White Paper

General Considerations in Assessment for Transplant Candidacy

OPTN Ethics Committee

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General Considerations in Assessment for Transplant Candidacy

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Executive Summary

Transplant programs in the United States evaluate the suitability of potential transplant candidates using medical and non-medical listing criteria. All the criteria used to evaluate the eligibility of patients for transplantation can affect the transplant team’s decision to waitlist a potential transplant recipient. This white paper offers an analysis of ethical considerations associated with non-medical criteria commonly used by transplant programs in listing decisions. The white paper addresses use of life expectancy, potentially injurious behaviors, adherence, repeat transplantation, incarceration status, immigration status, and social support as transplant evaluation criteria. This list is neither exhaustive nor immutable. In addition, this white paper also includes considerations about how pediatric, adolescent, and young adult patients may be impacted by the use of the aforementioned non-medical criteria in listing decisions.

The intent of this white paper is to provide transplant programs with information about the ethical considerations about the use of non-medical criteria. The Organ Procurement and Transplantation Network (OPTN) has the authority to publish this white paper based on the Final Rule’s requirement that “a transplant hospital which is an OPTN member may list individuals, consistent with the OPTN criteria...”\(^1\) Likewise, the Final Rule states that the OPTN standardizes “the criteria...for adding individuals to, and removing candidates from, organ transplant waiting lists.”\(^2\) This white paper supports the standardization of patient evaluation criteria by encouraging transplant programs to consider the ethical implications of commonly used criteria.

\(^1\) 42 C.F.R. § 121.5(a).
\(^2\) 42 C.F.R. § 121.8(b)(1).
Background

Ensuring equity in access to transplantation requires assessment and mitigation of structural barriers disproportionately impacting disadvantaged potential candidates who could medically benefit from transplantation. Such barriers include use of non-medical criteria, which can unwittingly introduce bias based on race, ethnicity, socioeconomic status, gender, and other non-clinical factors that may have a significant discriminatory impact on structurally disadvantaged populations. These criteria may compound the effect of social and healthcare disparities resulting in under referral of structurally disadvantaged patients for transplant evaluation and lower listing rates among those referred.

Transplant centers are encouraged to develop their own guidelines for potential transplant candidate evaluations. Listing guidelines used by transplant programs should be applied without bias. Use of non-medical criteria continues to raise ethical concerns insofar as they commonly: (1) lack clear standards and thresholds; (2) are inconsistently applied; (3) are susceptible to stereotyping and instrumental value judgments; (4) are not transparent to patients; and (5) are not consistently supported by evidence. As such, transplant evaluations should not exclusively rely on non-medical criteria. The transplant community should continue to research the use of non-medical criteria with regard to who gets a transplant in order to apply them in an evidence-based manner; work to reduce bias and stereotyping; and increase transparency and consistency in the evaluation.

Non-medical factors relevant to transplant evaluations and listing decisions often include, but may not be limited to, psychosocial factors (e.g., social support, patient adherence).³ Use of non-medical transplant evaluation criteria remains an area of concern to many in the transplant community.⁴,⁵ Non-medical criteria are thought by some to uphold the principle of utility by selecting candidates likely to be good stewards of a donated organ, who may have better post-transplant outcomes. Yet, ethical concerns pertaining to equity and justice remain with using non-medical criteria to evaluate potential candidate.⁶,⁷,⁸,⁹ These include concerns about disproportionate burden placed on structurally disadvantaged patients for transplant evaluation and lower list rates among those referred.

³ 42 C.F.R. § 482.90.
disadvantaged\textsuperscript{10} populations, who may face greater challenges meeting certain evaluation criteria, and who may face greater implicit bias against waitlisting when transplant teams use subjective criteria. Without clear standards, inconsistent and subjective use of non-medical criteria is likely to result in the inconsistent access to transplantation among potential beneficiaries, which undermines equity.

The non-medical criteria used in transplant evaluation should reflect the most current empirical evidence available and their use should reflect a balance of the ethical principles of utility, justice, and respect for persons. Importantly, these factors should be consistently applied to all potential transplant candidates, while ensuring that the evaluation process is transparent, evidence-based (where available), and revisable. Transplant clinicians overseeing psychosocial assessments are deeply committed both to promoting the best interest of patients while ensuring optimal stewardship of scarce organs. Clinicians often face the challenging task of balancing conflicting ethical principles when evaluating and listing patients. This ethical analysis is meant to clarify and resolve some ethical conflicts that arise in the use of psychosocial criteria in transplant evaluation and listing decisions.

**Purpose**

The OPTN Ethics Committee (hereafter, “the Committee”) has reviewed and revised its historical position statement on considerations for transplant candidacy, including non-medical criteria, on several occasions. The OPTN Board of Directors approved the *General Considerations in Assessment for Transplant Candidacy* in 2015. As part of the 2015 revisions, the Committee provided ethical analyses of several criteria cited in this document, including life expectancy, organ failure caused by behavior, compliance/adherence, and repeat transplantation.

In deciding to pursue this revised version of the *General Considerations in Assessment for Transplant Candidacy* analysis, the Committee determined that there may be aspects of the 2015 version that are outdated or could benefit from revision and updates. For example, the discussion of “Alternative Therapies” was removed from this re-write because consideration of alternative therapies before proceeding with transplantation is a common practice among programs now.

