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USING SIMULATION TO CRAFT A NATIONAL ORGAN TRANSPLANTATION POLICY

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ABSTRACT

For many years, we have been able to use simulations for studying manufacturing and service systems, resulting in the ability to make better managerial decisions. As simulation methods have become more sophisticated, we have talked about the benefits of conducting large-scale simulations to support the selections of alternative public and corporate policies. This paper presents a description and analysis of what can be accomplished when simulations are used to support policy analysis and selection. The National Liver Allocation and Distribution Policy is used as the vehicle for presenting specific details of how simulation can be used to support policy selection.

1 THE CHALLENGE: CRAFTING A NATIONAL TRANSPLANTATION POLICY

Imagine the challenge of establishing a set of national policies that regulate the allocation of donated liver organs to patients in need of a liver transplant. At an operational level, the simulation task uses past data to make future projections of performance measures for different methods of allocating the liver organs to waiting patients. However, the diversity of constituents, the multiplicity of performance measures and the emotional public concerns create an environment in which decision making and policy setting is extremely complex.

The simulation effort was sponsored by the United Network for Organ Sharing (UNOS), a non-profit national organization which sets transplantation allocation and distribution policy. UNOS sets policy by involving a diverse set of constituents which include physicians, surgeons, transplant centers, organ procurement organizations, patients, families of patients, hospitals, insurance companies, the government's Division of Organ Transplantation (DOT), national law makers and the general public.

To help simulate the impact of policy changes, UNOS sought the assistance of the Pritsker Corporation to apply simulation methods in early 1995. Because of the complexity and seriousness of this project, the assignment quickly escalated into a testing ground for simulation's ability to help formulate and evaluate complex medical and societal concerns.

2 USING SIMULATION TO EVALUATE TRANSPLANTATION POLICY ALTERNATIVES

An early series of meetings between UNOS and Pritsker personnel resulted in an agreement on the individual responsibilities concerning potential policy alternatives, model development, data availability, performance measures and model validation.

UNOS, through its constituent-based committee structure, would be responsible for defining and evaluating alternative policies for transplantation allocation and distribution. The Pritsker Corporation would be responsible for building a model of the national transplantation network based on patient-status, patient requests, organs available, geographic location, distribution methods, and organ-patient matching. UNOS and Pritsker Corporation would jointly develop component models for survival, removal and relist functions, patient status transitions, and organ and patient arrival processes. The initial approach was to build, verify and validate a model with the transplantation community defining the performance measures, specifying the policy alternatives and then running the simulations to objectively evaluate the policy alternatives. The UNOS committee structure would then have the responsibility of selecting a policy, based in part on the results of the simulations, and to recommend a policy alternative to the UNOS Board of Directors. If the Board of Directors accepts a recommendation, it is broadcast for public comment prior to final adoption by the Board of Directors.

3 APPLYING SIMULATION IN A POLICY-CRAFTING CONTEXT.

Typically, policy-level decisions are the result of a complex organizational process that involve social, economic, psychological and political dimensions (Allison, 1971). This complexity increases exponentially in public policy settings due to diverse constituents, qualitative performance measures and difficulties of implementing policy changes (Bryson, 1988). Given these conditions, there is a question as to how simulation can play a productive role in the setting of policy.

Our experience suggests that if simulation can assist in operational decisions, the same approach can be utilized to foster a more productive policy-crafting environment. Policy-makers have been aggressively searching for tools to assist them in objectively studying alternatives (Mockler, 1991), yet simulation as a support tool has been sparingly used. Unlike the operational uses of simulation (where one manager wants to analyze the impact of adding one machine based on three quantifiable performance objectives), policy applications face several dilemmas that complicate the simulation effort, by:

1. Involving a broad set of decision-makers with diverse interests, conflicting objectives and different internal thought processes (Peters, Hammonds and Summers, 1974);

2. Balancing quantifiable and non-quantifiable performance measures, thereby creating a potential conflict over the relative benefits of proposed alternatives (Eccles, 1991); and

3. Understanding the issues from a broader perspective because of the more significant long-term implications, suggesting the need to evaluate the "down-stream" implications of policy decisions (Armstrong, 1982).

The crafting of a national transplantation allocation and distribution policy illustrates the differences between policy setting and operational decision-making. This paper describes the use of simulation to support the shaping of policy in this complex setting over a fourteen month period. The major challenge was to carefully integrate the scientific/quantitative methods associated with simulation into a organizational policy-setting process.

4 OVERVIEW OF THE MEDICAL SITUATION

Organs for transplantation are a scarce resource. The number of people who donate organs has not kept pace with increasing demand. Thousands of people wait for organs every year, with many dying while they are on an organ transplantation waiting list. The list of waiting patients continues to grow at a faster rate than the number of donors. How to allocate such a scarce and valuable resource is indeed complex. Much is at stake among the potential recipients, doctors, Organ Procurement Organizations (OPO), and transplant centers. The formulation of a comprehensive transplant allocation policy revolves around developing an organ distribution system that is equitable, efficient and effective.

