

TESTIMONY OF
THE
NATIONAL TRANSPLANT ACTION
COMMITTEE

BEFORE

THE
DEPARTMENT
OF
HEALTH AND HUMAN SERVICES

ON

LIVER ALLOCATION
AND
ORGAN DONATION

December 10-12, 1996
Bethesda, MD.

EXECUTIVE SUMMARY

National Transplant Action Committee, (NTAC) is a publicly funded non-profit initiative whose mission is to protect and advance the rights and welfare of patients needing organ transplants and their family members. We actively participate in legislative and governmental deliberation that impact our constituents. Although the organization is relatively new, it's principles and directors have years of experience as representatives for organ transplant patients. The organization has a rapidly growing membership.

NTAC supports the Secretary's decision to hold hearings and to promulgate rules on the issue of organ allocation. We believe that the legislative intent of the National Organ Transplant Act clearly places the oversight of the Organ Procurement and Transplantation Network (OPTN) on the shoulders of the Secretary. Despite mandating that the OPTN be a "private non-profit organization" the role of the private contractor is narrowly defined in the legislation. Although the OPTN contractor has argued that the issue before the Department is purely a "medical issue," we believe that the decision of who lives and dies through our national transplant system is truly a public health issue.

Furthermore, despite a 3-year effort to develop a fair public policy on liver allocation the OPTN contractor, the United Network for Organ Sharing (UNOS), has been unable to do so. Instead, recent UNOS actions have instilled tremendous hostility in the public, a lack of trust in the system and panic among waiting liver transplant candidates. Public trust is paramount in our efforts to promote organ donation. We especially

condemn UNOS for its reoccurring attacks on the Department of Health and Human Services and especially its most recent flagrant attempts to stifle public criticism through this hearing process.

With respect to the issue of liver allocation, NTAC supports a system based upon medical necessity versus the current system of local priority. We view the allocation issue as a function of two variables: geography and medical urgency. We believe that the national allocation system should be founded on medical urgency with the most critically ill patients having the highest priority. Based upon the recent report of the UNOS Liver and Intestine Transplant Committee to the UNOS board we believe that a system based upon medical necessity will maximize both utility and equity within the OPTN allocation system. We find UNOS statements regarding the results of their computer modeling on this issue to be biased and misleading. We feel that the UNOS Liver Allocation Model could be an effective tool. However, the manner in which UNOS has utilized this tool is intellectually dishonest.

We feel that a fair allocation system will help in efforts to promote organ donation. For the past few years, UNOS has led an effort to promote organ donation through the "Coalition on Organ Donation." Despite spending millions of dollars the Coalition is unable to show any positive results in increasing organ donation rates. NTAC believes that the key to increasing organ donation is through enhanced professional education and the development of a system providing prompt referral of possible donors to qualified professionals within the Organ Procurement Organizations.

The organ allocation debate and the management of the Organ Procurement and Transplantation Network by UNOS is a great concern to

NTAC. We believe that the actions of the OPTN contractor necessitate a further examination of the National Organ Transplant Act and drastic changes to ensure that the public interest in this arena of health care is protected.

RULE MAKING AUTHORITY

In a letter to Assistant Secretary for Health Philip Lee, UNOS President James Burdick, MD. strongly urged that the Department postpone these liver allocation hearings and that HHS “Issue a public statement reaffirming that both the Department and HRSA “strongly believe that the complex scientific and clinical decisions surrounding these (liver allocation) issues are best made by the transplant community and, in particular, the OPTN board of directors, as a representative body of this community.”

This is not the only time that UNOS has challenged the authority of HHS to regulate the OPTN. UNOS filed an extensive complaint with the General Accounting Office regarding many of the provisions of the HHS Request for Proposals for the upcoming OPTN contract. Much of that complaint centered around the authority of HHS to regulate and oversee the operations of the OPTN and UNOS.

Not only is HHS oversight of the OPTN clearly the intent of the National Organ Transplant Act, it is also critical to the interest of the public health. 42 U.S.C. Section 274c places the administration of the National Organ Transplant Act under the jurisdiction of HHS. The law requires the Secretary to “maintain an identifiable administrative unit in the Public

Health Service to administer (the Act) and coordinate with the organ procurement activities under title XVIII of the Social Security Act...” Congressional reauthorization of the Act in 1990 resulted in important statements about the OPTN and the role of the contractor, specifically UNOS. Congress amended the Act to reduce the minimum requirement that must be met by an entity seeking to operate the OPTN. In doing so, it was the intent of Congress “to provide the Secretary with the opportunity to seek out the best possible potential applicants for this critical role. This change...reflect(s) deep concern on the part of the Committee in the manner in which the OPTN has functioned.” (Senate Report 101-530, U.S. Code Cong. and Adm. News, p. 4625). Congress also criticized the Secretary for a lack of leadership, “The Committee hopes that the Secretary will take a more personal interest in this important program and will be at the forefront of its success.”

Although the Act grants limited authority over medical issues with the OPTN, the legislative history is clear that the oversight of the OPTN is that of the Public Health Service of HHS. The matching of donors and recipients for organ transplantation involves key medical decisions that focus on histocompatibility and the scientific task of matching donors with possible recipients. However, once that has been completed, and a list of possible recipients compiled, it then becomes a public policy question as to who on that list should be given the first opportunity to receive a transplant, who will continue to wait for a transplant, and who will possibly die.

