OPTN

White Paper

General Considerations in Assessment for Transplant Candidacy

OPTN Ethics Committee

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Contents

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 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. 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. This list is neither exhaustive nor immutable.

The intent of this white paper is to advise transplant programs and provide them with information about the considerations discussed herein. 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 criteria by encouraging transplant programs to consider the ethical implications of commonly used criteria.

[1] 42 CFR § 121.5(a)
[2] 42 CFR § 121.8(b)(1)

Background

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 who may have better adherence or post-transplant outcomes. Ethical concerns with using non-medical criteria to evaluate potential transplant candidates involve equity and justice.[6,7,8,9] Inconsistent and subjective use of non-medical criteria without clear standards is likely to result in the inconsistent distribution of medical good among potential beneficiaries, undermining equal respect and concern for individuals.

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.

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.

Purpose

In deciding to pursue a 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

[3] 42 CFR §482.90.

[4] The following references identify specific ethical concerns related to the use of non-medical criteria: (a) Disability: National Council on Disability, *Organ Transplant Discrimination Against People with Disabilities*, September 25, 2019, accessed on September 23, 2020. https://ncd.gov/sites/default/files/NCD_Organ_Transplant_508.pdf; (b) Immigration: Ansell, David, Pallok, Kristen, Guzman, Marieli D, Flores, Marycarmen, and Oberholzer, Jose. "Illinois Law Opens Door to Kidney Transplants for Undocumented Immigrants." *Health Affairs (Project Hope)* 34, no. 5 (2015): 781-87.; (c) Immigrant Kidney Transplantation Outcomes: Shen, Jenny I, Hercz, Daniel, Barba, Lilly M, Wilhalme, Holly, Lum, Erik L, Huang, Edmund, Reddy, Uttam, Salas, Leslie, Vangala, Sitaram, and Norris, Keith C. "Association of Citizenship Status With Kidney Transplantation in Medicaid Patients." *American Journal of Kidney Diseases* 71, no. 2 (2018): 182-90.; and (d) Poverty: Simmerling, Mary. "Beyond Scarcity: Poverty as a Contraindication for Organ Transplantation." *The Virtual Mentor* 9, no. 6 (2007): 441.

[5] Ellen Jean Hirst, "Hunger Strikers Demand Chance at Organ Transplants," chicagotribune.com, September 8, 2018, accessed on September 29, 2020. https://www.chicagotribune.com/news/ct-xpm-2013-08-06-ct-met-hunger-strike-northwestern-0806-20130806-story.html.

[6] Ladin, Keren, Marotta, Satia A, Butt, Zeeshan, Gordon, Elisa J, Daniels, Norman, Lavelle, Tara A, and Hanto, Douglas W. "A Mixed-Methods Approach to Understanding Variation in Social Support Requirements and Implications for Access to Transplantation in the United States." *Progress in Transplantation* (Aliso Viejo, Calif.) 29, no. 4 (2019): 152692481987438-353.

[7] Majeske, R. A. "Transforming Objectivity to Promote Equity in Transplant Candidate Selection." *Theoretical Medicine* 17, no. 1 (1996): 45-59.

[8] Batabyal, Pikli, Chapman, Jeremy R, Wong, Germaine, Craig, Jonathan C, and Tong, Allison. "Clinical Practice Guidelines on Wait-listing for Kidney Transplantation: Consistent and Equitable?" *Transplantation* 94, no. 7 (2012): 703-13.

[9] OPTN Ethics Committee, Ethical Principles in the Allocation of Human Organs, June 2015, accessed 10/02/2020. https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/

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. In addition, new criteria were added, including incarceration status and social supports. 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.[10] 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.[11]

The following 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…"[12] Furthermore, 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."[13] 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, the ethical implications creates a minimum standard for use of the criteria.

Criteria Considered

This white paper revises the current version of the General Considerations in Assessment for Transplant Candidacy to ensure the transplant community is aware of the most current ethical discussions and research surrounding these topics at it related to suitability for transplant. It was determined that aspects of the current version are outdated and could benefit from revision. It was also determined that new criteria should be included.

The criteria discussed in this white paper were selected because they are not directly part of a medical evaluation or medical assessment for transplant candidacy, but are important enough to warrant consideration. The Final Rule requires criteria to be measurable and medical to the extent possible. When other criteria are used, it is appropriate to encourage the use of parameters in order to support the standardization of more qualitative criteria. Such parameters include the ethical considerations of employing that 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

[10] OPTN Ethics Committee. *Ethical Principles in the Allocation of Human Organs*, June 2015, https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/ (accessed online on September 19, 2020)
[11] OPTN Ethics Committee. *Ethical Principles in the Allocation of Human Organs*, June 2015, https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/ (accessed online on September 19, 2020)
[12] 42 CFR §121.5(a)
[13] 42 CFR §121.8.(b)(1)

- Incarceration status
- Immigration status
- Social support

NOTA and Final Rule Analysis

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.[14] 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. This paper provides an ethical analysis of some of those considerations.