New criteria have been added in this white paper, including incarceration status, immigration status, and social supports. The inclusion of immigration status is intended to re-state and re-emphasize the Committee’s position statement approved in 2015 by the OPTN Board of Directors, which posited that prisoner status should not preclude transplant evaluation.\textsuperscript{11} Specifically, the 2015 position statement recommended that “absent any social imperative, one’s status as a prisoner should not preclude them from consideration for a transplant” and highlighted that “prisoner status is not an absolute contraindication” to transplantation candidacy. Since then, questions about the barriers to transplantation faced by incarcerated individuals have remained a concern. For example, a 2020 survey of 122 kidney transplant centers found that two centers considered incarceration to be a “contraindication” to transplantation.\textsuperscript{12} While that represents a small number of respondents, it runs counter to the Committee’s 2015 position statement.


\textsuperscript{12} Lauren S. Faber, Madeline Palmer, Michael Davis, and Tania Lyons, “Disparities in Access to Kidney Transplantation: Are
In response to persistent concerns over the use of immigration status in transplant evaluations, the Committee decided that an analysis of the ethical implications of using immigration status as a listing criterion would be beneficial to the community. The Committee agreed that it was important to highlight that there are no OPTN policies restricting access to transplantation based on immigration status.

The following discussion offers an overview of the ethical challenges associated with the use of non-medical criteria. This analysis relies on the three ethical principles identified in the *Ethical Principles in the Allocation of Human Organs*, which include utility, justice, and respect for persons. As described in the *Ethical Principles*, utility refers to the maximization of net benefit to the community, and justice refers to the fair pattern of distribution of benefits. The principle of respect for persons primarily conveys the concept of respect for autonomy. Transplant evaluations should balance justice requirements and respect for persons with utility considerations, including efforts to avoid futility.

Although the purpose of this white paper does not include development or evaluation of resources for psychosocial evaluation, it is clear that this is a growing need for the transplant community. More comprehensive national data collection of pre-transplant evaluation and listing practices is needed to better understand barriers to equitable access to transplantation. To best support patients and clinicians, the transplant community should prioritize research about standardized evaluation tools and best practices for reducing bias in the evaluation of patients undergoing transplant evaluation. This white paper also acknowledges the challenges faced by social workers in attempting to advocate for patients while considering the scarcity of organs, and that social workers should be given support and resources to this end.

**White Paper for Board Consideration**

The criteria discussed in this white paper were selected because they present non-medical considerations routinely included in evaluations of transplant candidacy. The Final Rule requires criteria for determining suitable transplant candidates to be measurable and medical to the extent possible. When criteria are used that are not measurable or medical, it is appropriate to encourage the use of parameters, such as ethical considerations to support the standardization of more qualitative criteria. As such, ethical considerations related to the following criteria are included to aid transplant programs with their listing decisions:

- Life Expectancy
- Potentially Injurious Behavior
- Adherence
- Repeat transplantation
- Incarceration status

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15 42 C.F.R. § 121.8(b)(1)
• Immigration status
• Social support

Furthermore, this white paper discusses how the use of these criteria may impact pediatric, adolescent, and young adult patients.

Public comment feedback about this white paper can be grouped into four themes. First, public comment supported the ethical analysis associated with non-medical transplant candidate criteria discussed in the document. Second, public comment suggested addressing pediatric candidates. A third theme pertained to identifying opportunities for helping transplant programs and their staff address and overcome some challenges associated with utilizing non-medical criteria in psychosocial evaluations. The fourth theme centered on why disability and financial status were not included as factors.

Support for the Information Provided in the White Paper

This white paper was submitted for public comment starting on January 21 through March 23, 2021. The following graphics illustrate that sentiment feedback received during the regional meetings was overall supportive of the white paper. Figure 1 categorizes the sentiments submitted as part of the 11 regional meetings. A total of 184 sentiment responses were submitted. The white paper received an overall score of 3.9 out of a possible total of 5.0. While not shown on the figure, about 80 percent of the sentiment feedback was supportive or strongly supportive. (This is reflected by the two green bars in the Grand Total.) Sentiment opposed or strongly opposed to the white paper was very limited.

16 This chart show the sentiment for the public comment white paper. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for regional meetings only include attendees at the regional meeting. Region 6 uses the average score for each institution. The circles after each bar indicate the average sentiment score and the number of participants is in parentheses.

17 This chart show the sentiment for the public comment white paper. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for regional meetings only include attendees at the regional meeting. Region 6 uses the average score for each institution. The circles after each bar indicate the average sentiment score and the number of participants is in parentheses.
Figure 2 shows the sentiment received by member type. The white paper was soundly supported among all member types.

There was overall sentiment support for the document during the regional meetings. The vast majority of comments submitted to the OPTN website supported the white paper’s primary theme that evaluation criteria should be applied without any bias. The American Society of Transplant (AST) commented that the “strength of the document is the key message to consider all candidates equally, and not base adverse determinations only on the psychosocial aspects.” The American Society of Transplant Surgeons’ (ASTS) submission echoed that sentiment, stating that “it is critical to ensure that transplant candidate assessment criteria do not discriminate” against any potential candidates based on race, gender, socio-economic status, or other demographics. Another commenter posited that “[c]andidacy criteria should be transparent, non-discriminatory” and applied by the transplant program in a manner that engenders trust on the potential transplant candidate part.

**Need for Additional Research**

Public comment feedback questioned whether sufficient evidence exists to support an association between the use of the non-medical factors discussed in the white paper and positive post-transplant outcomes. In many cases, these comments were followed by calls for greater data collection and research on the pre-transplant evaluation and listing period.