THE “ULAM” COMPUTER MODELING

Although NTAC views this matter as a public health issue, we also

acknowledge the complexities of liver allocation.

In an effort to examine the organ allocation issue, UNOS developed the *UNOS Liver Allocation Model - "ULAM."* This tool facilitates a rational assessment of different allocation algorithms and on key outcome measurements. The ULAM modeling data makes it easy for any public policy maker, regardless of their medical training, to make informed decisions among the various system options.

Despite the usefulness of the ULAM data, NTAC feels that UNOS has used this tool with a bias toward maintaining the status quo. Also, the manner in which UNOS has organized and reported the ULAM data has not been consistent. UNOS model runs report on certain outcome measurements in one report and then on different measurements in later computer runs. This makes it difficult to make comparisons between the different allocation options.

We believe that there are key outcome variables that should be the focus of the public policy decision and the potential benefits of any given allocation option. Total life year measurements such as "*quality adjusted life years*" have been a standard tool used in the overall formulation of health care policy. As reported by Kaplan and Anderson (A General Health Policy Model: Update and Applications; HSR: Health Services Research 23:2, June 1988) life year measurements have been widely used in public policy decisions including Food and Drug Administration evaluation of the effectiveness of new products. The basic model involves the overall evaluation of two competing health care treatment options.

With respect to the ULAM outputs, "total patient life years" and even

“total pre and post transplant deaths” can provide us with an appropriate measurement of the overall benefits of the different allocation options. However, in its deliberations, UNOS has chosen to focus only on post transplant results and has ignored the other part of the equation: the outcome for those patients that do not receive transplants. Without consideration for the patient outcomes for both those who do and do not receive organ transplants we cannot derive the overall health benefits that accrue as a result of our policy decision.

In a recent report entitled “*The Relative Risk of Mortality for UNOS Status 3 Liver Recipients: A Comparison of the Risk Post-Transplant to the Risk on the Waiting List,*” UNOS researcher Erick Edwards concludes: “there is no net survival benefit of (liver transplantation) for Status 3 patients within the first two years following transplantation.” The following table, using recently published UNOS data, illustrates the point at hand:

RELATIVE BENEFIT FROM TRANSPLANTATION
TWO YEARS POST-TRANSPLANT

	survival				net benefit in life years
	with tx		without tx		
	1 yr	2 yr	1 yr	2 yr	
Status 1 patients	69.8%	65.5%	-0-	-0-	1.353
Status 3 patients	80.7%	76.1%	80.7%	76.1%	-0-

UNOS has argued that the slight improvement in survival between Status 1 and Status 3 patients is significant. But, as one can easily see, the

net benefit from transplanting status 1 patients is substantially higher than that of status 3 patients who are essentially receiving no benefit from liver transplantation.

With respect to the matter of equity, UNOS has given virtually no consideration to this issue despite the fact that inequities in waiting times is the heart of the allocation debate. Of the various outcome measurements we believe that the ratio of transplants to individuals on the waiting list is an appropriate marker to analyze the fairness of the different allocation options. Another appropriate measuring tool would be an indicator of those who die waiting for a transplant on a region by region basis.

ULAM RESULTS

Over the course of this debate UNOS has modeled many different allocation options. Based upon the results and our discussions above we support those options that place greater priority on medical status as opposed to geography. Based upon our analysis and review of the UNOS Liver Committee report to the UNOS Board, we believe that the "Inpatient First" policies and the "First Local National" policies show the best overall results and that these options maximize both utility and equity. Our review of these options and a comparison with the current system is included on the next page.

**COMPARISON OF VARIOUS
LIVER ALLOCATION OPTIONS**

TABLE 1

	CURRENT POLICY	FIRST LOCAL NATIONAL
TOTAL PATIENT LIFE YEARS	51,312	51,677
TOTAL PRE & POST TX DEATHS	6242	6105
TRANSPLANTS/PATIENTS LISTED PER REGION (RANGE)	35.29% PTS (H: 65.62% L: 30.33)	6.26% PTS. (H: 43.35% L: 37.09%)
WAITING TIME TO TX OR PRE TX DEATH (RANGE)		
STATUS 1	5.6 - 3.6 DAYS	2.6 - 1.9 DAYS
STATUS 2	10.6 - 5.0 DAYS	7.6 - 6.0 DAYS

(SOURCE: ULAM MODELING)

TABLE 2

	CURRENT POLICY	INPATIENT FIRST	FIRST LOCAL NATIONAL
TOTAL PATIENT LIFE YEARS	51,774	53,381	53,690
TOTAL PRE & POST TX DEATHS	7055	6794	6731
AVG. WAITING TIME TO TX STANDARD DEVIATION (REGIONAL)	28.36	11.55	1.59
PERCENT DYING PRE-TX STANDARD DEVIATION (REGIONAL)	4.64	1.92	.53

(SOURCE: CONSAD RESEARCH)

OTHER CONSIDERATIONS

There have been a number of other concerns expressed by UNOS we believe that these concerns only serve to distract from the real issues. Also, these UNOS concerns hold very little if any foundation.

1. "Local use of organs promotes donation." There is no documentation supporting this claim. In fact, we believe that public trust in a fair system is the cornerstone of organ donation.

2. "Greater organ sharing will result in the closure of some centers and will create an access problem for patients." As the enclosed map illustrates, most transplant centers are clustered around large metropolitan areas. We believe that greater sharing may result in consolidation within the transplant community but that it will have no impact on access. In fact, we believe that it may improve access.