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. When non-medical criteria are included in listing considerations, transplant programs should apply them without bias. This white paper is intended to help advise programs on the use of certain non-medical criteria.

[14] 42 CFR §121.5(b). OPTN Bylaws, *Appendix D.12.D: Candidate Selection Procedures*, effective December 7, 2020, *https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf* (accessed online on January 19, 2021)

White Paper

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 2020

Transplant centers are encouraged to develop their own guidelines for transplant consideration. Each potential transplant candidate should be examined individually and any and all guidelines should be applied without any type of ethnicity 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 accept a potential transplant candidate. 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. This list is neither exhaustive nor immutable.

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).[15] Use of non-medical

[15] 42 CFR §482.90.

transplant evaluation criteria remains an area of concern to many in the transplant community.[16,17] Non-medical criteria are thought, by some, to uphold the principle of utility by selecting candidates who may have better adherence or post-transplant outcomes. Ethical concerns with using non-medical criteria to evaluate potential transplant candidates involve equity and justice.[18,19,20,21] Inconsistent and subjective use of non-medical criteria without clear standards is likely to result in the inconsistent distribution of medical good among potential beneficiaries, undermining equal respect and concern for individuals.

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.[22] 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.[23]

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.[24][25] At the

[16] The following references identify specific ethical concerns related to the use of non-medical criteria: (a) Disability: National Council on Disability, *Organ Transplant Discrimination Against People with Disabilities*, September 25, 2019, accessed on September 23, 2020. https://ncd.gov/sites/default/files/NCD_Organ_Transplant_508.pdf; (b) Immigration: Ansell, David, Pallok, Kristen, Guzman, Marieli D, Flores, Marycarmen, and Oberholzer, Jose. "Illinois Law Opens Door to Kidney Transplants for Undocumented Immigrants." *Health Affairs (Project Hope)* 34, no. 5 (2015): 781-87.; (c) Immigrant Kidney Transplantation Outcomes: Shen, Jenny I, Hercz, Daniel, Barba, Lilly M, Wilhalme, Holly, Lum, Erik L, Huang, Edmund, Reddy, Uttam, Salas, Leslie, Vangala, Sitaram, and Norris, Keith C. "Association of Citizenship Status With Kidney Transplantation in Medicaid Patients." *American Journal of Kidney Diseases* 71, no. 2 (2018): 182-90.; and (d) Poverty: Simmerling, Mary. "Beyond Scarcity: Poverty as a Contraindication for Organ Transplantation." *The Virtual Mentor* 9, no. 6 (2007): 441.

[17] Ellen Jean Hirst, "Hunger Strikers Demand Chance at Organ Transplants," chicagotribune.com, September 8, 2018, accessed on September 29, 2020. https://www.chicagotribune.com/news/ct-xpm-2013-08-06-ct-met-hunger-strike-northwestern-0806-20130806-story.html.

[18] Ladin, Keren, Marotta, Satia A, Butt, Zeeshan, Gordon, Elisa J, Daniels, Norman, Lavelle, Tara A, and Hanto, Douglas W. "A Mixed-Methods Approach to Understanding Variation in Social Support Requirements and Implications for Access to Transplantation in the United States." *Progress in Transplantation* (Aliso Viejo, Calif.) 29, no. 4 (2019): 152692481987438-353.

[19] Majeske, R. A. "Transforming Objectivity to Promote Equity in Transplant Candidate Selection." *Theoretical Medicine* 17, no. 1 (1996): 45-59.

[20] Batabyal, Pikli, Chapman, Jeremy R, Wong, Germaine, Craig, Jonathan C, and Tong, Allison. "Clinical Practice Guidelines on Wait-listing for Kidney Transplantation: Consistent and Equitable?" *Transplantation* 94, no. 7 (2012): 703-13.

[21] OPTN Ethics Committee, Ethical Principles in the Allocation of Human Organs, June 2015, accessed 10/02/2020. https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/

[22] OPTN Ethics Committee. *Ethical Principles in the Allocation of Human Organs*, June 2015, https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/ (accessed online on September 19, 2020)

[23] OPTN Ethics Committee. *Ethical Principles in the Allocation of Human Organs*, June 2015, https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/ (accessed online on September 19, 2020)

[24] OPTN Ethic Committee, Report to the Board of Directors, March 2-3, 2009.

