Response to “A Critique of UNOS Liver Allocation Policy” by Kenneth Einar Himma (CQ Vol 8, No 3)

The Complexities of Organ Allocation Policies
James Burdick

Introduction
The critique of the United Network for Organ Sharing (UNOS) liver allocation policy by Kenneth Himma has flaws related to the complexities and evolutionary nature of the field. Recent improvements in transplantation have achieved national attention of this sort. There has been an evolution, unequaled elsewhere in medicine, of a national data set and national rules. The transplant community might have been more effective in communicating the details of this, and the problems associated with organ allocation policy. The novelty and complexity of the new rules understandably can produce misleading conclusions.

Mr. Himma’s article suffers in the first place from inaccurate conceptual premises. These incorrect premises lead to incorrect outcomes of his reasoning. Equally important, for practical implications in the field of transplantation, there are critical medical facts underlying the evolution of national allocation rules that are not accurately represented by him.

It is important to note at the outset that transplantation is distinguished from the rest of medicine, ethically and practically. Because there are not enough donated organs, all patients and practitioners are bound together by a community of medicine principle: whenever a patient receives a transplant, it diminishes the chance that other potential recipients will be able to receive this gift of life in time to save them.

In this response, I summarize the development and current status of UNOS policy, and point out the errors in Himma’s reasoning due to the above issues. The conclusion that UNOS policy is unethical is flawed by premises and facts on which that reasoning is based.

Evolution of the National System
Twenty years ago, kidney transplantation in the United States was done in a limited number of centers, with desultory results. Liver transplantation was a difficult, less successful enterprise done in three centers, and only one center was doing heart transplants. In 1984 it became clear relatively suddenly that the new immunosuppressive drug cyclosporine allowed greatly improved immunosuppressive effectiveness and safety. Transplantation blossomed, this advance greatly improving kidney transplant results and stimulating the proliferation of successful liver and cardiac transplant programs. The issues under discussion have evolved not analogous to plate tectonics in a slow, orderly pattern, but more like a volcanic explosion.

National attention, served by President Reagan’s sympathy with a national...
appeal for a liver for a child by her father, and a congressional hearing run by then-Congressman Albert Gore, resulted in a commission whose report helped form the basis of the National Organ Transplant Act (NOTA) in 1984.1

Recognizing the important role the community must play, the law established an Organ Procurement and Transplant Network (OPTN), a private nonprofit entity to collect data and establish rules. UNOS, the dominant early data and organ sharing organization, won the contracts through the Department of Health and Human Services (DHHS) for this. Because of the special, unprecedented, private nature of this as specified by NOTA, and a cost-sharing contract that provides relatively little of the operating funds and control, there has been chronic disagreement between DHHS and the OPTN and UNOS.

Liver allocation rules by UNOS were initially derived from kidney allocation, and were relatively uncontroversial due to the early state of the field. Rules in all the transplanted organs have been under evolution since, and liver allocation policy has become particularly prominent. A major factor in liver transplantation has been a marked shift in the past decade. The original large programs, accustomed to receiving organs from long distances around the country, have seen the numbers of donors available to them diminish, limiting their transplant volumes, because of the growth of successful local programs serving their local populations with locally donated livers. The pros and cons of the present system, and the possibilities for improvement, are argued in more detail elsewhere.2 For the present, it is worth noting that the development of long lists—and listing of patients in an urgent status—by some centers has been viewed with suspicion by other centers. Since it may be that wider sharing, at least for more urgent cases, could improve service to patients overall, the implications of assignment of status are critically important for continued evolution of this system. The status definitions with which Himma takes issue play a critical role in reassuring that all patients are being treated equally. Given the nature of the problems, it does not seem that this is an unethical consideration.

As the allocation process evolved, recognition of those patients in urgent need of a liver transplant, not an issue with kidney transplants, was made in the form of the “UNOS Stat” category. However, dissatisfaction with how realistic the assignments to this category were in some centers led to its abandonment. There has been an ongoing attempt to increase sharing, either within certain boundaries wider than the local area that is now the first level of distribution, or on the basis of the 11 UNOS regions.

