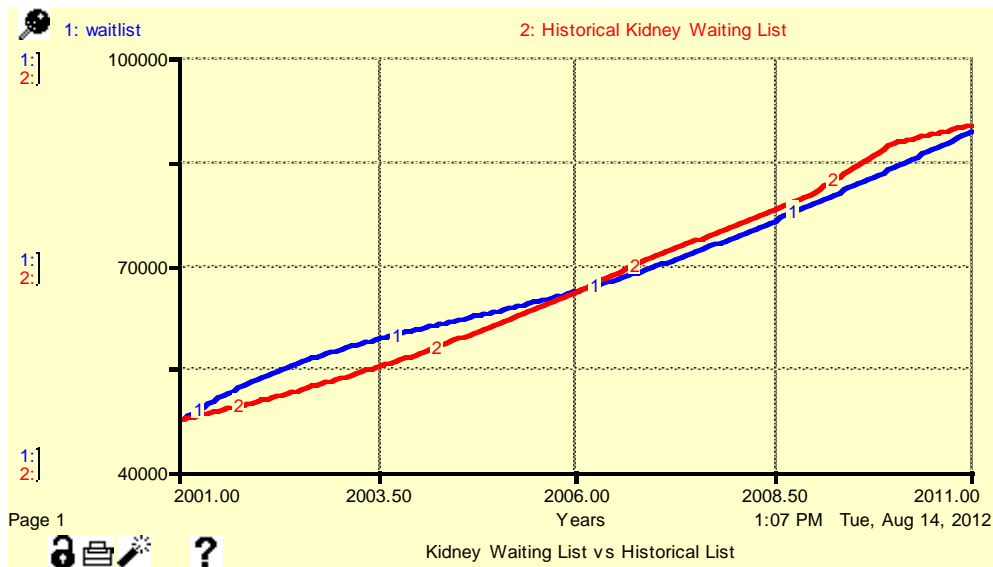


Figure 4.2: Kidney Waiting List vs. Historical Values

4.2 The Baseline Simulation

Results from the baseline simulation are shown in Figure 4.3. The simulation starts in 2001 and goes to 2021. The general trends that persist in the 2011-2021 time period highlight the concerns of the stakeholders of the system. The transplant rate (line 1-blue) is not rising in proportion to the wait list (line 2-red), hence wait lists are expanding. (Note that wait list is on a larger scale, 40,000 to 160,000, than the transplant rate, 10,000 to 20,000.) Also, while organs recovered have increased over the past decade, the rate of increase has tapered off and the gap between organs recovered and transplanted has widened, indicating that discard rates will rise (line 4-green) in the face of declining average organ quality (line 3-pink). Organ quality is an index that varies around a value of one and reflects the fraction of donors selected from potentially suitable donors compared to the initial fraction selected. Having to select more donors to support a higher number of transplants will result in lower average quality if it means drawing on less-than-ideal donors.

