

AN UPDATE ON A SUCCESSFUL SIMULATION PROJECT: THE UNOS LIVER ALLOCATION MODEL

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ABSTRACT

The UNOS Liver Allocation Model (ULAM) is a simulation of the cadaveric liver allocation system in the United States. ULAM was created by the United Network for Organ Sharing (UNOS) in collaboration with Pritsker Corporation/Symix Systems, to permit comparison of multiple liver allocation policy proposals so that policies can be tested prior to implementation. ULAM is extremely adaptable, and with it UNOS has been able to respond to varied and complex requests for policy analysis. ULAM has aided UNOS throughout the highly publicized national liver allocation debate, and its use is anticipated for the foreseeable future. The authors believe that ULAM is an excellent example of simulation technology used to resolve national medical policy issues. The success of ULAM, in terms of its ease of use, flexibility of design, and acceptance by the transplant community, has reinforced UNOS' desire to create other organ allocation models. This paper provides a brief description of ULAM's structure, and summarizes the evolution of ULAM from 1995 to 2000.

1 INTRODUCTION

The United Network for Organ Sharing (UNOS) is a tax-exempt, medical, scientific, and educational organization that operates the national Organ Procurement and Transplantation Network (OPTN) under contract to the Division of Organ Transplantation (DOT) of the Department of Health and Human Services (DHHS). UNOS maintains the organ-specific lists of all patients awaiting solid organ transplantation in the United States and operates a 24-hour Organ Center to assist in the placement of organs. This enables UNOS to perform its most critical function, that of organ allocation and distribution. The UNOS computer system matches donors and recipients according to UNOS' allocation policies, which are developed by UNOS Committees and distributed widely for public comment

prior to implementation. UNOS maintains databases that include information on every patient listed for an organ transplant, and is able to track each patient from listing to transplant or removal from the waiting list for death or other reason. UNOS member transplant centers are required to follow all transplant recipients for a minimum of two years post-transplant.

The UNOS Liver Allocation Model (ULAM) is a detailed computer simulation of the liver allocation process in the United States, designed to enable comparison of proposed liver allocation policies. ULAM uses either historical or simulated data streams for both patient listings (registrations) and donor arrivals (procurement). In ULAM, individual patients are listed at transplant centers throughout the country. Patients may change medical urgency status during the simulation, or be removed from the waiting list due to pre-transplant death or other reasons. Donor livers are procured by organ procurement organizations (OPOs) and matched against patients waiting at each liver transplant center. The patients on the list are ranked based on the allocation policy selected. Once transplanted, patients either die, relist, or survive for the duration of the simulation. Numerous outcome statistics are collected during the simulation for use in policy comparison. Through ULAM's user interface, a wide range of policies can be selected, and all parameters and statistical inputs can be changed as desired. The simulation period can range from 1999 to 2003, and generally four to ten replications of the simulation provide adequate estimates of the outcome statistics.

2 A BRIEF HISTORY OF ULAM

Between 1988 and 1998, the total number of patients waiting for a liver during each year has increased from 2,621 to 19,128. In contrast, the total number of transplanted cadaveric liver donors rose from 1713 in 1988 to 4267 in 1998 (UNOS 2000). The increasing gap between donor

supply and waiting list demand has led to increasing waiting times for liver patients. Moreover, waiting times can vary dramatically from one area of the country to another, a fact that gained significant media attention in the mid-1990s. Although variations were not seen in the most severely ill patients, who receive the highest priority on the waiting list within their geographic distribution unit, they did exist for patients of lesser medical urgency, primarily due to local differences in listing practices. Thus, perceptions that the system was unfair led to increased political pressure for a liver allocation policy with less emphasis on geography.

