

ORGAN TRANSPLANT RECIPIENT LISTING CRITERIA

**A Response to the BCH Task Force Request for Community Input
On the Use of Psycho-Social Criteria, focusing on Children with
Intellectual Developmental Disorders**

**A report for the Harvard Ethics Leadership Group
by the Community Ethics Committee**

February 2014

The Community Ethics Committee was created under the auspices of the Harvard Ethics Leadership Group and functions as a part of the nonprofit Community Voices in Medical Ethics, Inc. The Committee was developed to serve both as a policy-review resource to the teaching hospitals affiliated with Harvard Medical School and as an educational resource to the varied communities from which the members come.

The volunteer members of the Committee are diverse as to age, socio-economic status, religious affiliations, cultural and language groups, and educational backgrounds. Committee members, during all or part of this study, included:

Carol L. Powers, Chair

Christine Mitchell, Advisor and Liaison
to the Harvard Ethics Leadership Group

Herman Blumberg
Alex Gamez
Yvonne Joyner
Neville Lee
Paul C. McLean
Shukong Ou
Patrick Smith
Shehla Syed
Julian Willard

Barbara Foot
Molly Johnson
Kathleen Kaditz
Rachel Liu
Paresh Motiwala
Gayle Robertson
Adam Sonnenschein
Frank Tipton

Please address correspondence to:

Carol L. Powers, c/o Harvard Medical School, Division of Medical Ethics
641 Huntington Avenue #207, Boston, MA 02115,
or email at carollpowers@gmail.com.

Please visit our website to read our blog and review our prior Reports.
medicalethicsandme.org

**COMMUNITY ETHICS COMMITTEE REPORT to the
CHILDREN'S HOSPITAL BOSTON TASK FORCE and the
HARVARD ETHICS LEADERSHIP GROUP**

**Organ Transplant Recipient Listing Criteria –
The Use of Psycho-Social Criteria focusing on IDD**

February 2014

SETTING

For those who suffer from irreversible and otherwise fatal organ failure, organ transplantation can be a life-saving medical treatment option. Nevertheless, for every heart, lung, or intestine transplanted, the donor must die. And for every kidney and liver provided by a living donor, a significant surgery is required before the gift of such an organ can be given. Every such gift, whether from the living or the dead, is received as a public resource to be allocated for the common good according to criteria and oversight of multiple tiers of governmental and institutional regulations, policies, and procedures. Underpinning the enormity of the gift's value is the reality that not enough organs are donated to meet the need. The ethical complexities inherent in the allocation of scarce, life-saving, medical resources are no more starkly evident than in the realm of organ transplantation, where more patients die waiting than live to receive the gift of a new organ.

Organ transplants in the United States take place within a regulatory system created by the National Organ Transplant Act of 1984, which established the Organ Procurement and Transplantation Network (OPTN) operated under federal contract by the United Networks for Organ Sharing (UNOS), a private non-profit organization. The legislative intent in adopting a national transplant system was to create a system “for assuring equitable access by patients to organ transplantation and for assuring the equitable allocation of donated organs among transplant centers and among patients medically qualified for an organ transplant.” Congress sought to create a system in which “organs will be allocated according to objective standards of medical status and need” where there was “a reasonable likelihood of post-transplant survival.” In publishing the enabling legislation, the comments in the Federal Register specifically note that the transplant policies cannot violate the civil rights of candidates, but that federal oversight “should not micro-manage the development of purely medical criteria or routine decision-making of attending medical professionals.” (All quotations are from the Federal Register, 42 CFR part 121, October 20, 1999.)

Patients seeking transplants enter the organ transplant process by referral to a transplant team at one of the organ transplant centers overseen by UNOS. The local transplant team determines whether to add the patient to the specific organ transplant list. UNOS operates the allocation system that matches available organs to patients once they are on the waiting list. Using a computer-generated matrix designed to prioritize a particular patient based upon geographic proximity, physical compatibility, and medical need, the UNOS allocation system does not factor in psycho-social or other unique characteristics of the Recipient Patient. That individual level of review occurs during the transplant center's decision whether to list the patient. Transplant centers are required to report in minute detail what happens to the patients on their respective waiting lists, including the number of transplant candidates, age, survival, and time on the list. There are six approved heart transplant centers in New England, including four in Boston.

Perhaps because of its impartial, computerized nature, the UNOS system for organ allocation has earned public trust. Nevertheless, the fact that each transplant center uses different, subjective criteria when making the decision to list a potential organ transplant recipient results in the understanding that organ transplant listing occurs in a black box, with undisclosed criteria and unreported decision-making. The Community Ethics Committee was asked to give its perspective on one small piece of the discretionary screening process that patients must pass through – whether patients with an intellectual developmental disorder should be considered for listing.

The Recipient Patient must be referred to the transplant center with an irreversible and otherwise fatal disease resulting in organ failure, while still being otherwise healthy enough to survive and benefit from an organ transplant and to comply with a life-long medication regimen. The Recipient Patient must meet strict medical criteria which include not suffering from multiple organ failure, not wrestling with a persistent or pervasive infection, and not having any other treatment options available. In the case of a child, the entire process to obtain an organ transplant must be undertaken by a parent/surrogate who has the ability to advocate effectively for their child. In all events, the potential organ recipient is in dire need.

The network of a Recipient Patient's physicians and medical caregivers play a critical role in opening the doors necessary to proceed with an organ transplant. If the patient's primary care physician does not perceive a medical need or benefit, no referral to a specialist can occur. If the specialist makes a determination that a transplant is not a medical treatment option that will provide a likely benefit to the patient, no referral to a transplant center can occur. These highly discretionary decisions take place outside the system created by the federal transplant statutes and regulations.