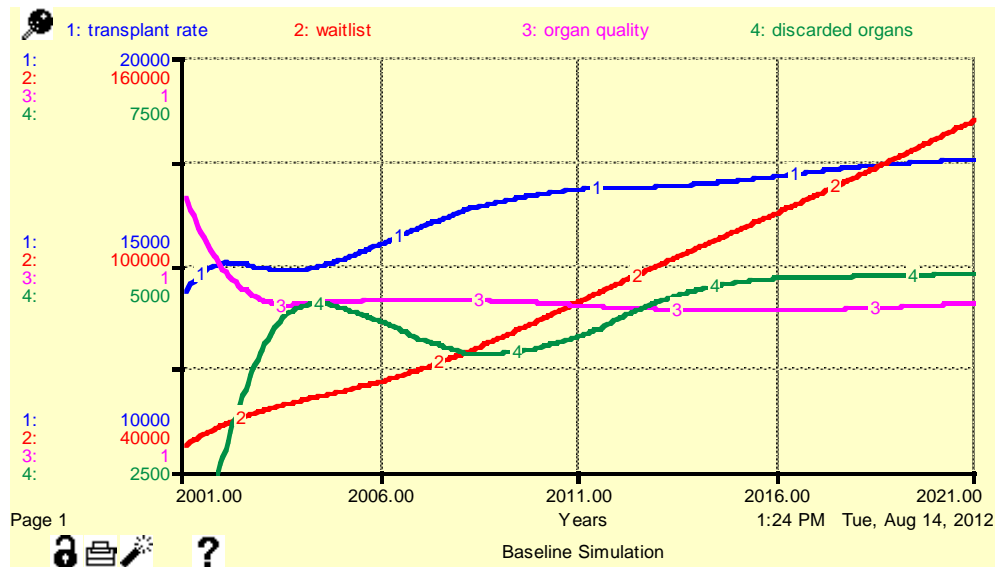


Figure 4.3: Results of Baseline Simulation

Why is the growth in the transplant rate (line 1) so constrained? Why would more organs be discarded (line 4) even as the waiting lists are growing? The causal factor diagrams in Figures 1.4 and 1.5 indicated that the underlying system contains a number of balancing feedbacks driven by performance and quality concerns that constrain growth.

Several loops are present to constrain growth. For example, transplant programs with long waiting lists may accept more organs and do more transplants, but may have to do so by expanding their criteria and accepting lower quality organs on average. Lower quality leads to the balancing feedback (red loop) through shorter graft and patient lifespans and reduced risk tolerance by the programs that result in reduced acceptance of organs and fewer transplants.

Figure 1.5 suggested that there are other balancing loops that involve the OPO's. OPOs may become more selective in the donors they pursue once they have generated enough revenue to cover their expense budgets and meet the demand of transplant programs within their

Donation Service Areas (DSA's). Similarly, OPO's may respond to transplant programs acceptance or rejection by adjusting their own criteria for the types of donors that are acceptable and thereby limit the number of donors they pursue. The net effect of these balancing loops is to constrain growth and maintain an equilibrium level of transplants that may be somewhat below what could be achieved without those constraints (true donor potential). The next section illustrates how the model can be used to assess how various strategic policy changes would relax those constraints and move the US organ procurement and transplant system closer to achieving that true donor potential.

4.3 Policy Analyses with the Model: Exploring Strategic Options in the Transplant Network

As stated earlier at the beginning of the paper, initial policy analyses done with the model represent strategic options and are only illustrative, pending further model development. However, these strategic options provide a good sense of the kinds of policies the model can help to evaluate. Results of these initial analyses are presented in the following sections. Results graphs show what would have happened relative to the baseline simulation if the particular options had been in place.

4.3.1 Increasing Transplant Program Capacity

One way of increasing the number of transplants is to increase the capacity of transplant programs. Figure 4.4 shows what the effects would have been if transplant capacity is based on an exogenous goal for a 33% capacity increase. There is a small improvement in the transplant rate (red line) as the transplant programs are willing to accept a wider range of organs in order to utilize their additional capacity. However, limits on organs available constrain the growth. Eventually, financial pressures on transplant programs created by having unutilized capacity cause them to reduce capacity.

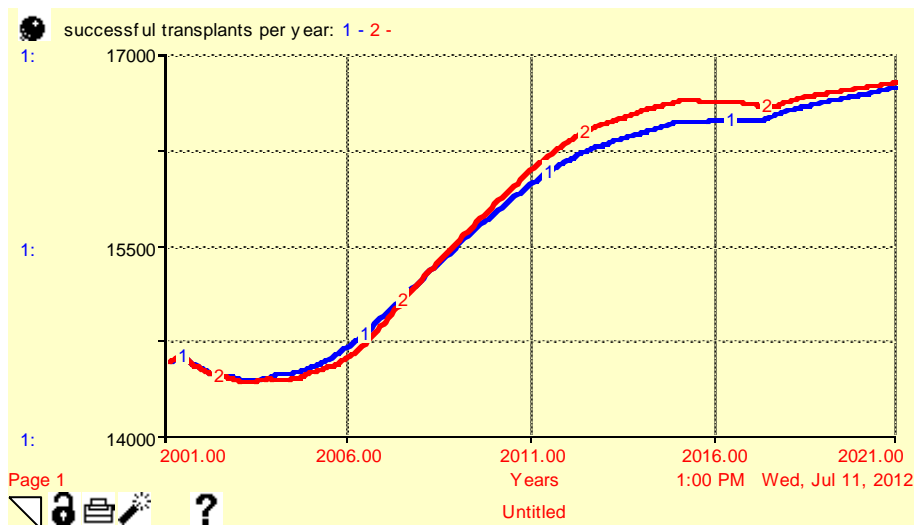


Figure 4.4 Transplant rate as affected by policy to adjust transplant capacity

4.3.2 Increasing Sign-Up Rates on Donor Registries

In dynamic feedback systems, growth can be promoted by strengthening reinforcing loops that promote growth or weakening balancing loops that constrain it. One of the reinforcing loops goes through donor registries where more people signing up would result in a greater number of consented donors, more transplants, greater awareness of the value of transplants, and more people signing up at donor registries. Another intervention considered was to step up efforts for people to sign up in registries as willing to be organ donors. Figure 4.5 compares the baseline transplant rate of successful transplants with an intervention that increases the population signed up on registries by 40% by 2021. Graph 1 (blue) shows base line behavior and graph 2 (red) shows behavior with the intervention to double organ donor sign up rate.