[25] OPTN, *White Paper: General Considerations in Assessment for Transplant Candidacy*, accessed 09/23/2020. https://optn.transplant.hrsa.gov/resources/ethics/general-considerations-in-assessment-for-transplant-candidacy/

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.

Life Expectancy

Supported largely by the principle of utility, as discussed in the *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.[26] 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.[27] Concerns of justice, the ability of all persons to benefit from transplantation, such as those articulated in the Age Discrimination Act of 1975,[28] preclude federally funded programs, like the OPTN, from engaging in age discrimination. In kind, the Affordable Care Act prohibits health care programs or activities from discriminating on the basis of age alone.[29] 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.

Potentially Injurious Behavior

Ethical concerns persist with using potentially injurious behaviors (e.g. substance abuse, unhealthy eating, non-adherence to medical recommendations, etc.) as criteria to rule out transplant candidacy. Although assessment based on a potential candidate's participation in these behaviors may be supported by the principle of utility, as they may be seen to influence graft survival and broader transplant outcomes, these considerations need to be weighed against considerations of justice and respect for persons. In terms of utility alone, the evidence linking potentially injurious behavior to transplant outcomes is essential but currently inconclusive.[30,31,32]

[26] OPTN Ethics Committee. *Ethical Principles in the Allocation of Human Organs*, June 2015, https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/ (accessed online on September 19, 2020)

[27] Eidelson, Benjamin. "Kidney Allocation and the Limits of the Age Discrimination Act." *The Yale Law Journal* 122, no. 6 (2013): 1635-652.

[28] 42 U.S.C §§6101-6107.

[29] 42 U.S.C §18116; and National Council on Disability, *Organ Transplant Discrimination Against People with Disabilities*, September 25, 2019, accessed on September 23, 2020. https://ncd.gov/sites/default/files/NCD_Organ_Transplant_508.pdf

[30] Pageaux, G-P, Michel, J, Coste, V, Perney, P, Possoz, P, Perrigault, P-F, Navarro, F, Fabre, J-M, Domergue, J, Blanc, P, and Larrey, D. "Alcoholic Cirrhosis Is a Good Indication for Liver Transplantation, Even for Cases of Recidivism." *Gut* 45, no. 3 (1999): 421-26.

[31] Koch, Monika, and Banys, Peter. "Liver Transplantation and Opioid Dependence." *JAMA : The Journal of the American Medical Association* 285, no. 8 (2001): 1056-058.

[32] Wakeman, Sarah E, Ladin, Keren, Brennan, Tim, and Chung, Raymond T. "Opioid Use Disorder, Stigma, and Transplantation: A Call to Action." *Annals of Internal Medicine* 169, no. 3 (2018): 188.

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.[33] For example, 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.[34] While potentially injurious behaviors may be due, in part, to personal choice, transplant providers should not automatically assume potential transplant candidates are solely responsible for engaging in those behaviors as they may be caused by factors over which patients do not have full control.

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. Consequently, to the extent that is possible, balancing the principles of utility, justice, and respect for persons requires that considerations meant to lessen the impact of behavioral factors, such as abstinence periods for alcohol use disorder, be objective and evidence-based.[35] Considering the contribution of multifactorial factors to both behavior and subsequent organ loss, and the insufficient 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.[36] In other words, the mere presence of a potentially injurious behavior, such as a history of substance use, should not automatically rule one out as a potential transplant candidate, as this would violate both respect for persons and justice.

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)[37] 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.[38]

[33] Goldblatt, Phillip B, Moore, Mary E, and Stunkard, Albert J. "Social Factors in Obesity." *JAMA : The Journal of the American Medical Association* 192, no. 12 (1965): 1039-044. Adler, Nancy E, Glymour, M. Maria, and Fielding, Jonathan. "Addressing Social Determinants of Health and Health Inequalities." *JAMA : The Journal of the American Medical Association* 316, no. 16 (2016): 1641.

[34] Bevilacqua, L, and Goldman, D. "Genes and Addictions." Clinical Pharmacology and Therapeutics 85, no. 4 (2009): 359-61. Sinha, Rajita. "Chronic Stress, Drug Use, and Vulnerability to Addiction." *Annals of the New York Academy of Sciences* 1141, no. 1 (2008): 105-30.

[35] Singhvi, Ajay, Welch, Alexandra N, Levitsky, Josh, Singhvi, Deepti, and Gordon, Elisa J. "Ethical Considerations of Transplantation and Living Donation for Patients with Alcoholic Liver Diseases." *AMA Journal of Ethics* 18, no. 2 (2016): 163-73.