When a Recipient Patient has passed the scrutiny of their primary care physician and specialist, the transplant center must then decide whether an individual patient gains access to placement on the list which will entitle them to consideration for a transplant should an appropriate organ become available. The transplant center team evaluates the medical status of the patient and the medical and psycho-social factors that determine whether the recipient patient will survive a transplant and benefit from a transplanted organ. Because placement on the list is an absolute prerequisite to obtain an organ transplant and because it is essentially a non-appealable decision, the transplant team's determination carries life-saving significance and power. Basing that determination on medical criteria alone is challenging due to the constantly changing status of the patient, the prognostic uncertainties of the patient's condition, and the shifting balance created by the failure of one organ escalating the adverse effect to the patient's overall health and well-being. Adding psycho-social criteria to the team's determination of eligibility for placement on the list is fraught with peril. At issue are such evaluative criteria as the patient's likely adherence to the strict, lifelong regimen of anti-rejection medicines; their ability to comply with follow-up medical appointments and sometimes invasive post-surgical interventions; the existence of support systems to assist with compliance; and their past history of drug abuse, mental health issues, and intellectual developmental disorders. Falling within the category of psycho-social criteria is the question of whether a potential recipient's quality of life will be enhanced enough to balance out the considerable rigors of both the organ transplant procedure and the intensive after-care required.

The introduction of non-medical discretionary listing criteria causes troubling questions to arise. Some of those questions include: What psycho-social criteria, if any, should be determinative for placement on the organ transplant list? Is there a fair way to exclude patients who are medically in need but who may not fit a clinical team's unique psycho-social paradigm? Are there psycho-social criteria that provide a legitimate basis to disqualify a patient who could otherwise potentially benefit from a transplant? Is there a way to measure a Recipient Patient's quality of life pre- and post-transplant? And who is to decide?

Reliance exclusively on medical criteria is troubling as well. The evaluation of an individual patient's medical need and the likelihood of that patient obtaining a minimal threshold of medical benefit are necessarily based upon multiple factors. What is the transplant team's expertise with a particular patient population? What are the team's beliefs about the medical benefits to be obtained from an organ transplant and how can those beliefs be separated from personal biases? How is the transplant team affected by past experiences with particular patients? Can psycho-social criteria be legitimately excluded from the listing decision? Can the determination to list a patient be genuinely based upon medical criteria alone?

These questions carry impossible weight. If a particular patient is determined eligible and "passes through the gate," they are included on the organ transplant list within a particular transplant center. Placement on the list does not guarantee receipt of an organ but it is impossible to get an organ without being placed on the list. If a particular patient is determined ineligible for placement on the organ transplant list, they have far fewer medical options. The patient can reapply if their medical condition changes; they might obtain a referral to a different transplant center which may use different listing criteria; or they can use social and news media sites to make a plea for special consideration through a public outcry, which on occasion has been sufficient to pressure a transplant center to change its determination. These alternatives all involve the passage of time and are available only to the extent the patient's organ failure does not worsen to the point a transplant is no longer a viable treatment option.

For organ transplants which require a dead donor, the solicitation and arrangements are made by the local organ bank. In the medical community, much discussion and controversy currently exist in connection with whether dead donors must be "brain dead" or whether there is an acceptable window of time in which to collect organs after cardiac death is declared. Some in the medical community are suggesting both of those criteria are elusive and organ donation should occur under a broader definition of death and dying. Adding to that complexity is the fact that the decision to donate organs often involves family members who are in the midst of actively grieving the unexpected loss of a loved one. In such circumstances, confusion is commonplace, an understanding of the whole transplant system is rare, and expectations are unclear. Does the donor's family understand that once the gift of an organ is made, there are no controls over who is to be the recipient? Does the donor's family care if their loved one's organ is given to a patient with a medical need but with no relational consciousness to understand the benefits of the gift given? Is there a "public trust" established with unarticulated expectations of who the recipient of an organ will be so that a "maximum benefit" to society can be obtained? Is "medical need" the sole criteria for the receipt of a scarce resource? And who is to decide?

Patients who suffer from intellectual developmental disorders are sometimes excluded from organ transplant lists even though a medical need is confirmed. The exclusion can occur at multiple points throughout the evaluation process - at the beginning, when a primary care physician does

not make a referral to a specialist and, after that, when a specialist does not make a referral to a transplant center. Even when those first two hurdles are overcome, transplant teams sometimes make determinations not to list patients with intellectual developmental disorders based upon idiosyncratic and non-transparent psycho-social criteria. Using the rubric of psycho-social criteria, individuals with intellectual developmental disorders are sometimes seen as having extra difficulties complying with rigorous medical treatment regimens and as not receiving a true or sufficient benefit from the transplant based upon quality of life determinations.

This Report addresses what members of the community think about whether individuals with intellectual developmental disorders should be treated differently when the decision is made to include a Recipient Patient on a transplant list. Should those with intellectual developmental disorders be categorically excluded from organ transplant lists? Should the possibility of medical benefit justify placement on an organ transplant list? Should all individuals who are medically qualified to receive a transplant and who would have a reasonable likelihood of post-transplant survival be placed on a transplant list, regardless of the presence of an intellectual developmental disorder? These questions are posed in the context of organ scarcity – if more organs were available, would Recipient Patients with intellectual developmental disorders have greater access to an organ transplant list? Are these decisions consistent with the stated goal of the federal transplant system “assuring equitable allocation of donated organs . . .”?

INTRODUCTION

The Community Ethics Committee (CEC) is a group of volunteers living in the Boston metropolitan area who are members of the various populations served by the Harvard-affiliated teaching hospitals. The CEC provides reports and opinions on topics brought forward by members of the Harvard Ethics Leadership Group – representatives of the various ethics services within the Harvard teaching hospitals. The need for such a consultative group has been evident for a long time, since the few community members on hospital ethics committees are unable to represent multiple communities. Solicitation for membership on the CEC has been cast widely through community, business and religious groups, with a specific application process to ensure selection of a dissimilar but effective working group.

CEC members are diverse as to age, socio-economic status, religious affiliations, cultural and language groups, and educational backgrounds. Ten members are women and eight are men; we range in age from our teens to seventies. Some have advanced degrees, some have high school diplomas, others are in high school now. Among members past and present are a high school administrator, and a high school teacher; a rabbi, an imam, a Muslim female attorney, and a professor at a Protestant seminary. Some of us are individuals with disabilities and parents with disabled children. Two are retired, one from a large Boston law firm. We are students and writers and small business owners. We volunteer in our communities, including on an Institutional Review Board and in local health care facilities. We belong to eight different religious traditions, including atheism, and we are fluent in seven different languages. Most of us have attended the annual Harvard Clinical Bioethics Course, where the original members first met in 2007 and began the conversation as the Community Ethics Committee. Since 2011, the CEC has been part of the nonprofit corporation, Community Voices in Medical Ethics, Inc., which was established in order to enhance the CEC’s mission to bring the issues of medical ethics into the community as well as to include the community’s voice in the dialogue already occurring in health care institutions, government, and academia.