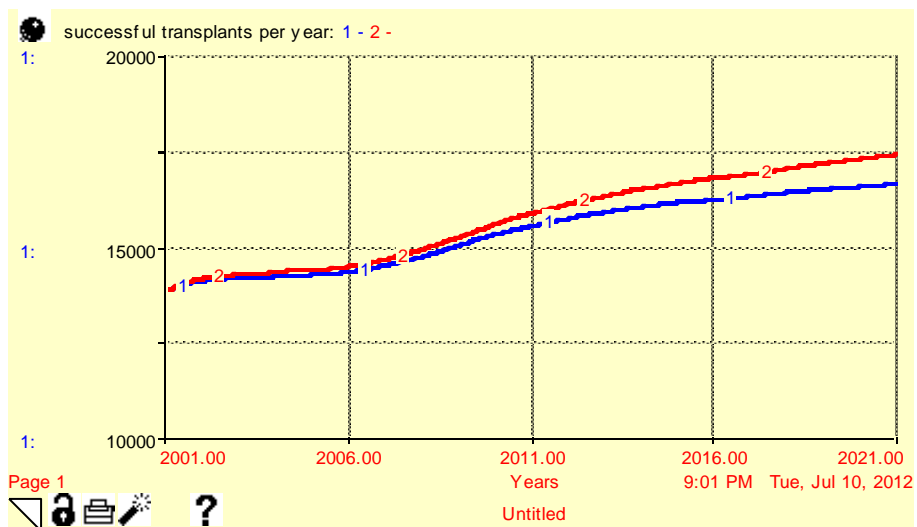


Figure 4.5 Transplant rate as influenced by aggressive campaigns to sign up organ donors.

The impact is at best marginal due to the balancing feedback control processes represented in Figures 1.4 and 1.5. While signing up more people on donor registries is always worth doing, the results shown in Figure 4.6 suggest that these campaigns can have only a limited impact on transplant rates. The limited impact can also be explained by where in the system the higher sign up rate has its impact. Improving the consent rate comes at a point when the “funnel” of deaths down to potential donors has already narrowed significantly and improvements due to a higher sign up rate can produce only small increases in selected donors.

4.3.3 Expanding Entries to Waiting Lists

The other reinforcing loop is one through entries to waiting lists and demand for organs, more accepted organs, more transplants and greater word of mouth about the potential benefits of transplantation, and increased entry to waiting lists. The next option to try is one that increases the number of people entering waiting lists by 50%. Figure 4.6 shows the effect of this policy (red line) compared to the baseline simulation (blue line). (Note the expansion in graph scale to 12,000-24,000.) It has a somewhat greater effect than strengthening the growth loop through sign ups in registries because the larger waiting lists and longer wait times that result create a greater pressure to accept more organs that permit more transplants to be

done. The waiting list is 32% longer at the end of this simulation compared to the baseline. This pressure helps to partially overcome the resistance of the balancing loop through organ quality and acceptance of organs. Larger numbers of people on waiting lists also increase the likelihood that a match will be found for organs that are offered to transplant programs, leading to fewer discarded organs. This effect, however, is only temporary and the rate of successful transplants reverts to what is achieved in the baseline simulation.