3. "Transplanting the sickest patients first is a poor use of donor organs." As illustrated above, status 1 patients derive the greatest benefit from transplantation. We point out that every system that was modeled using the ULAM tool began with transplanting local status 1 patients as the highest priority. The message from competing transplant centers is that status 1 patients are indeed the most important patients to transplant ... unless they are in another part of the country.

ALLOCATION AND MEDICAID

An important issue that has been raised is the impact that greater

sharing will have on the Medicaid population. NTAC President Craig Irwin serves on the Oregon Medicaid Transplant Criteria Committee and has devoted a great deal of time to improving access to transplantation for the Medicaid population.

There is no federal law mandating that states cover any organ transplants under their Medicaid programs. When states do cover organ transplants, often they require that beneficiaries use in-state facilities if they are available and if they are capable of providing the needed services. There are also options for rare cases. If coverage exists, but there are no in-state programs, then the state negotiates with a transplant facility in another state for the provided services. The rate of payment is based upon the reimbursement rate in the beneficiary's home state or the reimbursement is negotiated. There is tremendous latitude. In any event, whenever a Medicaid beneficiary requires services in an out-of-state facility, federal regulations mandate that the beneficiary's home state provide reimbursement for travel, accommodations for the patient, as well as for a necessary "caretaker/companion."

Based upon the federal regulations, and the options that are available to states and beneficiaries, NTAC strongly believes that any consolidation that results from greater liver sharing will not impact the ability of Medicaid beneficiaries to access liver transplant centers. Even if in state facilities are eliminated due to consolidation, then the states must make the appropriate arrangements to provide care with an out of state facility as well as assist in the transportation and accommodations of the patient.

RECOMMENDATIONS

We believe that the Secretary should proceed to publish final liver allocation rules. We further believe that it is in the best interest of the American public to have a system of liver allocation based upon medical necessity as opposed to geographic priority. It is apparent that status 1 patients who receive liver transplants do derive the greatest net benefits from the procedure. By combining these features into our allocation system NTAC believes that utility and equity will both be maximized.

We have offered the following proposal based upon our review of the Liver Committee report to the UNOS board of directors as well as our own assessment of the ULAM data.

NATIONAL TRANSPLANT ACTION COMMITTEE

PROPOSAL FOR

THE ALLOCATION OF LIVERS FOR

ORGAN TRANSPLANTATION

1. Livers should be allocated based upon the medical status of the patients. All patients within a given health status should be eligible for a donated liver before patients in a lower priority status.

2. The allocation order should be as follows:

	LOCAL	REGIONAL	NATIONAL
STATUS 1	1	2	3
STATUS 2	4	5	6
STATUS 3	7	8	9

3. NTAC supports two suitable options for defining geographic boundaries:

a. local = local OPO service area regional = UNOS region

b. local = 500 mile radius from donor regional = 1000 mile radius

4. Criteria should be developed for defining the patient statuses from 1-3. For example, patients who are currently listed in Status 3 but who exhibit esophageal varicies or, patients with small intra-hepatic tumors may deserve higher priority status on the waiting list. The goal of the criteria should be to increase use of clinical factors to determine priority on the waiting list instead of patient location (ie. at home, in hospital, etc...). The OPTN should monitor transplant centers for compliance.

5. Transplant center performance standards should be established based upon patient mix and patient mortality. Centers that fail to meet the performance standards should be placed on probation subject to elimination from the network if they fail to meet the established standards.

Deciding Which Patients to Save

The board of the organization that decides who gets liver transplants voted last week to change its rules for patients facing imminent death. Those who might benefit the most will go ahead of others who are also very sick but less likely to benefit. In many regions there are not enough livers for every patient who needs a transplant. Rationing is inevitable. But the prospect of weighing one patient's survival against another is an ethical quagmire. The board of the United Network for Organ Sharing deserves credit for tackling the troubling issue, though some experts say its recommendations come up short.

Under current rules, liver transplants go to patients who are sickest and have been on the waiting list longest, no matter what their chances of survival. The new rules would add another consideration for those close to death — the likelihood that a transplant would give the patient a good chance of surviving.

Thus the new rules would give first priority to patients suffering from a sudden and complete liver failure that is expected to kill them within days, while placing imminently threatened patients who suffer from long-standing, chronic liver problems in the second most urgent category. The rationale is that the acutely ill patients can be more successfully cured. Specifically, the new rules would put at the top of the transplant list patients whose livers have suddenly collapsed, or whose first liver transplant failed within a week, and children whose nervous systems would be threatened by delay. That means imminently threatened patients with chronic liver problems, such as cirrhosis or damage from hepatitis C or B infections, could be pushed too far down the list to receive a transplant they need to survive.

As long as livers must be rationed, factoring in

some measure of potential benefit makes sense. But every such comparison is troubling, which is why up to now the waiting lists have been based solely on severity of illness and time of waiting, which evades making judgments. Moreover, it is easy to imagine heart-wrenching comparisons that would be virtually impossible to make on any reasoned basis. That is presumably why the board identified specific, relatively easy-to-call cases of patients who should rise to the top.