5 THE TRANSPLANTATION SYSTEM ENVIRONMENT

Many issues arise with organ allocation. What may maximize medical benefit for one person may not necessarily result in equitable treatment for another. In pursuit of a policy to balance all aspects of this issue, UNOS organizes its activities through a Board of Directors and committees consisting of volunteers representing a broad cross-section of the transplantation community.

The national system for collecting data on patients and organs, called the National Organ Procurement Transplantation Network (OPTN), is operated by UNOS. Organ allocation policies are constantly reviewed and altered to reflect the advances being made in science, medicine and communications. These changes are regularly reviewed and modified to ensure equity among those in the transplantation community and to instill confidence in the community at large.

Because of the significance of the allocation process, the Federal Government has established a Division of Organ Transplantation (DOT) within the U.S. Department of Health and Human Services. DOT partially funds the National Organ Procurement and Transplantation Network and maintains oversight responsibility to ensure that medical utility and justice for potential recipients is maintained by organ allocation policies.

6 BUILDING A MODEL FOR COMPARING TRANSPLANTATION POLICIES

The objective of model building was to develop the UNOS Liver Allocation Model (ULAM) for comparing proposed alternative allocation policies. By focusing on

comparing alternatives, system components which do not have an impact on the comparison of policies could be eliminated from the modeling effort. A secondary objective was to create a model that could be used and updated at UNOS headquarters to meet the future needs of the transplantation community (Garvin, 1993).

The model building activities followed the process described in *Simulation with Visual SLAM and AweSim* (Pritsker et al, 1996) and in the WSC Proceedings (Withers et al, 1993). A model specification document was written to describe the entities, events and component models for the arrival streams of donors and patients, the patient-status change process, the offering and acceptance of organs by doctors/patients and the relist and survivability functions relating to patient post-transplantation status. A specification for the reports and displays to be output from ULAM was also detailed. The policies to be evaluated initially using ULAM were limited to those prescribed in terms of patient health status and the geographical areas where patients are located. An Allocation Modeling Oversight Committee was created to review the specification and, after discussion and modification, the specification document was approved. This committee played a critical role in validating the basic structure of the model (Benveniste, 1972).

From the model specification document, a list of significant factors was developed that served as the foundation of the ULAM effort. Figure 1 provides an overview of ULAM which is modeled and run using Visual SLAM and AweSim. The modeling and simulation techniques used in building ULAM include: fitting donor and patient arrival processes using non-homogeneous Poisson processes (NHPP) having exponential rate functions which may include both a polynomial and some trigonometric components; fitting distributions to data on transition times between states of medical urgency; applying variance reduction techniques using common random number streams and prior information; organizing data structures for efficient file searching and ranking capabilities; using bootstrapping techniques for attribute sampling; building submodels employing biostatistical procedures such as Kaplan-Meier and logistic regression; and estimating the performance measures suggested by the Oversight Committee.

All waiting patients have been diagnosed as having end-stage liver disease. Fundamental to liver allocations is a patient's medical urgency status. The definitions of medical urgency status are:

Status	*Definition*
1	Patients must be in an Intensive Care Unit (ICU) due to acute or chronic liver failure and have a life expectancy of less than 7 days without a liver transplant.
2	Patients have been continuously hospitalized in an acute care bed for at least five days, or are ICU bound.
3	Patients require continuous medical care.
4	Patients are at home and functioning normally and liver transplantation would be an elective procedure.
7	A patient listed as Status 7 is temporarily inactive; however, the patient continues accruing waiting time up to a maximum of 30 days.

Status transitions are made between these states and to two other statuses: Death where the patient has died while waiting for transplant (Status 8); and Removal where the patient is no longer considered as part of the UNOS system (Status 9). When either of these status changes occur, the patient is taken off the waiting list and all relevant statistics are updated.