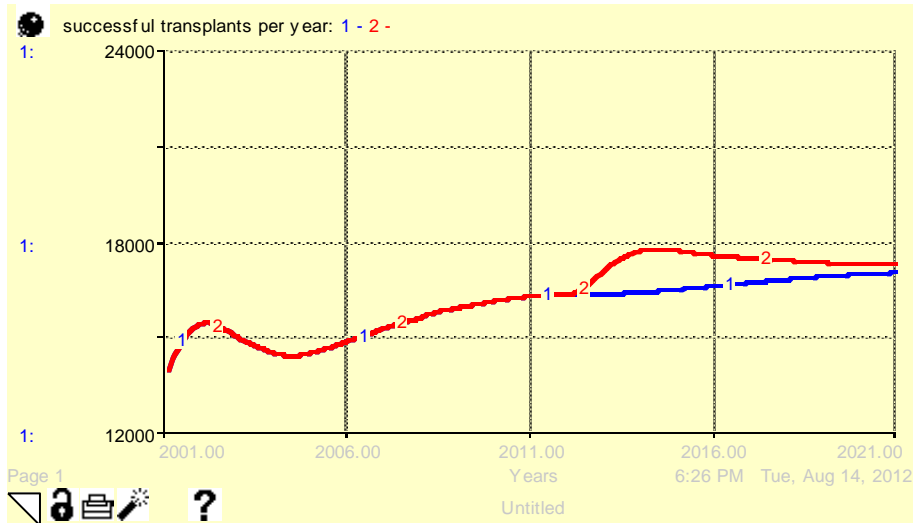


Figure 4.6 Effects of increasing entries to waiting lists

4.3.4 Increasing Timeliness and Expanding Range of Referrals from Hospitals

A different approach would be to increase referrals from hospitals to OPOs. While hospitals are required by law to make referrals, this could be accomplished by a combination of motivating hospitals to make referrals of patient deaths in a more timely manner and expanding the criteria by which people are considered potential donors or narrowing exclusionary criteria that would keep them from being considered as donors. OPO's can also make greater use of donors declared dead by circulatory criteria (DCD), something most of their counterparts are already doing. The graph in Figure 4.7 shows the effect of a 20% increase in timely referrals in simulation number 2 (red line) compared to the baseline simulation (blue line). The change produces an increase in the transplant rate despite the “push back” from the balancing loops in the system. Eventually, the increase in transplants levels off.

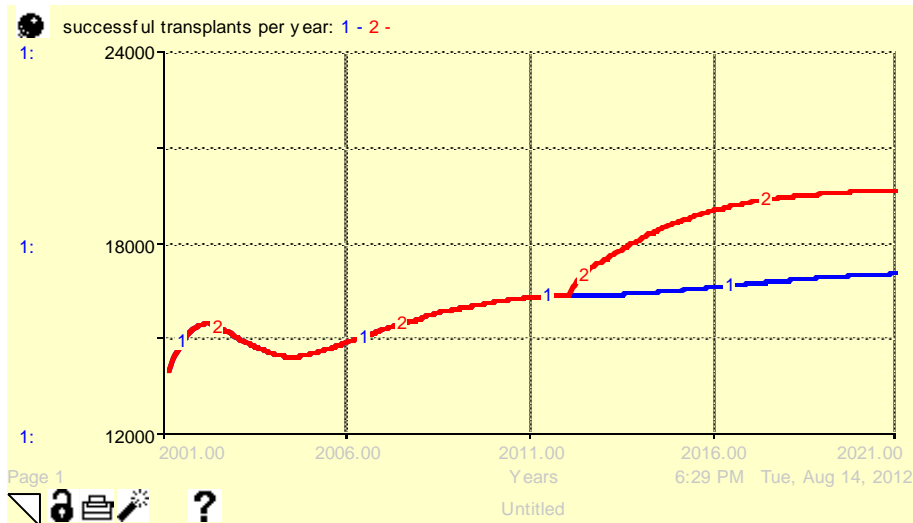


Figure 4.7: Effect of higher rate of referrals to OPOs

4.3.5 Increasing Acceptance Rates of Organs from Less-Than-Optimal Donors

As indicated earlier, weakening balancing loops that constrain growth is another way to promote growth. The balancing loops through organ quality and accepted organs are a significant constraint on growth. Quality in the real-world system is, to some extent, perceived quality based on what is known about a donor when the decision is being made to accept an organ. Donor age and health (e.g., presence of chronic conditions) will influence the decision. The next option to be considered is one in which this constraint on perceived quality is relaxed, making it possible to recover more organs from the same stream of potential donors. This might be achieved by being less conservative about accepting organs from less-than-ideal donors rather than actually sacrificing quality and using organs that would result in a higher graft failure rate. As shown in Figure 4.8, weakening this constraint can result in a significant number of additional transplants. New technologies for organ preservation may also help to improve the range of organs that can be acceptable. Average quality goes down as a result of relaxing this constraint and graft failures increase as a result, but more people are transplanted than would have been if this constraint remained at its original strength.