But some transplant experts, patients and surgeons, say that much of the liver scarcity for the most severely ill patients is an artificial construct of the organ-allocation rules. The country is carved up into regions with widely disparate waiting lists. Nationwide, last year, 7,297 people waited for liver transplants and only 3,922 received them. But the imbalance between the supply and demand for livers differs widely among specific regions. Many surgeons, such as the director of transplantation at Mount Sinai Hospital in New York City, Charles Miller, say the most important change needed is to even out the regional imbalance, thereby greatly alleviating the need to ration. It is also important to improve the mechanisms by which donors are recruited. More donors could greatly alleviate the need to ration.

The board's new rules do not correct regional imbalances. There will be hearings on this issue in Washington next month. But the board has taken a useful step. Some surgeons would prefer to decide themselves which of their patients can best take advantage of the limited number of livers available for transplantation. But other surgeons want no such responsibility and prefer, in giving a transplant to one dying patient before another, to put the onus on national rules that everyone can agree are free of personal bias.

The New York Times

MONDAY, NOVEMBER 18, 1996



DEPARTMENT OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

Liver Transplant File

Executive Secretariat

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THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

NOV -8 1996

Mr. David M. Matter
801 Undercliff Road
Pittsburgh, PA 15221

Dear Mr. Matter:

I am responding to your letter to the President regarding human organ transplants. You have cogently and succinctly summarized several of the issues with which the organ-transplantation community has been struggling for several years. In particular, I share your desire for a prompt and fair resolution to issues over allocation of human livers and am committed to achieving such a resolution.

Liver allocation is of special concern to me for three reasons. First, the number of patients in need of a liver transplant far exceeds the number of livers available. Second, on any given day, some of these patients are at a stage where they face imminent death if a transplant is not performed immediately; others are substantially more ill than they were when their names were entered on the waiting list. Third, good working relationships between organ-procurement organizations and organ-transplant centers are crucial to an efficient and successful system.

The challenge is to define sharing and allocation policies that are effective, efficient, and equitable. However, we must recognize from the outset that, so long as demand significantly exceeds supply, any policy for sharing and allocating livers will mean that some patients awaiting liver transplants--determined by transplant "status," geography, or other factors--will have a greater chance of a life-saving transplant than others and any policy will also create other trade-offs in areas such as quality of life and graft survival rates. Some patients and some transplant facilities will be winners and some losers. And any decision, whether it be a new policy or a reaffirmation of the current one, is certain to draw intense public and Congressional interest. In fact, the Conference Report for the FY 1997 Omnibus Spending Bill (H.R. 3610) specifies factors that the Congress expects to be considered in a revised liver allocation mechanism and states that no organ allocation changes are to be adopted until the Congress can be assured that these specified priorities are addressed.

My staff and I have paid close attention to the deliberations within the Organ Procurement and Transplantation Network (OPTN) regarding liver allocation. I understand that the OPTN Board and its associated committees have recognized the need to improve upon current policies and have offered some proposals related to standardizing wait list criteria. At the same time, I am disappointed that the allocation policies to date have provoked considerable unresolved controversy within the transplant

Page 2 - Mr. David M. Matter

community. In addition, I recognize that you believe that the decision-making processes of the OPTN are not well attuned to making these kinds of choices, i.e., that OPTN members may be perceived as hard-pressed to endorse any policy option that portends disadvantage for their own institutions and patients. I want to ensure that any federal decision regarding this issue is free from that perception.

Therefore, I intend to take three actions related to these issues. First, I have asked Assistant Secretary for Health Philip R. Lee, M.D. to chair a special panel which will hold public hearings on these important issues. The purpose of the hearings is to help the Department assess the issues associated with allocation of human livers for transplant, to review the OPTN policy and the principal alternatives, to advise me on their relative merits, and to seek ideas on how to increase organ donation. Second, on the basis of these consultations and the other public comments we have received, I will determine in the next three months which of the liver allocation policies promises the best result for the patients of America. Third, I then will submit to OMB the text for a final rule that codifies the structure and basic operating principles of the OPTN (and enables HHS and the general public to have greater input into significant OPTN policies such as liver allocation) and embodies my decision with respect to liver allocation. I wish that this process could be accomplished more rapidly, but I do not believe we can ensure a high-quality, credible outcome within a shorter time frame.

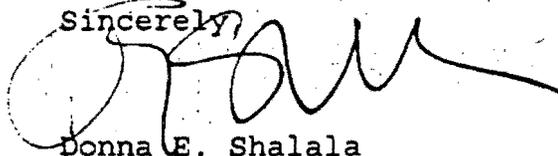
While these actions are under way, HHS will explore ways to intensify efforts to increase organ donations. The hearings will greatly assist the Department as we revise our plans. Currently more than 7,000 individuals are awaiting a liver transplant; yet, in the next 12 months, only about half the required number of donor livers is likely to become available. A similarly severe disparity between demand and supply exists for other organs such as hearts and kidneys.

On November 8, I forwarded to the Federal Register a notice announcing the public hearings, which are to be held December 10 and 11, 1996, in Bethesda, Maryland. I have enclosed a copy of the notice for your convenience. We welcome your participation.

Finally, appended are the answers to your specific questions.

Thank you for sharing your views on this important issue.

Sincerely,



Donna E. Shalala

Enclosure

RESPONSES TO QUESTIONS OF DAVID M. MATTER

Transmitted to President Clinton by letter dated September 30, 1996

INTRODUCTION

Over the last several years, the United Network for Organ Sharing (UNOS), the DHHS contractor for the Organ Procurement and Transplantation Network (OPTN), and the University of Pittsburgh, an advocate for an alternative to the current OPTN liver-allocation policy, have commissioned substantial computer modeling efforts to determine possible effects of different allocation policies. The modeling for UNOS has been performed by the Pritsker Corporation of Indianapolis, Indiana; and the modeling for the University of Pittsburgh Medical Center (UPMC) has been performed by the CONSAD Research Corporation of Pittsburgh, Pennsylvania.