In 1995, UNOS policy allocated donated livers first to the "local unit" that served the donor hospital (usually the OPO service area defined by the Health Care Financing Administration (HCFA)), then to the UNOS Region in which the donor hospital resides, then to the nation as a whole. Within each unit (local, regional, national), the organ was offered to the group of patients determined to be most medically urgent (status 1). If the offer was not accepted by any of the status 1 patients, the organ was then offered sequentially to the next levels of medical urgency (at the time, status 2, 3/4). If no patients in the local area accepted the organ, then the process was repeated at the Regional and National levels. Notation for this sequence is as follows: L1, L2, L3/4, R1, R2, R3/4, N1, N2, N3/4 where L, R, and N represent local, regional, and national, respectively, and 1 through 4 represent the medical urgency category of the patient. Patients within each of these nine categories were ranked based on their waiting time and blood type compatibility with the donor.

UNOS, through its allocation policies, is charged with the task of distributing the available organs in the most fair and equitable way possible. The UNOS Principles and Objectives of Equitable Organ Allocation state that medical justice (e.g., giving everyone an equal chance for a transplant) must be balanced with medical utility (e.g., making the best use of a scarce resource) (UNOS 1995). These goals are often competing, and changes to such a complex system can yield unexpected and unintended consequences. Historically, policies have been developed based on a consensus from the transplant community, implemented, and then monitored and adjusted after sufficient data had been collected for retrospective policy analysis. The rationale behind the development of ULAM was the belief that, through simulation modeling, allocation policy proposals could be tested and compared to one another *prior to implementation*. ULAM allows for effective policy comparison of numerous allocation systems.

In 1994, UNOS began compiling the data necessary to construct a simulation model for use in comparing alternative liver allocation policies. In November 1994, then UNOS President Margaret Allen placed computer modeling at the top of her list of priorities for her 1994-1995 tenure. In December 1994, UNOS began to search for an

outside expert in the field of computer simulation and modeling. In January 1995, UNOS contracted with the Pritsker Corporation to develop a computer simulation model for liver allocation to be used in evaluating alternative policy scenarios. An ad hoc UNOS Allocation Modeling Oversight Committee provided medical and scientific direction for development of ULAM. Additionally, a government oversight committee was appointed by DHHS to review the model development process. These committees were composed of transplant surgeons and physicians, hepatologists, organ procurement personnel, patient representatives, statisticians, and policy-makers. The model specification was approved in March of 1995, and a phase I model was developed by June 1995. ULAM was demonstrated at the June 1995 Board of Directors meeting, and results for 8 initial policy alternatives were presented. Since that time, UNOS has modeled over 100 policies using ULAM. ULAM has evolved to keep pace with the fast-changing field of liver transplantation.

3 OVERVIEW OF ULAM COMPONENTS

Since ULAM was designed to simulate the liver allocation process in the United States, it must include all the elements that are present in the existing system, such as donors, recipients, an offer/acceptance process, and so forth. The major components of the model are:

1. Initial Waiting List
2. Recipient Stream
3. Patient Medical Urgency Status Change Process
4. Donor Stream
5. Allocation Policy
6. Liver Offer/Acceptance Process
7. Post-transplant Relisting/Mortality
8. Outputs.

ULAM's structure has been described in greater detail elsewhere (Pritsker, et al 1995, Pritsker, Daily, Pritsker 1996, Pritsker, Martin, et al 1996, Pritsker 1998). The following is a brief description of the basic ULAM components.

3.1 Initial Waiting List/Patient Registrations

ULAM uses an actual "snapshot" of the UNOS liver waiting list at a specific point in time (e.g., December 31, 1998) as the starting point for the simulation. Patients are then added to the waiting list throughout the simulation. Generated recipients arrived originally based upon a non-homogeneous Poisson process (Kuhl, Wilson, Johnson 1995). Currently a piece-wise homogeneous Poisson process is employed. Projections are made at the transplant center level; there are currently 115 liver transplant centers in the U.S. Each patient's status at listing is based on historical probabilities for each transplant center. Demo-

graphics used for allocation and outcome statistics are assigned probabilistically by sampling historical data records obtained from each transplant center.

3.2 Patient Status Changes

UNOS Liver Allocation policy currently defines four states of medical urgency: 1 (most urgent), 2A, 2B, and 3 (least urgent). In ULAM, as in reality, patients transition between status codes during their time on the list, and may be removed from the list for death or other reasons. For example, a patient listed as a status 3 may transition to status 2B but return to status 3 once stabilized. ULAM uses a Markov matrix, based on the medical urgency status code changes made by patients on the UNOS Liver Waiting List, to determine daily transition probabilities. The transitions included in the matrix are those from 1, 2A, 2B, 3, and 7 (temporarily inactive), to 1, 2A, 2B, 3, 7, 8 (death) and 9 (removal).

