

**OPTN/UNOS Pediatric Transplantation Committee
Report to the Board of Directors
November 12-13, 2014
St. Louis, Missouri**

**Eileen Brewer, MD, Chair
William Mahle, MD, Vice Chair**

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This report reflects the work of the OPTN/UNOS Pediatric Transplantation Committee from May through September, 2014.

Action Items

1. General Principles for Pediatric Allocation

Public Comment: N/A

In 2013, the Chairs of the OPTN/UNOS Pediatric Transplantation and Ethics Committees recognized the need to articulate the special ethical considerations for pediatric candidates in an equitable allocation system. In January 2014, a Joint Subcommittee convened to begin drafting what would become a companion document to the Ethics Committee's 2010 white paper, "Ethical Principles in the Allocation of Human Organs" (Exhibit A). The Joint Subcommittee's product was reviewed by the Pediatric Transplantation and Ethics Committees. After careful review, the Pediatric Transplantation Committee voted to recommend the white paper for consideration by the Board of Directors (10-Support, 0-Oppose, 0-Abstentions):

RESOLVED, that the white paper entitled "Ethical Considerations in Organ Allocation to Pediatric Candidates," as set forth in Exhibit B, is hereby approved, effective November 13, 2014.

Committee Projects

2. Pediatric Transplant Training and Experience Considerations in the Bylaws

Public Comment: Spring 2015 (Estimated)

Board Consideration: June 2015 (Estimated)

Pediatric transplantation is a specialty within the field of transplantation; however, in the current Bylaws, pediatric experience is not required for surgeons or physicians to serve as key personnel at programs that perform transplants in pediatric patients. The Committee is working with the Membership and Professional Standards Committee (MPSC) to establish qualification criteria for key personnel at designated transplant programs that perform any transplants in patients less than 18 years old. After many months of reconciling professional societies' requests for more restrictive requirements with the community's concern for preserving pediatric access to transplant, the Committee presented their proposed requirements at the Spring 2014 regional meetings.

Throughout the twenty year history of this project, the primary pediatric transplant surgeon requirements have remained the most controversial aspect of the proposal. On June 17, 2014, Pediatric Transplantation Committee leadership met with the ASTS Executive Committee, at their request, to discuss their feedback on this proposal. The ASTS Executive Committee requested time to convene a Task Force to provide more specific

recommendations. Pediatric Transplantation Committee leadership agreed to postpone putting this proposal out for Fall 2014 public comment so they could consider the ASTS' recommendations at the full Committee meeting on August 26, 2014.

ASTS President Peter Stock presented the ASTS Task Force's recommendations by phone at the Pediatric Transplantation Committee's meeting in Chicago, Illinois, on August 26, 2014. To summarize the recommendations, the Task Force felt that the OPTN had not clearly defined the problem the proposal seeks to address. However, if the OPTN can produce evidence of a patient safety issue, then the proposed requirements are not robust enough. They mentioned that this proposal may benefit from a Joint Societies Work Group (JSWG) review. The Pediatric Transplantation Committee Chair led a discussion afterwards in which she acknowledged the Committee's shared frustration with the ASTS in not being able to secure community support for more robust training and experience requirements. However, the Pediatric Transplantation Committee believes that these minimal requirements address the most egregious issue of surgeons and physicians without pediatric transplant experience serving as key personnel in programs that perform pediatric transplants. The Committee affirmed their interest in submitting this proposal for January 2015 public comment and committed to continuing to work with ASTS to secure their support.

3. Revisiting the Pediatric End Stage Liver Disease (PELD) Score

Public Comment: Project On Hold pending Liver Redistricting
Board Consideration: TBD

The Pediatric End Stage Liver Disease (PELD) score has not been modified since it was implemented in 2002. A high proportion of pediatric patients are transplanted in Status 1 or with a PELD exception, which indicates that review is needed. The Committee has put this project on hold pending a timeline for redistricting from the Liver and Intestinal Organ Transplantation Committee.