The most recent modeling efforts include projections for (1) the current liver-allocation policy, (2) an alternative policy proposed by the UNOS Board of Directors (which functions as the OPTN policy board), (3) several policies proposed by OPTN committees, (4) a proposal for national allocation offered by UPMC among others, and (5) a policy called "In-Patient First". Pritsker has modeled approximately 30 alternative policies but was not asked to model the "In-Patient First" Policy. The projections available from these models include information on pre- and post-transplant deaths, days to transplant for waiting list patients, patient life years pre- and post-transplant, the number of different patients transplanted, graft (transplant) survival rates, and other factors.

In the answers that follow, both Pritsker and CONSAD projections are included wherever applicable numbers are available. They are the results of computer simulation models that take into account varying probabilities of dying with, or without, a liver transplant. Projections generated by such models are extremely sensitive to assumptions and formulae used. Moreover, the technology of transplantation is improving rapidly -- making projections necessarily uncertain; and neither of the models considers the possibility that either an increase or decrease in organ donation could result from a change in policy.

In addition to differences in the detailed structures for the models and the starting assumptions used for particular simulations, the models' projections often are presented in different ways. For example, Pritsker presents projections covering years 2 through 4 after each postulated policy change (recognizing that estimates for Year 1 will be heavily influenced by the phase out of the old policy and thus not be reasonably representative of the new policy); whereas CONSAD presents projections covering years 1 through 3. Notwithstanding the differences in the models and how their results may be presented, expert reviewers have found both models sufficiently credible for use as aids to policy-making.

The tables presented in answers to Questions 1-3 below include codes and abbreviations defined as follows:

Patient Status:

- A/PNF - Acute/Primary NonFunction;
patient is in intensive care unit (ICU).
- 1 - Patient is chronically ill and in ICU.
 - 2 - Patient is continuously hospitalized in an acute care bed for at least five days or is ICU bound.
 - 3 - Patient requires continuous medical care but not continuous hospitalization.
 - 4 - Patient is at home and functioning normally.
 - 7 - Patient is considered temporarily unsuitable for transplant.

Question 1. What projections or data has DHHS prepared or compiled which compare patient lives saved by Status, pre- and post-transplant, for the current liver allocation system, the UNOS Board proposed changes, the UPMC proposal and the In-Patient First proposal?

Neither Pritsker nor CONSAD presents results in terms of "lives saved"; rather, they project deaths over time. Therefore, in the tables below, differences in the number of projected deaths for each policy option when compared with the current policy are presented as "lives saved." Pritsker projections are "by status". CONSAD projections are for all patient groups in the aggregate.

LIVES SAVED PRE-TRANSPLANT

PRITSKER PROJECTIONS:

Patient Status	Current Policy # deaths	Board Proposal # deaths	Lives Saved (Board)1	UPMC Proposal # deaths	Lives Saved (UPMC)2	IP 1st Proposal # deaths	Lives Saved (IP 1st)
A/PNF	98	32	+ 66	87	+ 11	NA	NA
1	511	640	-129	79	+432	NA	NA
2	485	469	+ 16	399	+ 86	NA	NA
3	897	913	- 16	1067	-170	NA	NA
4	318	306	+ 12	328	- 10	NA	NA
7	1395	1411	- 16	1003	+392	NA	NA
Total	3704	3771	- 67	2963	+741	NA	NA

CONSAD PROJECTIONS:

All Status Groups	Current Policy # deaths	Board Proposal # deaths	Lives Saved (Board)1	UPMC Proposal # deaths	Lives Saved (UPMC)2	IP 1st Proposal # deaths	Lives Saved (IP 1st)3
Total	4571	4556	+ 15	4216	+355	4060	+511

1. column 2 - column 3

2. column 2 - column 5

3. column 2 - column 7

LIVES SAVED POST-TRANSPLANT

PRITSKER PROJECTIONS:

Patient Status	Current Policy # deaths	Board Proposal # deaths	Lives Saved (Board)1	UPMC Proposal # deaths	Lives Saved (UPMC)2	IP 1st Proposal # deaths	Lives Saved (IP 1st)
A/PNF	114	198	- 84	143	- 29	NA	NA
1	781	424	+ 357	1826	- 1045	NA	NA
2	902	1127	- 225	1124	- 222	NA	NA
3	712	633	+ 79	50	+ 662	NA	NA
4	30	69	- 39	1	+ 29	NA	NA
Total	2539	2451	+ 88	3144	- 605	NA	NA

CONSAD PROJECTIONS:

All Status Groups	Current Policy # deaths	Board Proposal # deaths	Lives Saved (Board)1	UPMC Proposal # deaths	Lives Saved (UPMC)2	IP 1st Proposal # deaths	Lives Saved (IP 1st)3
total	2468	2498	- 30	2527	- 59	2734	- 226

LIVES SAVED TOTAL (PRE-TRANSPLANT PLUS POST-TRANSPLANT)

Model	Current Policy # deaths	Board Proposal # deaths	Lives Saved (Board)1	UPMC Proposal # deaths	Lives Saved (UPMC)2	IP 1st Proposal # deaths	Lives Saved (IP 1st)3
Pritsk. pre:	3704	3771	- 67	2963	+741		
post:	2539	2451	+ 88	3144	-605	NA	NA
total	6243	6222	+ 21	6107	+136		
CONSAD pre:	4571	4556	+ 15	4216	+355	4060	+511
post:	2468	2498	- 30	2527	- 59	2734	-266
total	7039	7054	- 15	6743	+296	6794	+245

1. column 2 - column 3

2. column 2 - column 5

3. column 2 - column 7

Question 2. What projections or data has DHHS prepared or compiled which compare total patient life years saved by Status, pre- and post-transplant, for the current liver allocation system, the UNOS Board proposed changes, the UPMC proposal and the In-Patient First proposal?