[36] 42 U.S.C §18116; and National Council on Disability, *Organ Transplant Discrimination Against People with Disabilities*, September 25, 2019, accessed on September 23, 2020. https://ncd.gov/sites/default/files/NCD_Organ_Transplant_508.pdf.

[37] World Health Organization. 2003. Adherence to Long-term Therapies : Evidence for Action. Geneva: World Health Organization. Accessed October 8, 2020. ProQuest Ebook Central.

[38] Dobbels, Fabienne, Vanhaecke, Johan, Dupont, Lieven, Nevens, Frederik, Verleden, Geert, Pirenne, Jacques, and De Geest, Sabina. "Pretransplant Predictors of Posttransplant Adherence and Clinical Outcome: An Evidence Base for Pretransplant Psychosocial Screening." *Transplantation* 87, no. 10 (2009): 1497-504.

Justice requires that a history of consistent and documented treatment non-adherence should be considered by the transplant team in the context of barriers to adherence and other medical and psychosocial criteria. A transplant program should also consider an individual's expressed willingness to follow treatment regimes. Patients may experience disparities in access to care based on geography, resources and financial status which can adversely affect both their ability to adhere to recommendations, and the implicit perceptions held by the clinicians about their ability to so adhere. Transplant program staff may evaluate these barriers and consider providing support, 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 allocating multiple 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, poor criminal history, negative peer associations, substance use, and antisocial personality disorder),[39] face barriers to successful transplantation. 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."[40] Additional steps should be taken to collaborate with correctional authorities to provide comprehensive post-transplant care to incarcerated individuals, should the patient be deemed a candidate for transplantation.

Immigration Status

Consistent with current 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.[41] While immigration status may be tightly intertwined with other psychosocial and financial factors that affect a person's candidacy for transplantation[42] immigration status *alone* should neither determine nor

[39] Government of Western Australia, Office of the Inspector of Custodial Services, *Recidivism rates and the impact of treatment programs*. ISSN 1445-3134. September 2014. Accessed October 8, 2020. https://www.oics.wa.gov.au/wp-content/uploads/2014/09/OICS-Recidivism-review.pdf

[40] OPTN, Ethics Committee, Convicted Criminals and Transplant Evaluation, accessed on September 23, 2020. https://optn.transplant.hrsa.gov/resources/ethics/convicted-criminals-and-transplant-evaluation/

[41] OPTN, *Policy 5.4.A; Nondiscrimination in Organ Allocation*, accessed on 10/02/2020. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf

[42] Ellen Jean Hirst, "Hunger Strikers Demand Chance at Organ Transplants," chicagotribune.com, September 8, 2018, accessed on September 29, 2020. https://www.chicagotribune.com/news/ct-xpm-2013-08-06-ct-met-hunger-strike-northwestern-0806-20130806-story.html.

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.[43] The principle of reciprocity highlights that it seems 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.[44]

Theories of distributive justice, including Rawls' Theory of Justice, suggests 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, is also 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, emotional ties, and meaningful connection to others, which many find comforting especially during periods of vulnerability, such as transplant evaluation and recovery.[45,46] Transplant teams using social support criteria commonly require a potential transplant candidate to demonstrate existing social support to assist with the wide range of post-transplant requirements, such as transportation, medication management, and monitoring symptoms. However, at present, there is limited evidence that social support is predictive of graft failure or graft survival.[47] Moreover, the use of social support in transplantation evaluations as a proxy for a patient's ability to meet functional needs (e.g., self-care and transportation) introduces value judgments and biases into the listing decisions.[48] Likewise, using social support as a proxy for patient motivation and ability to adhere to treatment introduces the same concerns.[49] Patients' difficulty demonstrating adequate social support is commonly associated with other social vulnerabilities or with having non-traditional supports (absence of a spouse, parent, sibling for example), amplifying these justice concerns. For example, demonstrating social support may be more challenging for persons with limited English language

[43] Wightman, Aaron, and Diekema, Douglas. "Should an Undocumented Immigrant Receive a Heart Transplant?" *AMA Journal of Ethics* 17, no. 10 (2015): 909-13.
[44] Summit, Steering Committee. "Organ Trafficking and Transplant Tourism and Commercialism: The Declaration of Istanbul." *The Lancet* (British Edition) 372, no. 9632 (2008): 5-6.
[45] Barrera, Manuel. "Distinctions between Social Support Concepts, Measures, and Models." *American Journal of Community Psychology* 14, no. 4 (1986): 413-45.
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proficiency and those who do not have flexible employment schedules. As such, use of social support to determine transplant eligibility may exacerbate socioeconomic, racial, ethnic, and gender disparities.[50]

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.

Summary/Conclusion

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.

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