PROCESS

The Committee met throughout 2013 to educate ourselves about the criteria used by Transplant Center teams to make the decision whether a particular patient will be placed on the organ transplant list. In particular, we were asked to consider whether pediatric patients who have neurodevelopmental disabilities should be treated differently in deciding whether to be placed on an organ transplant list. Children's Hospital Boston created a Task Force to look at this issue, with the possible outcome of presenting a policy recommendation. The Task Force wanted community input into this delicate question and members of the Task Force met with the Committee several times and presented their concerns. The Committee examined this issue among ourselves, corresponding by e-mail and sharing articles we had found and information we had gathered. Based on our group discussions and in order to obtain everyone's viewpoints in an anonymous format, we developed a survey that solicited individual Committee members' thoughts on the questions asked by the Task Force, as well as questions raised at our meetings. Some of the responses from that Survey are included in this Report.

RESPONSES and COMMENTS

The CEC was presented with eight questions by the Children's Hospital Task Force. Those questions with our brief answers are set forth below. We will also provide a broader and independent perspective on the topic since we were very aware of the fact that the way a question is framed directly affects its answer. The fact that the Committee approached the topic in a more expansive manner is in no way intended to take away from the integrity with which we perceived the Task Force approached this vexing issue and we are very grateful for the opportunity to speak in this open way. The questions and our brief answers are provided directly below as well as our independent approach to the topic and our community perspective.

QUESTIONS and ANSWERS

1. It is a given that the duration of likely survival will be considered in "listing" or eligibility decisions. Please comment on the ethical strengths and pitfalls associated with transplant eligibility criteria that are tied not to survival *per se*, but to anticipated quality of life post-transplantation.

The Committee is wary of the phrase "anticipated quality of life" since we were not sure who was doing the "anticipating" and whose definition of "quality of life" was to be applied. Part of our concern lay in the fact that "anticipated quality of life" as a proposed listing criteria was far too elusive to inspire confidence in the soundness of the transplant listing decision. One of the stated goals of the federal system which oversees the allocation of organs is to "standardiz[e] the criteria for determining suitable transplant candidates through the use of minimum criteria (**expressed, to the extent possible, through objective and measurable medical criteria**) for adding individuals to, and removing candidates from, organ transplant waiting lists" (42 CFR 121.8(b) bold added). The Committee concluded that the subjectivity inherent in evaluating a potential recipient's "anticipated quality of life" could not possibly qualify as "objective and measurable medical criteria" and, therefore, should not be an evaluative criteria used in transplant listing decisions.

2. If we do offer transplant based on anticipated quality of life post-transplant, what are the ethical strengths and weaknesses of the following approaches? Does one seem better than the other?

a. *Comparative benefit:* Preference would be given to people whose likely benefit is greater than others'. For example, a child who is likely to be able to play conventional sports or excel in school would be accepted as a transplant candidate, while a child who cannot walk, feed himself/herself, is unable to speak, or requires constant help from others with activities of daily living (ADL) might not be.

b. *Minimum threshold of benefit:* Anyone who can derive at least a minimum amount of benefit from receiving an organ would be treated the same with respect to eligibility, all other things being equal. For example, any patient who is at least minimally interactive with his/her environment would be considered as eligible for transplant as anyone else.

(Alternatively, the threshold could be set at a higher or lower level, according to criteria such as those explored in question 4.)

The Committee concluded that the only benefit that could possibly be included in a transplant listing evaluation was a “minimum threshold of benefit” as described in Discussion Question b above. The benefit to be provided had to be medical – in other words, every expectation would be that the recipient would be better off physically after the transplant than before. This very basic medical evaluation of benefit provides the strongest ethically supportable baseline for a transplant listing decision.

3. Improved quality of life is obviously a major goal of transplantation. Wise use of scarce organs would include making sure organs are used to advance this goal. Should evaluation of quality of life for the purposes of determining transplant eligibility be left entirely to the patient and parents/guardians, or, should there be guidelines set by organ committees, with input from the community and other stakeholders? Who would these stakeholders be?

The Committee agrees that improved quality of life is a major goal of transplantation BUT the Committee found it impossible to come to any sort of definable standard that would provide a comfortable, ethically supportable footing upon which to make a transplant listing decision. The evaluation which should be done in connection with a transplant listing decision should focus on the minimum threshold of medical benefit as generally outlined above – focusing on whether there was every expectation that the recipient would be better off physically after the transplant than before.

The Committee exists with a primary mission to include more voices in the institutional process of policy development. A broader number of stakeholders should be participating in an open discussion when the criteria used for listing evaluations are established by transplant center internal committees. The Committee unanimously recommends the inclusion of community members, organ recipients and donors, and their families in the framing of guidelines to be used in determining transplant listing eligibility. Without those additional voices, institutional biases toward including some on the transplant list and denying others can possibly jeopardize the integrity of the entire transplant system, if for no other reason than lack of transparency and accountability.

4. If we suppose that anticipated quality of life post transplant can be thought about on a continuum, and that we ought to ethically and practically differentiate between those that would be eligible and ineligible for transplant based on some validated measure of anticipated quality of life, what kinds of thresholds would be ethically acceptable to use? Why, or why not? Consider the following possible thresholds:

- i. The patient can independently perform the basic activities of daily living (e.g., bathing, dressing, eating) at an age-appropriate level.
- ii. The patient is capable of understanding why painful interventions are needed in connection with the transplant and can appreciate that the resulting benefits are worth the burdens.
- iii. The patient can communicate with others.
- iv. The patient can recognize family, friends or other familiar persons and seems to derive pleasure or comfort from this.
- v. The patient interacts with others when they attempt to interact with him/her.
- vi. The patient responds to stimuli in the environment (e.g. tracking TV, withdrawing from needle-stick, smiling or cooing in response to pleasure).
- vii. The patient shows more evidence of pleasure/comfort/satisfaction than of pain/discomfort/distress (positive net benefit).
- viii. The patient is clearly and consistently conscious. (In other words, if this is the threshold, transplants would not be offered to patients whose consciousness is absent or unclear, such as those in “vegetative” or “minimally conscious” states, respectively.
- ix. The patient’s family believes his/her quality of life is meaningful, or is adequate to justify the transplant.