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18 This chart show the sentiment for the public comment white paper. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for regional meetings only include attendees at the regional meeting. Region 6 uses the average score for each institution. The circles after each bar indicate the average sentiment score and the number of participants is in parentheses.


Need for research about psychosocial predictors of post-transplant outcomes

Public comment feedback called for better evidence about the impact of psychosocial factors on post-transplant outcomes. Many transplant programs call for more evidence to support current practices, but still rely on the evidence that is available. Comments submitted by the Society for Transplant Social Workers (STSW), for example, reference the Kidney Disease: Improving Global Outcomes (KDIGO) guidelines which state that there is little evidence suggesting that the absence of social supports is an absolute contraindication to transplantation, but still recommends that potential kidney transplant recipients who cannot care for themselves should have an identified support system in place prior to transplantation.22

Need for research about populations most affected by use of psychosocial criteria

Public comments also focused on the need for additional data collection and analysis pertaining to underserved and disadvantaged populations who are most impacted by biases and face the most challenges in meeting evaluation criteria. As part of AST’s public comment, it stated that non-medical criteria are often based on limited data but are still used to reject more challenging patients, who are more likely to be ethnic and racial minorities, lower socio-economic statuses, and socially isolated.23 Participants in the regional meetings called for greater discussions about the issues socially disadvantaged people experience when trying to access transplantation services, and the challenges associated with using the social determinants of health.24 Other regional meeting attendees commented on how the use of incarceration status may exacerbate racial disparities in health care when not carefully considered as a factor.25

In describing the health impacts of discrimination, the authors of Healthy People 2020 cite an ongoing need for additional research “to increase the evidence base on the effects of discrimination on health outcomes or disparities.”26 The Committee and public commenters supported efforts to reduce the potential for inconsistent and arbitrary evaluations, to reduce implicit bias in transplant evaluations, and to adhere to practices which best align with the most reliable outcomes.

Need for research into minimum thresholds and standardized evaluation measures

Several comments identified a need for better data and research to support a standard approach to guide transplant programs when evaluating potential candidates.27 While listing decisions would remain

26 Office of Disease Prevention and Health Promotion, “Discrimination.”
the purview of each individual program, some public comments suggested that a consistent tool or tools would be beneficial for transplant clinicians and may be more uniformly applied, improving transparency and consistency in patients’ experiences. For instance, such an instrument might allow for collection of more uniform data about evaluation decisions across transplant programs. Some such tools identified through public comment include the Stanford Integrated Psychosocial Assessment for Transplant (SIPAT) and the Clinical Practice Guideline on the Evaluation and Management of Candidates for Kidney Transplantation.\textsuperscript{28,29} A small number of comments suggested that consideration be given to creating a scoring system to objectively assess potential candidates.

\textit{Partnership to improve transparency and objectivity in psychosocial evaluations}

Some commenters questioned whether the guidelines offered in the white paper are sufficient to improve consistency in psychosocial evaluations in a manner that better demonstrates the principle of respect for persons. To this end, some recommended forming an ad hoc task force consisting of the OPTN Ethics Committee and other sponsoring bodies to evaluate mechanisms for scoring potential candidates more objectively. This could take the form of a quantitative rubric documenting the presence or absence of a given criterion. For example, a potential candidate might be evaluated in terms of “social support: on a range of post-transplant requirements including transportation, medication management, and the monitoring of symptoms.”

While the Committee agreed that objective scoring assessments may help improve consistency and transparency, such scoring assessments are outside the scope of this white paper. Members indicated that additional research is still needed to better establish the relationship between identified attributes and outcomes, particularly in order to demonstrate which factors are most predictive post-transplant. Moreover, Committee members indicated that a task force of diverse evaluators could be created that would have the best chance of identifying and eliminating implicit bias. The task force could address scoring assessments by organ type.

\textbf{Evaluating Potential Pediatric Candidates Using Psychosocial Criteria}

Multiple comments focused on the impact of certain non-medical factors on pediatric patients. Commenters cited that social support, adherence, and other psychosocial criteria may be disproportionately used in the case of pediatric candidates. For instance, OPTN Pediatric Committee members identified matters pertaining to disability, social supports, adherence, and the roles of parents and caregivers as special points of emphasis when examining the impact of psychosocial criteria in evaluation practices on pediatric patients. Furthermore, the impact of such factors may be especially problematic for younger patients who must rely exclusively on parents or caregivers for support.


In 2014, the OPTN approved the white paper, *Ethical Principles of Pediatric Organ Allocation*, which discusses the lack of availability of life-sustaining therapies that confront pediatric candidates awaiting transplantation. The OPTN acknowledges that there are limited bridge to transplant technologies available to pediatric patients with end-stage organ failure. Additionally, there is inconclusive evidence that the few options available to pediatric patients result in successful outcomes. Compounding these problems, delays in transplantation for pediatric candidates are also associated with growth and developmental harms.

Some of the public feedback notes that when potential pediatric candidates are involved, the evaluation criteria is also applied to the parents or other caregivers. Some cited this as an additional barrier that pediatric patients are faced with as part of the process to be listed for transplant. The OPTN Transplant Coordinators Committee (TCC) clarified that younger pediatric candidates’ access to transplantation is often based on non-medical, psychosocial factors associated with their families and caregivers.