These issues have affected the evolution of rules assigning patients to the different statuses. Concern about equivalence of listing at various centers inhibited this becoming national policy. Fueling the controversy about this was the perception of increasing lobbying of the U.S. government at all levels by some centers, and the inherent concerns DHHS had for this aberrant entity, UNOS, in spite of its fine record as a contractor. Ultimately, the UNOS board passed a resolution in late 1997, stipulating that: (1) status 1 would be narrowly defined as acute fulminant failure (including post-transplant primary nonfunction and hepatic artery thrombosis); (2) criteria would be established for placement on the list and for increased status for chronic liver disease; (3) review committees would be established to provide assurance that listing was appropriate; and (4) regional sharing for Status 1 should be established. Note that the assignment of acute liver fail-
ure (ALF) to a higher category than chronic liver failure (CLF) was part of a general program to improve organ sharing. Shortly thereafter an additional rule was passed that distinguished between the sick but more stable CLF patients (Status 2b) and the more seriously ill CLF patients likely to die soon (Status 2a). Further, the rule now precludes listing patients as 2a if they have certain criteria that specify low chance of transplant success (unresponsive extrahepatic sepsis, high pressor requirement, or multisystem organ failure).

At present, certain large centers with long waiting times blame the community in general for not moving toward wider national sharing, but rather keeping organs for less needy patients at smaller local centers. The smaller centers perceive the large as advocating wider sharing merely to protect their own interests and market share, putting patients on the lists as pawns in the competition, rather than from a general desire to help patients around the country. These views were hardened, unfortunately, when DHHS finally issued regulations that were apparently critical of the progress being made within UNOS. The regulations were also widely interpreted as siding, in an apparently politically motivated way, with large centers impatient to start national sharing. The reaction among many in the community resulted in a rare congressional stay of the regulations, and gave rise to laws in several states declaring that organs from that state would not be allowed to leave unless the transplant personnel within that state agreed with the share.

Perceptual Inaccuracies

The distinction between CLF and ALF stands on its own medically, and therefore ethically, as shown in the next section. However, the dominant perceptual inaccuracy in Himma’s paper is its treatment of this as an isolated issue. It is part of an overall process and is in evolution. It will be reassessed and changed as necessary, this rule being the next best, but probably not final, decision in the evolution of the rules. This is the most important inaccuracy of perception in the criticism of UNOS: a major value of the distinction between acute liver failure and chronic liver failure is its potential to maximize the benefits of transplantation, mainly by facilitating the development of the system in general. Ethical analysis of this more complex system is, of course, more difficult, but this does not justify drawing ethical conclusions about one of the isolated ingredients, ignoring the larger system, if one wishes to illuminate reality.

Another inaccurate perception underlying the argument is Himma’s assumption that potential transplant recipients can be considered in isolation with regard to whether to do a transplant, in other words, whether to commit an organ to their care. This is simply not so. Approximately 1,000 patients die annually before a liver becomes available for them. Whenever a patient receives a transplant, his or her good fortune decreases the chances of other patients being rescued by receiving a transplant. Most centers have patients dying on the list from failure to receive a transplant. There is no escaping that the medical decisions and advocacy by a professional on behalf of one patient directly affect the care of others in the patient’s own and other centers. Ethical considerations about individual doctor–patient relationships that may apply in other areas of medicine are therefore critically incomplete for the field of transplantation. Since the treatment of each patient affects the system as a whole, it is appropriate and necessary.
that the effect on the system as a whole be part of the ethical analysis of the situation for each patient. In other words, it is ethically appropriate and necessary to include likelihood of optimum outcome for all patients on the list in the algorithm that dictates the treatment for each individual patient.

Moreover, the fact that each transplant affects the system as a whole makes it impossible to rely only on doctor–patient relationships and judgments. A doctor cannot know all the patients around the country who will necessarily be affected by each decision on doing a transplant. Therefore there needs to be a code that impersonally places patients in categories that maximize the ability for the comparisons, necessary to optimize outcome, to be accurate. Facilitating optimal operation of the system in this way means that each individual patient potentially benefits.

An important ethical point raised by Himma is the issue of how much difference in expected outcomes it should take for a distinction in likelihood of difference in outcomes to disadvantage one patient relative to another. Further, some categories (age, gender, race) are not factors included in the rules, even though these may have an important impact on outcomes. It is true that the distinction between true fulminant failure and progression of chronic disease has not been made in UNOS data until recently. Prospective data collection and analysis will be done parallel to the ongoing evolution of the rules, and it may be that more sophisticated distinctions could evolve. As is evident from Himma’s discussion, there is an intrinsic ethical judgment in this that the transplant community must continue to reassess. The Status 1/2 distinction is likely to prove dominant for the medical realities described below. At present only the major items of infection, pressor requirement, and multiorgan failure are absolute contraindications to Status 2a listing. However, if other factors prove to have an impact that is quantitatively similar, it will be necessary to reassess including them in the rules.