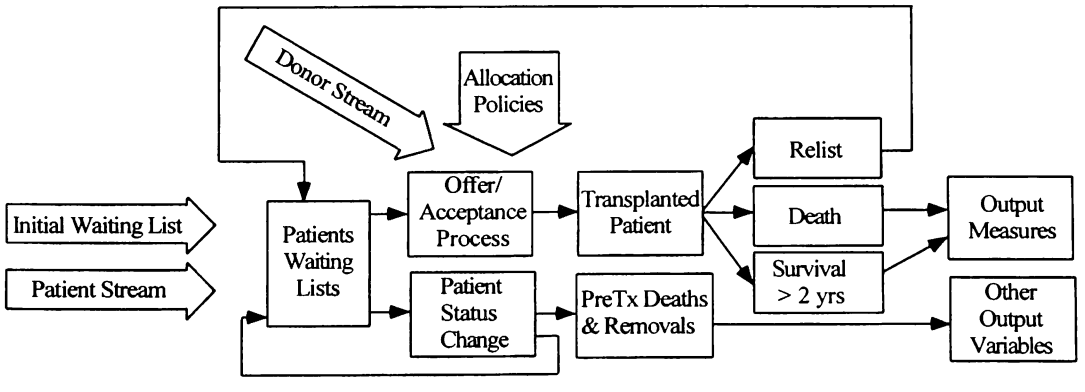

Figure 1. Overview of ULAM

Eligibility for allocation of a donated organ to a waiting patient is determined from blood type compatibility, ranges of organ weight and patient age. In allocating livers to patients in a geographical area, a ranking criterion is used. The ranking criterion is computed as the sum of points given to a patient based on the patient's status, blood type compatibility with the donor, and ranking with respect to other patients in the prescribed geographical area relative to amount of time waiting. This allocation method was included in ULAM and a model of the offering/acceptance of organs to patients was also included.

7 COMPARING NATIONAL LIVER ORGAN TRANSPLANTATION POLICIES

The initial use of ULAM in June 1995 discovered that the differences in alternative policies were clinically not large enough to recommend a change from the current policy. The first set of policies that were modeled allocated organs to the sickest patient first within different geographical areas. For example, in a local area such as an OPO which has 1 to 5 transplant centers associated with it, allocation would be to Status 1 patients first, then Status 2 patients and then Status 3 and 4 patients combined. Thus a local Status 3 patient could be allocated an organ before a Status 1 patient outside the OPO. Under these conditions, ULAM results showed that the trade-off between pre-transplant deaths (deaths occurring while people are waiting for an organ) and post-transplant deaths resulted in the total number of deaths being approximately the same for the policies considered (within the clinically significant difference). Prior to the modeling effort, the intuition of the transplantation community was that there would be clinically significant differences in the total deaths associated with policies concerning local, regional and national allocation methods.

The identification of this surprising result began the iterative process between the modeling effort and the transplantation allocation policy setters. As such, the policy-crafting process could be viewed as a discontinuous process (Hedberg and Johnson, 1977). To address the difference in expectation with regard to total deaths, a greater amount of discussion was held with the transplantation community and the model development effort intensified. This interaction produced a better understanding of the policy issues associated with transplantation (Morimoto 1973) and resulted in a greater level of confidence in ULAM's ability to compare policies.

Over the next several months, ULAM was enhanced by defining new status types; making geographical boundaries based on a percentage of total patients on the National Waiting List; devising new point systems to include population about the donor site; and using waiting time directly. In addition, restrictive capabilities were included in policies to allow a limit on the number of transplants for an individual patient and to require an identical blood type match between donor and patient.

In parallel with the modeling, a subcommittee of the Liver Committee was established to select performance measures which should be used for policy selection. The modeling team developed a categorization of performance measures according to utility and equity as viewed from medical, patient and system perspectives. The categorization of performance measures is presented in Table 1 and was a major step toward understanding and evaluating policies. The performance measure subcommittee selected a subset of these measures to be the basis for comparing policies.

8 NEW POLICY DEVELOPMENT AND POLICY SELECTION

The Liver Committee recommended a hybrid policy which maintains the local OPO structure while using the 20% of the National List as the definition of a regional allocation. The Liver Committee also recommended that the Board of Directors give consideration to retaining the current policy. The Allocation Committee developed its own recommendation by modifying the Liver Committee proposal. The change established two definitions of a local area based on percentages of the total National List; i.e., 5% of the National List for Status 1 and 2 patients and 2% of the National List for Status 3 patients. Both the Liver and the Allocation Committee policies involved allocating organs first to those acute patients who were, by distance, the closest 20% of all patients to the donor hospital.

After each new policy was suggested and upon approval of the appropriate committee, ULAM was enhanced in order to estimate the necessary performance measures. ULAM's flexible modeler and user interfaces provided direct access to outputs in the form of charts, plots, tables, and animations. Many of the proposed changes fit into the flexible organization that was developed for ULAM. However, some of the changes were more fundamental and created difficulties, for example, changing the definition of status types and the inclusion of both geographical boundaries and dynamic boundaries based on percentages of the national list. These changes were difficult because they required rebuilding component models since survival, relist and removal functions and transition matrices are all dependent upon the definition of medical status. In June 1996, the Board of Directors approved the change in definitions of medical status, approved the integration of

Table 1. Listing of Potential Liver Allocation and Distribution Performance Measures.