"Life-years" is an alternative measure of life-saving effects. It is particularly appropriate when, as in the case of liver transplants, very few patients achieve normal life expectancies even if they receive treatment. Neither Pritsker nor CONSAD present results in terms of patient life years "saved." Instead, they show total life years for patients over a three-year period.

PATIENT LIFE-YEARS PRE-TRANSPLANT

PRITSKER PROJECTIONS:

Patient Status	Current Policy life-yrs	Board Proposal life-yrs	diff. (Board) life-yrs1	UPMC Proposal life-yrs	diff. (UPMC) life-yrs2	IP 1st Proposal life-yrs	diff. (IP 1st) life-yrs
A/PNF	32	7	- 25	31	- 1	NA	NA
1	90	117	+ 27	10	- 80	NA	NA
2	507	487	- 20	417	- 90	NA	NA
3	13904	14138	+ 234	16830	+ 2926	NA	NA
4	9184	8858	- 326	9628	+ 444	NA	NA
7	2883	2885	+ 2	2998	+ 115	NA	NA
Total	26600	26492	- 108	29914	+ 3314	NA	NA

CONSAD PROJECTIONS:

All Status Groups	Current Policy life-yrs	Board Proposal life-yrs	diff. (Board) life-yrs1	UPMC Proposal life-yrs	diff. (UPMC) life-yrs2	IP 1st Proposal life-yrs	diff. (IP 1st) life-yrs3
Total	15093	17105	+ 2012	18683	+ 3590	19580	+ 4487

1. column 3 - column 2

2. column 5 - column 2

3. column 7 - column 2

PATIENT LIFE-YEARS POST-TRANSPLANT

PRITSKER PROJECTIONS:

Patient Status	Current Policy life-yrs	Board Proposal life-yrs	diff. (Board)1 life-yrs	UPMC Proposal life-yrs	diff. (UPMC)2 life-yrs	IP 1st Proposal life-yrs	diff. (IP 1st) life-yrs
A/PNF	653	1276	+ 623	811	+ 158	NA	NA
1	3812	2077	- 1735	8755	+ 4943	NA	NA
2	8629	10817	+ 2188	11300	+ 2671	NA	NA
3	11199	9983	- 1216	882	- 10317	NA	NA
4	419	1101	+ 682	17	- 402	NA	NA
Total	24712	25254	+ 542	21765	- 2947	NA	NA

CONSAD PROJECTIONS

All Status Groups	Current Policy life-yrs	Board Proposal life-yrs	diff. (Board)1 life-yrs	UPMC Proposal life-yrs	diff. (UPMC)2 life-yrs	IP 1st Proposal life-yrs	diff. (IP 1st)3 life-yrs
Total	3107	36074	- 33	36465	+ 358	35537	- 570

PATIENT LIFE-YEARS TOTAL (PRE-TRANSPLANT PLUS POST-TRANSPLANT)

Model	Current Policy life-yrs	Board Proposal life-yrs	diff. (Board)1 life-yrs	UPMC Proposal life-yrs	diff. (UPMC)2 life-yrs	IP 1st Proposal life-yrs	diff. (IP 1st)3 life-yrs
Pritsk. pre:	26600	26492	- 108	29914	+ 3314	NA	NA
post:	24712	25254	+ 542	21765	- 2947		
total	51312	51746	+ 434	51679	+ 367		
CONSAD pre:	15093	17105	+ 2012	18683	+ 3590	19580	+ 4487
post:	36107	36074	- 33	36465	+ 358	35537	- 570
total	51200	53179	+ 1979	55148	+ 3948	55117	+ 3917

1. column 3 - column 2

2. column 5 - column 2

3. column 7 - column 2

Question 3. What projections or data has DHHS prepared or compiled which compare disparities in waiting times by Status by UNOS region, pre- and post-transplant, for the current liver allocation system, the UNOS Board proposed changes, the UPMC proposal and the In-Patient proposal?

Both Pritsker and CONSAD have modeled the expected effects of various liver-allocation policies on waiting times for a transplant. The Pritsker projections are both "by status" and "by UNOS region". CONSAD projections are "by UNOS region" only. These tables are presented on the following two pages.