These considerations stem from a major problem with ethics in medicine: the presumption of physician infallibility or total knowledge. Actions that may seem inappropriate based on some assumption about a disease state may, on the other hand, be understandable in the light of some degree of uncertainty about the facts. End-of-life decisions are a common source of such uncertainty. Where absolutes (e.g., brain death as certified by verifiable absence of any brain stem function, or absence of cerebral perfusion) exist, ethical aspects regarding care follow easily. Many patients, however, die in a much less mechanical fashion. As shown below, the distinction between fulminant acute liver failure and progression of chronic liver disease is clear in the way brain death is; much of the rest of liver allocation requires judgments that may be argued and changed with time.

**Factual Inaccuracies**

The critical factual misconception is that progression toward death in CLF and ALF are characteristically potentially quite similar. In fact, the clear distinction is that patients die of ALF (Status 1) due to acute absence of liver function, usually causing primary catastrophic cerebral herniation or massive generalized hemorrhage. Progression to death from chronic liver failure (Status 2a), on the other hand, does not occur from these causes, but rather from associated complications—such as variceal hemorrhage, renal failure, overwhelming sepsis, or pulmonary failure—that accompany chronic wors-
ening of end-stage CLF. In the hours before death, some CLF patients may have severe bleeding or encephalopathy, but this is not from acute liver failure, but rather secondary to other concomitants such as infection or renal failure.

Thus the policy distinction made by UNOS between Status 1 and Status 2a is supported by an essentially absolutely accurate medical distinction. This medically justified distinction between ALF and CLF could possibly still be subject to ethical concerns as an isolated issue. Some of these possibilities are discussed by Himma. However, treatment of the distinction as an isolated issue is incorrect, as described above.

Parenthetically, the issue of hepatic cancer is not related to this. Hepatic cancer that is not resectable by partial hepatectomy, but which can be removed with clear margins by total hepatectomy, in patients without demonstrable metastases, is considered an appropriate category for transplantation. In fact, UNOS policy now provides for upgrading these patients while they are still transplantable.

Another factual error in Himma’s premises is that all patients with CLF are placed at a disadvantage to ALF patients, in a discriminatory way. The opposite, in fact, is true. CLF patients who have a transplant, but then suffer acute loss of their liver function due to primary nonfunction or hepatic artery thrombosis, may be relisted as Status 1. There is no distinction made regarding the underlying etiology of their liver disease. This consistency with the Status 1/2 distinction between acute and chronic liver disease underscores the medical appropriateness of the distinction between sudden loss of liver function and the complex medical complications that characterize gradual progression of chronic liver disease.

The Community as an Ethical Instrument

Himma’s essay leaves a further, fundamental misimpression. In describing the actions of UNOS as “unethical,” it appears that the Status 1/2 distinction and allocation rules are being imposed by UNOS on patients, the medical profession, and the country. This misrepresents the fact. UNOS process involves a wide and extensive discussion among all elements in the community, consensus generation, and dissemination for public comment. Included in many UNOS actions, among them principles leading to the liver listing rules, are deliberations by the UNOS ethics committee, composed of disparate community members and experts in this field. Action is taken to make rules by UNOS only after there is a clear sense of appropriate direction. This process can never be perfect, and there will always be many with doubts or criticism from various viewpoints; this is characteristic of any representational consensus-building process of this sort. However, it is very comprehensive and complete. Therefore if UNOS is acting “unethically” it is because the community has, by this long deliberative interchange, failed to find a more “ethical” course of action. This is not, in the abstract, impossible. Perhaps groups of people, or countries, can act in a way that may be deemed “unethical.” Indeed, mankind itself may be in a gradual incomplete evolution toward being an ethical entity. But if so, then ethical evaluation of the transplant community’s work must take into account, as Himma’s analysis does not, the complex nature of the community as an ethical instrument.

Notes

In “A Critique of UNOS Liver Allocation Policy,” I argued that the UNOS policy of placing acute liver failure patients (ALF patients) above chronic liver failure patients (CLF patients) on the transplant list fails to satisfy the principles of utility and justice that ostensibly guide UNOS allocation policy. Further, I argued that physician discretion in evaluating ALF and CLF patients should be expanded—not constrained. In response, Dr. Burdick attempts to justify the policy constraints on physician discretion on the strength of objective differences between ALF and CLF; as he puts it, “the distinction between acute liver failure and progression of chronic liver disease . . . is clear in the way brain death is.”