Medical Utility Measures

MU1	Total (nonrepeated) transplants
MU2	Total deaths
	MU2.1 Pre-transplant deaths
	MU2.2 Post-transplant deaths
MU3	Total other patients removed
MU4	Percent of transplanted patients that survive
MU5	Total patients relisted
MU6	Number of life-years
MU7	Number of quality life-years
MU8	Size of the end waiting list

Patient Utility Measures

PU1	Probability of receiving a transplant
PU2	Probability of dying on the waiting list[1]
PU3	Patient transitions from status at registration to other medical statuses

System Utility Measures

SU1	Distance organs travel
SU2	Size of the end waiting list
SU3	Total costs of transplantation

Medical Equity Measures

ME1	Total (nonrepeated) transplants[1]
ME2	Differences in percent of status types transplanted

Patient Equity Measures

PE1	Differences in the probability of receiving a transplant
PE2	Differences in the probability of dying on the waiting list
PE3	Differences in waiting time across across categories

System Equity Measures

SE1	Impacts on geographic areas or individual centers
SE2	Local use of organs and its impact on organ donation
SE3	Differentials in size of waiting lists

[1] Several measures may be classified as either utility measures or equity measures

medical statuses with their associated points for ranking, decided to maintain the geographical areas for distribution, and approved the priority allocation to acute patients based on a percentage of the total number of acute and chronic patients.

9 POLICY CRAFTING ISSUES

At the Winter Simulation Conference 1996, a description of ULAM will be presented as well as a chronological description of the interaction between the various UNOS committees and the support provided by the UNOS/Pritsker Team. A panel discussion will then be held dealing with issues that arise in using simulation to craft policy. Some of the issues are listed in Table 2 along with illustrative examples from the transplantation field. Many of these issues relate to the establishment of the demarcation lines between a system and its environment which is a key to successful modeling (Pritsker et al 1996).

10 CONCLUSION: SIMULATION'S EXCITING OPPORTUNITIES IN CRAFTING POLICY

Simulation has an outstanding track record in assisting operational decision-making by systematically estimating the performance implications of various alternatives. As companies today are examining broader, more large-scale changes, the application of simulation can help in the crafting of the best policy alternative.

The UNOS transplantation example illustrates how policy crafting involves broader issues with complex implications impacting diverse groups. Simulation's future application in supporting policy setting is highly dependent upon how modeling and simulation programs can foster meaningful executive communication and systematic understanding of the issues being considered.

For fourteen months, the UNOS/Pritsker Corporation team worked closely together to evolve a recommendation for a new national transplantation policy for livers based on delicately balancing of the intuitive solutions of the various participants and the analytic performance estimation of ULAM. During this time, many lessons were learned concerning how to best apply simulation methods into an organizational policy crafting context. These lessons can be grouped into three major areas:

Table 2 Issues Related to Crafting Policy

Issue	*Discussion*
1. Personal and organizational relations	Are geographical boundaries necessary in order to build personal relations and organizational ties?
2. Evaluation of benefits	How do you measure transplant center proficiency which is dependent on the experience of the surgical team, facilities available, rate of performing transplants and patient mix?
3. Ownership of assets	Does the local procuring organization have a claim to the organs they procure or are organs a national resource?
4. Distributions of a scarce life-saving resource.	Given that an organ is a scarce resource, should patients who have a higher probability of survival have preference in allocation?
5. Setting standards for policy statements.	If waiting time points are calculated based on registration time, how is a standard established for time of registration for terminally ill liver patients?
6. Evaluating downstream implications.	Are there ways to "game" the policy?
7. Can a national public policy be properly evaluated using a democratic process?	Can fair and effective policy be developed through a consensus process and by committees whose members have different points of view?

1 Reaching Consensus on the Goals, Methods and Approaches of Simulation

Policy issues, by definition, involve a broad spectrum of participants with diverse viewpoints, experiences and expectations. In order to have quantitative outputs accepted in such a decision-making environment, the various policy-makers must acquire a confidence in the simulation methods and models.

2 Specifying Definitions, Values and Measures

Policy selection requires the use of intuition, experience and judgment by those closest to the issue being evaluated. Conversely, simulation is based on precision, quantification and probabilistic reasoning. The key to blending these complementary approaches is to use qualitative information and simulation model outputs in such a way as to create a continuous dialogue that is aimed at improving policy setters intuition while improving the model's comparative ability.

3 Developing Policy Alternatives and Models Concurrently

Conceptually, a model's performance measures and policy selection criteria should be separate from the process of generating policy alternatives. However, to ensure a model can accurately capture the implications of the policy alternative, an iterative process between model specification, policy articulation and simulation testing is necessary. While the managing of this iterative process is difficult, the benefits in terms of model capabilities and output acceptance make the effort worthwhile.

The use of simulation to address policy-level issues offers new opportunities and challenges for our field. Our success at integrating the systematic science of simulation with the organizational process of policy development will make a vital contribution to effective policy selection.

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