4. Pediatric Classification for Liver Allocation

Public Comment: [September 29 – December 5, 2014](#)
Board Consideration: June 2015 (Estimated)

Most organ candidates automatically retain pediatric priority if they turn 18 while waiting for a transplant^{1,2,3,4}. Under current liver policy, if a candidate turns 18 years old while waiting in a MELD score (i.e., not Status 1A, Status 1B, or inactive status), the candidate does not automatically retain pediatric classification. Rather the registering transplant program is responsible for requesting a pediatric classification exception from the Regional Review Board (RRB). Currently only Status 1A and Status 1B liver candidates turning 18 years old while waiting automatically retain pediatric classification. Additionally, if a candidate was ever registered as a pediatric patient and was subsequently removed from the waiting list,

¹ OPTN/UNOS Policy 6.1 (Status Assignments)

² OPTN/UNOS Policy 8.5.H (Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%)(pending implementation)

³ OPTN/UNOS Policy 8.5.I (Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 20% but Less Than 35%) (pending implementation)

⁴ OPTN/UNOS Policy 11.4.A (Kidney-Pancreas Waiting Time Criteria for Candidates Less than 18 Years Old)(pending implementation)

but returns to the waiting list as an adult, the registering transplant program has the ability to apply to the RRB for a pediatric classification exception for this candidate. Pediatric classification operationally means prioritization as a 12 to 17 year old candidate on the liver match run. Both of these exception processes are inconsistent with allocation policy for most other organs.

In spring 2013, the Pediatric Transplantation Committee requested that staff publish an article explaining the pediatric classification exception process for liver candidates. Committee members did not believe that the current policy was well-understood in the community. This speculation was verified when 12 applications were submitted after the June 13, 2013 article was published, when only 3 had been requested in the previous 9 years.

In reviewing the exception applications, the Committee learned that the RRBs have been consistent in their decision-making; candidates that turn 18 while waiting for liver transplant have been approved for pediatric classification, while adult candidates returning to the waiting list were denied. Committee members proposed the automatic transfer of pediatric classification for all candidates who turn 18 while waiting for a liver transplant. They also proposed eliminating the pediatric classification exception process for a candidate who was ever on the waiting list prior to age 18, but has since been removed and reregistered as an adult. These changes would make liver policy consistent with that of most other organs in regards to how candidates in these specific situations are classified and would contribute to the fair and efficient management of the OPTN.

Initial feedback from the Liver and Intestinal Organ Transplantation Committee requested that the proposed policy specify an age after which a candidate would no longer qualify for pediatric classification, also referred to as a cap. After careful consideration, the Committee decided to proceed without a cap. Members could not propose an evidence-based cap due to the small number of pediatric liver candidates that turn 18 while waiting. Furthermore, a cap is inconsistent with other organ allocation policies. They affirmed that, as with any allocation policy, adequate and appropriate registration of patients and good waiting list management is always necessary.

The Pediatric Transplantation Committee voted to approve final policy language on July 9, 2014 (14 yes, 0 no, 0 abstentions). The Liver and Intestinal Organ Transplantation Committee considered this proposal on an August 6, 2014 conference call and unanimously voted to support it. The “Proposal to Automatically Transfer Pediatric Classification for Registered Liver Candidates Turning 18” is currently out for public comment.

5. Pediatric Lung Allocation Policy Review

Public Comment: *Spring 2015 (Estimated)*
Board Consideration: *June 2015 (Estimated)*

The Pediatric Transplantation Committee is collaborating with the Thoracic Organ Transplantation Committee to conduct a comprehensive review of pediatric lung allocation policy to identify any opportunities for improving pediatric access to transplant. For more information, see the **OPTN/UNOS Thoracic Transplantation Committee Report to the Board**.

Committee Projects Pending Implementation

6. Proposal to Change Pediatric Heart Allocation Policy

Public Comment: [March 15 – June 15, 2013](#)

Board Approval: [June 24, 2014](#)

The Board approved four modifications to pediatric heart allocation policy on June 24, 2014:

- Redefine pediatric heart Status 1A and 1B criteria.
- Increase insohemagglutinin titers needed to qualify for ABO-incompatible heart offers to 1:16 or less for candidates who are one year of age or older but registered before their second birthday.
- Improve allocation priority of urgent heart candidates registered before their first birthday, as well as candidates eligible to receive ABO-incompatible heart offers.
- Eliminate *in utero* heart registrations.