At the outset, it is worth noting that there are two different kinds of argument that would bear on the issue of whether physician discretion should be constrained. Consider the following argument: ALF patients nearly always need a transplant more urgently than CLF patients. Unfortunately, we do not know what it is about ALF that makes ALF a medically more urgent condition than CLF. While there are instances in which a CLF patient needs a transplant more urgently than a competing ALF patient, they are extremely rare and difficult to identify. Thus the only empirical evidence we have for determining the medical urgency of an ALF patient’s condition relative to that of a CLF patient’s condition is the statistical evidence indicating that the condition of an ALF patient is nearly always worse than that of a CLF patient. Moreover, ALF patients are statistically more likely to benefit from a liver transplant than CLF patients. Thus considerations of both utility and medical justice support constraining physician discretion by moving ALF patients ahead of CLF patients on the list.

This argument provides a sufficient medical and ethical justification for constraining physician discretion. Since the only thing a physician has to go on is the statistical evidence that indicates ALF patients are nearly always in more urgent need of a transplant than CLF patients, any decision to prefer a CLF patient over a competing ALF patient is more likely than not to be mistaken. Moreover, since ALF patients are statistically more likely to benefit long-term from a liver transplant, any decision to prefer a CLF patient over a competing ALF patient is statistically less likely to result in a successful transplant.

Under these hypothetical circumstances, then, a decision to list a CLF patient above an ALF patient offends utility because that decision is more likely than not to increase the number of deaths; and any transplant criteria more likely than not to increase the number of deaths offends the utilitarian goal of maximizing the number of lives saved. Likewise, a decision to list a CLF patient over an ALF patient offends medical justice because a transplant criterion that leads to decisions more likely to favor people in less need offends the applicable principle of medical justice: allocate scarce resources to the sickest patients first (assuming, of course, that the sickest patients stand a comparable chance relative to other candidates of benefiting from the resources). Thus, under these circum-
stances, the best policy from both standpoints is to constrain physician discretion by listing ALF patients above CLF patients.

While this kind of reasoning would provide an adequate justification for constraining physician discretion, it is not the reasoning that Burdick offers in defense of the UNOS policy. Burdick argues as follows:

In fact, the clear distinction is that patients die of ALF (Status 1) due to acute absence of liver function, usually causing primary catastrophic cerebral herniation or massive generalized hemorrhage. Progression to death from chronic liver failure (Status 2a), on the other hand, does not occur from these causes, but rather from associated complications—such as variceal hemorrhage, renal failure, overwhelming sepsis, or pulmonary failure—that accompany chronic worsening of end-stage CLF. In the hours before death, some CLF patients may have severe bleeding or encephalopathy, but this is not from acute liver failure, but rather secondary to other concomitants such as infection or renal failure.

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In this passage, Burdick points to a number of observable conditions that distinguish the ALF patient from the CLF patient and, equally important, help to determine the comparative medical urgency of an ALF patient’s condition relative to that of a CLF patient.

Indeed, UNOS policy presupposes that determinations of medical urgency can be made on the basis of empirically observable considerations to a high degree of accuracy. Status 1, which formerly included both ALF and CLF patients, is expressly defined in terms of medical urgency: Status 1 patients have a life expectancy of less than 7 days. That CLF patients were once eligible for Status 1 presupposes that a transplant physician can accurately estimate on the basis of observable considerations that a CLF patient’s life expectancy is less than 7 days. The considerations adduced in the remarks quoted above provide further empirical bases for assessing the medical urgency of a “critical” CLF patient’s (i.e., a CLF patient who would formerly have qualified for Status 1) condition relative to that of an ALF patient.

Thus Burdick’s argument assumes, where the hypothetical argument I described does not, that there is a reasonably reliable way to evaluate the urgency of an ALF patient’s need for a transplant relative to the urgency of a competing CLF patient’s need for a transplant. This means that the very ethical considerations that UNOS cites in defense of its policy, utility and justice, are better served by identifying those ALF patients who are not in greater danger than the critical CLF patients on the list, and moving the latter ahead of the former. Utility is served because a policy that allocates scarce resources to those CLF patients who (1) are sufficiently likely to benefit from a transplant,1 and (2) whose need for a transplant is most medically urgent provides the highest likelihood of minimizing the number of deaths among CLF patients who could have been saved. Justice is served because the liver goes to the patient whose medical condition is the more urgent. Thus Burdick’s argument provides a medical and ethical justification, not for constraining physician discretion, but rather for expanding it.2

Burdick faults me for considering the UNOS policy as an “isolated issue” instead of in relation to transplant policy as a coherent system of allocation principles. He writes, “[E]thical analysis of this more complex system is, of course, more difficult, but this does
not justify drawing ethical conclusions about one of the isolated ingredients, ignoring the larger system, if one wishes to illuminate reality.”