**Criteria Impacting Access to Transplant Not Addressed in White Paper**

This white paper primarily focused on the subjective criteria and psychosocial criteria that transplant programs use when evaluating a potential transplant candidate for listing. Specifically, this white paper addresses criteria often used to describe someone’s ability to adhere to treatment following transplantation. Public comment feedback raised questions about why financial considerations and disability were excluded from this paper, pointing to their significance on candidacy assessment, and access to transplantation, especially given the significant focus and national discussion currently placed on equity in access. Similar concerns were expressed by the OPTN Patient Affairs Committee and the OPTN Minority Affairs Committee.

The Committee is well aware of the role a patient’s financial status has in determining access to transplantation and identifies this as an important area of future work. The Committee found criteria related to financial status and financial resources to be qualitatively different from the psychosocial criteria in that financial criteria rely on objective thresholds, and are largely dependent on insurance coverage. The Committee chose not to address issues that might be interpreted as a discussion about how medical care is financed in the United States. There is a large body of literature examining the topic of health insurance, insurance gaps, and their influence on disparities in access to health care, including access to transplantation. Use of financial status, or minimal savings, as a criterion for transplant candidacy is crucial and should be examined on its own in future work. This white paper focused on non-medical (largely psychosocial) criteria that tend to be evaluated more subjectively, such as the presence and efficacy of social support or a potential transplant candidate’s history of adherence to treatment regimens. As such, insurance status and ability to pay were outside the scope of psychosocial criteria the paper was intended to address.

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Another area that drew attention during public comment was the lack of discussion of the assessment of disabilities in transplant evaluations. As part of its public comment response, ASTS urged that the white paper be revised to “explicitly state that a potential candidate’s disability alone should not disqualify him or her from being waitlisted.”32 Another comment noted that the white paper should have addressed disability as part of a discussion of anti-discrimination laws, which include the Americans with Disabilities Act, the Rehabilitation Act, and Section 1557 of the Affordable Care Act.33 While not directly addressed through public comment, multiple states have enacted legislation to prevent discrimination in transplantation against individuals with physical and/or intellectual disabilities (Appendix A).

The Committee recognizes the importance of such issues, and has undertaken work analyzing such issues as recently as March 2019. The Committee was in the process of developing a white paper analyzing the ethical implications of using intellectual disability as a contraindication to solid organ transplantation when the Committee learned that the U.S. Health and Human Services Department’s Office of Civil Rights (OCR) was undertaking similar work. As such, the OPTN drafted a memo to the U.S. Health Resources and Services Administration (HRSA) highlighting the analysis to date, to be shared with OCR as they prepare their guidance document for public comment.34 Highlights of that analysis included the OPTN asserting there was no clear and consistent definition of intellectual disability used across transplant programs. The lack of such a definition undermines transparency and consistency in the evaluation process.35 The memo discussed other actions taken by the OPTN, such as an ethical analysis using the principle of respect for persons and the need to assess an individual’s capacity and the challenges associated with that assessment. The OPTN also assessed the impact of intellectual disability on transplant outcomes and described implications of transplanting patients with intellectual disabilities in light of the principle of utility.

The Committee is monitoring the progress of the OCR’s guidance and will evaluate the need for future analysis when the OCR’s proposal is complete. In January 2021, OCR announced the issuance of a Request for Information concerning, among other items, information addressing “discrimination on the basis of disability by covered health entities in the provision of life-sustaining care, including the context of organ transplantation.”36

**NOTA and Final Rule Analysis**

The white paper is submitted under the authority of the OPTN Final Rule, which states that “a transplant hospital which is an OPTN member may list individuals, consistent with OPTN criteria…”37 Furthermore,

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34 OPTN President on behalf of OPTN Ethics Committee, email to Health Resources and Services Administration, Division of Transplantation, August 2, 2019.


37 42 C.F.R. § 121.5(a).
the OPTN has the authority under the Final Rule to standardize the criteria that are used “for adding individuals to, and removing candidates from, organ transplant waiting lists.”

This white paper addresses common criteria transplant programs use for adding and removing individuals from the waiting list. Encouraging transplant programs that use such criteria to consider, at a minimum, their ethical implications creates a minimum standard for using these criteria. The Centers for Medicare and Medicaid Services (CMS), within the U.S. Department of Health and Human Services, notes that “there are factors that some transplant programs can and do use in their patient selection criteria including age, ability to pay, ability to adhere to immunosuppression regimen, presence of an active infection, etc. Consideration of these types of factors is permissible.”

Determining suitability for transplant, and thus, determining whether a patient should be listed as a candidate with the OPTN, is a decision that lies with transplant programs. While transplant hospitals primarily rely on objective, measurable medical criteria, they also often incorporate psychosocial, non-medical considerations into their determination of suitability for listing.

Conclusion

Use of non-medical criteria continues to raise ethical concerns insofar as they commonly: (1) lack clear standards and thresholds; (2) are inconsistently applied; (3) are susceptible to stereotyping and instrumental value judgments; (4) are not transparent to patients; and (5) are not consistently supported by evidence. As such, transplant evaluations should not exclusively rely on non-medical criteria. The transplant community should continue to research the use of non-medical criteria with regard to who gets a transplant in order to apply them in an evidence-based manner; work to reduce bias and stereotyping; and increase transparency and consistency in the evaluation.