As noted earlier, the Committee concluded that, because “anticipated quality of life” can be neither measured nor validated, it is unusable as a listing criteria. Every one of the standards provided above were found to be problematic to some extent and in no event could they be used as a sole criteria for inclusion or exclusion from an organ transplant list.

- i. Each Committee member knew children who could not do an activity at an “age appropriate level” who were, however, gifted in other ways, loved, and hopeful for potential improvement.
- ii. Even though most infants and toddlers cannot understand why a painful intervention might be beneficial, that lack of understanding should not exclude them from the opportunity to receive that medical benefit.
- iii. Using the child’s ability to communicate as a measure for organ transplant listing is fraught with potential misunderstanding and conflict. What is perceived to be communication by parents, loved ones, nurses, physicians, and other caregivers may or may not be an accurate deciphering of the individual’s needs, wants, and intentions. The raised eyebrow of Leonard Bernstein as he conducted his orchestra was communication enough for the performance to become celestial.
- iv. Recognition of loved ones and the perceived pleasure derived is, again, a measure for organ transplant listing that is fraught with potential misunderstanding and conflict.
- v. Basing an organ transplant listing decision on a child’s ability to interact with others is another perilous criteria. Those children with attachment disorders should not be excluded from an organ transplant list based upon that criteria alone. The potential for greater connection is always the hope.

- vi. Basing a listing decision on a child’s ability to interact with their environment is problematic because the very need for an organ transplant compromises, or at least changes, the child’s ability to interact. They are terminally ill, often heavily medicated, with invasive medical interventions being used to prolong their lives until an organ becomes available for transplant. How a particular child interacts in such an environment is not going to be a sound basis for a transplant listing decision.
- vii. Whether a child is able to evidence pleasure or pain is also far too subjective a measure upon which to base an organ transplant listing decision. The “minimum threshold of benefit” discussed above carries with it the expectation that the medical benefit and the physical improvement that a transplant will provide also enhances pleasure and reduces pain.
- viii. Consciousness is a medical standard without definition and therefore, it would appear to be unusable as ethical validation for an organ transplant listing decision. Particularly in the realm of those who are minimally conscious, the Committee could not conclude that such a one should be categorically excluded from listing.
- ix. For the Committee, a child’s caregiver’s perception of “sufficient” quality of life to justify undergoing the rigors of a transplant did not provide a sufficient measure upon which to base an organ transplant listing decision.

Although the above discussion would seem to imply that the Committee felt every child with a medical need for an organ, who met a minimum threshold of benefit, should be listed, that is not the case. Even though the Committee could not conclude “quality of life” or “consciousness” determinations had sufficient measurable and verifiable certainty upon which to make an organ transplant listing decision, the Committee did conclude that an individual in a persistent vegetative state should be categorically excluded from an organ transplant list. The basis and rationale for coming to that conclusion are elaborated upon below.

5. [Comment on the ethical strengths and liabilities associated with eligibility criteria being stricter for organs with waitlist mortality exceeding 20% \(e.g. pediatric hearts\) than for organs with almost no wait list mortality \(e.g. pediatric kidneys\)? Waitlist mortality means the proportion of patients awaiting transplant who die before they are able to receive an organ.](#)

The Committee concluded that the difference among organs as evidenced by waitlist mortality should not provide a difference in evaluating the medical benefit to be received by a particular child, affecting an organ transplant listing decision. The medically determined eligibility of a patient for transplant should not vary based upon the “scarcity” of the organ needed – those two evaluative criteria are in some senses “apples and oranges.” The basic concern expressed by the Committee was that as soon as the eligibility criteria are tightened and made more stringent for some organs and not others, subjective criteria are interjected into the process that could taint the integrity of the entire transplant system. Under the current system of evaluation, the greater availability of kidneys means those individuals who have an intellectual developmental disorder have a greater opportunity to be listed for a kidney transplant and to obtain a kidney transplant. The reverse is also true – the scarcity of hearts means that children with intellectual developmental disorders who would otherwise receive a “minimum threshold of benefit” are less likely to be listed for a heart transplant based upon a perceived need to preserve the public resource for a “highest and best use.” The Committee concluded that the issue of waitlist mortality is a sliding scale that provides an uncomfortably slippery basis upon which to include or exclude children with intellectual developmental disorders.

6. Discussion of organ allocation often includes reference to several general considerations. What place do you think these should have, if any, in determining eligibility for listing based on NDD? Please rank them in descending order of importance.
- a. Getting the most benefit possible from the organ
 - b. Fairness in sharing organs
 - c. Obligation to the donor family
 - d. Expense to the public of maintaining a patient's life post-transplant (e.g., should it matter if a NDD patient requires long-term care independent of the transplant – say, for ADLs the patient cannot manage alone – and transplant effectively prolongs the period of need for public funding?)

Although the Committee did not feel any of these general considerations should provide a basis for determining eligibility for listing any particular patient, the Committee did conclude these considerations had value in the discussion of decision-making guidelines and our answers are provided below in that context.

- i. Fairness in sharing organs is the highest priority – meaning, in order to be fair, access to any organ transplant list must be based solely upon the patient obtaining a minimum threshold of medical benefit and not upon psycho-social criteria.
- ii. Getting the most benefit possible from the organ – meaning a medical evaluation has determined there is every expectation that the potential organ transplant recipient would be better off physically after the transplant than before.
- iii. Obligation to the donor family – meaning, in actuality, there is an institutional and governmental obligation to steward and allocate the valuable and scarce medical resource well in order to protect the community's interest. Unless it is a designated transplant, the gift of an organ is given to the community as a whole, becoming part of its “common good.”

The Committee could not find an ethically supportable justification for taking into consideration the expense to the public of maintaining a patient's life post-transplant. A child who is medically and/or socially expensive should not be treated differently for purposes of the decision to list a medically needy individual for an organ transplant.