Pritsker Projections:

AVERAGE WAITING TIME (DAYS) TO TRANSPLANT BY STATUS AT REGISTRATION
(UNOS Liver Allocation Simulation Models Summary)

UNOS REGION	Status A/PNF			Status 1			Status 2			Status 3			Status 4		
	Cur.	Brd	UP MC	Cur.	Brd	UP MC	Cur.	Brd	UP MC	Cur.	Brd	UP MC	Cur.	Brd	UP MC
Region 1	27	3	15	54	125	9	255	243	147	476	491	445	726	716	683
Region 2	25	5	14	132	228	61	217	251	172	417	445	434	796	822	810
Region 3	12	4	10	31	43	5	60	68	100	168	191	346	365	351	479
Region 4	19	2	21	43	66	5	93	104	91	241	253	356	594	554	704
Region 5	13	3	6	49	108	14	136	144	109	321	346	368	605	609	603
Region 6	41	10	24	59	81	5	132	161	96	283	303	352	419	517	516
Region 7	14	3	9	66	117	20	132	138	107	331	357	378	527	521	592
Region 8	28	1	13	60	100	8	144	149	114	290	294	364	452	424	517
Region 9	16	3	10	47	88	9	147	150	104	420	420	398	750	735	731
Region 10	19	4	13	54	76	7	132	127	110	316	319	382	523	538	636
Region 11	24	4	20	44	727	5	93	97	121	212	216	355	391	376	484
Total	19	4	12	63	107	20	134	145	123	301	319	383	577	577	639

AVERAGE WAITING TIMES (DAYS) TO TRANSPLANT FROM REGISTRATION
BY UNOS REGION

UNOS REGION	Current Policy		Board Proposal		UPMC Proposal		In-Patient First Proposal	
	Consad	Pritsker	Consad	Pritsker	Consad	Pritsker	Consad	Pritsker
Region 1	102	427	107	451	105	354	110	N.A.
Region 2	126	371	127	414	124	319	121	N.A.
Region 3	23	159	25	172	109	221	81	N.A.
Region 4	91	232	93	240	113	270	100	N.A.
Region 5	121	318	117	358	119	296	109	N.A.
Region 6	56	231	62	253	107	234	94	N.A.
Region 7	118	300	120	322	110	275	105	N.A.
Region 8	110	236	110	240	123	227	106	N.A.
Region 9	119	391	116	410	115	334	107	N.A.
Region 10	88	263	91	266	110	261	93	N.A.
Region 11	70	186	70	189	123	226	88	N.A.
Standard Deviation	32	N.A.	31	N.A.	7	N.A.	12	N.A.

Question 4. If the In-Patient First proposal will save more patient lives, increase total patient life years, and equalize waiting times for patients in a similar medical status across the country when compared to the current system, are there demonstrated negative effects to patients of such proposal which outweigh the benefits?

Question 5. If the UPMC proposal will save more patient lives, increase total patient life years, and equalize waiting times for patients in a similar medical status across the country when compared to the current system, are there demonstrated negative effects to patients of such proposal which outweigh the benefits?

The modeling results are not as straight-forward as presumed in Questions 4 and 5 for the three measures specified: lives saved, patient life-years, and waiting times. Moreover, for certain others measures (in particular, total patients transplanted and quality of life), neither the In-Patient First proposal nor the UPMC proposal appears to offer an improvement over the current policy.

As indicated by the tables provided in response to questions 1-3, Pritsker has modeled the current OPTN liver-allocation policy, the Board proposal, and the UPMC proposal but not the In-Patient First proposal. CONSAD has modeled all four. The models show similar results in some areas and divergent results in some other areas, as highlighted below.

1. Lives Saved

With respect to "lives saved total", the modeling results are similar. Pritsker projects that the Board proposal would yield an outcome almost identical to the outcome for the current policy (i.e., a 0.3% improvement) and that the outcome for the UPMC proposal would be better than both (i.e., about a 2% improvement). CONSAD also projects that the outcomes of the Board proposal and the current policy would be almost identical (i.e., a 0.2% increase in deaths with the Board proposal) and that the outcomes for both the UPMC proposal and the In-Patient First proposal would be better than those for the other two proposals (i.e., about 4% and 3.5% improvement, respectively).

However, the modeling results diverge somewhat when broken down by "lives saved pre-transplant" and "lives saved post-transplant". For example, Pritsker projects that the UPMC proposal, compared to the current policy, would produce about a 20% improvement in the pre-transplant category but an almost 24% decrement in the post-transplant category. CONSAD projects a similar pattern (albeit with changes of smaller magnitude) for both the UPMC proposal and the In-Patient First proposal when each is compared to the current policy. In particular, CONSAD projects improvements of about 8% (UPMC) and 11% (In-Patient First) in the pre-transplant category and decrements of about 2.5% (UPMC) and 11% (In-Patient First) in the post-transplant

category. These discrepancies probably stem from differences in the structures of the models, the assumptions used for particular simulations, and the way results are presented (see Introduction). For example, the CONSAD model seems to include more favorable assumptions regarding post-transplant mortality than does the Pritsker model.

2. Patient Life-Years

With respect to "patient life-years total", Pritsker projects that the outcomes for the Board proposal and the UPMC proposal would be almost identical to the outcome for the current policy (i.e., improvements of 0.8% and 0.7%, respectively). In contrast, CONSAD projects that all three proposals for a new policy would be superior to the current policy: i.e., a 3.9% improvement (Board), a 7.7% improvement (UPMC), and a 7.6% improvement (In-Patient First).

As with "lives saved", the modeling results for "patient life-years total" diverge when broken down by "pre-transplant patient life-years" and "post-transplant patient life-years". For example, for the pre-transplant category, Pritsker projects a 12.4% improvement for the Board proposal over the current policy; whereas CONSAD projects improvements over the current policy of 23.8% (UPMC) and 29.7% (In-Patient First). Further, for the post-transplant category, Pritsker projects an almost 12% decrement for the UPMC proposal compared to the current policy; whereas CONSAD projects almost no change from the current policy for either the UPMC proposal (a 1% improvement) or the In-Patient First proposal (about a 1.5% decrement).