38 42 C.F.R. § 121.8(b)(1).
RESOLVED, that the white paper entitled General Considerations in Assessment for Transplant Candidacy, as set forth below, is hereby approved, effective July 15, 2021.

Proposed new language is underlined (example) and language that is proposed for removal is struck through (example).

General Considerations in Assessment for Transplant Candidacy

Reviewed in 2015

Transplant centers are encouraged to develop their own guidelines for transplant candidate consideration. Each potential transplant candidate should be examined individually and any and all guidelines should be applied without any type of ethnicity bias.

Preamble

The concept of non-medical transplant candidate criteria is an area of great concern. Most transplant programs in the United States use some type of non-medical evaluation of patients for transplantation. Historically, psychosocial evaluations of potential transplant candidates have been conducted and the results have influenced the possible listing of these patients in a variety of ways. There is general agreement that non-medical transplant candidate criteria need to be evaluated. The legitimate substance of such an evaluation could cover a very wide range of topics. To the greatest extent possible, any acceptance criteria should be broad and universal.

The UNOS Ethics Committee has chosen to address the criteria of life expectancy, organ failure caused by behavior, compliance/adherence, repeat transplantation and alternative therapies. The list is recognized as neither exhaustive nor immutable. The elements of non-medical transplant candidate evaluation will and should reflect changes that occur in technology, medicine and other related fields while reflecting the most current knowledge of scientific and social issues in transplantation. Therefore, the non-medical transplant candidate criteria should be continuously reassessed and modified as necessary. However, because we are serving individual human beings with highly complex medical situations, a process of individual evaluation must be maintained within the broad parameters.

The Ethics Committee also realizes the catalyst for all transplant candidate criteria is the shortage of available organs for transplantation. Because donated organs are a severely limited resource the best potential recipients should be identified. The probability of a good outcome must be highly emphasized to achieve the maximum benefit for all transplants. Were there an ample supply of transplantable organs, nearly every person in need could be a transplant candidate. To this end, it is affirmed that transplantation is not a universal option. Medical professionals, while honoring the moral obligations to extend life and relieve suffering whenever possible, must also recognize the limitations of transplantation in meeting these ends.

Life Expectancy

While the Committee would not recommend arbitrary age or co-morbidity limits for transplantation, members generally concur that transplantation should be carefully considered if the candidate's
reasonable life expectancy with a functioning graft, based on factors such as age or co-morbid conditions, is significantly shorter than the reasonably expected “life span” of the transplanted organ.

Organ Failure Caused by Behavior

In social and medical venues, debate continues to focus upon alcoholism, drug abuse, smoking, eating disorders and other behaviors as diseases or character flaws. Such behaviors are associated with disease processes in many adults. The Ethics Committee has historically supported the conclusion that past behavior that results in organ failure should not be considered a sole basis for excluding transplant candidates. However, additional discussion of this issue in a societal context may be warranted.

Compliance/Adherence

It is difficult to apply broad measures of compliance to accepting transplant candidates, since empirical measures are limited and medical professionals often approach these issues subjectively. However, transplantation should be considered very cautiously for individuals who have demonstrated serious, consistent, and documented non-compliance in current or previous treatment.

Repeat Transplantation

The Ethics Committee acknowledges the issue of justice in considering repeat transplantation. Graft failure, particularly early or immediate failure, evokes significant concerns regarding repeat transplantation. However, the likelihood of long-term survival of a repeat transplant should receive strong consideration.

Alternative Therapies

The presence or absence of alternative therapies should be carefully weighed against other factors in evaluation. In some cases the need for a transplant may be delayed, even prevented, by judicious use of other medical or surgical procedures.

Revised in 2021

Transplant centers are encouraged to develop their own guidelines for transplant consideration. Each potential transplant candidate should be examined individually and all guidelines should be applied without of bias.

Preamble

Transplant programs in the United States evaluate the suitability of potential transplant candidates using listing criteria developed by the transplant programs. The criteria are both medical and non-medical in nature. The use of non-medical criteria in evaluating patients for transplantation can affect the decision to list a potential transplant candidate for transplantation. This white paper offers an analysis of ethical considerations associated with non-medical criteria commonly used by transplant programs in listing decisions. It addresses use of life expectancy, potentially injurious behaviors, adherence, repeat transplantation, incarceration status, immigration status, and social support as transplant evaluation criteria. It also incorporates a section devoted to pediatric, adolescent, and young adult candidates for transplantation as these groups warrant separate and special consideration. This list is neither exhaustive nor immutable. Some factors the transplantation community has identified as important, such as intellectual disability and financial considerations, are not addressed in this white
paper. Intellectual disability considerations are under review at the federal level, and thus not addressed here.\textsuperscript{43} The OPTN continues to monitor this progress and may consider additional analysis in the future.

Additionally, ethical considerations associated with the use of financial requirements for transplantation may also be considered for additional analysis in the future.

Non-medical factors relevant to transplant evaluations and listing decisions often include, but may not be limited to, psychosocial factors (e.g., social support, patient adherence).\textsuperscript{42} Use of non-medical transplant evaluation criteria remains an area of concern to many in the transplant community.\textsuperscript{43,44} Non-medical criteria are thought, by some, to uphold the principle of utility by selecting candidates who can medically benefit from transplant. Their use is often supported as an effort to ensure optimal stewardship of a scarce resource. Yet, ethical concerns with using non-medical criteria to evaluate potential transplant candidates involve equity and justice.\textsuperscript{45,46,47}

The elements of non-medical transplant candidate evaluation should reflect the most current evidence available and their use should reflect a balance of ethical principles of utility, justice, and respect for persons. Importantly, these factors should be consistently applied to all potential transplant candidates, while ensuring the evaluation process is transparent, evidence-based (where available), and revisable.