3.3 Organ Procurement

ULAM's annual donor procurement (transplanted livers) projections increase from 4,345 in 1999 to 4,729 in 2003. This projection does not include the relatively small number of living donor, foreign donor or split liver transplants that take place in reality, since these allocations are not included in ULAM. The projected liver recovery rates are based on recent historical trends, and employ the same methodology used for the patient projections. Projections are made for each of the OPOs that procure livers in the U.S.; there are currently 61 OPOs in the U.S. Demographics used for allocation and outcome statistics are assigned to each donor using a method similar to that used to assign characteristics to recipients.

3.4 Organ Acceptance Rates

For various medical and logistical reasons, livers are not always accepted for the highest-ranked candidate on the list. To simulate this behavior, ULAM utilizes probabilities derived from historical data to determine whether the organ will be accepted or declined based on donor quality and the patient's medical urgency status. Rates are stratified by transplant center, patient medical urgency status at the time of offer, and donor quality.

3.5 Post-transplant Relist and Survival Rates

The post-transplant relist and survival rates in ULAM are based on the cohort of patients transplanted between 1993 and 1995, the most recent cohort for which 3-year patient follow-up is available. Relist rates are stratified by status at transplant and whether the patient received a primary or repeat transplant. The survival curves used in ULAM are

stratified by patient medical urgency status at transplant, previous transplant status, and transplant center volume; thus, a total of 16 individual survival curves are used in ULAM to estimate post-transplant mortality.

3.6 ULAM Simulation Parameters

The probabilities used in ULAM are derived from actual historic data and statistical analyses. Through the User Interface, it is possible to alter any of these probabilities. For example, procurement rates or survival rates could be increased or decreased, and waiting time or blood type compatibility could contribute more or fewer points if desired.

3.7 ULAM Outputs

ULAM produces numerous statistics for each run and set of runs made. A data file containing key outcome measures is created based on the average of all runs made and can be pulled directly into an Excel spreadsheet that allows side-by-side policy comparison. These "key measures" were determined by the transplant community to be the most valuable in evaluating policy changes. Additionally, ULAM produces a data record for each patient entering the simulation that includes demographic and outcome information (transplanted, died, removed from the waiting list, etc.). These patient file records are then transported into SAS[®] datasets that can be analyzed in almost limitless ways. These data are used for model validation, and have been used to "debug" ULAM after a recent change has been made.

4 THE EVOLUTION OF ULAM

ULAM has consistently proven its flexibility, and has been modified as needed to reflect the ever-changing field of liver transplantation in the United States. Much of the internal reprogramming that has occurred in ULAM was related to changes in the types of policies that the transplant community wanted to evaluate. Changes to ULAM's statistical components were largely driven by changes in the allocation system, such as the revisions to the medical urgency status codes occurring in 1996-1998, or at the request of UNOS Committees, Board, or the federal government, such as changes to ULAM's post-transplant survival component.

4.1 Changes to Policy Types

The "phase I" version of ULAM, completed in 1995, appeared to answer several basic questions about liver allocation. For example, it was clear that policies that offered organs locally prior to offering them elsewhere offered the best chance of transplanting a mix of urgent and less urgent patients. Policies that eliminated local and

regional primacy but retained the “sickest-first” allocation sequence tended to transplant very sick patients to the exclusion of the rest. Because ULAM’s post-transplant survival rates were adjusted to reflect the generally poorer outcomes for critically ill patients, the “sickest first local” policy had better overall survival rates than the “sickest first national” policy. The two policies captured, to some extent, the range of opinions engaged in the liver allocation debate, and demonstrated a fundamental trade-off in the allocation of this scarce resource.