7. One allocation proposal has been published by Loma Linda University Children's Hospital. On page 227 (table reproduced below, entitled “Table 2”), a graded approach is described for invasive testing and *retransplantation* in children with cognitive impairment. For the purposes of this inquiry, we would like you to consider this approach for *initial* transplants. What are the ethical strengths and liabilities associated with this approach? What are the ethical implications of offering, but not recommending transplant to patients with severe disability and near normal survival potential?

Table 2
 Proposal Guidelines for Invasive Testing and Retransplantation in Children with Cognitive Impairment

Class	Name	Description
1	Normal	Recommend monitoring and retransplantation, but will forgo if parents or surrogates decline
2	Mild disability	Recommend monitoring and retransplantation, but will forgo if parents or surrogates decline
3	Moderate disability	Recommend monitoring and retransplantation, but will forgo if parents or surrogates decline
4	Severe disability	(a) With normal or near normal survival potential—recommend against invasive testing and retransplantation, but will provide if parents or surrogates insist (b) With significantly limited survival potential—invasive testing or retransplantation will not be done
5	Vegetative	Invasive testing or retransplantation will not be done

The Committee could not find an ethically supportable justification to base an organ transplant listing decision upon a definition of “cognitive impairment” that was tied solely to IQ. Perhaps because the members are not professionals in the field of pediatric consciousness and neurodevelopment and because we have absolutely no expertise in evaluating levels of disability, the use of the Loma Linda chart was not helpful. We wanted it to be helpful, but we could not find a way to make it so.

The Committee did, however, conclude that those children in a persistent vegetative state are inappropriate candidates for an organ transplant based upon a perception of medical benefit and not based upon levels of cognitive abilities or disabilities. It was the Committee’s understanding that those individuals who are in a persistent vegetative state have no measurable or verifiable cortical function. Their bodies, to the extent they are maintained without mechanical interventions, are sustained by brain stem activity alone. The medical benefit to be derived from an organ transplant – to be physically better off after the transplant than before – in such individuals would not be sufficient to support the gift of an organ. The Committee recognizes that categorically excluding those in a persistent vegetative state from an organ transplant list may not be logically consistent or ethically justifiable. We concluded nevertheless that resource allocation values do have a part in this discussion and those in a persistent vegetative state would not receive a sufficient medical benefit from an organ transplant.

Although a deceased donor no longer retains an interest in the gift once it is given, the community as a whole has an interest in how a valuable and scarce resource is allocated. The expectation in our community is that an organ will be allocated fairly, based upon the medical good it can do. That medical good is provided in the context of a non-medicalized life lived “outside” in the community. An individual in a persistent vegetative state is not such a one. Again, the Committee concluded that a minimum medical benefit from receiving an organ would be required in order to be listed - every expectation would be that the recipient would be better off physically after the transplant than before.

8. What are the ethical similarities and differences between children and adults with respect to NDD as an eligibility criterion for transplantation? For example, no 2-year-old, regardless of neurodevelopmental status, would be expected to take medication or comply with therapy independently. However, a 25-year-old would be expected to be reasonably independent in seeking and complying with medical care, a criterion often used by adult transplant programs in deciding whom to list. Does this mean that neurodevelopmental delay should be viewed differently in children and adults?

The Committee concluded no appreciable difference exists between children and adults with respect to intellectual developmental disorders being a criterion for placement on an organ transplant list. The evaluation of medical need and a minimum threshold of benefit is the same. The unexpressed expectation is, of course, that a child has a greater opportunity to benefit from an organ transplant based upon expected years of relative health provided by the transplant. But given the uncertainties of what can be “anticipated” and given the value of each individual’s life, the Committee did not find an ethically supportable rationale upon which to treat a child and an adult differently.

DEFINING THE TOPIC, FINDING A FRAMEWORK

The language used in discussions of bioethics, medical diagnosis and prognosis, and treatment options can be obtuse to a layman and the CEC has found the first step in any review of a topic must involve defining our terms. As we reviewed this topic, the lack of a consistent and uniform understanding of neurodevelopmental disability and the myriad terms used with overlapping but often unclear meanings made the use of psycho-social criteria troubling and difficult to clarify. We concluded that clarity in the words we chose to describe this category of patients and the structure we gave to our discussion would be crucial to ensuring the ultimate usefulness of this report to caregivers, patients and families and the public.

Cutting through the confusion of the language and coming to an understanding of the complexity of the continuum of neurodevelopmental disabilities was central to achieving consensus about the appropriate criteria for organ transplant listing. In other words, before we could discuss the problem, we needed a language we all understood. This was not a simple task. Neurodevelopmental disability, intellectual disorders, and related terms may hold clear meaning for medical professionals and, more particularly, within a transplant center, but they do not seem to mean the same thing from center to center, and certainly they held no consistent or clear meaning among the members of the Community Ethics Committee.

What distinguishes a disability from a disorder from a deficit from a dysfunction from a difficulty from a disease? What is neurological as opposed to cognitive or intellectual? The differences are often indistinct. In an effort to ensure we were using language that is grounded in professional scholarship and public accessibility, we went to both the World Health Organization’s International Classification of Diseases and Related Health Problems and the American Psychological Association’s Diagnostic and Statistical Manual of Mental Disorders (DSM-5). Both showed wisdom in replacing the category of “mental retardation” with “intellectual developmental disorder.” Using “intellectual” over neurological or cognitive helps the discussion because it is widely used and understood – socially, scientifically, and politically – and transcends the use of IQ alone. The use of “developmental” introduces the context of brain development, taking into account the process and possibility of change. As the WHO International Classification of Functioning, Disability and Health Report of 2002 notes “every human being can experience a decrement in health and thereby experience some disability. This is not something that happens to

only a minority of humanity.” We are all developing both health and disability. Use of the term “disorder” is key, meaning a “clinically recognizable set of symptoms or behavior” which is both flexible and capable of improvement. The Committee concluded use of the phrase “intellectual developmental disorder” is preferable to its alternatives and its use could help engender trust in the organ transplant listing process.