This analysis relies on the three ethical principles identified in the Ethical Principles in the Allocation of Human Organs, which include utility, justice, and respect for persons.\textsuperscript{49} As described in the Ethical Principles... utility refers to the maximization of net benefit to the community and justice refers to the fair pattern of distribution of benefits. The principle of respect for persons primarily conveys the importance of the concept of autonomy. Transplant evaluations should balance justice requirements


\textsuperscript{44} C.F.R. § 482.90.


and respect for persons with utility considerations, including efforts to avoid futility.\textsuperscript{50} The OPTN recognizes that listing decisions are complex and that transplant clinicians try to work with patients to identify and mitigate risk factors for negative outcomes and foster positive ones. The OPTN recognizes that, to support centers in reducing reliance on non-medical criteria, transplant center reporting metrics may need to be revised to increase emphasis on pre-transplant access measures and do a better job risk-adjusting for post-transplant outcomes.

The OPTN has reviewed and revised its historical position statement on transplant candidacy for considerations, including non-medical criteria, on several occasions, most recently in 2015.\textsuperscript{51,52} At the time, the OPTN provided ethical analyses of several criteria cited in this document, including life expectancy, organ failure caused by behavior, compliance/adherence, and repeat transplantation. In deciding to pursue a revised version, it was determined that there may be aspects of the 2015 version that are outdated or could benefit from revision and updates. The following discussion offers an overview of the ethical challenges associated with the use of non-medical criteria.

\textit{Life Expectancy}

Supported largely by the principle of utility, as discussed in the \textit{Ethical Principles in the Allocation of Human Organs}, potential transplant candidates with longer life expectancy may, with a successful transplant, achieve the greatest benefit in terms of years of life saved.\textsuperscript{53} The OPTN concurs that a patient’s ability to benefit from transplant should align with the organ’s potential longevity. While both a patient’s life expectancy and current state of health may be correlated to age, age itself should not be used to restrict transplantation owing to considerations of justice and respect for persons.\textsuperscript{54} There are ethical reasons to avoid the sole use of age as an eligibility criterion for transplantation, including concerns of justice and respect for autonomy. There are also legal limitations such as those articulated in the \textit{Age Discrimination Act of 1975},\textsuperscript{55} which preclude federally funded programs, like the OPTN, from engaging in age discrimination. In kind, the \textit{Affordable Care Act} prohibits health care programs or activities from discriminating on the basis of age alone.\textsuperscript{56} While the use of age by itself should not be used as a sole criterion for determining eligibility for potential transplant, it is ethically permissible to consider longevity and success of the graft. Age does not offer the full picture in determining the life expectancy and it precludes the possibility of some individuals being listed who might otherwise have made good candidates, thereby not respecting their autonomy.


\textsuperscript{55} 42 U.S.C. §§ 6101-6107.

Potentially Injurious Behavior

Ethical concerns persist with using potentially injurious behaviors (e.g., substance use, unhealthy eating, non-adherence to medical recommendations, etc.) as criteria to rule out transplant candidacy. The principle of utility, may support the use of potentially injurious behaviors in transplant evaluation, as these behaviors may be seen to influence graft survival and broader transplant outcomes. Reliance on potentially injurious behaviors for transplant listing decisions must be evidence-based. Evidence linking some potentially injurious behaviors to transplant outcomes is essential but currently inconclusive.\(^{57,58,59,60,61}\) For other behaviors, there may be emerging evidence to suggest that their presence may be associated with poorer outcomes. Potentially injurious behaviors may be considered in transplant evaluations where they are ongoing, untreated, and are likely to compromise successful transplant outcomes. Persons actively engaging in potentially injurious behaviors may not medically benefit from transplantation owing to higher risk of graft failure. By contrast, mere history of potentially injurious behavior that has been addressed or effectively treated, should not, on its own, disqualify persons from access to transplantation.

Utility considerations associated with use of potentially injurious behaviors must be weighed against considerations of justice and respect for persons. This entails clearly articulating the potential harms (exclusion of candidates in need, who may be disproportionately structurally disadvantaged) and weighing them against the benefits (superior post-transplant outcomes) needed to understand the tradeoffs in balancing ethical principles.\(^{62,63,64,65,66}\)

Potentially injurious behaviors associated with negative outcomes may be partly due to personal choice and as such may involve personal responsibility or autonomy. However, these behaviors are also known to be significantly influenced by underlying psychological, genetic, economic, and systemic factors, including early life exposures – factors over which patients may have little control.\(^{67,68}\) For example,

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one’s diet is not a straightforward reflection of personal choice, but rather determined by several factors including one’s access to a grocery store which sells healthy food. Factors predicting substance use disorders similarly are shared between genetic and social precursors, as only some are related to personal choice. While potentially injurious behaviors may be due, in part, to personal choice, transplant providers should, to the extent that is possible, balance the principles of utility, justice, and respect for persons, which requires that considerations meant to lessen the impact of behavioral factors, such as abstinence periods for alcohol use disorder, be objective and evidence-based. Justice and respect for autonomy dictate that transplant centers consider social determinants that may affect patient behavior when potentially injurious behaviors are implicated. Transplant centers have an ethical duty to work with patients to help them overcome the structural barriers to obtaining treatment and remaining in remission before transplant to ensure a successful outcome after transplant.