Initially, various combinations of the “standard” policy were explored; for example, one proposed policy ranked the patients as “L1, R1, L2, R2, L3, N1, R3, N2, N3” while another used “L1, N1, L2, N2, L3, N3.” Other policies substituted the state or region for the first allocation unit. Regions were grouped together to form “Super Regions” for allocation. Soon, however, more creative ideas came forth, such as the “Patient-Grouped Distribution System” (PGDS), the “Home-OPO” concept, and the “modified Single National List.”

In the PGDS, distribution areas were based on a specific percentage of total patients waiting (i.e., 5%, 20%, 100%), closest to the donor hospital. Thus, the distribution area differed for each donor. Within each distribution area, livers would be offered to each status separately, with the sickest status first. Within each status and distribution area, patients would be ranked based on points assigned for waiting time and blood type compatibility. The idea behind the “Home-OPO” proposal was that patients should be able to list wherever they choose, but the organs must come from their “OPO of Residence,” thus causing the organs to follow the patients. Under the “Modified Single National List” types, the distribution area encompassed the entire national list, with points assigned for medical urgency status, waiting time, blood type compatibility and transplant center proximity. One variation on this policy type included points for the “population density” between the donor hospital and the recipient center, such that patients at centers clustered within a geographic area would receive the same number of points, with the number of points diminishing as the distance between the donor hospital and recipient center increased. These policy types were later combined with the existing L, R, N allocation structure to form hybrids (i.e., a PGDS with a 20% “circle” for status 1s, then reverting back to local, regional, and national allocation for other statuses). With each new policy proposal, ULAM was modified to allow these policies to be modeled and compared to other policies, often under fairly short deadlines. ULAM’s flexibility was demonstrated time and time again, as policy proposals became more complex and creative.

4.2 Changes to ULAM Components

4.2.1 Medical Urgency Status Codes

In 1996, the UNOS Liver and Intestinal Transplantation Committee began to reexamine the medical urgency status codes that were in use at the time. The primary concern was that the status codes were based on subjective, non-medical criteria and could therefore be interpreted differently by different centers. A second, related concern was that the statuses were to a large extent based on a patient’s location and duration in the hospital: a status 3 patient did not require hospitalization, while a status 2 patient had to have been hospitalized for 10 days, and a status 1 patient was in the ICU with a life expectancy of 7 days. There were no standardized criteria that determined when a patient should be listed for transplantation. These factors led to mistrust amongst the transplant community, especially between centers with relatively short lists/short waiting times and those with lengthy lists and waiting times. The UNOS Liver and Intestinal Transplantation Committee agreed to develop new, more medically-based urgency criteria in parallel with standardized listing criteria, and asked the ULAM developers to model several policies using the proposed status codes prior to asking for approval from the UNOS Board.

This posed an enormous challenge to the ULAM team, as the proposed (and subsequently adopted) medical urgency criteria were based on laboratory values and other patient information not collected in the UNOS data system. Furthermore, nearly every component in ULAM is driven by the medical urgency status codes. The ULAM developers had to use available information to reclassify the patients in the existing database to reflect the new status codes, with the aid of several liver transplant surgeons, and to redefine the status codes throughout ULAM. This included re-estimating the patient status change matrix, which is a sensitive component of the model, organ acceptance rates, and post-transplant outcomes. Once completed, it was not possible to validate the outputs; acceptance of the model had to be gained by a perception of “reasonableness” by the transplant community. The status codes were changed incrementally, with interim medical urgency codes in place from August 1997-December 1997. The current status code definitions were adopted in January 1998. In January 1999, the ULAM team was able to use existing data to update some of the key ULAM components driven by medical urgency status.

4.2.2 Other Key Changes

In 1999, UNOS responded to a modeling request that required alterations to ULAM’s basic assumptions. The DHHS wanted UNOS to compare several allocation

policies under four different scenarios: (1) the “baseline” scenario, using standard ULAM inputs; (2) a scenario in which donor procurement increased by 10% per year; (3) a scenario in which survival rates increased each year; and (4) a combination of scenarios (2) and (3). UNOS agreed to explore these assumptions, with the guidance of the UNOS Liver and Intestinal Transplantation Committee. ULAM was adapted to accommodate these requests, and data were provided to the DHHS in early 1999.