The addition of psycho-social criteria as a basis for an organ transplant listing decision makes definitional certainty absolutely imperative. Perhaps no phrase used in this area is more challenging than “Quality of Life,” impossible of measurement and, therefore, completely unusable as an organ transplant listing criteria. In wrestling with this topic, the Committee concluded that any determination of “quality of life” is the rightful domain of the Recipient Patient and their parents/caregivers to determine. It is clear that the intensity and commitment of parental supports provided to intellectually challenged children play a significant role in a Recipient Patient’s quality of life both pre- and post-transplant. Those outside that familial circle can provide advice and counsel, but deciding what constitutes quality of life is solely within the purview of the patient and parents/caregivers.

This discussion also highlights the difficulties of applying the recognized decision-making standard for children - which treatment options are legitimately and persuasively in the best interests of the patient? Our concern in this regard centered upon the fact that an organ transplant patient transitions from a terminal illness to a chronic illness. Both situations have definable and recognizable burdens. Defining the benefits in both situations, terminal illness versus chronic medical condition, is a more challenging endeavor. The benefits of allowing a terminal illness to take its course when a treatment option may be available are not clear or knowable – when is death a benefit? The benefits of requiring a child, adolescent, young adult, mature adult, and aging adult to take scores of anti-rejection medications and undergo a lifetime of medical tests are also unclear and, to some extent, unknowable – when is a chronic medical condition a benefit? It was clear to the Committee, the balancing of benefits and burdens of an organ transplant for a particular child is not an easy or straightforward exercise.

Up to this point in the Committee’s Report, we have posed many questions, and we have focused on the challenges of the dilemma, not unlike the CHB Task Force that originally came to us asking for our perspective. The intellectual struggle must, however, result in some practical answers - an equitable and ethical way must be found to allocate a scarce life-saving medical resource to a dying patient. And the decision to include or exclude patients with an intellectual developmental disorder must be made.

The Committee began its review of this topic with a concern about rationing scarce resources – recognizing that a “public trust” was established upon the Donor’s gift of an organ. We spent time evaluating criteria for organ transplant listing based upon what kind of patient would receive the organ – would they be compliant with demanding medical regimens; would they obtain a sufficient medical benefit from the surgery; would their quality of life be enhanced? We were concerned that, if the organ went to a patient who was also afflicted with a severe intellectual developmental disorder, the public trust would be compromised – the gift was given with an assumption of its “highest and best use.” As we delved into the subject, however, our perspectives began to change. As we pushed and pulled, testing the criteria used for listing a particular patient, the only criteria that held validity in the end was medical necessity. No matter how many matrixes and grids were found, we concluded we could not judge someone else’s quality of life. The psycho-social criteria commonly used by a transplant center in making the organ transplant listing decision provided no solid ground on which to base such a weighty decision - equitable access and ethical confidence were not to be found outside solidly medical criteria.

As we have noted, the UNOS system of organ allocation has gained a measure of public trust. The discretionary nature of the organ transplant listing decision is largely unnoticed, however. The Committee concluded that all patients with medical need who would receive a sufficient medical benefit should be included in the opportunity to be listed for an organ transplant. Patients with intellectual developmental disorders should not be categorically excluded from that opportunity. The Committee understands that having the opportunity to be listed does not automatically result in being listed – medical criteria must still be applied and discretionary professional judgments must still be made. (The only patients that could be categorically excluded were those in a persistent vegetative state, based upon the Committee’s conclusion that the medical benefit of an organ transplant was insufficient.)

In suggesting expansion of the pool of patients who would have the opportunity to be listed for an organ transplant, the Committee recognizes there are difficulties ahead. As a result, we are providing one recommendation about establishing a more transparent process for listing decisions and one observation about expanding the pool of organ donors.

RECOMMENDATION – A Process for the Organ Transplant Listing Decision

Just as we looked for accessible language with which to discuss this topic, we looked for established procedural models to strengthen the equitable and ethical standing of the discretionary organ transplant listing decision. We concluded that instituting a review process was the best way to protect the values that were important to the Committee – maintaining both the importance of a physician’s advocacy for their individual patient and the need for institutional stewardship of a scarce societal resource.

Why did the Committee conclude a process was necessary and not just the provision of suggested guidelines for decision-making in organ transplant listing? Perhaps the best way to illustrate the need for a process is to draw upon a perspective shared by a Committee member in the context of the legal system. She noted that, in an ethics course in law school, the dean of the school made what to her was a shocking statement - the lawyer’s job was not “justice.” She was told that the lawyer’s job was zealous advocacy for her client. When that happened, when each lawyer brought zealous advocacy for her client to the table, the legal process could then yield justice. The integrity of the process ensured justice would be rendered.

In the context of organ transplant listing criteria, the conundrum has been how could a physician zealously advocate for an individual patient – one that was dying – and still preserve the role of responsible steward of a scarce, life-saving resource. The Committee concluded the only way to ensure “justice” was to ensure a process was in place to allow zealous advocacy in the context of scarcity.

We found such a model of process in Norm Daniels’ and Jim Sabin’s Accountability for Reasonableness - a decision-making process which was developed in the context of setting limits where scarce resources exist, addressing the question “How can a society meet population health care needs fairly when resource limitations exist?” The table below describes the values upon which this model is based and the questions it raises, modified to focus on organ transplant listing decisions.

Table - Accountability for Reasonableness Framework

Conditions for fair priority-setting processes according to the “Accountability for Reasonableness” (A4R) framework developed by Daniels and Sabin (1997, 1998, 2002): Descriptors taken from Daniels (2001) and Mitton and Donaldson (2004)

<u>Condition</u>	<u>Description</u>
Publicity/Transparency	Decisions regarding whether a particular category of patients can be listed for a possible organ transplant and the rationales for those decisions must be publicly accessible.
Relevance	These rationales must rest on evidence, reasons and principles that fair-minded parties (clinicians, recipient patients, donor patients, and the general public) can agree are relevant to deciding how to meet the diverse needs of patients under organ scarcity constraints.
Revision and Review	A mechanism for review of policies which affect individual patient listing decisions must exist, including the opportunity for revising policies regarding listing criteria in light of further evidence or arguments and reviewing, in an advisory capacity, policy decisions affecting individual patients.
Enforcement/Compliance	Either voluntary or public regulation of the process must be established to ensure that the first three conditions are met.