Excluding patients from transplantation due to potentially injurious behaviors that are influenced by factors beyond patients’ control can exacerbate disparities in health and access to health care, thereby undermining justice and respect for persons in access to transplantation. Considering the contribution of many factors to both behavior and subsequent organ loss, and the limited evidence supporting the use of some factors, the OPTN continues to affirm that evaluation and listing decisions should be driven primarily by medical benefit, and that potentially injurious behavior should not be considered a sole basis for excluding transplant candidates unless the overwhelmingly outweighs the benefit.

Adherence

Adherence (understood to be a bi-directional, proactive process of discussion and agreement between the patient and the medical team, on a course of therapy or management) has limited objective measures. Adhering to a medical regimen post-transplant increases the likelihood of a successful transplant, increasing utility. Thus, transplanting patients who will be adherent is supported by the principle of utility. However, there are few reliable predictors of post-transplant adherence, and medical professionals commonly approach these issues inconsistently.

Justice requires that a history of consistent and documented treatment of non-adherence be considered by the transplant team. Ideally, this should take place keeping in mind barriers to adherence and other medical and psychosocial criteria. A transplant program should also consider an individual’s expressed willingness to follow treatment regimes. Objective measures of adherence such as attending dialysis treatment and visits for transplant evaluation should be considered when available. These measures


should be assessed in the context of disparities in access to care based on geography, resources and financial status, all of which can adversely affect both patients’ ability to adhere to recommendations, and the implicit perceptions held by the clinicians about their ability to adhere. For example, transportation, lack of job security or time off for treatment, and financial constraints may directly affect dialysis adherence. Transplant program staff should evaluate these barriers and provide support where possible, including ancillary services such as counseling to candidates who lack adequate resources or have psychosocial challenges.

**Repeat Transplantation**

The OPTN acknowledges that repeat transplantation raises concerns about justice, namely, that repeatedly allocating organs to a single person may be considered less ‘fair’ while others await a first transplant. That said, graft failure can occur at any time after transplantation and for many reasons, many beyond the control of the patient, such as poor initial quality of the transplanted graft, or other factors, including having been a living donor. Evaluations of potential transplant candidates for repeat transplantation should consider psychosocial and medical factors as well as the likelihood of long-term survival of a repeat transplant. Repeat transplantation should not be regarded as the sole criterion either to restrict or promote candidacy.

**Incarceration Status**

The OPTN recognizes that incarcerated individuals, as well as individuals who are at high risk for recidivism for incarceration (as determined by evidence-based indicators such as age, criminal history, negative peer associations, substance use, and antisocial personality disorder), face barriers to successful transplantation. At present, not all transplant centers are willing to evaluate currently incarcerated individuals, most commonly citing fear of poor post-transplant follow up and medication adherence as perceived barriers. The OPTN affirms its position established in the white paper, *Convicted Criminals and Transplant Evaluation* that “absent any societal imperative, one’s status as a prisoner should not preclude them from consideration for a transplant; such consideration does not guarantee transplantation.” That is to say that unless a currently incarcerated individual’s comprehensive transplant evaluation concludes that there are other contraindications to transplant present, their status as an inmate should not be a contradiction on its own. Additional steps should be taken to collaborate with correctional authorities to provide comprehensive post-transplant care to incarcerated individuals in the event the patient be deemed a candidate for transplantation.

**Immigration Status**

Consistent with OPTN policy, immigration status should not be used as a criterion in determining transplantation candidacy. Consistent with OPTN policy, a candidate’s citizenship or residency status must not be considered when allocating deceased donor organs to candidates for transplantation.

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While immigration status may be tightly intertwined with other psychosocial and financial factors that affect a person’s candidacy for transplantation, immigration status alone should neither determine nor exclude a person’s candidacy for organ transplantation as these would be unduly compromise justice and respect for persons.

Many noncitizens participate in the transplant system as donors. The principle of reciprocity implies that it is unjust for a system to use organs from a group of persons categorically excluded from access. Participation as organ donors and long-term residents in the U.S. also means that undocumented immigrants are not considered “transplant tourists” under the definition of the Declaration of Istanbul.

Theories of distributive justice, including some interpretations of Rawls’ Theory of Justice, suggest that persons, irrespective of immigration status, can be considered members of the society by virtue of participating in complex schemes of social cooperation (through sustained social ties, participation in community organizations, paid and unpaid labor, taxes, etc.). Furthermore, the Difference Principle, sometimes referred to as the “maximum” principle, has been used to support granting access to transplant for persons irrespective of immigration status because such persons are often vulnerable members of society, facing unique challenges owing to language barriers, often lower socioeconomic status, and access to fewer safety net resources.

**Social Support**

Social support can refer to informal care and emotional ties to others, which for many is comforting and helpful especially during health challenges and transitions, such as transplant evaluation and recovery. Transplant teams using social support criteria commonly require a potential transplant candidate to demonstrate social support to assist a wide range of post-transplant requirements, including: transportation, medication management, and symptom monitoring. Social support requirements vary significantly by program and organ type, and often require multiple people to be available for extended time periods. These requirements may not be transparent or well understood by patients.