These changes seek to reduce waiting list mortality, particularly among pediatric heart Status 1A and 1B candidates. Programming is scheduled to begin in June, 2015.

7. Pediatric Liver: Remove ICU Requirements and Modify Hepatoblastoma Requirements

Public Comment: [March 3 – June 10, 2011 \(Remove ICU Requirements\)](#)

[March 3 – June 10, 2011 \(Modify Hepatoblastoma Requirements\)](#)

Board Approval: [November 15, 2011 \(Both\)](#)

The Board approved these projects individually on November 15, 2011. They have been bundled for the purposes of programming and implementation, and programming is scheduled to begin in April, 2015.

Implemented Committee Projects

8. Evaluation of Kidney Share 35 Policy: Inactive Status and Refusal Reasons among Pediatric Registrations

Board Approval: *November 18, 2004*

Implementation: *September 28, 2005*

The Pediatric Transplantation Committee continues to monitor the Share 35 Kidney Policy, which was implemented on September 28, 2005. Under this policy, candidates less than 18 years old at listing receive local priority for non-zero HLA mismatch kidneys from donors less than 35 years old. Data presented at the April 9, 2014 meeting showed that pediatric candidates 0-5 years old at listing had a higher percentage of inactive candidates as compared to those 6-10 or 11-17 years old at listing. The Committee requested additional data on inactive pediatric candidates, including reason for inactivity, length of inactivity, and whether the candidate was waiting for a primary or repeat transplant. This data was reviewed at the following in-person meeting on September 26, 2014.

The Committee learned that of the 1,425 pediatric, kidney-alone registrations waiting on July 18, 2014, 59% were inactive. Registrations 0-5 years old at listing continued to have the highest proportion of inactivity at 64%, followed by 11-17 years old at 59% and 6-10 years old at 57%. The most common reason for inactivity among all pediatric registrations was incomplete work-up (46%), followed by temporarily too well (19%) or temporarily too sick (13%). More than 75% of inactive pediatric registrations were waiting for a primary transplant. Most registrations (68%) that were currently inactive had been waiting for less

than 2 years, and most had been inactive for the same length of time as they had been on the list.

The Committee discussed varying listing practices responsible for these trends, including listing pediatric candidates prior to completion of the work-up so they can begin accruing waiting time. However, they acknowledged while there may be legitimate reasons to inactivate a candidate, some of these trends could be due to poor waiting list management or difficulty transferring a pediatric candidate to an adult program. The Committee has requested an update of this analysis to include additional organs (liver, heart, and lung) as well as adult candidates for comparison.

9. Evaluation of Open Variance for Segmental Liver Transplantation

Board Approval:

Implementation:

At the recommendation of the Board of Directors in March 2011, the Pediatric Transplantation Committee tabled discussion on their proposed split liver policy in favor of monitoring data from OPOs and regions participating in the Board-approved segmental liver variance. The Committee routinely reviews match run data to identify the number of pediatric candidates prioritized above the second recipients of split livers but who did not receive the livers on the original match run within the OPO or region. They most recently reviewed this data at their in-person meeting on August 26, 2014.

From the beginning of the variance through April 30, 2014, 42 deceased donors were transplanted as splits at four OPOs and one Region. After limiting the analysis to split liver transplants where one segment was transplanted into an adult recipient and the other into a pediatric recipient at the same or an affiliated center, there were 20 donors. An examination of the match run data for these 20 donors found the following:

- For 16 donors, the pediatric candidate was the index patient and allocation of the remaining segment appeared to follow *Policy 9.6.A: Segmental Transplant and Allocation of Liver Segments*.
- For the remaining 4 donors, where the adult candidate was the index patient, only one remaining segment appeared to follow *9.8.A: Open Variance for Segmental Liver Transplantation*. In this instance, 7 pediatric candidates were bypassed above the pediatric acceptor. Of these, six were not waiting at the same or an affiliated center, and one required a multi-organ transplant at the same center.