Publicity/Transparency

The Committee recognizes that the medical professionals evaluating a potential organ transplant recipient must be able to exercise discretion in whether to list a particular patient or not. Such discretion lies at the heart of the “practice of medicine.” Nevertheless, when a public resource is involved (the donated organ), the decision about patients’ access to that resource must include a certain modicum of transparency. The Committee is not suggesting that the rationales behind individual patient listing decisions be made public but it is suggesting that the rationales for listing or not listing certain categories of patients be publicly accessible. In other words, if there are no longer categorical exclusions for listing patients with intellectual developmental disorders, there may still be other categorical exclusions which exist – prisoners, mentally ill, substance abusers, non-US residents, patients without surrogates, the obese. The rationales for all categorical exclusions from organ transplant listing should be publicly accessible.

Relevance

As we discussed earlier in this Report, medical criteria are the primary, if not sole, relevant rationales for making organ transplant listing decisions. The use of psycho-social criteria to make listing decisions is problematic and fraught with implied bias and discrimination. If psycho-social criteria are used in listing decisions, then the specific psycho-social requirement’s relevance must be established. For example, if a transplant center decides that patients without surrogates cannot be listed for an organ transplant, then the relevance of that decision must be established by data showing the lack of success of transplants in such patients due, perhaps, to the lack of a necessary support system. That relevance should be confirmed by the stakeholders involved, including representatives of the public.

It should be noted here that the Committee found it helpful to name the various persons involved in organ transplantation as a way to ensure their “voice” will be heard in the development of any process instituted to review organ transplant listing decisions:

- a. The Recipient Patient who is dying from organ failure;
- b. In the pediatric setting, their parents/surrogate;
- c. The Recipient Patient’s primary care physician;
- d. A Specialist with advanced professional knowledge of the medical field in which the Patient’s need resides;
- e. The Transplant Center Team which includes a committee that evaluates whether the Recipient Patient can be put on the organ transplant list;

- f. The UNOS representatives who oversee the distribution of organs to those patients on “the list” based upon a complex data-driven priority system which includes geographic proximity, physical compatibility, and medical need;
- g. The Donor Patient who, in some circumstances, has died;
- h. In many settings including the pediatric setting, the Donor Patient’s family/surrogate;
- i. The community at large to whom the gift of an organ is given (those donations that are not specifically designated) and for whom health care and governmental institutions steward the resource for the greatest common good.

All of these stakeholders have a perspective as to the relevance of particular organ transplant listing criteria and the Committee recommends some process be instituted that would include their perspectives at some point in the transplant center’s policy deliberations.

Revision and Review

The Committee found it disturbing that, as we were discussing the discretionary nature of the criteria used in listing patients for organ transplant, the topic of listing and organ transplant priorities was front and center in the news and social media. The use of news and social media to mount an appeal of a particular institution’s listing or transplant decision was especially concerning because there was a sense that only those pediatric patients with parents who were savvy about making their case in the media would be re-considered. No formal process for revision and review was available institutionally and it should have been. The due process that such an opportunity for revision of criteria listing standards and review of the decision made in an individual patient’s case would provide is an effective public policy tool that could establish greater societal trust in the organ transplant system, in general, and the decision to include an individual on an organ transplant list, in particular. It is important to note here that OPTN provides an appeal process that brings decisions to an expert panel for review. The appeal must be presented by a physician on behalf of a patient, and without physician support, no appeal can be made. The Committee was concerned that patients of lower socioeconomic status, those who are less informed about the option to appeal, and those lacking advocates may be vulnerable to fewer treatment options. It is arguably far better to provide an appeal process at the preliminary stage of the decision to list a patient, particularly when volatile psycho-social factors may come into consideration, and the Committee recommends such an appeal process be open to initiation by both physicians and patients/family members.

The Committee suggests a group of individuals be available to consider organ transplant listing policies with two primary tasks – (a) regular review of the criteria used categorically to include or to exclude certain classes of individual patients, with a primary focus on any non-medical criteria used on which to base a listing decision; and (b) review of the policies relied upon to make an individual patient listing decision, upon request whether brought by a physician or the patient. Such a group would be comprised of representatives of the various interested parties noted above including the institution’s transplant team and members of the community. The group would act in an advisory capacity, similar to an Ethics Advisory Committee, but with a sole focus on application of the institutional policies to a particular organ transplant listing decision. Such a group could be called the Organ Transplant Listing Policy Advisory Committee.

Enforcement/Compliance

The Committee’s recommendation that a formal policy review process be instituted by transplant centers to guide the difficult discretionary organ transplant listing decisions involved is made with the belief that judicial and legislative interventions in this area could be more harmful than helpful. Some state legislatures have addressed the issue of access to organ transplantation by those who are disabled through legislative mandate. California has passed a law which prohibits denying a person with a disability a referral, evaluation, and recommendation for transplant solely on the

basis of a non-medically significant disability. (California Uniform Anatomical Gift Act, Section 7151.35) Federal legislative protections are found in the ADA (the Americans with Disabilities Act of 1990). The law suggests that health care providers must give persons with disabilities the same access to organ transplant programs as they do persons who do not have disabilities. Judicial involvement in enforcing these legislative mandates is problematic – health care policy-making and individual patient decision-making are not within the professional expertise of the judiciary. Legal enforcement of equitable access to organ transplant programs is unwieldy, time-consuming, and arguably destructive to the public trust in the health care system. Although occasions may arise when a judicial appeal is the only alternative left, the Committee recommends that a secondary task be assigned to the Organ Transplant Listing Policy Advisory Committee - to put into place a data monitoring mechanism at the transplant center's institutional level so that discretionary decisions to include or exclude particular groups of patients for listing are shown to be nondiscriminatory and fair. The Organ Transplant Listing Policy Advisory Committee's compliance oversight could be as simple as maintaining and monitoring data to ensure that vulnerable populations are not systematically excluded from the organ transplant list. This data would complement the data sets maintained by institutional transplant centers and UNOS with respect to patients on transplant lists.