Evidence that social support is predictive of graft failure or graft survival is limited, possibly due to selection bias. Social support has mostly been associated with improved quality of life post-transplant, but not outcomes such as graft or overall survival. Use of social support in transplantation evaluations as a proxy for a patient’s ability to meet functional needs (e.g., self-care transportation), motivation, or future adherence may obscure the true demands (transportation to appointments, etc.) undermining transparency, and may unintentionally introduce implicit biases into listing decisions.

Difficulty demonstrating adequate social support is commonly associated with social vulnerabilities or with having non-traditional supports (e.g., friends, distant relatives, coworkers, etc.), amplifying social justice concerns. Demonstrating social support may be more challenging for persons with limited English language proficiency, and inflexible employment schedules. As such, use of social support to determine transplant eligibility may exacerbate socioeconomic, racial, ethnic, and gender disparities.

The OPTN affirms that access to life-saving and/or life-enriching care should not be contingent upon demonstrating social support or relationships. Patients’ ability and willingness to meet vital post-operative demands (e.g., transportation, medication sorting, etc.) should be assessed with interventions aimed at ensuring equitable access to all candidates who may benefit from transplant.

Additional research should identify factors most predictive of post-transplant challenges that could negatively impact success after transplant, alongside interventions likely to reduce related risks. These include interventions to support post-transplant recovery and rehabilitation.

**Considerations for Pediatric, Adolescent and Young Adult Patients**

As with pediatric priority in organ allocation, the committee recognizes that pediatric, adolescent and young adult candidates for transplantation require separate and special consideration as children are dependent and vulnerable. Due to their age and developmental stage, children rely on adult caregivers and other social supports to be successful transplant candidates. As a result, psychosocial assessments inherently include both the patient and their caregivers. Children are not considered responsible for, nor do they have control over, factors such as their caregivers’ limitations, citizenship, ability to pay, family function or dysfunction, or their environment. At present, there is limited objective data on the impact.

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of these caregiver factors on a child’s transplant outcomes. As with adults, these criteria and assessments of nonadherence may be impacted by implicit or explicit biases about race and ethnicity.

Children are generally considered a vulnerable population for which the “best interest” standard is commonly applied in decision-making. Successful transplantation is clearly in a child’s best interest as it fulfills essential medical and developmental needs, and thereby should not be denied solely due to limited caregiver resources. As such, psychosocial assessments should identify patient and family strengths and risk factors that could affect post-transplant outcomes with the goal of bolstering support for children (and their families) to be successful transplant recipients. This may involve leveraging local, community, or state resources to promote child flourishing and success as a transplant recipient.

Involving a multidisciplinary team of experts including social workers, educators, school counselors, pediatricians, and other stakeholders in addition to the immediate family may be helpful to address some of these psychosocial factors early. Transplant centers should consider standardizing and ensuring accessibility of evaluations to promote transparency and equity in the transplant evaluation process.

Concerns for nonadherence may be particularly high for patients in adolescence and early adulthood. Recognition of this concern should promote early assessment and strategies to foster adherence in the pediatric candidate, particularly during the period of developing patient autonomy, independence, and transition to adult medicine. Programs should also work closely together to ensure seamless transition of listed pediatric or adolescent candidates between centers. This may be especially important in pediatrics as a child’s behavior may be viewed as more dynamic and past behavior may be less predictive of future behavior. The principles of justice, utility, and equity in the current context should be balanced with the urgency of transplant for pediatric patients, allowing them to thrive in the future.

Summary/Conclusion

Ensuring equity in access to transplantation requires assessment and mitigation of structural barriers disproportionately impacting disadvantaged potential candidates who could medically benefit from transplantation. Such barriers include use of non-medical criteria, which can unwittingly introduce bias based on race, ethnicity, socioeconomic status, gender, and other non-clinical factors that may have a significant discriminatory impact on structurally disadvantaged populations. These criteria may compound the effect of social and healthcare disparities resulting in under referral of structurally disadvantaged patients for transplant evaluation and lower listing rates among those referred.

Transplant centers are encouraged to develop their own guidelines for potential transplant candidate evaluations. Listing guidelines used by transplant programs should be applied without bias. Use of non-medical criteria continues to raise ethical concerns insofar as they commonly: (1) lack clear standards and thresholds; (2) are inconsistently applied; (3) are susceptible to stereotyping and instrumental value judgments; (4) are not transparent to patients; and (5) are not consistently supported by evidence. As


such, transplant evaluations should not exclusively rely on non-medical criteria. The transplant community should continue to research the use of non-medical criteria with regard to who gets a transplant in order to apply them in an evidence-based manner; work to reduce bias and stereotyping; and increase transparency and consistency in the evaluation.
Appendix A: State Legislation Enacted Prohibiting Discrimination in Transplantation Against Individuals With Physical and/or Intellectual Disabilities as of April 23, 2021

- California, California Acts of Assembly, Chapter 96.
- New Jersey, P.L. 2013, Chapter 80.
- Maryland, 2015 Laws of Maryland, Chapter 383.
- Massachusetts, 2016 General Laws, Chapter 111.
- Oregon, 2017 Laws, Chapter 396.
- Delaware, 2017 Laws of Delaware, Volume 81, Chapter 169.
- Kansas, 2018 House Bill 2343.
- Ohio, 2018 House Bill 332.
- Pennsylvania, 2018 Public Law 594, No. 90.
- Indiana, 2019 Public Law 2.
- Iowa, 2020 Iowa Acts, Chapter 1101.
- Florida, 2020 Chapter No. 2020-139.