The Committee acknowledges that although some research indicates that a higher MELD is not associated with split liver graft failure, surgeons are still hesitant to split or accept segments for adult candidates with high MELD scores. Due to geographic disparity, adult candidates are transplanted at increasingly high MELD scores. The Committee will continue to monitor the segmental liver variance and will be vigilant of the impact of liver redistricting on the future of this policy.

Review of Public Comment Proposals

The Committee reviewed five policy proposals released for public comment from March 14 – June 13, 2014, not including two reviews that appear in the June 2014 Board Report.

10. Proposal to Modify Existing or Establish New Requirements for the Informed Consent of All Living Donors (Living Donor Committee)

After a presentation of this proposal, the Committee discussed the following issues:

Regarding the requirement to inform the living donor of “abnormal post-donation lab results which could lead to additional testing with associated risks”:

- Should policy specify what information needs to be shared, as well as guidance on educating the donor about the appropriate level of risk?
- Should policy also specify when and why post-donation tests would be performed?
- How much discretion does a program have in how to present this information to a living donor based on the individual’s level of potential risk?

One Committee member was concerned that this policy does not include special disclosures for living lung, pancreas, or intestine donors. The Living Donor Committee liaison explained that the Living Donor Committee did not find evidence in the literature supporting special disclosures, and the member agreed that evidence is lacking because of how uncommon these procedures are.

The Committee voted to support this proposal (11-Support, 0-Oppose, 0-Abstentions).

11. Proposal to Modify Existing or Establish New Requirements for the Psychosocial and Medical Evaluation of All Living Donors (Living Donor Committee)

After listening to a presentation of the proposal, one Committee member questioned whether donors with alpha-1-antitrypsinphenotypes should be excluded if they have a normal liver histology. After brief discussion, the Committee voted to support this proposal (11-Support, 0-Oppose, 0-Abstentions).

12. Proposal to Align OPTN Policies with the 2013 PHS Guideline for Reducing Transmission of HIV, HBV, and HCV through Solid Organ Transplantation (Ad-Hoc Disease Transmission Advisory Committee)

After listening to a presentation of the proposal, most of the discussion focused on the HCV NAT testing requirement for all donors. Several members thought that data would be necessary to evaluate the need for this requirement and its potential impact, specifically the rate of false positive HCV NAT tests, particularly in pediatric donors, and the prevalence of HCV in CDC Increased Risk versus CDC Non-Increased Risk donors. Several members felt that false positive HCV NAT tests could prevent a surgeon from accepting a healthy organ for their pediatric patients.

Following a robust discussion, the Committee voted to approve this proposal with the comment that the DTAC should review data on HCV NAT false positives and conclude that

HCV NAT testing should be for Increased Risk Donors only (10-Support, 1-Oppose, 0-Abstentions).

13. Proposed Membership and Personnel Requirements for Intestine Transplant Programs (Liver and Intestinal Organ Transplantation Committee)

After a presentation of this proposal, the Committee discussed the following issues:

- Members asked for a definition of “fresh transplant.” The presenter explained that this term exists in bylaws for other organs but conceded that it is not clearly defined since there has not been consensus on a timeframe.
- Several members voiced concern that the “currency” requirement would restrict access to intestine transplant.
- Some members cautioned that hospital credentialing committees may interpret this Bylaw as guidance in forming credentialing standards for all, and not just key, personnel.

The Committee voted to disapprove of this proposal, cautioning against such restrictive standards for a procedure with a diminishing and uncertain future and recommending that the timeframe for the primary surgeon’s qualifications be lifelong (8-Support, 3-Oppose, 0-Abstentions).

Other Committee Work

None

Meeting Summaries

The Committee held meetings on the following dates:

- June 4, 2014
- July 9, 2014
- August 25-26, 2014

Meetings summaries for this Committee are available on the OPTN website at: <http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=15>.