4.2.2.1 Donor Arrivals

The DHHS wanted to assess the potential impact of increased donor procurement predicted to occur as a result of its donor initiative launched in late 1997. However, in order to increase the donor procurement rates in ULAM, the donor arrival stream to each OPO had to be refitted. Originally, ULAM employed a non-homogeneous Poisson process (NHPP) in determining future donor arrivals. However, the complex process of fitting the donor arrivals at each OPO over a six-year period required manual processing, and the modeling team needed to streamline the process in order to provide a quick response to policy- and decision-makers. Tests were made at Symix to determine the effect of eliminating the time-of-season and time-of-day effects in the donor and patient arrivals. The results showed that, over the six years, the aggregate results were the same using both methods, and the data generator was rewritten using a piece-wise HPP. This allowed UNOS to experiment more easily with changes to the donor and recipient forecasts. ULAM’s donor and patient streams can now easily accommodate changes in the organ donation or patient registration rates.

4.2.2.2 Survival Rates

Like most of the statistical probabilities used in ULAM, the post-transplant survival probabilities were fixed throughout the duration of the simulation. This seemed to be a reasonable assumption, as the initial model runs were 4 years in length. However, in 1997 the potential run length was increased to 8 years, and UNOS began looking at policy comparisons for 1996-2003. This led some to question whether ULAM was adequately capturing increases in post-transplant patient survival that had been occurring over time. As a result, the DHHS asked UNOS to model several policies with increasing survival rates over time.

UNOS statisticians analyzed the trends and determined that survival rates appeared to be flattening out, with the exception that status 1 rates seemed to be improving over time. With the approval of the UNOS Liver and Intestinal Transplantation Committee, UNOS agreed to examine the impact of a ½ percent increase in status 1 survival rates each year. This required reprogramming to the post-

transplant survival logic. Furthermore, increasing survival implies a simultaneously decreasing relist rate. The modifications allow the user, through the User Interface spreadsheet, to adjust annual survival and relist rates by any percentage desired.

5 ULAM VERIFICATION/VALIDATION

5.1 Aggregate Validation

Whenever changes are made to ULAM, the Symix staff takes steps to verify that the model is working as intended. ULAM is then validated against historical data to determine that ULAM (as a whole system) is able to adequately represent the complex process of liver allocation in the U.S. The 1998 validation compared quite favorably to the U.S. national data (Table 1). It should also be noted that changes to the allocation system that occurred in 1996 through 1999 have made model validation quite a challenge.

Table 1: January 1, 1998 – December 31, 1998. Basic Validation Results.

	ULAM	Actual
Transplants		
Total	4285	4197
% Repeat	9.4	9.1
% Pediatric	10.3	10.2
% Status 1	10.2	10.9
% Status 2A	14.3	17.4
% Status 2B	59.4	53.7
% Status 3	16.2	17.1
Registrations		
Total	9624	9494
# Pre-Tx death	1386.6	1330
# Other Removals	1260.7	1363
# Pts at beginning	9740	9740
# Pts at end	12410.5	11900

The most recent validation is still in progress. Ten ULAM runs were made for the year 1998-1999 and the results averaged across the ten runs. ULAM outputs for August 1, 1998 though July 31, 1999 (a period during which no liver allocation policy changes took place) were then compared to the actual data for that period. Some of the results of this validation are provided in Table 2. Based on these and other, more detailed validation results (i.e., stratified by status) UNOS is planning to update ULAM in 2000.

Recent changes in liver allocation policy, specifically the revision of the medical urgency status codes and the implementation of regional sharing for status 1 patients, have led to changes in the mix of patient registrations and transplants by status which necessitate changes to ULAM’s inputs, as indicated by preliminary validation results.

Table 2: ULAM August 1, 1998 – July 31, 1999. Basic Validation Results.