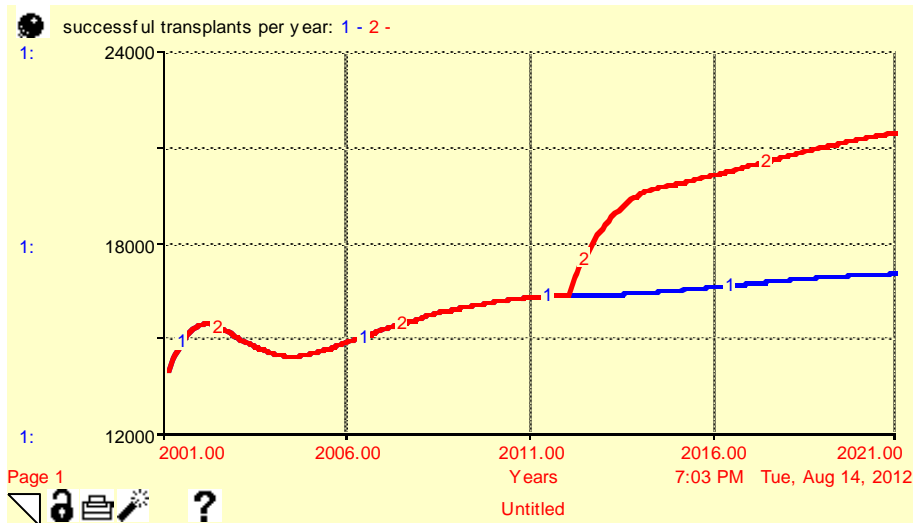


Figure 4.8 Effect of relaxing (perceived) quality constraints on organ acceptance

4.3.6 Combined Strategies

One lesson learned from working with system dynamics models is that combined strategies focused on different parts of a system will yield better results than strategies with a single focus, no matter how much in the resources are devoted to that single strategy. Figure 4.9 shows the effects of combining the two previous strategies to expand referrals from hospitals and relax quality constraints on organ acceptance.

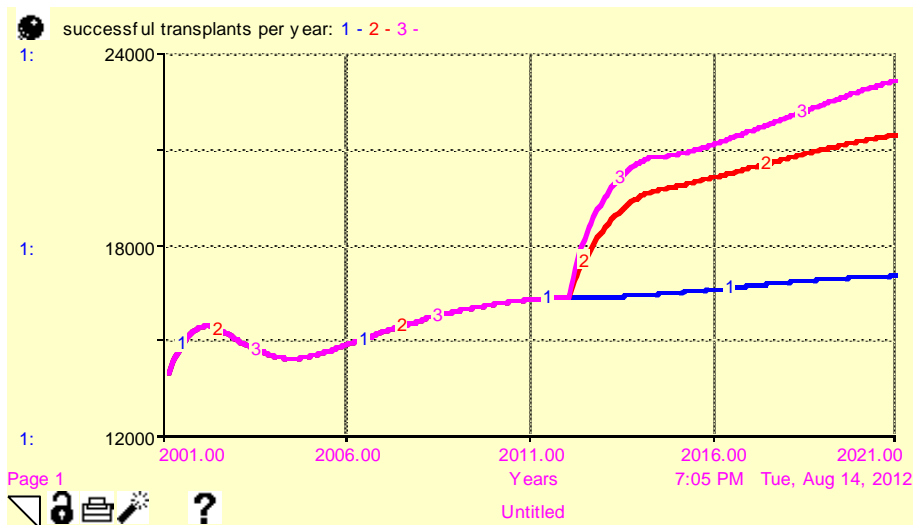


Figure 4.9: Results of combined strategy with increased referral from hospitals and relaxed quality constraints on organ acceptance.

For comparison purposes, Line 2 (red) in Figure 4.10 represents the relaxed quality constraint policy alone while Line 3 (pink) represents the combined strategy. The combination of an increased referral flow and greater flexibility in which donors are accepted could produce an additional number of transplants in the future.

Conclusions and Further Development

This paper has described a model of the US organ procurement and transplantation system along with illustrations of how the model can be used for policy analysis. It provides a context for understanding how various strategic policy options and other system characteristics can constrain or enhance donor potential; and, in particular, how particular policies can affect donor potential. Further development of the model is proceeding in several directions. The structure itself is being extended in order to more closely tie the model to mortality data coming out of other parts of the larger deceased donor potential study. We have already developed the demographic sector further to include age cohorts and other demographic and epidemiologic data that will drive mortality rates and donor potential. We will also be applying the model at the DSA level, working with several OPO's and transplant programs to validate the model and possibly adapt the model for their use as a decision support tool.

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