Special Ethical Considerations in the Allocation of Human Organs to Pediatric Candidates

Pediatric Transplantation Committee

Summary and Goals of the Proposal:

The OPTN must make organ allocation policy that is consistent with the regulatory framework of the National Organ Transplant Act (NOTA) and the Final Rule. While these regulations embody ethical principles, neither NOTA nor the Final Rule are intended as a source of ethical guidance for creating, evaluating, or modifying organ allocation policy. The National Organ Transplant Act requires that the OPTN adopt policies that provide for the “unique health care needs” of pediatric patients.¹ In 2013, the Chairs of the OPTN/UNOS Pediatric Transplantation and Ethics Committees recognized the need to articulate special ethical principles to be considered when determining the priority of pediatric candidates in the allocation system. This white paper, a companion to the 2010 “Ethical Principles to be Considered in the Allocation of Human Organs,” is a resource for OPTN Committee and Board members to evaluate current or proposed allocation policy for fairness to pediatric patients. It also describes to the public for the first time the ethical deliberations behind policies that impact pediatric candidates.

Background and Significance of the Proposal:

The OPTN must make organ allocation policy that is consistent with the regulatory framework of the National Organ Transplant Act (NOTA) and the Final Rule. The Final Rule requires that the OPTN develop policies for the “equitable allocation” of deceased donor organs, while also requiring that these policies achieve “best use” of the organs.² While this and other of its regulatory requirements embody ethical principles, neither NOTA nor the Final Rule are intended as a source of ethical guidance for creating, evaluating, or modifying organ allocation policy. In June 2010, the OPTN/UNOS Ethics Committee published “Ethical Principles to be Considered in the Allocation of Human Organs,” which affirmed that the ethical principles of utility and justice must be balanced in organ allocation.

The National Organ Transplant Act also charges the OPTN to “recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, policies, and procedures that address the unique health care needs of children.”¹ In 2013, the Chairs of the OPTN/UNOS Pediatric Transplantation and Ethics Committees recognized the need to articulate special ethical considerations when determining the priority of pediatric candidates in the allocation system. A Joint Subcommittee convened in January 2014 to begin work on what would become a companion white paper to the 2010 Principles of Allocation. The Joint Subcommittee had intensive discussions regarding the scope of this project and eventually decided it was appropriate for the final product to be a white paper rather than a guidance document. Joint Subcommittee members believed specific guidance

¹ 42 USC Sec. 274 (b)(2)(M).

² 42 CFR §121.8.

could infringe on the ethical and clinical judgment of the OPTN organ-specific Committees. They also believed an ethical framework for decision-making, presented in a white paper, would be a more permanent resource for the OPTN than specific guidance that could easily become obsolete in the evolving field of transplantation. With this finished product, the Committees have provided a resource for OPTN Committee members to evaluate current or proposed allocation policy for fairness to pediatric patients without being prescriptive. This resource is also easily accessible on the OPTN website, so the general public can better understand the ethical deliberations behind policies that impact pediatric patients.

After the Joint Subcommittee completed a well-developed draft white paper, the Ethics Committee Chair presented it to both the Pediatric Transplantation and Ethics Committees to solicit feedback. The final product contains thoughtful revisions the Joint Subcommittee made in consideration of the full Committees' feedback. Dr. Norman Daniels, Professor of Ethics and Population Health at the Harvard School of Public Health and author of the Prudential Lifespan Account, has also reviewed this work. The Pediatric Transplantation Committee voted to recommend the final draft for consideration by the Board of Directors (10-Support, 0-Oppose, 0-Abstentions).

The Committees recognize that age is one of a number of relevant equity concerns that must be considered in organ allocation. They also recognize that one cannot solely argue pediatric priority on the basis of justice or equity and that good policy achieves a balance between these principles.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

The ethical arguments presented in this white paper are consistent with NOTA and the Final Rule, which require that the OPTN develop equitable allocation policy that especially considers the unique health care needs of children.^{2,1} This white paper is also intended as a resource in support of Goal 2 of the OPTN Strategic Plan, increasing access to transplant for pediatric candidates.