	ULAM	Actual
Transplants		
Total	4355.3	4392
% Repeat	11.1	9.7
% Pediatric	10.2	10.2
% Status 1	10.6	12.5
% Status 2A	16.2	19.7
% Status 2B	60.0	56.5
% Status 3	13.2	11.0
Registrations		
Total	10176.0	10265
# Pre-Tx death	1772.3	1580
# Other Removals	1556.2	1640
# Pts at beginning	11153	10957
# Pts at end	13640	13599

5.2 Validation at the Local or Regional Level

ULAM was developed to assess the effects of changes in allocation policy at the national level. However, there have been several cases when a UNOS Committee or the DHHS has requested results at the center, state, or regional level. While ULAM validates well against national data, it is not as likely to validate at the local level.

The primary reason for this that several key model components are based on aggregate (national) probabilities. Aggregate probabilities are used because there are insufficient data at the level of the OPO or the transplant center to provide reliable probability estimates when stratified by all relevant variables (e.g., medical urgency status or previous transplant status). For example, it was necessary to use aggregated data to construct the patient status change matrix, which includes daily probabilities for each of 35 possible combinations of status code changes (3 to 2A, 3 to death, 2B to 2A, etc.). This means that in ULAM, all patients progress through their liver disease at a statistically similar rate regardless of the transplant center at which they are listed. In reality, the rates of disease progression may differ substantially by listing center. It can be assumed that ULAM's accuracy at the center level would be greatly enhanced if it were possible to obtain reliable estimates of these probabilities at the center level. The following components use aggregated probabilities: patient status changes, marginal donor probabilities, post-transplant relist, and post-transplant survival (however, this component does incorporate transplant center volume).

Several components (donor procurement, initial waiting list/waiting list additions, organ acceptance rates) are center- or OPO-specific, and thus provide some level of reliability at that level. In providing local-level data to end-users, several *caveats* are always applied, with the suggestion that the results may not provide an accurate indicator of what will happen at that level, but that the

trends suggested by the data might be meaningful. UNOS conducted validation tests on groups of OPOs (based on the number of patients listed), and was shown to validate well against the large- and medium-sized OPO groups. Very aggregate outcome measures, such as the total number of transplants, validated well against all three OPO size categories.

ULAM is a discrete-event simulation with Monte-Carlo events, so scheduled events have a probabilistic, or random component. Because each replication represents a unique set of circumstances and outcomes, model results will vary from one run to the next. For this reason, model outputs are based on the average of the ULAM runs made. Empirically, four runs were found to provide adequate results on a national level; however ten runs are made when providing results at the state or local level. Since ULAM is simulating a nonstationary system where demand exceeds supply, the dynamics of deaths, waiting times, etc., are captured by producing files of transplanted patients and patients that have died or removed. SAS[®] programs used to analyze actual data are then employed to detect and quantify changes in performance over a period of years.

6 ACCEPTANCE OF ULAM

Liver transplantation has made headline news throughout 1995-2000, with emphasis on patient waiting times and pre-transplant deaths. ULAM has been ever present in the debate, its data used by the transplant community, DHHS, Congress, and the media. Much of this was prompted by the DHHS OPTN "Final Rule" published in April 1998, which ultimately led to the Institute of Medicine (IOM) report "Organ Procurement and Transplantation" published in 1999. A brief summary of ULAM's diverse audiences include:

- September 1996: ULAM data used during UNOS hearings on liver allocation, St. Louis, Missouri.
- December 1996: A. Alan B. Pritsker, Ph.D. participated in the allocation modeling panel during DHHS hearings on liver allocation, Bethesda, MD.
- Summer 1998: Alan Pritsker testified in front of a Congressional panel on behalf of UNOS, as the expert in simulation modeling and as the key ULAM developer.
- Spring 1999: A panel on ULAM and organ allocation modeling was included during the Institute of Medicine forum in Washington D.C.

During each of these proceedings simulation was viewed as a viable, even necessary tool to evaluate the complex issues surrounding liver allocation. ULAM proved to be flexible, responsive, and able to provide vast amounts of data to its end-users. It is clear that the shape of the debate changed with the quantitative results

produced by ULAM. No longer were subjective concepts presented but questions centered about the data used for the component models and how the component models were integrated to produce system performance measures. We feel that ULAM helped to select policies that have saved patient lives and produced more quality life-years for them. UNOS continues to rely upon simulation as a tool; the Phase I version of the UNOS Kidney Allocation Model (UKAM) is scheduled for completion in June 2000, and it is likely that a thoracic organ allocation model will be developed in the next few years. It appears that simulation is here to stay in the field of organ transplantation.