CONCLUSION as to Process

In conclusion, the Committee found that using psycho-social criteria for transplant listing decisions was problematic and ethically challenging. Quality of life determinations were impossible. As a result, pediatric patients with intellectual developmental disorders should not be categorically excluded from listing for an organ transplant. A minimum threshold of medical benefit should be used to determine a patient's eligibility for listing and is the only ethical basis upon which to make such a determination. This minimum medical benefit would be a determination that the patient is reasonably likely to survive the post-transplant process and will likely be better off physically after the transplant than before, hence the Committee's conclusion that those patients in a persistent vegetative state would not qualify for listing. The Committee recommends an advisory process be established within the transplant center that operates alongside the transplant team's individual patient deliberative process as a resource to facilitate the equitable and ethical operation of the organ transplant listing program. Such a process would entail the establishment of an Organ Transplant Listing Policy Advisory Committee, comprised of a broader array of stakeholders. It would be an advisory committee that would review the relevance and promote the transparency of policies used in listing decisions; it would act as a resource which might advise the transplant team with respect to individual patient decisions; and it would review data to ensure compliance of organ transplant listing policies that provide equal access to the organ transplant program.

OBSERVATION – Safe Environments and Organ Donations

As noted earlier, the Committee's first approach to the topic of organ transplant listing criteria was to take the Donor's perspective – a valuable gift was being given and the public trust required attentive stewardship. Our concerns about equity and ethics centered upon whether "questionable" organ transplant recipients would harm the public's trust in the system in such a way that the number of organ donations would diminish. That was a consequence we did not intend or want.

The Committee's process of ethical deliberation led us in quite a different direction, however. We concluded the need to maintain zealous advocacy from individual physicians on behalf of individual patients to be listed for transplant was a value worth protecting. We concluded the establishment of a Review Committee would provide a process that would protect the societal need to steward a scarce public resource well.

Nevertheless, we do not intend to discount institutional and societal concerns about psycho-social factors that have been shown to affect the success of an organ transplant – success being a healthier life for the recipient who was previously dying of organ failure. We recognize social realities exist that adversely affect a transplant’s success, in particular the ability of the patient to receive ongoing and life-long care in a consistently safe and supportive environment. We know a realistic and attainable post-transplant plan of care is necessary to ensure success, but the Committee cannot solve the overarching and overwhelming societal problems that remain after a listing decision is made. Again, we have concluded that a decision to list a particular patient on an organ transplant list must be based upon strictly medical eligibility criteria and the insertion of any other criteria must be (a) transparent, (b) justified by its relevance, (c) subject to revision and review, and (d) compliant with values of equity and ethics.

In addition, The Committee cannot solve the issue of organ scarcity with the recommendations in this Report. We can draw attention to scarcity’s impact on the decision-making process whether to list certain categories of patients and we can highlight the very real competition for organs that currently exists in our society. The gift of an organ, given to society at large, must be allocated with fairness and thoughtfulness. Every decision along the path to an individual patient’s organ transplant takes on an aspect of divine dispensation – in deciding whether a patient is medically desperate enough for someone else’s organ and yet otherwise healthy enough to survive and benefit from the rigors of incredibly invasive medical procedures or whether a patient does not qualify for listing – decisions made in the context of monitoring the heart and brain activity of another patient in anticipation of organ harvest. If there is maleficence in the harvest, there can be no beneficence in the transplant. Like the organ transplant listing process, the organ donation process must be scrutinized and monitored for its own set of concerns about equity and ethics. In organ transplantation, we are convinced the ends do not justify the means and the organ donation process must withstand the rigors of public review and comment.

In starting its review, the Committee’s original question was whether organ transplantation is, in itself, a good thing. Our consensus answer was “yes” but it is imperative to qualify that “yes” with the caveat – organ transplantation is a good thing only if the organ is ethically procured and the recipient is equitably chosen.

CONCLUSION

The question of whether a patient, solely because of an intellectual developmental disorder, should be excluded from an organ transplant list is answered - no. But the dilemma of allocating a scarce resource remains. The federal government established an organ allocation system overseen by UNOS. It also mandated protection of the disabled against discrimination in the Americans with Disabilities Act. Although this governmental oversight protects the public good – the commonweal – it does not provide a platform to advocate for individual patients. That advocacy is the role of the patient and family and physicians and transplant teams and transplant centers. That advocacy was what the Committee heard when the Task Force presented its dilemma – how are clinicians to choose when their patient is dying and desperately in need of an organ? While answers are sought, hearts break.

Perhaps one of the best commentaries on the dilemma of a physician’s advocacy for an individual patient and the rationing of societal goods can be found in an article by James E. Sabin entitled “Fairness as a problem of love and the heart: a clinician’s perspective on priority setting” in the Boston Medical Journal, Vol. 317, October 10, 1998, pp 1002-1004. He concludes by observing:

“I believe that our path towards societal resolution of the conflicts between individual and community needs and desires demands more of the heart than the brain. Clinicians are inextricably in the midst of these conflicts. . . . Patients and society need clinicians to love both the individual and the collective and need to join with them in deliberating about solutions to this painful but ultimately unavoidable conflict of the heart. The key requirements are an expanded healthcare ethic and courageous political leadership.”

EXECUTIVE SUMMARY

The Committee recommends that all patients with the potential for a minimal threshold of medical benefit be considered for organ transplant listing. Such a minimum medical benefit would require a determination that the patient is reasonably likely to survive the post-transplant process and will likely be better off physically after the transplant than before. An intellectual developmental disorder is not, in and of itself, grounds for exclusion from an organ transplant list. We could find no equitable or ethical grounds for such exclusion. We also recommend an Organ Transplant Listing Policy Advisory Committee be established at each Transplant Center which includes the voices of a broader spectrum of stakeholders, and which can speak in an advisory way to the decisions made surrounding organ transplant listing. Such an Advisory Committee would promote the transparency and assess the relevance of any non-medical criteria used in listing decisions; provide an avenue of review of policies supporting individual patient listing decisions; and monitor data to ensure equitable access to the organ transplant list. In the end, the interests of the individual patient have always been the focus of the CEC’s endeavors, even as we are representatives of the community at large. We value both the physician’s zealous advocacy for the individual patient’s welfare and a review process that can ensure ethical stewardship of a scarce societal resource. We hope the recommendations made in this Report will support both physician advocacy and institutional stewardship, to the ultimate benefit of the individual patient with terminal organ failure whose future hangs in the balance.