Unfortunately, Burdick makes no attempt to specifically locate the role this particular policy plays against the context of the bigger picture. It would be one thing if Burdick could plausibly argue (1) that the policy at issue may result in less utility and justice with respect to decisions regarding ALF and CLF patients but that these “losses” are offset by greater “gains” occurring elsewhere in the system; and (2) that the greater gains elsewhere cannot be achieved without the losses in the context of decisions regarding ALF and CLF patients. This would be a first step toward justifying the UNOS policy as part of a system of allocation principles in which the principles governing allocation in one context have significant consequences for allocation decisions in other contexts.

But Burdick does not make this argument precisely because he cannot make the argument. It is utterly implausible to think, for example, that decisions pertaining to allocation of livers have any bearing on decisions pertaining to allocation of hearts. The criteria regarding ALF and critical CLF patients are self-contained; what is at issue here is how to divide up the finite number of livers that will go either to ALF patients or to critical CLF patients. While Burdick does suggest that the policy is necessary to alleviate suspicions that may arise at one center when another develops a long list of urgent patients, this is implausible. The UNOS policy at issue does not prevent the development of long lists of urgent patients; it simply requires that the list of urgent patients be carved up into two categories: Status 1 ALF patients and Status 2 CLF patients. This, of course, accomplishes nothing if the goal is to alleviate these escalating suspicions.

Nevertheless, as Burdick points out, physicians sometimes make mistakes in evaluating patients for transplant, and this should be taken into account in formulating allocation policy: “Actions that may seem inappropriate based on some assumption about a disease state may, on the other hand, be understandable in the light of some degree of uncertainty about the facts.” Accordingly, to best serve the ends of utility and justice, it may be necessary to constrain physician discretion so as to minimize the incidence of such mistakes. And though Burdick fails to mention it, UNOS modeling analysis suggests that the very UNOS policy I criticize will result in a small increase in the number of lives saved.

But the question is why UNOS has chosen to restrict physician discretion in only this particular context when they could accomplish as much by constraining physician discretion in many other contexts. In my original essay, I cited an embarrassingly large number of examples in which one group A has a significantly higher probability of long-term survival benefit than another group B, but is nonetheless not placed above B on the transplant list. Presumably, all of these sorts of cases involve “some degree of uncertainty about the facts.” Yet UNOS has chosen to single out the uncertainties associated with estimating the survival prospects of CLF patients as justifying an unprecedented set of constraints on physician discretion. Unfortunately, nothing in Burdick’s response provides even the beginning of a medical or ethical justification for this singular treatment of CLF patients relative to ALF patients.

In closing, it is also worth noting that technological developments since 1997 also militate decisively against the UNOS policy. There has been considerable progress in the development of bioartificial livers that can be used to prolong ALF patient survival while an
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appropriate donor organ is found. Indeed, a Chicago-area woman suffering from acute liver failure was recently kept alive by a bioartificial liver for eight days until a suitable donor organ was found. Unfortunately, such devices cannot generally be used to prolong CLF patient survival because, as Burdick points out, the factors that cause the death of CLF patients do not typically involve wholesale cessation of liver function. Thus, as this technology becomes more widely available, it will no longer make sense to assume that the condition of an ALF patient is more medically urgent than that of a competing CLF patient.

Notes

1. Burdick chides me for assuming that the decision whether to allocate an organ to a given patient can be made entirely on the basis of a consideration of that patient’s condition without regard for the fact that giving an organ to one patient means another is likely to go without. Nothing in my argument depends on that obviously problematic assumption. Indeed, I explicitly argued that survival prospects must be taken into account in making allocation decisions precisely because the allocation of an organ to one patient means that another patient is likely to die. See Himma KE. A critique of UNOS liver allocation policy. Cambridge Quarterly of Healthcare Ethics 1999; 8(3):311–320.

2. I regret having used the word “unethical” in describing the policy because it seems to suggest that I am attributing unethical behavior to UNOS or the persons making up UNOS. That was not my intent. My intent was to say that the policy is unfair or unjust, in part, because there is no valid justification, medical or ethical, supporting it.


4. Indeed, one might argue that as this technology becomes universally available, the very considerations of justice and utility that guide UNOS policy will require reversing the policy by placing CLF patients above ALF patients on the list.