7 THE FUTURE OF ULAM

UNOS is currently planning a full-scale overhaul of ULAM. Virtually every component will be updated using the most current data available. Several liver transplant programs have closed since ULAM was first developed, and others have opened; these changes will be reflected in the new version. Because ULAM was designed with the user in mind, all of these changes can be made in-house by UNOS staff. This upgrade will be important for several proposed changes to the liver allocation system that are scheduled for 2000.

In the summer of 2000, the UNOS Liver and Intestinal Transplantation Committee is expected to again revise the medical urgency codes used for liver allocation. It is anticipated as many as 30 levels of medical severity will be identified. As before, it is likely that many of the factors involved in the categorization (laboratory values, daily clinical information) are not currently collected by UNOS. The challenge will lie in obtaining reliable estimates for each of ULAM's components based on a radically different medical urgency scale. Another anticipated change, one that should be easier to model, is a realignment of OPOs to form new organ allocation areas (OAAs) to provide patients broader access to donated organs, as recommended by the IOM. Neither of these changes can be validated for some time, and ULAM's past successes will hopefully pave the way for its acceptance during this process.

Once new status codes and OAAs are defined, it is likely that UNOS will once again begin experimenting with changes to the allocation system, in hopes of finding the balance between increased access to organs (medical justice) and the best use of those organs (medical utility). Ironically, the outcome measure that drove many of the original liver allocation debates, waiting time, was found by the IOM to be "a poor measure of differences in access to transplantation" and "not a good indicator of medical urgency or priority." UNOS must now focus on other measures of equity and justice, such as pre-transplant mortality.

ULAM outputs will no doubt be in the center of the discussion, as the transplant community has come to rely on simulation as a tool for policy development.

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REFERENCES

- Institute of Medicine, 1999. *Organ Procurement and Transplantation: Assessing Current Policies and the Potential Impact of the DHHS Final Rule*, Committee on Organ Procurement and Transplantation Policy, Division of Health Sciences Policy, National Academy Pres. Washington, D.C.
- Kuhl, M. E., J. R. Wilson, and M. A. Johnson. 1995. Estimation and simulation of nonhomogeneous poisson processes having multiple periodicities. In *Proceedings of the 1995 Winter Simulation Conference*, ed. C. Alexopoulos, K. Kang, W. Lilegdon, and D. Goldsman. 374-383. Piscataway, New Jersey: Institute of Electrical and Electronics Engineers.
- Pritsker, A.A.B. et al. 1995. Organ transplantation policy evaluation, In *Proceedings of the 1995 Winter Simulation Conference*, ed. C. Alexopoulos, K. Kang, W. Lilegdon, and D. Goldsman 1314-1323. Piscataway, New Jersey: Institute of Electrical and Electronics Engineers.
- Pritsker, A.A.B., Daily, O.P., and Pritsker, K.D. 1996. Using simulation to craft national organ transplantation policy, In *Proceedings of the 1996*

Winter Simulation Conference, ed. J. M. Charnes, D. J. Morrice, D. T., Brunner and J. J. Swain. 1163-1169. Piscataway, New Jersey: Institute of Electrical and Electronics Engineers.

Pritsker, A.A.B., Martin, D.L., et al., 1996. Organ transplantation modeling and analysis. In *Proceedings, 1996 Western Multiconference of the Society for Computer Simulation – Simulation in the Medical Sciences*, 229-35.

Pritsker, A.A.B. 1998. Life and death decisions: organ transplantation policy and analysis, *OR/MS Today*, August.

UNOS 1995. UNOS statement of principles and objectives of equitable organ allocation, *Seminars in Anesthesia*, Vol 14, pp. 142-166. *UNOS OPTN data as of March 24, 2000*.

U.S. Government. 1998. 42 CFR Part 121, Organ Procurement and Transplantation Network; Final Rule (63 Federal Register 16295, at 16332, April 2, 1998).

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