Communication and Education Plan:

Upon Board approval, the OPTN will publish this white paper to the Resources section of both the OPTN and other websites. UNOS staff will also publish articles on websites to promote it to the transplant community. Staff will provide Committee members with a customizable email marketing this online resource and encourage them to share it with their professional networks.

UNOS staff will also work with the Committee to develop educational resources and training regarding the content of the white paper to offer to other OPTN/UNOS Committees, with specific focus on the organ-specific Committees and leadership.

OPTN/UNOS Pediatric Transplantation Committee: Special Ethical Considerations in the Allocation of Human Organs to Pediatric Candidates

October 3, 2014

I. Purpose

The purpose of this collaboration between the OPTN/UNOS Pediatric Transplantation and Ethics Committees is to provide guidance about how organ allocation policies should address the needs of pediatric patients within the ethical framework established by the National Organ Transplant Act and the Final Rule from US Department of Health and Human Services. The National Organ Transplant Act charges the OPTN to “recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, policies, and procedures that address the unique health care needs of children.”¹ The Final Rule requires that the OPTN develop policies for the “equitable allocation” of deceased donor organs, while also requiring that these policies achieve “best use” of the organs.² In June 2010, the OPTN/UNOS Ethics Committee published “Ethical Principles to be Considered in the Allocation of Human Organs,” which affirmed that the principles of justice and utility must be balanced in organ allocation.³

In this new analysis, we describe justifications for pediatric priority in organ allocation by focusing primarily on four areas, the Prudential Lifespan Account, the Fair Innings Argument, the “Maximin” Principle, and the concept of utility. The Committees recognize that the arguments for pediatric priority in organ allocation must be considered within the clinical context of each type of organ transplantation and the alternative therapies available while waiting for an organ.

II. Context

The Committees are aware that many stakeholders in transplantation feel particularly sympathetic to the needs of children. Providing resources to protect children and help them thrive is a fundamental human instinct.⁴ This conviction has been articulated by the international community. For example, in 1959, the United Nations General Assembly first adopted the Declaration of the Rights of the Child, which still applies and states:

*Whereas the child, by reason of his physical and mental immaturity, needs special safeguards and care, including legal protection ... Whereas mankind owes to the child the best it has to give ... The child shall enjoy special protection, and shall be given opportunities and facilities, by law and by other means, to enable him to develop physically, mentally, morally, spiritually and socially in a healthy and normal manner ... In the enactment of laws for this purpose, the best interests of the child shall be the paramount consideration.*⁵

III. The Prudential Lifespan Account (The prudent allocation of healthcare resources over the lifespan)

In addition to the survival and quality of life benefits enjoyed by transplant recipients at any age, children with end-stage organ failure have a time-limited opportunity for growth and development and may suffer lifelong consequences if not expeditiously transplanted. As a result, these pediatric candidates have the potential to receive unique benefits from transplantation that will positively affect their lives as children and later, as adults. An allocation

system established to promote this set of unique benefits for pediatric patients could be supported by the Prudential Lifespan Account.

Bioethicist Norman Daniels, in his Prudential Lifespan Account, argues that we should make decisions about resource allocation in society similar to how an individual would if he or she did not know his or her exact age (or life expectancy) but had to make decisions about allocation across the stages of his or her own individual life. Daniels explains:

If we are concerned with net benefits within a life, we can appeal to a standard principle of rational choice: It is rational and prudent that a person take from one stage of his life to give to another in order to improve his life as a whole.⁶

Instead of viewing different age groups as competing for scarce resources, such as deceased donor organs, the Prudential Lifespan Account challenges us to come to a consensus in how each individual would want to invest resources across one life with the goal to “make a life go as well as possible.”⁶ This consensus can be reached by imagining that each person must make allocation decisions for his or her own life while blinded as to his or her own age. The Prudential Lifespan Account draws attention to the universality of age, making this characteristic fundamentally different from other demographics such as race. From this perspective, as a society, it makes sense to preferentially allocate resources to children and young people in order to maximize the potential for these individuals to thrive in early and later stages of life.⁷