3. Waiting Time to Transplant

The substantial differences in the absolute values of the waiting times projected by Pritsker and CONSAD (see tables in response to Question 3) suggest some fundamental differences in their approaches to this aspect of the modeling -- possibly different definitions of waiting time. Even the rankings of Regions with respect to projected waiting times under the current policy are different. Direct comparisons of the modeling results therefore could be seriously misleading.

Nevertheless, the projections of both models are qualitatively consistent with the reduction in waiting-time disparity across Regions that one would expect for the UPMC proposal. For example, the CONSAD model projects that the UPMC proposal, in achieving a cross-Regions standard deviation of 7 days compared to 32 days for the current policy, reduce waiting time slightly in four Regions while increasing waiting times in seven Regions - in some cases substantially (e.g., greater than 4 times in Region 3).

4. Other Considerations

The UPMC and In-Patient First proposals seem certain to reduce the total number of individuals who receive a transplant. That is, by transplanting a higher percentage of sicker patients, one would expect an increase in the number of transplant failures and therefore an increase in the number of second (and even third) transplants. For every liver used for a repeat transplant, one fewer individual can receive a first transplant.

According to Pritsker projections, the current policy would enable 12,650 total transplants over three years; of these, 10,990 would be to first-time (non-repeat) patients and 1,660 would go to repeat transplants. For the UPMC proposal, Pritsker projects that first-time patients would receive only 10,230 transplants -- a reduction of 760.

In addition, the UNOS Liver Committee and the OPTN Board have considered a wide variety of other measures. One of the most important is quality of life. Any policy changes that were to increase waiting time for a transplant significantly could have an adverse effect on quality of life overall -- for, in general, post-transplant health for liver patients is better than pre-transplant health. In this regard, the Pritsker model projects that the UPMC proposal would increase the lower-quality pre-transplant life years from 26600 to 29914 while decreasing the higher-quality post-transplant life years from 24,712 to 21,765. The CONSAD model projects a similar increase in pre-transplant life-years (from 15093 to 18683) for the UPMC model but also projects a modest increase in post-transplant life-years (from 36107 to 36465).

Question 6. DHHS has data which indicate significant differences in risk of mortality for liver patients, pre- and post-transplant, between centers performing more than 35 transplants per year and those performing fewer than 12 transplants. Are there demonstrated medical benefits to patients to encourage patients to choose to be transplanted at high risk centers?

There are data that would indicate that in the aggregate centers that do fewer than 12 transplants per year are higher risk centers, and that the centers with more than 35 transplants annually have the lowest mortality rates. However, not all low volume centers (i.e., fewer than 12 transplants per year) are higher risk centers. Some have high survival rates and some have low survival rates. In 1993, four out of 17 centers doing under twelve transplants per year had a survival rate above the national average and above the Medicare standard.

In other words, volume is an imperfect proxy for risk.

The reasons a patient may choose a low volume center or a higher risk center are that it may be closer to home and more convenient, and that the waiting time may be shorter at the low volume or higher risk center.

Question 7. Of those centers performing fewer than 35 liver transplants per year, how many are approved for participation in Medicare, Medicaid, VA or other federal government programs for reimbursement for liver transplants?

There were 73 liver transplant programs performing fewer than 35 transplants in 1995. Twenty-two of these were Medicare approved centers. Both VA approved programs did fewer than 35 transplants in 1995.

As of October 2, 1996, there are a total of 118 liver transplant programs in the U.S. Sixty of these are Medicare approved centers and two are VA approved programs.

Question 8. How many centers are performing fewer than 12 liver transplants per year, and are any of those centers approved for participation in Medicare, Medicaid, VA or other federal government programs for reimbursement for liver transplants?

The minimum number of transplants that a Medicare-approved liver transplant program can perform is 12.

None of the Medicare centers did fewer than 12 in 1995. Neither of the VA approved programs did fewer than 12.

Question 9. Has DHHS established any criteria for determining when the mortality rate at a liver transplant center is unacceptable so that the center may not participate in government reimbursement programs or receive livers for transplants?

The Health Care Financing Administration (HCFA) has established performance criteria for approval under Medicare. HCFA requires liver transplant programs approved for Medicare to achieve 77% one-year survival and 60% two-year survival rates. Centers must notify HCFA if their volumes fall below 12 and if their survival rates fall below the initially required survival rates. HCFA will allow the program an opportunity to explain and improve its numbers. If there is no improvement HCFA has the choice of discontinuing reimbursement. To date, HCFA has not discontinued reimbursement for a liver program.

These HCFA standards are intended to protect Medicare and Medicaid patients and do not prevent centers that are not approved from transplanting private pay patients.

The OPTN Membership and Professional Standards Committee has put in place a peer review process for monitoring any transplant programs whose outcomes are in the lowest performance level. This process includes provision for an on-site review of the program. The intention is to correct deficiencies that have resulted in its being a low-performing program.

Transplant Center-Survival Rate Reports produced by HHS show that some transplant programs do bring their survival rates up to the national average over a period of several years. For example, of the 17 lowest performing liver programs in the first Center-Survival Rate Report, all either inactivated or improved following the UNOS review. In the second Report there were only 5 liver programs in the lowest performing category. Only two were the same as in the first Report. Both were site visited and both improved their performance.