Before we can determine how we would want resources distributed throughout our lives, the Prudential Lifespan Account requires that we first develop a way to achieve equitable resource allocation among all individuals in society. A complete scheme of equitable allocation addresses both interpersonal issues of distributive justice, as well as distribution across one’s whole life. The “Ethical Principles to be Considered in the Allocation of Human Organs” document provides important guidance.³ We affirm the core distributive requirements of this document, specifically the prohibition against discrimination in the allocation system based on race, gender, socioeconomic group, or social usefulness. “In a public program, all members of the public are morally entitled to fair access to its benefits.”³ Furthermore “even if data were to show that socially disadvantaged groups have worse transplant outcomes, considerations of justice require that patients be assessed individually rather than only by group membership in an attempt to reduce healthcare disparities related to social inequities.”³ Within the broader ethical framework for organ allocation, the Prudential Lifespan Account provides useful guidance about the prioritization of children.

The Prudential Lifespan Account provides a reasonable basis to prioritize children with End Stage Renal Disease (ESRD) for kidney transplantation, rather than subjecting them to a prolonged period of dialysis. Despite the relative rarity of ESRD in children, its long-term consequences are fairly well-documented in the medical literature and include cognitive delays in fine and gross motor, language, learning, and psychosocial development, as well as growth impairment.⁸ Early age of onset of ESRD and longer duration may accelerate the development of comorbidities, such as cardiovascular disease.⁹ Kidney transplant corrects, where dialysis only mitigates, the harmful effects on the maturing brain of several conditions associated with ESRD, including uremia and malnutrition.^{10,11,12} Early transplantation affords the pediatric candidate a better quality of life in childhood, including regular school attendance. Transplant prior to marked growth impairment can prevent lifelong growth deficits and delayed puberty.^{13,14,15,16} Given these time-limited opportunities to benefit from transplant, it is prudent to prioritize allocation for kidney in childhood versus adulthood to remedy the unique problems of ESRD in childhood. These human capital gains are likely to improve quality of life and in some cases, may be expected to prolong life.

Similar arguments can be made about the unique benefits of transplantation in terms of development for pediatric lung, heart and liver transplantation candidates.^{17,18} For pediatric transplant candidates with end-stage organ disease, transplantation is likely to create time-limited opportunities to get an education, socialize with other children, grow and prepare for adulthood. These benefits are unique to pediatric vs. adult transplant. Therefore, to make one's life go as well as possible, it would be prudent to preferentially make these high quality life years available to children.

IV. Fair Innings

The “Fair Innings” perspective on equity also provides a relevant basis for pediatric priority in organ allocation. The Fair Innings perspective argues that every individual deserves to experience a full life and that the allocation of society's resources should try to maximize the opportunity for each person to reach a full lifespan. Children with end-stage organ failure are at risk of premature death, which denies them opportunities in adulthood to complete their education, establish a career, or have a family.¹⁹

V. The “Maximin” Principle (Maximizing the minimum benefit to the least advantaged or Giving priority to the most disadvantaged groups)

When allocating a scarce resource, such as deceased donor organs, inequalities will always exist. There is a strong ethical argument that society should only tolerate inequality in our organ allocation system when those inequalities are arranged so that “they are the greatest benefit to the least-advantaged members of society” (philosopher John Rawls).²⁰ While it is sometimes difficult to achieve consensus on who among those waiting for a lifesaving transplant is most disadvantaged, there are several factors that make pediatric candidates particularly vulnerable and in need of expeditious transplant. The particular disadvantages faced by children with end-stage organ failure include diminished quality of life during development, age and size-specific barriers to transplant, unique challenges in providing life-sustaining therapy for pediatric patients awaiting transplant, and the risk of premature death.

Children with end-stage organ failure suffer a diminished quality of life in childhood, the effects of which may extend into adulthood. As previously discussed, children have a time-limited opportunity for growth and development, and end-stage organ failure in childhood is associated with cognitive delays, growth deficits, delayed puberty, and comorbidities. Absence from school can have a negative impact on social integration, academic achievement, and future employment opportunities. Social isolation results from prolonged absence from school and exclusion from normal activity with family and friends. Children experiencing such isolation often have poor self-esteem and are at risk of suffering from anxiety or depression.²¹ Healthy childhood confers a lifelong advantage that children in need of organ transplant do not have.

Pediatric candidates also experience barriers to transplantation as a result of their small size and developing anatomy. In addition to the universal issue of donor scarcity, availability of organs is further restricted to pediatric patients requiring size-matched organs. For this reason, children on the waiting list may need to have ready access to a particular subset of organs for which anatomical compatibility will allow transplantation.

The lack of availability of life-sustaining therapies while awaiting transplant further compounds the problem of donor scarcity for pediatric candidates. Technologies to manage end-stage organ failure while waiting for an appropriate organ, also known as Bridge to Transplant technologies, for pediatric patients are limited with inconclusive evidence of success. Bridge therapy for pediatric heart candidates have significant complications, which increase with the duration of technological support and can require intensive multi-disciplinary rehabilitation.²²

This had led some researchers, such as Fiser, et al, to insist that alternative therapies “must be developed in the pediatric population that will allow for improved outcomes, comparable with outcomes achieved in the adult population.”²³ Children on some forms of mechanical circulatory support have increased risk of stroke compared to adults and are unlikely to be discharged home.²⁴ Mechanical circulatory support options are very limited for infants and children weighing less than 5 kilograms and have a suboptimal success rate.²⁴ Organ scarcity and unavailability of life-sustaining therapy contribute to high waitlist mortality rates, especially among the smallest pediatric candidates (less than 6 years old) waiting for any organ and all pediatric lung candidates.

Even the long-term modality of dialysis for pediatric ESRD has limitations for providing high quality care for children awaiting transplantation and must be considered. Vascular access for chronic dialysis may be difficult to place due to small blood vessels.²⁵ In young children with arteriovenous fistula/graft access, the insertion of large bore needles with every treatment is often difficult for them, their families, and dialysis staff. Dialysis units experienced in providing care for children are often far from the child’s home and school.

Children with end-organ failure are at risk of premature death, which denies them opportunities to complete their education, establish a career, or have a family. The earlier in life a person receives an organ transplant, the more likely that he or she will be able to lead a productive and fulfilling life.²⁶

VI. Utility Considerations

In organ transplantation, utility outcomes are typically measured in terms of patient or allograft survival. The Committees recognize that preferentially allocating organs to children will be consistent with the goal of maximizing utility in some but not all circumstances. Yet, across the entire population of pediatric versus adult transplant recipients, pediatric transplant recipients will on average enjoy lower mortality rates due to the strong association between younger age and longer survival.

As an example, in kidney transplantation, some subgroups of children pose particular surgical challenges for transplantation (e.g. children under 2 years or those with complicated urological anomalies) or have high rates of organ rejection vs. adults (e.g. adolescents). One study of recipients of highest-quality deceased donor kidneys demonstrated that adolescents had allograft survival that was lower than most other age groups. Mortality rates, however, were lower in all pediatric age groups than among adult recipients over age 40 years.²⁷

Overall patient survival is greater for pediatric recipients than adults. We analyzed OPTN data for ten and twenty year Kaplan-Meier patient survival of solitary deceased donor heart, lung, liver, and kidney transplants performed from 1990 to 1997. While 10 year patient survival rates among children less than 18 years old at transplant is only slightly higher than that of adult recipients of heart and lung transplants, pediatric liver and kidney recipients had a markedly better 10 year patient survival than adult recipients (74% vs. 56% and 90% vs. 65%, respectively). For recipients of any organ, children less than 18 years old have over two times the 20 year patient survival rate of adults.

VII. Conclusion

Drawing from regulatory guidance and ethical principles, we find that there is a reasonable basis for giving preference to pediatric transplant candidates for allocation. This preferential allocation must take into account the organ-specific clinical context faced by candidates of all ages.

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